A Public Matter? : An Ethical Analysis of the Canadian Pharmacare Public Policy Debate, 1997-2019

by

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Abstract

Background: Canada lacks universal pharmaceutical coverage (pharmacare). Calls for the implementation of national pharmacare date back to the introduction of Canadian Medicare and have recently resurfaced on the federal health policy agenda. Although public policies raise ethical and political questions, to date there has been limited analysis of the normative rationales that underpin arguments in the Canadian pharmacare debate. Accordingly, the objective of this study was to examine how bioethics—as a practically-oriented, normative inquiry—could contribute to understanding and informing the contemporary pharmacare policy debate.

Methods: I conducted a qualitative, empirical bioethics case study of the Canadian pharmacare public policy debate from 1997 to 2019. I used an adapted thematic analysis to characterize the main policy arguments in 72 policy documents and transcripts in terms of their underlying normative rationales. To inform my analysis and interpretation of the data, I drew on a theoretical framework of four philosophical accounts of the division of public and private responsibility in the organization, financing, and delivery of health insurance.

Findings: The contemporary pharmacare policy debate has shifted from considering whether to determining how universal pharmaceutical coverage ought to be realized; three main forms of universal coverage have been considered: public single-payer, a ‘fill-in-the-gaps,’ multi-payer program that builds on the existing mix of public and private insurance, and catastrophic coverage. The three proposals appeal to distinct normative rationales and accounts of political responsibility vis-à-vis health and health insurance. In turn, they frame and justify the problems of access, costs, and appropriateness and their attendant policy solutions differently. Growing support for public single-payer pharmacare in the contemporary debate is justified in reference to more explicit appeals to its efficiency-promoting features in addition to its equity- and community-promoting ones.

Conclusion: This study provides an understanding of how arguments in the Canadian pharmacare policy debate are justified normatively. It suggests that the pharmacare debate is a politically normative debate that will require adjudicating between distinct policy objectives. The analysis illustrates how normative policy analysis can help discern and reframe underlying normative disputes in public policy debates.

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Chapter 1
Introduction

> […] what become evident was that the study of healthcare was, for all intents and purposes, essentially the study of Canada itself. To trace the historical evolution of health care as a public policy and as a political debate was to understand how Canada works: its political institutions, constitutional origins, political organization, ideological cleavages, and evolving values. And an understanding of health care required the unraveling of larger questions about government spending, the role of the modern state, and the crucial elements of the relationship between state and society. (Maioni 2015:5)

1 Introduction

Securing universal health coverage[1] has been a mainstay of state activity and responsibility in most industrialized countries—and a central feature of welfare states—since the mid-20th century. Yet the design of health insurance—including the scope of coverage, the goods and services covered, and the responsibility for financing and administration—continues to be contested and undergo reform within Canada as well as internationally (Flood et al. 2008; Tuohy 2018). That health care policies are politically contested is unsurprising as they raise ethical and political questions concerning the nature of membership and civic life in, and goals of, a political community, the nature of individual responsibilities and mutual obligations as they relate to health, the scope of legitimate political authority, and the contours of just resource distribution and priority setting in and beyond health care. Indeed, at the core of many health care reform debates lies a disagreement about the appropriate scope and responsibility of public and private actors and institutions in the organization, financing, and provision of health insurance—a dispute which is itself situated within broader debates about political objectives in contemporary welfare states.

As in most other industrialized countries following the Second World War, Canada introduced publicly-funded, universal, comprehensive health insurance covering medically necessary hospital and diagnostic services in 1957 and medical services in 1968. Although Canada's public

[1] According to the World Health Organization (2019), universal health coverage "means that all individuals and communities receive the health services they need without suffering financial hardship. It includes the full spectrum of essential, quality health services, from health promotion to prevention, treatment, rehabilitation, and palliative care."

'Medicare' system has undergone relatively few significant reforms since its introduction, it has remained an ongoing topic of public interest and debate (Tuohy 2018). Moreover, it has even taken on the status of a national symbol or point of pride for many Canadians and is often invoked as such.[2] Yet one issue that has attracted recurring attention is the notable absence of universal pharmaceutical insurance (or 'pharmacare') in Canada. While introducing broad pharmaceutical coverage has been considered by policy-makers at the federal level as far back as the 1940s, repeated calls for the implementation of national pharmacare—including in 1964, 1972, 1997 and 2002—have yielded no significant policy reform to date (Boothe 2015). By 2016, pharmacare resurfaced as a full-fledged topic of public debate. In 2019, following several years of public debate and media coverage, the publication of numerous policy reports, two government inquiries, and two federal elections in which pharmacare featured as an election issue (albeit not the central one), then newly re-elected Prime Minister Justin Trudeau signaled his government's intent to pursue pharmacare reform as he instructed the Minister of Health to "continue to implement national universal pharmacare" (Trudeau 2019).

Against the backdrop of revived public debate and growing interest in pharmacare on the part of key political actors, I set out to explore how bioethics could contribute to understanding and informing the decades-long pharmacare policy debate and seeming impasse in pharmaceutical insurance policy reform in Canada. The renewed interest in pharmacare has brought questions concerning public responsibility for health and the purpose of health insurance to the fore of public discourse. Despite the government's purported commitment to implement national pharmacare, a pharmacare policy has yet to be legislated and implemented.

Pharmacare and Medicare attract public debate as they raise questions concerning whether, and to what extent, health and health insurance are matters of public concern—necessitating policy intervention by states or as being emblematic of mutual obligations—or are private matters better left to individuals, markets or other private mechanisms. Canada's existing, public, single-payer health insurance system continues to garner broad public support (Ipsos 2019). However,

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[2] In Canada, the publicly-funded health insurance system is often cited as a point of national pride and a defining feature of the country's national and civic identity (Maioni 2010). For example, when asked to identify the 'greatest Canadian' on a 2004 television program presented by the national public broadcaster, the Canadian Broadcasting Corporation, viewers conferred the honour on a politician, Tommy Douglas, who was dubbed 'The Father of Medicare' (Marchildon 2007).

questions about the division of public and private responsibility and priority setting have persisted amidst criticism of the system (especially during the 1990s in response to concerns about long wait times and declining quality of care) and legal challenges to restrictions on private health insurance and medical billing (e.g., *Chaoulli v. Quebec* 2005, *Cambie Surgeries Corporation v. British Columbia (Attorney General) 2020*).

Whether financing, administration and provision are public or private, health insurance requires determining eligibility, pricing and purchasing strategies, and setting priorities concerning which goods and services are covered and under what conditions. While different countries have addressed these questions through a variety of policy approaches and insurance financing and reimbursement models, questions about priority setting have dominated health reform debates since the 1980s and 1990s across jurisdictions, irrespective of the model of health insurance that they have adopted (Flood et al. 2008). Indeed, health insurance is at least in part ripe for debate because the range of goods and services that are deemed 'medically necessary'—and thus insurable—continues to expand rapidly. As Kenny and Joffre (2008:145) observe, the commitment by welfare states to provide coverage for 'medically necessary' services coincided with the expansion of the concept of medical necessity itself; in turn, this has left many health care systems facing "'crises' of access, quality, financing, and sustainability."

In many ways, pharmaceuticals exemplify the urgency of priority setting, since drug research and development has largely shifted from developing 'blockbuster,' or lower-cost, high volume medications to 'nichebuster,' or specialized and usually expensive drugs, biologics, and therapies aimed at offering targeted treatments, often for conditions that are deemed rare. An ever-expanding range of resource-intensive therapies and health technologies is being developed to deliver on the much-lauded promises of 'personalized' or 'precision' medicine. At the same time, these pharmaceuticals often bear high prices, which pose challenges to the long-term sustainability of public and private health insurance alike, and raise concerns about therapeutic cost-effectiveness and affordability. In this sense, discussions concerning drug pricing and priority setting in the Canadian pharmacare debate mirror broader conversations occurring internationally around the sustainable and 'fair' pricing of medicines (e.g., WHO 2017; Balderrama et al. 2020; Moon et al. 2020).

Determining how pharmaceutical policy, as a subset of health policy and ultimately public policy, ought to be structured requires identifying normative standards for assessing the moral relevance of and justification for policy goals and processes. Public policies and policy analysis are increasingly recognized as enterprises where "normative rationales operate implicitly even when not analyzed explicitly" (Kenny and Giacomini 2005: 249). That is, far from being purely scientific, technical, and objective, policy-making is a fundamentally value-laden endeavor. Although policy-makers and analysts may not engage with values and normative questions systematically or in-depth, normative criteria and judgements provide the parameters that shape policy objectives and justifications and inform the legitimacy of policy processes and political authority. Yet despite the growing recognition that public policies are imbued with normative concerns, positivist tendencies persist. Normative policy analysis remains the most neglected form of policy analysis (Kenny and Giacomini 2005; Stone 2012) and the turn to 'evidence-based policy-making' reinforces the idea that ethics is extra-evidentiary. In the context of Canadian health policy, few analyses explicitly examine the normative underpinnings and features of the Canadian pharmacare policy debate.

Coinciding with the growing recognition that policy is a normative enterprise, the birth of bioethics and the revived interest in political philosophy in the mid-20th century prompted philosophers to engage with and offer theoretically-informed accounts aimed at addressing normative questions facing policy-makers—from macro-level considerations concerning the basic structure of society, political community, or the nature of political authority—to meso- and micro-level questions concerning resource allocation in organizational and clinical settings. While policy analysis and philosophy remain largely distinct, bioethicists and philosophers are increasingly called upon to advise on matters of policy in the recognition that they can aid in identifying implicit normative rationales and articulating guiding principles and justifications in order to inform or legitimize policy decisions (Wikler 1991; Kymlicka 1996; Wolff 2018). As Kenny and Giacomini (2005:249) observe, bioethics, as a branch of applied ethics, is well suited to informing policy-making and analysis as they both share an aspirational and pragmatic spirit: "There is a resonance between the "praxis" of ethics and the "polis" of policy: both involve developing shared ideas about not only ideals, but also pragmatic possibilities."

1.1 Research Objective and Questions

Amidst growing interest in normative policy analysis and reinvigorated public policy debate concerning pharmacare, I set out with the objective to explore how bioethics—understood as a normative mode of inquiry that is both conceptually-informed and practically-oriented[3]—could contribute to understanding and informing the contemporary pharmacare debate in Canada.

I posed two research questions to guide my inquiry and address the study objective:

1. What normative rationales are invoked, explicitly and implicitly, in arguments in the Canadian pharmacare public policy debate?
    a. How are normative concepts used, in what contexts, and to what ends?
    b. Are normative concepts employed consistently? If not, in what ways does their use differ?
2. How can normative and political philosophy contribute to understanding and informing the pharmacare policy debate?
    a. How do philosophical accounts concerning the nature and purpose of health insurance compare with the normative rationales of pharmacare policy identified in question 1?
    b. How can philosophical accounts inform policy arguments in the pharmacare debate?

As I describe in greater depth in my Methodology and Methods chapter, I conducted an empirical bioethics case study of the Canadian pharmacare debate to answer my research questions and to address my inquiry's descriptive, analytic, and normative research aims. My first aim, which addresses research question one, is descriptive as I characterize the main policy arguments in the debate in terms of their underlying normative justifications. My second aim, which addresses both research questions, is analytic. I draw on philosophical concepts, theories, and methods of reasoning to identify points of normative convergence and tension within the debate and to consider how the normative discourse in the debate compares with the theoretical perspectives outlined in my Theoretical Considerations chapter. I seek to further an understanding of what is *morally* at stake in the pharmacare debate by making the underlying norms explicit and illustrating how distinct policy positions in the debate are associated with particular normative commitments. Finally, my third aim, which concerns research question two,

[3] I describe what I take to be the nature of bioethics as it relates to my inquiry in Chapter 3 (Methodology and Methods).

is normative; I consider how normative and political philosophy can contribute to understanding and informing the pharmacare policy debate.

Before proceeding with my inquiry, it is worth briefly describing the existing pharmaceutical insurance and regulatory landscape in Canada (including the organization of insurance, its impact on access and costs, and the division of jurisdictional and regulatory responsibilities) as well as introducing the case study that forms the basis of my analysis: the Canadian pharmacare policy debate from 1997 until 2019.

1.2 The Canadian Pharmaceutical Insurance Landscape

Canada introduced publicly-funded, universal, comprehensive health insurance covering medically necessary hospital and diagnostic services in 1957 and physician services in 1968. Canada is a federation whose constitution dictates that the administration and delivery of health insurance and health care services is under the jurisdiction of regional (provincial or territorial) governments. Accordingly, each province and territory administers its own single-payer health insurance program supported by financial contributions from the federal government. To promote consistency in coverage, the federal government stipulates the conditions that provincial and territorial governments must abide by when designing and administering health insurance in order to qualify for federal financial contributions. These conditions are outlined in the *Canada Health Act* (CHA), which specifies the types of services that must be publicly insured (which currently include medically necessary hospital, physician, surgical-dental, and diagnostic services) as well as five criteria for the organization of insured services: public administration, comprehensiveness, universality, portability, and accessibility. Notably, while pharmaceuticals administered in hospitals fall under insured hospital services and are thus covered through hospital budgets, the CHA does not mandate public coverage of pharmaceuticals in outpatient and community settings.[4] Overall, health care financing in Canada is split between public and private payers—a split which is largely dependent on the health care sector.[5] Meanwhile, health

[4] In 2017, spending on drugs dispensed in hospitals comprised 4.7% of total hospital spending (excluding Quebec) (CIHI 2019).

[5] For example, while medically necessary medical and hospital based services are financed almost entirely though the public sector, most other areas including pharmaceuticals, dental, and home care are financed through a mix of public, private, and out-of-pocket spending (Flood et al. 2002).

care delivery is largely private (including through self-employed health care providers who bill public or private payers, non-for profit hospitals financed through provincial budgets, private for-profit labs or clinics, and private long-term care facilities).

In the absence of a federal mandate for universal pharmaceutical insurance, individual provinces, territories, and federal branches (e.g., Veteran Affairs, Correctional Services of Canada, and the First Nations and Inuit Health Branch) introduced limited public drug benefit programs starting in the 1970s in order to subsidize drug costs for certain subpopulations such as social assistance recipients and seniors (Grootendorst 2002; Boothe 2015). Subsequently, private insurance programs became commercially available and were commonly integrated into employment benefits (Boothe 2015). Since their inception, provincial pharmaceutical benefit programs have undergone incremental reforms. Reflecting the legacy of incremental policy reform, Canada's contemporary pharmaceutical insurance landscape is often characterized as a 'patchwork' as it consists of over 100 public drug plans and tens of thousands of private plans which provide different amounts of coverage on different terms and conditions (Health Canada 2019). In 2019, public payers covered 43.1% of national prescription drug spending, private payers covered 36.9%, and the remaining 19.9% was financed through out-of-pocket spending by individuals (CIHI 2019).

While provinces and territories have constitutional authority and obligations to provide health insurance and care (apart from the federal government's responsibility for registered First Nations, federal inmates, members of the Canadian Forces, veterans, and refugees), pharmaceutical regulatory authority and obligations are split between the federal and provincial/territorial governments. Provincial jurisdiction includes the delivery of health care, including pharmaceuticals, as well as associated considerations, such as determining provincial formularies that inform drug reimbursement, negotiating drug prices with manufacturers, and licensing and regulating the practice of health professions such as pharmacy.

Canada does not have a central drug regulatory body. Rather, several federal or pan-Canadian bodies and agencies are responsible for regulating and assessing drugs. The federal government bears sole authority for authorizing drugs for market entry through Health Canada on the basis of safety, efficacy, and quality of manufacture. Health Canada is also responsible for the post-market surveillance of drug safety and effectiveness. The federal government also legislates drug

patents, which last twenty years following the date from when a patent application is filed. In an effort to rein in rising drug prices, the federal government established the Patented Medicine Prices Review Board (PMPRB) in 1987. The PMBRB is an arms-length, quasi-judicial body that is mandated with ensuring that the prices of patented medicines in Canada are not 'excessive'[6] (PMPRB 2018); it can also initiate legal proceedings against manufacturers to enforce its recommendations. However, the provinces are responsible for regulating generic drug pricing. In a further effort to rein in drug prices and to facilitate equitable drug pricing across jurisdictions, provincial and territorial governments established the pan-Canadian Pharmaceutical Alliance (pCPA) in 2010 to facilitate joint drug price negotiations with manufacturers.[7] The prices negotiated by the pCPA are confidential and only available to public payers, so private payers and individuals paying out-of-pocket are charged higher prices for the same drugs.

Another area of federal leadership and pan-Canadian collaboration is that of Canada's national health technology assessment agency, the Canadian Agency for Drugs and Technologies in Health (CADTH). CADTH is responsible for providing independent, evidence-based evaluations of new pharmaceuticals, therapies, technologies, and health care services. Through the Common Drug Review and pan-Canadian Oncology Drug Review, CADTH provides public payers with recommendations as to whether a drug or technology ought to be reimbursed on the basis of value for money (e.g., considering clinical benefits, cost-effectiveness, budget impact).[8] While CADTH plays an important role in informing drug policy, the decision of whether to include a drug on a provincial formulary ultimately rests with each province or territory.

1.2.1 Access to Pharmaceuticals in Canada

In Canada, pharmaceutical coverage is shaped by a variety of disparate factors such as province of residence, age, employment status, income, and disease type. Most often, eligibility for public pharmaceutical benefits is tied to income (where subsidies are a function of income or are

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[6] To determine whether a drug price is excessive, the PMPRB assesses drug prices relative to pricing in comparator countries. In an effort to lower drug prices, the PMPRB is set to change its assessment criteria to use eleven (rather than seven) comparator countries and to no longer include Switzerland and the US as comparators as of July 2021.

[7] Quebec and the Federal Government joined the pCPA in 2016.

[8] Quebec maintains an independent health technology assessment agency, the Institut national d'excellence en santé et en services sociaux (INESSS). CADTH and INESSS are working to align their review processes.

means-tested, such as in British Columbia), age (most often covering seniors over the age of 65, such as in Ontario), or employment status (where residents are required to purchase either private or public insurance depending on employment status, such as in Quebec). Most provinces and territories also offer a 'safety net' of coverage for the general population in the form of catastrophic coverage for drug costs exceeding a deductible, which is usually defined by a percentage of household income. Quebec is the only jurisdiction to mandate universal drug coverage; it requires employers who offer health benefits to include pharmaceutical coverage and requires that all other residents enroll in a premium-based public plan. However, no public pharmaceutical benefit plan in Canada offers comprehensive coverage with both first-dollar (i.e., partial or full coverage starting with the first prescription) and last-dollar coverage (i.e., catastrophic coverage paying for costs exceeding an annual deductible) for all of its residents. In addition to varying eligibility criteria between jurisdictions, public drug programs vary with respect to their formularies, which determine which drugs are reimbursed, and cost-sharing mechanisms, such as whether they are financed through deductibles, co-pays, or premiums. As a result, Canadians with public drug coverage incur different costs for the same drugs depending on where they reside.[9]

In Canada, the odds of having pharmaceutical coverage increase with being a senior citizen, being employed, having a spouse or partner, having a high school diploma, and being White, which suggests that already marginalized and vulnerable groups are least supported by the existing system (Dewa et al. 2005). Private coverage is also declining as fewer Canadians receive employee health benefits. In 2012, only 64% of Canadians, and only 24% of part-time workers, had health coverage through employee benefits—percentages which are expected to decline as part-time, contract positions, and 'gig' work represent an increasing share of the labour market (Barnes and Anderson 2015). Having private drug coverage is also correlated with having a higher household income (Bolatova and Law 2019).

Pharmaceuticals are increasingly being prescribed in outpatient or community settings and thus no longer being publicly financed through hospital budgets. This can result in 'passive

[9] For example, out-of-pocket costs for a prescription drug for congestive heart failure costing $1283 varied between $74 and $1332 across provinces (Demers et al. 2008). See also scenarios in Health Canada (2019:41-50).

privatization,' which occurs as result of Canada's sector-based approach to delineating public and private responsibility for health care financing (i.e., public financing for medical and hospital services, but not for pharmaceuticals, dental, vision, or other services) (Flood et al. 2002:304). For example, hospital downsizing and the accompanying shift to ambulatory care have resulted in an increased number of outpatient prescriptions (Pomey et al. 2007). Moreover, not all medical conditions are similarly impacted by the sector-based approach to insurance financing. For example, pharmaceuticals are often central to treating mental illnesses, but they are primarily prescribed in the outpatient and thus uninsured context (Dewa et al. 2005). Moreover, whether a patient has pharmaceutical insurance can affect the course of otherwise insured clinical care; unequal access to medicines has a regressive effect on the utilization of publicly available health care services, such as physician services, which further impacts access to health care for those lacking pharmaceutical coverage (Allin and Hurley 2009).

1.2.2 Pharmaceutical Costs in Canada

Canada's existing pharmaceutical insurance landscape poses cost-related challenges for individuals as well as for private and public insurance payers. Pharmaceuticals have constituted the second largest expense of total health system spending in Canada since 1997, second only to hospitals, with total prescription drug costs reaching $34.3 billion in 2019 (CIHI 2019). Pharmaceutical costs are impacted by a variety of factors, including patent legislation, the fragmentation of the insurance market, and the changing nature of pharmaceuticals (PMPRB 2018). Presently, Canadian payers employ several mechanisms to manage drug prices (including the PMPRB and pCPA described above). Despite these efforts, per-capita spending on pharmaceuticals in Canada exceeds all but two OECD countries (the US and Switzerland), and prices are on average 17% higher in Canada as compared to other OECD countries (PMPRB 2018). Pharmaceutical spending is also escalating in part due to changes in the pharmaceutical landscape as pharmaceutical companies move away from developing 'blockbuster' drugs to developing highly specialized drugs, biologics, and therapies for targeted populations. Targeted medicines are often highly expensive and may require resource-intensive diagnostic and administration or infusion regimens.[10] Since 2006, the number of medications on the market

[10] Drugs for rare diseases are often expensive as they aim to recoup R&D costs and profits through fewer sales. R&D costs of orphan drugs are estimated to be half of those for conventional drugs (Jayasundara et al. 2020).

exceeding an annual cost of $10,000 has more than tripled, while their average cost has also risen from $15,111 to $20,394 (Health Canada 2019). Similarly, claims for high-cost drugs have risen. In Ontario, the percentage of residents making claims through the province's public catastrophic drug coverage (the Trillium Drug Program) has tripled from 3.6 beneficiaries per 1000 in 2000 to 10.9 per 1000 in 2016, as have claims for high-cost biologics (Tadrous et al. 2018). The prescribing and reimbursement of potentially inappropriate medications for older adults is also estimated to contribute to high pharmaceutical costs ($419 million in 2013) (Morgan et al. 2016).

Pharmaceutical insurance is financed through a variety of sources. Public pharmaceutical coverage is financed primarily through taxation as well as through limited use of cost-sharing mechanisms (such as co-pays, premiums, or deductibles depending on the plan). Approximately 60% of Canadians have some form of private insurance coverage (Bolatova and Law 2019). Private pharmaceutical insurance is financed primarily through employer and employee-financed premiums. Plans vary in their design, including the extent to which they rely on cost-sharing mechanisms or take the form of health care spending accounts, and increasingly, private insurance plans are instituting annual or lifetime maximums in response to the increased availability of high cost drugs (Health Canada 2019). Notably, employer-sponsored health insurance premiums are not considered as taxable income and thus are indirectly publicly subsidized, since employees receive benefits for which they would otherwise be taxed.

With respect to costs to individuals, 1 in 10 Canadians state that they did not fill a prescription as required due to costs, while cost-related nonadherence (CRNA) rises to 35.6% in the uninsured (Law et al. 2012; Commonwealth Fund 2016). Furthermore, although some provincial benefit plans cover the elderly, 1 in 12 Canadians over the age of 55 report issues with CRNA, most of whom have low incomes and lack private insurance. CRNA is associated with increased morbidity (Piette et al. 2004; Egede et al. 2014) and greater overall health care costs due to increased hospitalizations and emergency department visits (Anis et al. 2005; Goldman et al. 2007). People with lower incomes, precarious employment, or mental illness are disproportionately un- and under- insured and affected by high out-of-pocket costs and CRNA

Moreover, whether drugs for rare diseases only treat truly 'rare' conditions and whether orphan drug policies have effectively incentivized innovation is contested (Marselis and Hordijk 2020).

(Law et al. 2012; Barnes and Anderson 2015). For example, between 1997 and 2009, out-of-pocket prescription drug expenditure for the lowest income quintile increased by 64% to exceed out-of-pocket expenditures in the highest income quintile, whose expenses had only increased 24% (Sanmartin et al. 2014). Furthermore, nearly 80% of households with incomes exceeding $80,000 have private coverage while fewer than 50% of households earning between $40,000 and 59,999 and fewer than 30% earning less than $39,999 have private coverage (Bolatova and Law 2019). Accordingly, the cost-related burdens associated with accessing pharmaceuticals track and exacerbate existing income inequalities. Even in Quebec, which is the only province to mandate universal drug coverage for its residents, the mixed multi-payer system imposes disproportionate burdens on lower income households as it is largely financed through premiums and user charges that represent a greater percentage of household income for lower-income households (Morgan et al. 2017).

1.3 Introduction to the Case Study: The Canadian Pharmacare Policy Debate, 1997-2019

The absence of national pharmaceutical insurance in Canada is not for lack of consideration; indeed, it has garnered political interest since the 1940s. In 1964, the Royal Commission on Health Services (also referred to as the 'Hall Commission') recommended the introduction of national, publicly-funded pharmaceutical insurance. Nevertheless, pharmaceutical insurance was not included in the major health insurance reforms of the 1950s and 1960s that resulted in the implementation of Canada's existing universal, publicly-funded, single-payer, comprehensive medical and hospital-based insurance. Instead, the foundations of Canada's contemporary pharmaceutical insurance landscape were laid in the 1970s; in the absence of a national policy, individual provinces and territories began introducing limited drug benefit programs, which usually covered social assistance recipients and the elderly, and employers began offering pharmaceutical insurance as an employee benefit (Grootendorst 2002; Boothe 2015). Despite repeated calls for national pharmacare in political circles and the media, including in 1964, 1972, 1997 and 2002, there has been no significant national pharmaceutical insurance policy reform (Booth 2015). Instead, pharmaceutical insurance reform has occurred through incremental reforms at the level of individual provinces (Daw and Morgan 2012). Moreover, from the late 1950s through to the 1990s, federal pharmaceutical policy reform focused primarily on pricing and patents, rather than on financing and insurance (Boothe 2015).

1.3.1 1990s and 2000s: Resurgent Interest in Pharmacare

In the 1990s, difficult economic conditions and funding cuts strained Canada's public health insurance systems and contributed to overcrowding in hospitals and longer wait times; such concerns prompted debate about the quality, sustainability, and future of publicly-funded health insurance in Canada and resulted in increased interest in privatization (Boothe 2015; Maioni 2015). Interest in pharmacare also resurfaced in this context. In 1994, then-Prime Minister Jean Chrétien fulfilled an election promise by establishing the National Forum on Health (NFH) "to advise the federal government on innovative ways to improve [Canada's] health system and the health of Canada's people" (NFH 1997). Chaired by the Prime Minister and comprised of 24 volunteer members, the NFH published its recommendations and final report, *Canada Health Action: Building on the Legacy*, in February 1997. The NFH identified pharmacare, or the integration of prescription drugs into Canada's existing publicly-funded, single-payer health insurance programs, as a priority for action. While the NFH fell short of specifying how pharmacare should be implemented, and instead urged governments and other stakeholders to begin negotiations to that end, pharmacare had never before received as much national attention (Boothe 2015:98). The NFH's report prompted further discussion, inquiries, and publications concerning the future of Canadian health care—including pharmacare—which persisted into the early 2000s. The NFH Report remains cited to this day. The federal Liberal party also used the NFH Report to inform its 1997 election platform, in which it cited pharmacare as a "long-term national objective" (Boothe 2015:98).

At the time, the province of Quebec, which maintains autonomous decision-making and organization of health and social services for its residents, was also considering implementing universal, public pharmaceutical insurance (Gagnon 1995). In 1997, Quebec introduced universal pharmaceutical coverage through a hybrid public-private system, and it remains the only Canadian jurisdiction to mandate universal pharmaceutical coverage for its residents.

In January 1998, Health Canada and Saskatchewan Health organized the Conference on National Approaches to Pharmacare. It was the first of three conferences supported by the Health Transition Fund (HTF), which had been established in the 1997 Federal Budget in response to the NFH's recommendations. The conference brought together various stakeholders, including Federal Health Minister Allan Rock and Saskatchewan Health Minister Clay Serby, to discuss

goals and possible approaches to developing national pharmacare. According to the conference proceedings, participants identified provisional recommendations and future areas for research, but other than general agreement "that a national pharmacare program would be desirable," there was no consensus on whether the implementation of pharmacare should proceed incrementally or through wholesale reform, nor whether it should be financed and administered primarily through the public or private sectors (Graham 1998:3).

Debate concerning how to improve and ensure the sustainability of Canada's Medicare and health care systems continued into the early 2000s and was bolstered by two major federal inquiries. Starting in 1999, the Senate Standing Committee on Social Affairs, Science and Technology held hearings under the leadership of Liberal Senator Michael Kirby. The Committee was tasked with examining and reporting on "the state of the health care system in Canada" with a focus on the system's historical development, fundamental principles, pressures and constraints, the role of the federal government, and a comparative analysis of foreign health care systems (Standing Senate Committee on Social Affairs, Science and Technology 2002:vii). The Committee published its final report, *The Health of Canadians – The Federal Role* (the 'Kirby Report') in 2002. The Committee identified two central objectives of Canadian federal health policy: ensuring that "all Canadians have timely access to medically necessary health services regardless of ability to pay" and that "no Canadian suffers undue financial hardships as a result of having to pay health care bills" (Standing Senate Committee on Social Affairs, Science and Technology 2002:6). Motivated by these objectives, the Kirby Report recommended establishing a federally-subsidized universal system of catastrophic drug coverage that would build on the existing mix of public and private insurance programs to cap out-of-pocket prescription drug costs for all Canadians and protect them from undue financial burdens associated with high drug costs (Standing Senate Committee on Social Affairs, Science and Technology 2002). It also recommended creating a national drug formulary that "could lead the way to the creation of a single national buying agency," which could attain more affordable drug prices through joint negotiations and purchasing (Standing Senate Committee on Social Affairs, Science and Technology 2002:143).

The second federal inquiry, the Commission on the Future of Health Care in Canada, was launched by the federal government in April 2001 as an independent Royal Commission under the leadership of Roy Romanow, a former Attorney General and Deputy Premier of

Saskatchewan. The Commission was tasked with holding broad public consultations on the future of Canada's public health care system in order to:

> recommend policies and measures respectful of the jurisdictions and powers in Canada required to ensure over the long term sustainability of a universally accessible, publicly funded health system, that offers quality services to Canadians and strikes an appropriate balance between investments in prevention and health maintenance and those directed to care and treatment. (Commission on the Future of Health Care in Canada 2002: xi)

In November 2002, the Commission released its final report, *Building on Values: The Future of Health Care in Canada* (the 'Romanow Report'). Similar to the Kirby Report, the Romanow Report recommended introducing a universal, federally-funded Catastrophic Drug Transfer, which would reimburse provincial and territorial public drug plans above a certain cost threshold to cap individual drug costs. Romanow justified implementing the Catastrophic Drug Transfer on the basis that it would minimize the financial burden associated with high drug costs as well as minimize regional disparities in coverage (Commission on the Future of Health Care in Canada 2002:197). Unlike the Kirby Report, the Romanow Report explicitly characterized its recommendations as incremental steps that would "lay the groundwork for the ultimate objective of bringing prescription drugs under the Canada Health Act" (Commission on the Future of Health Care in Canada 2002:190). Indeed, the Catastrophic Drug Transfer was regarded as a first step "in integrating prescription drugs into Canada's health care system" (Commission on the Future of Health Care in Canada 2002:198). Moreover, the Catastrophic Drug Transfer was only one component of a broader national drug strategy proposed in the Romanow Report. Additional recommendations included developing a national drug agency, which would be tasked with evaluating drugs, negotiating prices, and providing information to health care professionals and patients, establishing a national formulary, improving medication management and information systems, and reviewing patent legislation (Commission on the Future of Health Care in Canada 2002).

The Kirby and Romanow Reports sparked public interest in and debate about pharmacare (e.g., in the form of media coverage and policy publications), and pharmacare would receive even more attention in subsequent years during the Health Accord negotiations (Daw et al. 2013). Both reports had recommended increasing federal spending and involvement in health care. In 2004, the federal government (now under the leadership of Liberal Prime Minister Paul Martin

Jr.) negotiated an unprecedented 10-year agreement—the 2004 Health Accord—with the provinces and territories guaranteeing 6% annual increases in federal health transfer funds. The 2004 Health Accord identified ensuring access to timely care as a primary national priority, but it also introduced the National Pharmaceutical Strategy (NPS). Although the NPS fell short of explicitly recommending wholesale pharmacare reform, it drew on recommendations from the Kirby and Romanow Reports to identify nine action points for pharmaceutical policy reform. Priority reform areas included: studying options for national catastrophic drug coverage; establishing a national drug formulary; drug pricing and purchasing strategies; drug safety, effectiveness, and cost-effectiveness evaluation; prescribing practices; and access to non-patented and breakthrough drugs. The NPS also included the provision that Quebec would maintain its own pharmacare program in keeping with the principle of asymmetrical federalism, which respects Quebec's jurisdiction and interest in exercising its own responsibilities over health care organization and delivery (Government of Canada 2004).[11] Interest in national catastrophic coverage in the early 2000s echoed incremental pharmaceutical benefit reforms that were underway in individual provinces, including Saskatchewan, Manitoba, and British Columbia, which were shifting away from offering comprehensive drug coverage for seniors to implementing income-based, catastrophic coverage and which in effect reduced the scope of public drug coverage (Daw and Morgan 2012).

The NPS dominated pharmaceutical policy discussions for the remainder decade (e.g., Coalition for a Canadian Pharmaceutical Strategy 2006; Best Medicines Coalition 2006; Health Council of Canada 2009). By 2006, some progress had been made on most of the NPS action points; however, while several models for catastrophic drug coverage had been costed, no concrete recommendations for insurance reform were offered (Federal/Provincial/Territorial Ministerial Task Force 2006). In 2008, the Ministerial Task Force proposed a national standard for catastrophic drug coverage that would cap out-of-pocket spending to, on average, 5% of net income and would be funded equally by the federal and provincial or territorial governments (Canadian Intergovernmental Conference Secretariat 2008). However, disagreement over the cost-sharing arrangements stalled progress and a national catastrophic drug coverage program

[11] Although Quebec maintains a separate drug insurance and health technology assessment system, it shares health information and best practices nationally (Gagnon 2014).

was not implemented (Health Council of Canada 2009; Philips 2016). A Senate review of the 2004 Health Accord also recommended, albeit to no avail, that the federal, provincial, and territorial governments develop a national, universal pharmacare program that would include national catastrophic drug coverage and a national formulary (Standing Senate Committee on Social Affairs, Science and Technology 2012).

1.3.2 The 2010s: The Contemporary Debate

Pharmacare received only periodic attention into the early 2010s, as evidenced by fewer policy reports and newspaper articles published on the topic (Daw et al. 2013), but it started garnering more attention in 2013 and 2014. By 2016, it had developed into a full-fledged topic of public debate when the Canadian House of Commons' Standing Committee on Health (HESA) began holding hearings on the development of a national pharmacare program. In the early days of the contemporary pharmacare debate, interest in pharmacare—especially in universal, publicly-funded, comprehensive insurance—was in part galvanized by a series of publications and advocacy campaigns led by a group of academic researchers, including some who had been engaged in earlier iterations of the debate (e.g., Lexchin 2001, Morgan and Willison 2004). Several academics, including Steven Morgan (University of British Columbia), Joel Lexchin (York University), and Marc-André Gagnon (Carleton University), who were members of the Pharmaceutical Policy Research Collaboration, a CIHR/Health Canada Emerging Team on Equity in Access to Necessary Medicines (2009–2014), published widely on pharmacare in academic journals and policy reports for think tanks (e.g., Gagnon and Hébert 2010; Morgan et al. 2013; Morgan et al. 2014; Gagnon 2014; Morgan et al. 2015a; Morgan et al. 2015b). Of these publications, those that received the greatest media coverage and public attention were reports that modeled the potential cost-savings associated with adopting public, single-payer pharmacare (e.g., Gagnon and Hébert 2010; Gagnon 2014, Morgan et al. 2015a).

The Pharmaceutical Policy Research Collaboration also hosted a national symposium in February 2013 to launch the 'Pharmacare 2020' public advocacy campaign calling for the development of national, universal, public pharmacare by 2020. In 2015, they released an eponymous report, *Pharmacare 2020: The Future of Drug Coverage in Canada,* calling for the implementation of universal, comprehensive, publicly-funded pharmaceutical insurance on the grounds that it would improve access to needed prescription drugs, promote a fair distribution of

costs, improve safe and appropriate prescribing, and increase the value for money spent on drugs (Morgan et al. 2015b).

Politicians also began demonstrating interest in pharmacare around this time. In December 2014, Dr. Eric Hoskins, then-Ontario's Minister of Health and Long-Term Care, published an opinion editorial proclaiming that "the time for national pharmacare has come" (Hoskins 2014). Hoskins would later be instrumental to overseeing the introduction of OHIP+, a policy that expanded Ontario's public pharmaceutical coverage for seniors (the Ontario Drug Benefit) to include residents 24 years and younger.[12] Later, he would go on to chair the federally-appointed Advisory Council on the Implementation of National Pharmacare. In June 2015, Minister Hoskins and the Government of Ontario hosted a Ministerial roundtable on pan-Canadian pharmacare, with a focus on universal access to pharmaceuticals.[13] While there was broad agreement concerning the need to both improve pharmaceutical coverage and lower drug costs, ministers disagreed on how to best achieve these objectives (Health Quality Ontario 2015).

In 2015, pharmacare also attracted greater attention in media, civil society, academia, health professions, and industry as more pharmacare policy publications were released. Two public opinion polls conducted in July 2015 reported that there was public appetite for some form of pharmacare across all demographic and political subgroups in Canada. One poll found that 91% of those surveyed expressed "support for the concept of a national 'pharmacare' program that would provide universal access to prescription drugs" (Angus Reid 2015:12). However, the same poll reported lower agreement around the specifics of a pharmacare program, with many (61%) of those surveyed expressing concerns about costs and 70% preferring to finance pharmacare by raising corporate rather than personal or sales taxes (Angus Reid 2015). The second poll also found that a large majority (79%) of those surveyed supported the idea of national pharmacare,

[12] OHIP+ illustrates the political nature, as well as path dependency, of pharmaceutical insurance policy in Canada. OHIP+ came into effect in January 2018 and offered public drug coverage for all Ontario residents 24 years and younger. However, following provincial elections in June 2018, the newly elected Conservative Government announced its intention to roll back OHIP+ within a month of being elected. In April 2019, the changes to OHIP+ came into effect; children and young adults who previously had private coverage were reinstated on their original coverage, but public coverage remained for those who had previously had none.

[13] The Ministerial roundtable included all of the provincial and territorial ministers of health.

but that opinions were split concerning the type of program pharmacare should entail (e.g., public, universal; fill-in-the gaps, mixed public-private; or catastrophic) (Abacus Data 2015).[14]

Pharmacare also made it into the federal election platforms of the National Democratic Party (NDP) and Green Party in 2015. In October 2015, the Liberal Party of Canada won a majority in the federal general elections and replaced the Conservative Party of Canada, which had by then been in power for a decade. Although the Liberals had not endorsed pharmacare in their election platform, Prime Minister Justin Trudeau identified pharmaceuticals as a priority in his mandate letter to the Minister of Health, which emphasized addressing access to and affordability of necessary medications and "exploring the need for a national formulary" (Trudeau 2015).

Interest in pharmacare further increased in 2016 when the House of Commons Standing Committee on Health (HESA), the federal health committee comprised of elected Members of Parliament (MPs), began holding hearings on the development of a national pharmacare program. From April 2016 through to October 2017, HESA heard from 99 witnesses from various stakeholder groups over the course of 22 hearings and received 31 policy brief submissions. The HESA hearings were accompanied by a notable increase in policy publications and media coverage concerning pharmacare. Several organizations became vocal supporters of universal, public pharmacare. The Canadian Federation of Nurses Unions (CFNU) was an early and vocal advocate of universal public pharmacare, making pharmacare one of its priority advocacy areas, commissioning several related reports (e.g., Gagnon 2014, Mackenzie 2017, Lopert et al. 2018, Batt 2019), and hosting parliamentary briefings about pharmacare for senators, members of parliament, and healthcare stakeholders.[15] In 2017, the Canadian Labour Congress (CLC), Canada's largest trade union organization, launched a national public advocacy campaign ("Pharmacare – A Plan for Everyone") calling for universal public, single-payer pharmacare (CLC 2017). As a part of its campaign, the CLC hosted a year-long, national town hall tour.

[14] Dr. Steven Morgan, who was mentioned earlier and is a proponent of universal, public pharmacare, contributed to the research and analysis of the first (Angus Reid) opinion poll. The second poll (Abacus Data) was commissioned by the Canadian Pharmacists Association, which advocates for mixed, multi-payer pharmaceutical insurance.

[15] The CFNU had also advocated for a public, single-payer pharmacare system in the 2000s.

While the early stages of the contemporary pharmacare debate were dominated in large part by proponents of universal, public pharmacare who argued against the status quo, a broader range of stakeholders, including some who advocated for a 'fill-in-the-gaps' insurance model that would build on the existing system of public and private coverage, became more vocal during the HESA hearings. For example, a costing report commissioned by the Canadian Pharmacists Association disputed the cost savings associated with adopting national, public pharmacare that had been reported by Morgan et al. in 2015 and were being widely cited as evidence in favour of reform; instead, it concluded that a pan-Canadian model focused on increasing access for the uninsured within the existing insurance landscape would be more feasible constitutionally and would shift fewer costs to governments and taxpayers (Palmer et al. 2016). Similarly, the private insurance industry (CLHIA 2014; Standing Committee on Health 2016a; Sun Life Financial 2018) and brand-name pharmaceutical industry (Standing Committee on Health 2016b) advocated for a mixed public-private pharmacare system, while conservative and market-oriented think tanks opposed public single-payer pharmacare and even expressed skepticism about the need to reform or expand pharmaceutical insurance to begin with (Esmail and Barua 2015; Labrie 2015; Acri 2018).

By 2017, the debate had shifted from considering whether to implement universal pharmacare to discussing how it should be designed (e.g., through a public, single-payer system or by addressing gaps in coverage in the existing hybrid insurance landscape).[16] In April 2018, HESA released its final report, *Pharmacare Now: Prescription Medicine Coverage for All Canadians*, outlining 18 recommendations for pharmaceutical policy reform. The majority of HESA members (all of the MPs from the Liberal Party of Canada and New Democratic Party) recommended amending the *Canada Health Act* to include prescription drugs as an 'insured health service' to be provided through universal, public, single-payer insurance (Standing Committee on Health 2018). A minority of the MPs (all from the Conservative Party of Canada) voiced concerns regarding the feasibility and costs associated with a publicly-funded, single-payer plan. As in previous pharmacare proposals, HESA recommended additional reforms

[16] Only a minority of stakeholders challenged the need for reform by questioning the evidence concerning gaps in coverage; for example, they cited that the overwhelming majority of Canadians, including individuals on social assistance, were already eligible for public pharmaceutical insurance coverage, whether or not they took advantage of it (e.g., Esmail and Barua 2015).

including developing a voluntary national prescription drug formulary, improving drug pricing and reimbursement processes, and improving data and information systems to support better drug management and adverse event reporting.

Perhaps the best indication that the debate had refocused on considering how rather than whether to implement pharmacare was the establishment of the Advisory Council on the Implementation of National Pharmacare (the 'Advisory Council'), which was announced in the 2018 Federal Budget. The Advisory Council was tasked with submitting detailed recommendations on how to implement national pharmacare to the federal Ministers of Finance and Health. Chaired by Dr. Hoskins, the Advisory Council held in-person and online consultations with stakeholders and members of the public from June 30, 2018 to September 30, 2018. In a discussion paper prepared to guide its consultations, the Advisory Council identified two primary areas of concern in the pharmaceutical insurance landscape—access and costs—and three questions that required addressing with respect to implementation: 1. Who will be covered and under what circumstances?; 2. Which drugs are covered?; and 3. Who pays? (Health Canada 2018).

The Advisory Council released an interim report in March 2019; it identified core principles that ought to underpin national pharmacare and recommended that the government create a national drug agency, develop a comprehensive national formulary, and invest in drug data and information technology—all of which would serve as foundations for a national pharmacare program (Hoskins 2019). Two weeks later, the Federal Government released its 2019 Budget in which it followed the Advisory Council in identifying lowering drug costs and improving drug coverage as key objectives for national pharamacare. The 2019 Budget also committed $35 million over four years starting in 2019-2020 to establish a Canadian Drug Agency Transition Office as well as up to $1 billion over two years, starting in 2022–23, with up to $500 million per year ongoing, to help expand access to expensive drugs for rare diseases (Canada 2019). In June 2019, the Advisory Council released its final report, *A Prescription for Canada: Achieving Pharmacare for All* (Health Canada 2019). The report recommended that the federal government work with the provinces and territories to establish universal, public, single-payer pharmacare in accordance with the principles outlined in the *Canada Health Act* in order to address "gaps in coverage and access that are unfair and lead to poor health outcomes" as well as "spiraling drug costs that are unsustainable" (Health Canada 2019: 9-10). The report outlined an eight-year (2020-2027) plan for implementing national pharmacare and implementing supporting features

such as a national drug agency, a national comprehensive drug formulary, and a strategy for expensive drugs for rare disease.

Interest in pharmacare has persisted since the Advisory Council published its recommendations. Pharmacare featured in the election platforms of three major federal parties (the Liberal Party, New Democratic Party, and Green Party) in the October 2019 federal elections. Following the re-election of the Liberal government, albeit as a minority government, Prime Minister Justin Trudeau instructed the new Minister of Health to continue implementing "national universal pharmacare, including the establishment of the Canada Drug Agency, and implementing a national formulary and a rare disease drug strategy to help Canadian families save money on high-cost drugs" (Trudeau 2019). The Liberal government reiterated its intentions concerning pharmacare in the Throne Speech in September 2020. Polling suggests that pharmacare has also continued to garner public support (Nanos 2020; Angus Reid 2020).

1.4 Chapter Overview

Chapter 2 outlines the context and rationale for my inquiry and situates my study within two bodies of literature. First, I examine literature concerning the nature of the relationship between ethics and public policy. I describe the ways in which normative concepts are understood as being implicated in policy-making, discourse, and analysis, and I review the contributions and limitations of ethics and philosophical analysis to policy analysis. A central tenet motivating my inquiry is that public policy and policy-making are inherently normative enterprises, since they raise and require engagement with fundamentally moral and political questions. In the second half of the chapter, I situate my research in the context of existing analyses of the Canadian pharmacare debate. While many analyses draw attention to the significance of values and normative ideas in the pharmacare policy debate—especially as they are seen as relating to national identity and values—few represent an explicitly or primarily normative analysis that address justificatory questions. My inquiry proposes to address this gap by conducting a systematic normative analysis of pharmacare policy arguments in order to offer conceptual clarity around key principles and arguments, to identify areas of congruence and tension within the debate, and to establish a basis for the critical analysis of normative arguments within the debate. It is for this reason—as I expand on in Chapter 3—that I chose to conduct an empirical bioethics case study, which is well suited to normative policy analysis.

Chapter 3 describes the methodological orientation and methods that I used to address my research objective and questions. I describe how bioethics offers a normative mode of inquiry for analyzing public policy discourses that is both practically-oriented and conceptually-informed—bridging moral reasoning with policy and practice. I conducted a critical realist, pragmatic empirical bioethics inquiry, which draws both on qualitative research methods for data collection and analysis and philosophical methods of moral reasoning to address the pragmatic and analytic objectives of my inquiry. In particular, I conducted a single case study of the Canadian pharmacare policy debate. I describe how I designed my case study and selected 72 policy documents and transcripts from 1997 to 2019 to form the basis for my analysis. Furthermore, I describe how I adapted an approach for thematic analysis in order to identify and characterize the normative rationales underlying the main arguments in the pharmacare debate.

Chapter 4 outlines the theoretical considerations that I draw on from political philosophy and public health ethics to inform the interpretation and analysis of my findings and discussion in Chapters 5 and 6. I outline four theoretical orientations in political philosophy—libertarianism and classical liberalism, public economics, egalitarianism, and communitarianism—which offer distinct accounts and justifications for the legitimate role of public and private institutions, including in the financing and provision of health insurance. The normative rationales and concepts that I describe from each respective account contribute to a theoretical framework which I draw on to inform the analysis of arguments in the pharmacare policy debate in Chapter 5. As I discuss in Chapter 3, this theoretical framework offers a conceptual grounding and language to facilitate the interpretation and analysis of normative rationales that underpin policy arguments presented in the documentary and testimonial data in my case study. In addition, I put my findings into conversation with the theories presented in this chapter in Chapter 6.

Chapter 5 presents the findings of my empirical bioethics case study. Drawing on the theoretical framework from the previous chapter, I characterize the main policy arguments in the debate in terms of their underlying normative positions. I describe two primary findings: first, that different pharmacare policy proposals appeal to different underlying normative positions, which in turn shape distinct framings of issues related to access, costs, and appropriateness, and accordingly, ideas about the purpose of pharmaceutical insurance and who ought to be responsible for realizing it; second, I describe the progression of arguments and normative justifications in the debate since 1997, noting that the contemporary debate can be characterized

by agreement around universalizing access (in some form), and that public single-payer pharmacare has attracted particular attention on the basis of not only its equity- or community-promoting features, but especially its efficiency-promoting ones. However, what is deemed efficient and fair is disputed between different stakeholder groups, often as a result of distinct understandings of the purpose of insurance, and accordingly, prioritizations and appeals to medically necessary or appropriate pharmaceutical prescribing and use.

Chapter 6 consists of the discussion in which I analyze the findings described in the previous chapter in light of the policy and theoretical literature from Chapters 2 and 4 to address the analytic and normative aims of my inquiry guided by my second research question. I discuss how the pharmacare debate is characterized by normative tensions between competing accounts about the legitimate scope of state activity and collective responsibility vis-à-vis health and health insurance. Moreover, I contend that certain cost-related concerns in the debate are not merely 'neutral' economic concerns, but rather are indicative of tensions between competing accounts of justice. Finally, I critically analyze the normative rationales in the debate. I assert that insofar as Canada seeks to have a system of universal pharmaceutical coverage, the efficiency of a single-payer system offers the most compelling justification for why a system of universal, comprehensive, progressively-financed insurance should be financed and administered publicly. To achieve similar equity and efficiency objectives, a system of mixed multi-payer insurance would require greater public regulation than has been advocated for. While Canadian Medicare has been recognized as expressing a sense of solidarity, it is unclear whether solidarity necessitates or is sufficient for justifying a single-payer system in particular. Nonetheless, solidarity bridges both deeper considerations of relational or distributive justice—such as those pertaining to a common good in which citizens share a commitment to universal coverage and to risk and income solidarity—and more instrumental ones in the form of efficiency, where the chance solidarity inherent to insurance makes it a productive mechanism for collectivizing responsibility in cases where responsibility is difficult to or ought not be adjudicated.

Chapter 7 presents my conclusion, in which I describe how my analysis has addressed the study objective and research questions and I discuss the substantive and methodological contributions of my inquiry. I conclude with a reflection on the limitations of my inquiry as well as several outstanding questions and possible avenues for future research.

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Chapter 2
Background

> On the one hand [policy analysis] is empirical but not rigorously scientific in the classical sense of the term. On the other hand it is fundamentally concerned with the realization of norms and values, but is not ethics per se. Policy analysis lies squarely (if not uncomfortably) between science and ethics. (Fischer and Forester 1987:13)

2 Background

This chapter provides the background context and rationale for my inquiry and positions my study within two relevant bodies of literature. First, I examine literature concerning the nature of the relationship between ethics and public policy; public policies are increasingly recognized as being normative entities and relatedly policy analysis is an inherently normative enterprise. I describe the ways in which normative concepts are understood as being implicated in policy-making, discourse, and analysis, and I review the contributions and limitations of ethics and philosophical analysis to policy analysis. A central tenet motivating my inquiry is that public policy is inherently normative as it raises and requires engagement with fundamentally moral and political questions concerning desirable and legitimate policy ends and processes. As a sub-set of public policy, health policy is no exception. Although policy makers and analysts may engage with values only superficially or implicitly, a bioethics analysis—understood as being both normative and practically-oriented—can contribute to understanding and informing health policies by making underlying normative rationales explicit to form the basis for a reasoned critique of and deliberation about policy objectives, arguments, and proposals. It is for this reason, as I expand on in my Methodology and Methods Chapter, that I opted to conduct an empirical bioethics analysis, which is well suited to analyzing the normative features of the discourse in the pharmacare public policy debate.

Following the discussion of the relationship between ethics and policy, I describe how the Canadian pharmacare debate has been analyzed and understood thus far. While normative concepts and justifications feature in, and are important to, health insurance policy and reform, including in the Canadian pharmacare debate, they have seldom been the focus of policy analyses. In this sense, the majority of existing analyses of the pharmacare debate reflect a

tendency in Canadian policy analysis to focus on historical, political science, or economic analyses rather than on normative analysis or argumentation.

Embracing the value of normative policy analysis, this inquiry set out to examine how a bioethics analysis could contribute to understanding the normative underpinnings of arguments in the pharmacare policy debate and the grounds on which different pharmacare policy options are justified. However, this chapter does not discuss normative accounts of health insurance; rather, the Theoretical Considerations chapter outlines theoretical accounts of the role of public and private institutions in health insurance policy, which inform the analysis in later chapters.

2.1 Ethics and Public Policy

Public policies are amenable to various types of analysis. Sociologists, for example, examine the social norms that operate within policy and policy processes in particular contexts and consider "the ways the symbolism of their language matters, the ways the consideration of their audiences matters, the ways they construct problems before solving them" (Fischer and Forester 1993:7). Political scientists, meanwhile, study what governments and political actors do rather than what they ought to or purport to do; they examine how values feature in policy processes, such as in framing policy problems, and how policy arguments "are intimately involved with relations of power and the exercise of power, including the concerns of some and excluding others, distributing responsibility as well as causality, imputing praise and blame as well as efficacy, and employing particular political strategies of problem framing and not others" (Fischer and Forester 1993:7; Stewart 2009). Sociological and political analyses are primarily concerned with analyzing and explaining the 'how' of policy rather than being as explicitly normative. As an explicitly normative discipline grounded in normative and political philosophy, bioethics offers an additional approach for rendering explicit often implicit normative assumptions, critiquing the normative concepts and rationales invoked within policy arguments and proposals, and offering reasoned justifications for policy recommendations based on accounts of what *ought* to be the case. As the objective of my inquiry is to examine what bioethics—as a normative discipline—can contribute to understanding and informing the pharmacare policy debate, it is worth examining the relationship between ethics and policy to understand how bioethics can contribute to public policy.

In the first half of this chapter, I expand on Kenny and Giacomini's (2005:249) aforementioned observation that "there is a resonance between the "praxis" of ethics and the "polis" of policy: both involve developing shared ideas about not only ideals, but also pragmatic possibilities." First, I present a brief overview of the contested history of policy analysis as a normative enterprise. Next, I describe the features that distinguish ethics and policy as discrete, albeit overlapping, entities to identify the limits of normative policy analysis. Then, I outline where ethics and policy resonate and I position my study by discussing the role and contributions of the ethicist in public policy and the ways in which ethics can contribute to policy analysis.

2.1.1 Policy Analysis as a Normative Enterprise: A Brief History

According to an oft-cited definition, public policies can be understood as being "anything a government chooses to do or not to do" (Dye in Howlett and Cashore 2014:17; Stewart 2009:1). More concretely, public policies "exist as combinations of goals and means put together and implemented by a variety of authoritative policy actors interacting within an environment of multiple actors and organizations over both time and space" (Howlett and Cashore 2014:20). Policies are often understood as being public insofar as they are adopted or endorsed by governments, which uniquely bear the legitimate political authority required to implement and enforce policies affecting those under their jurisdiction (Howlett and Cashore 2014). Policy analysis is a practice within the policy-making process in which policies are studied, formulated, evaluated, critiqued, and improved. As policy analysis has formalized and professionalized over the past century, it has faced a fundamental question: whether policies and the processes through which they are developed and analyzed are value-neutral (technical, scientific, objective) or are inherently value-laden (political, normative, negotiated).

The normativity of public policy has not always been acknowledged nor embraced. As Deborah Stone (2012:379) suggests, "for centuries, governing through knowledge instead of politics has been a utopian dream"— a dream motivated by the desire to transform policy-making into a rational, orderly practice through objective, scientific methods in place of the seemingly "messy, irrational, selfish, and shortsighted" processes that have long characterized political life. The impulse to transform policy-making and analysis into a technical science grounded in value-neutral, rational, and objective methods has multiple origins: Enlightenment rationalism, which emphasized that knowledge consisted of objective truths; 19th century empiricism, which

considered experimentation as the only legitimate means of acquiring true knowledge through sensory experience; and 19th and 20th century positivism, which delineated strictly between facts and values (Jennings 1987). Although ethics and policy have a long, interrelated history,[17] the positivist tradition in policy science saw values as subjective and not subject to rational analysis and deliberation and thus beyond the purview of a policy science concerned primarily with the rational analysis of objective, empirically-determined facts (Emanuel 2002). Moreover, value neutrality featured as a central tenet of liberalism, which posited that liberal political institutions ought to be neutral with respect to questions of fundamental values or conceptions of the good.

It may have seemed that an objective, evidence-driven policy science would be realized following the Second World War when policy analysis was formalized, giving rise to a class of professional policy analysts and experts who adopted technical methods of policy analysis with the aim of delivering objective, evidence-based policy recommendations (Fischer and Forester 1987). This 'rationality project' aimed to remove policy analysis from the seemingly chaotic domain of politics by emphasizing administration over governance (Stone 2012:9). The dominance of rational choice theory, which adopted economic reasoning (including methodological individualism and value-neutrality) and elevated the pursuit of efficiency through cost-benefit analysis as a primary policy objective, reflected the desire to adopt a technical and instrumental rationality to achieve a scientifically rigorous and value-neutral approach to policy analysis (Fischer and Forester 1987). Despite efforts to excise normative considerations from policy analysis, it proved difficult to ignore the underlying 'value' problems—including questions concerning the nature of the good life and the objectives of shared life within a political community—that lay at the heart of many prominent and seemingly intractable public policy debates and prompted questions of "efficiency for what?" (Fischer and Forester 1987:11).

In the 1980s and 1990s, policy analysis underwent an 'argumentative turn' as it began to attend to the normative and discursive features of policies and policy-making (Fischer and Forester 1987; 1993). Policy analysis was increasingly recognized as more than a technical exercise of calculating costs and benefits, since planners and analysts were actively engaged in reason-

[17] For example, see Jennings 1987 and Jennings 1993.

giving, having to "make practical arguments that are internally coherent *and* externally compelling, persuasively gauged to real and thus diverse political audiences" (Fischer and Forester 1993:4-5). The process of analysis was itself recognized as a form of argumentation, which necessarily involved making decisions about what to emphasize and what to exclude (Stone 2012).

Rather than doing away with techno-scientific approaches to policy analysis, policy-making is now commonly recognized as "both a technical and political process of articulating and matching actors' goals and means" (Howlett and Cashore 2014:17). In other words, policy analysis "inevitably involves a clarification and ordering of values" and "rests on some conception of public purpose" rather than simply being "a doctrine of instrumental rationality, a fitting of efficient means to stipulated ends" (Anderson 1987:23). The growing recognition that policy-making and analysis are normative and deliberative arguably also reflects its origins; the term policy originates from the Greek *polis,* which denotes a city-state, but also a citizenry, or a body of individuals engaged—as a collective—in deliberating on common purposes or ends in a shared public space (Malone 1999; Stone 2012). Drawing on the notion of the polis, Stone (2012:20) simply describes public policies as being about "communities trying to achieve something as communities," which expands the notion of *public* policy described earlier to explicitly emphasize its nature as collective enterprise or action between co-citizens.

Accordingly, public policies are increasingly recognized as being inherently normative as they raise and require engagement with moral and political questions concerning political authority and desirable policy ends, means, and processes (Fischer and Forester 1987; Kenny and Giacomini 2005; Stone 2012; Howlett and Cashore 2014). Understanding policies as normative entities has substantive, epistemological, and methodological implications. Policies are recognized as being substantively normative as "normative rationales operate implicitly even when not analyzed explicitly" (Kenny and Giacomini 2005: 249). Normative rationales are implicit in policy, since normative concepts such as principles and values are fundamental to evaluative and prescriptive reasoning and to identifying, articulating, and justifying policy objectives and priorities. Relatedly, the very act of defining an issue as a policy 'problem' requires evaluating it against a normative standard or some desirable political end, while policy solutions are identified and justified using evaluative decision-making criteria (Anderson 1979; Stone 2012).

Policies are recognized as normative entities for epistemological and methodological reasons as well. As described above, there is a growing recognition that there is "a false dichotomy between good ends or goals and efficient and effective means," since evidence and technical criteria are not value-free and "moral imperatives underlie policy instruments (e.g., regulation, markets, institutions) regardless of the ends to which they are used" (Kenny and Giacomini 2004:249). In other words, public policies are not solely the result of technical analyses, but also take shape through political deliberation, argumentation, and negotiations which appeal to normative concepts and reasons. As Stone (2012:10) suggests, "the very categories underlying rational analysis are defined in political struggle." For example, the goals of health care—whether they be the prevention of diseases and injury and the promotion of health, the relief of pain or suffering, the care and cure of maladies, or the avoidance of premature death or pursuit of a peaceful death—and the priorities among them are neither self-evident nor inevitable, but rather are open to and shaped by political debate (Callahan 2002).

The growing recognition among policy scholars that policies are normative entities has prompted calls for the establishment of a field of 'health policy ethics' to foster normative policy analysis, which has been the most neglected form of policy analysis (Danis et al. 2002; Kenny and Giacomini 2005). That policy analysis and public policies are inherently normative is a central tenet motivating my inquiry, so I now turn to describing what it means for policies to be normative, as well as the ways in which ethics can contribute to policy analysis and public policy.

2.1.2 Differences between Ethics and Policy

Calls for the establishment of a field of health policy ethics, or forms of analysis that more explicitly attend to the ethical and political dimensions of policy, are at least in part motivated by observations that normative reasoning is often implicit in policy analysis while other forms of reasoning (e.g., scientific or economic) receive more explicit consideration (Danis et al. 2002; Hoedemakers 2003; Kenny and Giacomini 2005; Stone 2012). Normative reasoning is in part less emphasized owing to the legacy of positivist education and training in policy sciences in the 20th century, which posited a strict distinction between facts and values. Yet ethics and policy do also have distinct purposes. Before describing how ethics is pertinent to public policy, it is worth

delineating how the two are also distinct to determine the contributions of ethicists and the field of health policy ethics to public policy.

Ethics, or normative philosophy, is a branch of philosophy that engages in the systematic analysis of normative questions, concepts, justifications, and arguments to understand and justify how we ought to act or be. Ethics concerns both axiological (evaluative) considerations about the good as well as deontic considerations, such as whether actions or policies are morally right, permissible, required, or just. While ethics is traditionally understood as primarily governing private life, political philosophy expands the scope of systematic moral analysis to social or political life and focuses on analyzing criteria for a good or just society, relations between individuals and states, and political authority. Public policy and policy analysis, meanwhile, are intrinsically more practical. Policy can be conceived of as the "practical pursuit of the good" or, more aptly, the pursuit of *a* politically-defined good (Kenny and Giacomini 2005). Similarly, policy analysis aims at improving policymaking rather than justifying theories or systems of thought (Anderson 1987). Ethics, as a subset of philosophy, and policy can thus be conceived as having distinct purposes; philosophy, as an academic discipline, is primarily concerned with the pursuit of truth, while policy-making is concerned with the practical consequences of policies (Brock 1987). As a result, policy analysts make use of a broad array of evidence, techniques, tools, and types of reasoning (including legal, logical, empirical, and normative reasoning) in their work (Gillroy and Wade 1992).

Public policies differ from philosophy, including normative and political philosophy, in at least three ways: public policies are decision-oriented, emphasize consensus, and are biased towards the status quo (Wolff 2011:5). While philosophy "thrives on disagreement" and leaves all assumptions open to scrutiny, policy-makers cannot "agree to disagree" as they ultimately must reach a policy decision (Brock 1987; Wolff 2011:3). Relatedly, policy-making also aims at reaching some form of consensus to be able to move forward with policy implementation. Accordingly, it often matters more for policy whether a position is broadly shared among the constituents or stakeholders to whom policy-makers are accountable than whether it is necessarily morally right or persuasive (Wolff 2011:5). Accordingly, policy-makers are concerned with framing arguments in a way that persuades those affected by a policy of its merits (Brock 1987). Finally, public policy is conservative in that it favours the status quo and places the justificatory onus primarily on those advocating for reform (Wolff 2011). These

features of public policy have several related implications for philosophical and ethical policy analysis.

Policy-making requires engaging with the world (including the moral agents and political actors who inhabit it) as it is. Accordingly, non-ideal normative theories or accounts, in which normative obligations are discerned within the real-world contexts in which they are intended to be applied, are more directly applicable to public policy analysis. Philosophical analyses, however, often take the form of ideal theory.[18] Analyses that rely on idealized assumptions may have limited policy relevance if they: offer implausible policy recommendations (e.g., if they ignore policy legacies or contravene realities of human psychology or existing social or cultural norms and practices); demonstrate blindspots concerning other ethical issues that warrant policy attention; suggest 'second best' cases where partial implementation of a policy leads to worse outcomes than if no policy reform were undertaken; or face conceptual inadequacy, such as when the basic concepts on which an analysis is grounded do not reflect the realities of the very people for whom they are most pertinent (Wolff 2018). Another limitation (albeit not an inherent flaw) of philosophical analyses is that they may underdetermine policy decisions. A philosophical theory or argument may underdetermine concrete policy directions if, for example, it defends a particular idea of justice or approach to priority-setting that is compatible with multiple policy options (Emanuel 2002; Wolff 2018). These considerations support a problem-driven approach to normative policy analysis.

In pluralist societies, public policy also requires a pragmatic orientation that can accommodate multiple political positions. While normative or political philosophy can aim at discerning moral or political 'truths' through systematic reasoning and distinction-making, public policy is not a scholarly pursuit or "sphere of pure reason" (Brock 1987; Wolff 2011:4). Prospects for policy reform are shaped by institutions or the interests of stakeholders and policymakers as well as a plurality of policy ideas, which include principles, values, and normative reasons. Securing support for policy reform often involves recognizing and pursuing policies for which there is an "overlapping consensus," or where different stakeholders may support the same policy for distinct ethical reasons (Rawls 1985:225; Wolff 2011). Philosophical analyses that proceed by

[18] I revisit this distinction between non-ideal and ideal theory in chapter 4 (Theoretical Considerations).

applying a single theory which they take to be true to a policy problem in a top-down fashion run the risk of being dogmatic and thus undermining policy coalitions and consensus (Wolff 2018).

The very notion of normative policy analysis, or overtly drawing attention to the ethical and political dimensions of policies, can be considered politically disadvantageous as ambiguity about policy goals or reasons can be strategic when it facilitates a broader coalition of supporters who nonetheless have distinct underlying political positions and value commitments. Kingdon (2002), for example, cautions that overtly identifying policy goals and priorities through ethics analysis can be politically disadvantageous if deep-rooted ideological and political differences that undermine policy coalitions and consensus are made explicit. Nonetheless, Kingdon (2002) acknowledges that ideas, including those about justice, play a significant role in persuasion and argumentation in policy processes. Amy (1987:57) similarly cautions that normative policy analysis can undermine the apparent political and intellectual legitimacy of decisions reached by unelected policymakers, policy analysists, or bureaucrats; technocratic justifications can offer a "valuable political shield" for analysts by appearing to limit their work to implementation—rendering it a matter of technical expertise and administration—rather than overt policymaking or governance. While these assertions point to certain political perils facing normative policy analysis, they do not preclude all normative analysis. Indeed, if anything, there is a growing body of ethics literature, and moreover, growing engagement by ethicists and philosophers, on matters of public policy. Having described some of the ways in which ethics and policy are distinct, I now turn to describing the ways in which ethics can nonetheless contribute to policy analysis.

2.1.3 The Role of the Ethicist in Public Policy: Implications for Methodology and Theory

If public policy is normative and at the same time distinct from ethics, what then is the appropriate role of the ethicist or philosopher in policy analysis and public policy? Keeping in mind the problem-oriented and pragmatic nature of policy-making described in the previous section, there are two main projects that an ethicist can contribute to public policy: a more immediate objective of pragmatic policy analysis that aims to inform ethical policy-making and a longer-term objective of contributing arguments to illuminate other possible ethical futures, which can shape the tenor or parameters of public policy debates in the long-term (Wolff 2011:195).

For several decades now, governments have engaged philosophers and ethicists through specialized advisory groups or as members of government panels for policy commissions (e.g., various Presidential Bioethics Commissions in the US, the Values Working Group in the National Forum on Health, the Public Health Ethics Consultative Group at the Public Health Agency of Canada, etc.). Even when they have not occupied formal roles as policy advisors, ethicists and political philosophers have increasingly engaged with concrete policy problems and issues over the past several decades. The presence of philosophers in the policy arena has prompted consideration of what the appropriate and legitimate role of a philosopher is within the policy process. It is commonly recognized that the contributions of ethicists and philosophers to policy should not proceed in a deductive, theory-driven or 'top-down' manner, such as through the selection and application of an *a priori* preferred ethical theory to a particular policy problem[19] (Brock 1987, Kymlicka 1996, Powers 2005, Rogers 2007, Wolff 2011, Wolff 2018). Owing to the pragmatic and political nature of policy described earlier, the ethicist is not considered an ethical expert in the sense of bearing greater moral authority by virtue of their occupation (Powers 2005). Rather, the ethicist's content expertise is primarily circumscribed to facilitating the identification, clarification, and justification of normative concepts, arguments, and issues, which can then be subject to broader deliberation and analysis in public fora.

Envisioning the role of the ethicist as being one that is primarily pragmatic and which aims at identifying and clarifying ethical concepts and considerations in policy, rather than as a definitive, expert arbiter of moral 'truths' has several methodological implications.[20] At its core, a problem-driven approach to normative policy analysis requires the ethicist to engage with the policy context at the outset of the analysis. This can include identifying current practices and facts, present and comparative regulations and policies, the historical context of the policy, and identifying areas of agreement and disagreement within a policy debate, including about values (Wolff 2011:196-197; Wolff 2018). As Wolff (2011:192) notes, considering the world as it is places at least two constraints on ideal-building in normative policy analysis: first, certain

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[19] Wolff (2018) calls the deductive approach to philosophical analysis 'applied' philosophy, which he distinguishes from 'engaged' or problem-driven philosophy. However, I use 'applied' philosophy, and ethics, in a broader fashion that includes deductive, inductive, and other approaches to normative justification. This is discussed in greater depth in Chapter 4.

[20] I revisit these and expand on the methodological implications of a pragmatic normative analysis in my Methodology and Methods Chapter.

policies or ideal states may no longer be possible; and second, identifying policy reforms that ought to be pursued requires knowing the broader historical, social, political, and economic context of the policy in question.

Understanding normative policy analysis as a pragmatic and political endeavor also has methodological implications for how normative analyses and arguments are constructed and presented. For example, reflecting on his experiences as a staff philosopher on the US President's Commission for the Study of Ethical Problems in Medicine, Brock (1987) distinguishes between the purposes of philosophy as a scholarly discipline aimed at discerning truths and policy analysis, which he claims ought to be primarily concerned with policy consequences. Echoing Kingdon (2002) and Wolff's (2011) assertions about the importance of consensus and coalition building in public policy-making, Brock notes that philosophers working directly in the policy-making context ought to be concerned not only with the consequences of the policies that they analyze, but also the consequences of their own analyses. For, if it is feasible to generate agreement about policy directions but not fundamental justifications, then, it is justified and even necessary to frame or justify an argument in a way that fosters consensus, even if the policy would be otherwise be better (or more soundly) justified for different reasons (Brock 1987). Accordingly, normative policy analysis requires identifying the normative positions of various stakeholders both to inform the substance of the analysis and recommendations and to understand which normative concepts and justifications may resonate with a broader range of stakeholders to generate the consensus required to adopt and implement policy.

While normative policy analysis is a pragmatic endeavor, ethicists engaged with policy can also pursue a second objective. Jennings and Dawson (2015:31) describe how one of the contributions of bioethics (or applied ethics more broadly) is to foster "moral imagination" or "the capacity to take a critical distance from the given, to think reality otherwise." Moral imagination can serve not only to help critically analyze and identify ethical considerations in concrete policy problems, but also to consider broader changes in social and communal structures. By presenting long-term visions and goals that envision other possible ethical futures, philosophers can contribute to gradually shaping policy ideas and the tenor of public debate (Wolff 2011).

2.1.4 What Ethics Offers Policy Analysis

Normative analysis is commonly recognized as contributing to policy in at least four, interrelated ways, including through: the identification and clarification of policy problems, goals, and evaluative standards or decision-making criteria; critical analysis and normative justification; legitimation; and motivation. These contributions draw on the various analytic approaches used in ethics analysis, including descriptive analyses of prevailing norms, theoretical analyses that aim to systematically justify what constitutes good or right action, and normative analyses, which articulate arguments for what ought to be the case in a particular situation (Kenny and Giacomini 2005:252).

2.1.4.1 Identification and Clarification

The first and most foundational contribution that ethicists can make to policy analysis is through the identification and clarification of policy problems, goals, evaluative standards, or decision-making criteria. One of the hallmarks of philosophical analysis is the systematic ‘unmasking’ of and critical reflection about presuppositions concerning ethical and political values, social and political relationships, and human reason and psychology (Pettit 2006:36). Normative analysis can render explicit the normative dimensions of policies, which are often tacit, and ‘disambiguate’ the different ways in which normative concepts and policy problems are defined (Wikler 1991:246; Rogers 2007). As discussed earlier, policy analysis and the identification of issues as policy ‘problems’ is necessarily an evaluative endeavor. Normative or ‘value’ concepts can be categorized according to their function in a claim or argument as being: procedural, if they serve to guide policy processes; substantive, if they serve as criteria for justifying policy decisions; or terminal, if they represent a policy objective or goal (Giacomini et al. 2009). These categories can help discern how different normative concepts interrelate and may be used when evaluating the soundness of a policy argument and its underlying normative logic. Studies of Canadian health policy reform documents suggest that there is disagreement about the meaning, nature (e.g., policy goals, principles, values, entities, etc.), and role (e.g. justification, legitimation, etc.) of ‘values’ or normative concepts within health policy and, moreover, that they often operate tacitly or are described vaguely within policies (Giacomini et al. 2004; Giacomini et al. 2009). Similarly, for example, in an analysis of public policy debates in the United States informed by interviews conducted with legislators, policy makers, and activists, Stark (2010) describes how policy arguments between opposing political positions (e.g.,

conservative vs. liberal) often appealed to the same values to justify their proposed policy solutions, but framed the values in distinct ways. The process of normative analysis, then, can advance the task of conceptual clarification of normative policy concepts by drawing on a variety of perspectives in order to identify and clarify the similarities, differences, and inconsistences between policy problems and positions within a policy debate (Kymlicka 1996).

Moreover, normative analysis can help discern how concepts that may otherwise appear technical, and thus value-free, are normative. For example, concepts such as ‘effectiveness’ in public health (e.g., Bensimon and Upshur 2007; Komparic et al. 2015) or ‘efficiency’ in economics (e.g., Putnam 2002; Heath 2014) are normative despite often being invoked or framed as purely technical terms. Recognizing that concepts such as effectiveness and efficiency are normative does not preclude their use in policy analysis. Rather, it invites the explicit consideration of the nature of their normative implications and justification for their use as policy principles that can be weighed against or used in tandem with other principles.

Relatedly, normative analysis can help make explicit and clarify normative implications of policies, such as: who benefits from a policy, how benefits and burdens should be distributed, which benefits should be maximized, who is responsible for realizing policy benefits, and whether policy decisions are legitimate (Krubiner and Faden 2017). The process of identifying and clarifying policy concepts, goals, and principles can form the basis for critical reflection on the logical consistency of proposed policies, or what Wikler (1991:246) refers to as ‘logic monitoring’, which considers whether a proposed policy follows logically from the identified normative objectives and justifications. Identifying and clarifying normative concepts can also serve to consider whether they align with prevailing societal norms, the expectations of citizens, and ethical and political principles that have been identified as significant for policy-making and which form the basis for critical analysis and justification.

2.1.4.2 Critical Analysis and Justification

In addition to identifying and clarifying the normative concepts that are invoked explicitly or operate implicitly in policy arguments, normative analysis can serve to critically analyze and justify policy goals and evaluative standards to inform policy-making. Critical analysis and evaluation include considering whether the proposed normative reasons and justifications are logically valid, but also whether they are substantively justified and sound. In other words,

normative analysis can also analyze the evaluative standards that form the basis for justifying policies. Specifying normative criteria to guide policy development is necessary as distinct principles have different implications for a variety of considerations, including who the relevant policy beneficiaries are, who is responsible for executing a policy, how policy benefits and burdens are to be distributed, how evidence is to be weighed, and how policies ought to be assessed.

Although the ethicist does not have a monopoly on moral expertise in the realm of public policy, critical normative analysis of policy reasons and taken-for-granted policy objectives and concepts can serve to foster more nuanced and ethically-attentive public discourse and debate (Rogers 2007; Wolff 2011). Additionally, critical analysis can buttress policy analysis against being solely "a collection of rationalizations of those in power" (Fischer and Forester 1987:19). Moreover, a descriptive analysis of prevailing or dominant norms and values—be they of constituents, policy-makers or philosophers—does not in and of itself justify policy; rather, in pluralist societies, policies can be evaluated using principles that represent criteria for good or legitimate policy-making (Kenny and Giacomini 2005). In pluralist societies and liberal democracies, evaluative criteria for policy making often take the form of mid-level principles such as equality and liberty, which place certain limits on democratic rule, rather than fundamental values over which there may be greater and more intractable disagreement (Anderson 1979, Heath et al. 2010). [21]

2.1.4.3 Legitimation

Normative analysis can also contribute to the legitimacy of policies and policy-making. As discussed in the section on the role of the ethicist, the legitimacy of normative analysis in pluralistic societies does not stem from the deductive or top-down application of moral theory, but rather through helping surface ethical issues and considerations which can be subjected to public debate and deliberation as well as through just processes for policy decision-making. Daniels and Sabin (2002) articulate one prominent account of procedural justice, 'accountability for reasonableness', which describes four conditions for just priority setting in situations where reasonable disagreements about policy are expected to arise among fair-minded people:

[21] I revisit the concept of liberal neutrality in the Theory Chapter.

publicity, relevance, revisability, and enforcement. Empowerment, or increasing effective opportunities for participation and reducing power imbalances in decision-making processes is an additional ethical consideration for fair decision-making (Gibson et al. 2005). Thus, normative analyses can help identify conditions of procedural justice as well as advocate for and contribute to the use of public deliberation, which may strengthen political legitimacy and make policy institutions and actors more trustworthy (Abelson et al. 2009).

Normative analysis can both help identify and justify fair policy-making processes as well as contribute to such processes by helping make policy reasons transparent and accessible through the identification and clarification of policy objectives and decision-making criteria. Additionally, normative policy analysis or the inclusion of deliberative tools such as ethics frameworks in policy can itself legitimate particular principles or conceptions of policy issues, including by shaping public discourse about values (Kenny and Giacomini 2005:251).

2.1.4.4 Motivation

Normative policy analysis can also contribute to motivating policy change. In addition to interests and institutions, policy ideas play an important role in shaping prospects for policy reform. Policy ideas are “claims about descriptions of the world, causal relationships, or the normative legitimacy of certain actions” and thus include both factual claims (e.g., social or economic assumptions) as well as value claims (Parsons 2002: 48). Policy ideas can shape the expectations and motivations of policy-makers and electors and influence which issues make it onto the policy agenda (Béland 2010). Ideational analyses, or the study of ideas in policy sciences, has garnered greater recognition over the past several decades (Béland 2010; Parsons 2016) and policy-making has been characterized as a “struggle over ideas” (Stone 2012:13) or a realm where participants “traffic in the world of ideas” (Kingdon 2002:113). Insofar as normative policy analysis can help shape ideas about normative concepts, it can modify the tenor of policy debates. Similarly, the practice of identifying and clarifying normative policy concepts and arguments can further inform causal or explanatory analyses in the policy sciences by helping clarify the normative ideas that exist within a policy debate and which influence the conditions for policy change. Moreover, framing policies in terms of ethical principles can also ‘enable’ policy by helping motivate compliance or cooperation and prompt reflection about “ethically based reasons for action” (Goodin 2017:273).

Ethical and political principles can help shape ideas about the possibilities for policy reform and collective action. Indeed, the processes of identifying, clarifying, and critically analyzing normative policy concepts and justifications can sometimes serve to identify principles and interests that "form the basis for common decisions and action" (Giacomini et al. 2009:67) and to avoid arguing "at cross purposes about vastly different things without realizing it" (Giacomini et al. 2004:22). In such cases, normative analysis can contribute to consensus building in policy.

2.1.5 Summary

In sum, I have discussed how public policy and policy analysis are increasingly recognized as being normative as they raise and require engagement with fundamentally moral and political questions concerning desirable and legitimate policy ends, means, processes and political authority. At the same time, as ethics and policy are distinct, normative policy analysis must primarily be problem-driven and pragmatic. Normative analysis can nonetheless contribute to policy analysis in multiple ways, including through the identification and clarification of policy problems, goals, and evaluative standards, critical analysis and normative justification, legitimation, and motivation.

2.2 Policy Analysis and the Canadian Pharmacare Policy Debate

Interest in pharmacare resurfaced in the 1990s at a time when "talk of 'values'" permeated health and public policy and governments sought to discern shared public values that could inform policy-making (Giacomini et al. 2004:16). For example, The Citizens Panel on the Future of Canada was convened in 1990 during a period of regional and linguistic divisions to discuss Canada's political future; it identified a list of shared values that purportedly reflected Canadian national identity (Heath 2003; Longo 2017). Similarly, the National Forum on Health, which was convened in 1994, included a 'Values Working Group' which was tasked with studying the principles and values that Canadians espoused with respect to health and health care. In its final report, the NFH (1997) justified its recommendations for health care reform, including for pharmacare, by appealing to values identified by the Values Working Group. The Romanow Commission's final report, which was published in 2002, also appealed to values in framing its recommendations, including in its title—*Building on Values: The Future of Health Care in Canada*. The growing interest in values in Canadian health policy in part prompted calls to establish a field of health policy ethics as mentioned earlier (Kenny and Giacomini 2005).

In the first part of the chapter, I discussed how policy analysis is increasingly recognized as being normative and how ethics can contribute to policy analysis. In this section, I review how the focus of this inquiry—the Canadian pharmacare policy debate—has been analyzed in peer-reviewed academic scholarship. I do not review policy reports and grey literature that primarily advocate for a particular pharmacare policy position, since these reports constitute the documentary data that forms the basis for my own analysis. Additionally, I do not discuss philosophical and public health ethics literature articulating normative accounts of the division between public and private responsibility in the organization, financing and delivery of health insurance in this chapter, since that scholarship is reviewed the Theoretical Considerations chapter. Rather, I restrict my discussion to analyses of the Canadian pharmacare policy debate in particular.

I describe how existing policy analyses of the pharmacare debate primarily address causal or explanatory questions, such as explaining the genesis of Canada's present-day pharmaceutical insurance policy, or evaluating the substantive economic, systems, and health implications of different policies. Nonetheless, many of these analyses identify and acknowledge that normative considerations permeate the debate, and moreover, invoke normative concepts as starting assumptions, such as when describing Medicare as an embodiment of Canadian values. Yet, few analyses explicitly attend to normative or justificatory questions, such as on what grounds policies ought to be justified, how competing policy goals ought to be prioritized, or which normative positions underpin different arguments in the debate.

2.2.1 The History of Canadian Medicare

The pharmacare policy debate is a subset of the broader debate about Medicare (or public health insurance) policy in Canada. Marchildon (2018; 2020) argues that understanding prospects for further reform requires historical analysis to reconstruct a historically contextualized and viable narrative of the establishment and evolution of universal health coverage policies. Marchildon (2012:6) characterizes the history of Canadian Medicare as a political history and thus as "a contested history, largely because it continues to be the focus of great political and ideological debate." Although Marchildon suggests that Canadian Medicare has attracted relatively limited attention by historians owing to declining interest in political history, several other historical analyses recount the role and interests of stakeholder groups, such as organized medicine, in the

development of Medicare (e.g., Taylor 1979; Naylor 1986). Given this inquiry's primary focus on normative rationales and ideas, I focus on Marchildon's (2016; 2020) scholarship, which more explicitly attends to the rationales underlying key policy decisions and highlights the role of ideas in political agenda setting, policy design, and formulation. I review related political science scholarship which explains the genesis of Canadian Medicare with reference to other causal factors such as institutions and interests in the subsequent section.

Notably, Marchildon (2012:6) asserts that, "at the root of the story of Canadian Medicare lies a profound, value-laden conflict involving two disparate visions of public health care and the role of the state"—a conflict concerning the legitimate role of the state as well as the government's efficacy at controlling insurance costs, and which both predates and persists since the implementation of Medicare. The conflict occurs at two major decision points: first, a debate over whether Medicare ought to be financed through a single-payer or a multi-payer program, which originated in the 1940s when individual provinces began introducing limited forms of public insurance and came to a head in the 1960s when the federal government moved to expand the newly introduced public hospital insurance to include physician services; and second, a dispute over the permissibility of hospital user charges and physician extra-billing, which persists through legal challenges to this day (Marchildon 2020).

Canadian 'Medicare,' or national public, single-payer health insurance, was introduced by the federal government in two stages. National coverage for hospital and diagnostic services was introduced in 1957, while coverage for physician services was introduced in 1968. When the federal government moved to expand coverage to include physician services in the 1960s, the Premiers of Alberta, British Columbia, and Ontario advocated for the legitimacy and permissibility of multi-payer programs such as those which they had already or were in the process of instituting. The Premier of Alberta, Ernest Manning, advocated for a multi-payer model that was voluntary and which publicly subsidized private health insurance premiums for low-income residents (Marchildon 2020:24). Alberta had already instituted such a program, which was known as 'Manningcare.' Manning advocated for multi-payer voluntary insurance on ideological grounds, believing that it "would address the problem of access without damaging the principle of individual responsibility, while universality on a single-payer model would eliminate both choice and individual responsibility" (Marchildon 2020:20).

British Columbia's Premier, W. A. C. Bennett, similarly preferred a multi-payer program, although he approached it more pragmatically and demonstrated a willingness to compromise with the federal government by limiting BC's plan to non-profit health insurers. Moreover, BC's plan required that insurers offer a common, comprehensive package of medical services (21). Ontario, meanwhile, instituted and advocated for a multi-payer plan subsidizing private health insurance premiums on the grounds that there was no evidence demonstrating that a single-payer plan would achieve greater cost savings than a multi-payer plan, which would benefit from market competition (21). Indeed, unlike Manning, Ontario's Premier Robarts considered single-payer insurance disadvantageous from a "more pragmatic standpoint" (24). Yet, Ontario's plan was not without criticism; for example, newspapers pointed out that Ontario's reasoning contradicted that of Lord Beveridge who had justified implementing the UK's National Health Service on the grounds that traditional principles of insurance did not offer sustainable financing for comprehensive medical services (22). Multi-payer insurance for physician services was supported by the medical profession, insurance companies, the business establishment, and all provinces other than Saskatchewan, New Brunswick, and Newfoundland (Marchildon 2014; Marchildon 2020:20).

Ultimately, however, the federal government opted to introduce a publicly funded, single-payer program offering universal, comprehensive coverage for hospital, diagnostic, and physician services. Saskatchewan had already implemented public single-payer insurance covering hospitals in 1947 and physician services in 1962; the latter expansion was met with a twenty-three day strike by physicians in the province. Organized medicine resisted implementing single-payer coverage for physician services across Canada (e.g., Naylor 1986). Saskatchewan introduced its single-payer program under the leadership of then-Premier and leader of a social-democratic party, Tommy Douglas, who had also acted as his own minister of health during the introduction of hospital insurance (Marchildon 2016). Douglas went on to found and lead the federal New Democratic Party and advocate for single-payer insurance at the federal level in the 1960s. Describing Douglas' legacy, Marchildon (2007:37-38) asserts that:

> Universally available health care is an essential underpinning for a society in which all citizens are to have the opportunity to live their lives to their fullest potential. To Douglas, this meant a real democracy with the participation of all *and* [emphasis original] a just economy with opportunity for all. Tommy Douglas's ultimate objective was to transform health from a commodity that was

> bought and sold into a basic human right, available to anyone on the basis of need rather than ability to pay.

Marchildon (2020:23) describes how the federal Liberal government was influenced by Douglas as well as the 1964 report of the Royal Commission on Health Services (or 'Hall Report'). The Hall Report recommend adopting universal insurance (including for pharmaceuticals) financed through general taxes because it did not require stigmatizing means tests, eradicated costs associated with insurance risk rating, and would achieve near universal coverage more quickly than a voluntary plan that offered subsidies for private insurance. The Hall Report acknowledged that a multi-payer plan that was regulated in the public interest and reported to the provincial government may be considered as well (23). While the federal minister of health, Allan MacEachen initially entertained a voluntary multi-payer plan to appease provincial governments, he "insisted that eligible provincial plans would have to provide comprehensive medical coverage and meet the definition of universal in the sense of access based on uniform terms and conditions for coverage of physician services, as had been required under the national insurance plan for hospitalization." (24). Marchildon (2020:25) notes that:

> When the federal *Medical Care Act* went to first reading in the House of Commons on 12 July 1966, MacEachen stated the basic principle upon which the bill was based—"that all Canadians should be able to obtain health services of high quality according to their need for such services and irrespective of their ability to pay," and "that the only practical and effective way of doing this is through a universal, prepaid, government-sponsored scheme."

Tuohy (2018a:16) similarly notes that the Hall Report's reasoning was motivated both by considerations of efficiency, for example in favouring a government-run single-payer plan over a means-tested one, as well as principled concerns for human rights, including rights to obtain healthcare from a physician of one's choice as well as the rights of professions to self-govern.

Thus, several distinct normative rationales operated in the original debates concerning national health insurance. Notably, the implementation of a public single-payer health insurance program left a significant legacy on Canadian health policy and public policy discourse more broadly (Tuohy 2018a). The principles in the *Medical Care Act* and later the *Canada Health Act,* and the notion of a 'stronger' universalism in which all citizens are covered under the same terms and conditions, have themselves become equated with 'Canadian values' or as defining features Canadian identity (Marchildon 2014; Tuohy 2018a). This is reflected in the pharmacare debate,

such as when an editorial calling for national pharmacare in the *Canadian Medical Association Journal* opened with the statement that "Canadians embrace universal public health care as a core national value" (Stanbrook 2015:1).

Acknowledging that "it is a truism to observe that medicare is a Canadian icon," Tuohy (2018:12) argues that the implementation of Medicare predates its rise to the status of a symbol embodying national values. The adoption of national, single-payer insurance was originally driven by the decisions and ideas of policy elites, as recounted by Marchildon (2016), rather than those of the public, and it was Medicare itself that "profoundly shaped Canadians' understanding of themselves as a sharing community" (Tuohy 2018a:12). Tuohy (2018a) compares the trajectory of health insurance policy in Canada with that of the US and the UK, noting that the level of public support for universal public insurance was similar in all three countries in the 1940s. By the 1960s, the Canadian public had become accustomed to private coverage and support for universal public coverage had declined. Indeed, following the introduction Saskatchewan's public single-payer insurance for physician services, public support for voluntary medical coverage narrowly outweighed support for a universal public plan (14). Rather, the ideas of policy elites in part contributed to Canada's divergent path relative to the US, in addition to institutional factors described in the next section (Tuohy 2018a; Marchildon 2020). Once established, Canadian Medicare became an institution itself, in that it shapes expectations, "establishes a balance of interest, certain rules of governance, certain organizing principles, either implicitly or explicitly, that over time come to take on a value in themselves" (Tuohy 2018a:17). The institutionalization of Medicare and its benefits to both public and professional interests have contributed to its remarkable staying power despite varying political and economic climates since its inception (Tuohy 2018a). I now turn to describing how political scientists have approached the study of Canadian Medicare, and in particular, how they have sought to explain the genesis of Medicare as well as the anomaly of Canadian pharmacare—or lack thereof—on the basis of institutions as well as interests, ideas, and the pace of change.

2.2.2 Political Science: Institutions, Interests, Ideas, and the Pace of Change

Marchildon's historical analysis offers an account of the reasoning, including normative ideas, of policy elites involved in the debate surrounding the implementation of Canadian Medicare. However, a review of Canadian political science literature reveals that the majority of

scholarship concerning Medicare has taken the form of institutionalist analysis (O'Neill et al. 2011). This echoes Marchildon's (2016) observation that the study of ideas in policy formation receives less attention. Political scientists have endeavored to explain why Canada's health insurance policy developed in the way that it did, including why it diverged from comparator countries such as the US in the adoption of single-payer public insurance and why it failed to include pharmaceuticals as publicly insured goods as in Australia or the UK. Here, I briefly review institutionalist literature concerning the genesis of Canadian Medicare, which provides the background for Boothe's (2015) analysis of the subsequent trajectory of pharmaceutical policy reform. As the focus of my inquiry is on the normative dimensions of the pharmacare debate, I focus primarily on ideational considerations and acknowledge that much more could be discussed (and has already been written) on intuitional and interest-based considerations, which I only review briefly.

2.2.2.1 The Genesis of Canadian Medicare

Historical institutionalism explains lower-level phenomena, such as policies or interests, in terms of higher-order analytic factors, usually at the macro-political and macroeconomic level, where institutions are broadly defined "as formal or informal procedures, routines, norms, and conventions in the organizational structure of the polity or the political economy" that both constrain and facilitate the opportunities for action and influence (Amenta and Ramsey 2010:16). Historical institutionalists emphasize the importance of historical sequence, timing, and contingency, since policy development is held to be 'path dependent' as past decisions and institutional arrangements constrain or facilitate the emergence of new policies, interests, and motivations, and public expectations (Hacker 1998). In its strongest form, path dependence suggests that policies can incentivize actors to make decisions that 'lock-in' a policy direction, which creates societal commitments that may be difficult to reverse (Hacker 1998:77). In addition to explaining the stability of existing institutions, path dependence may also clarify how policies give rise to opportunities for institutional change, especially when existing institutions are unable to adequately achieve their intended objectives (Campbell 1997; Hacker 1998). Historical institutionalists also appeal to the notion of 'critical junctures', or periods of significant change, such as the establishment of a constitution or changes in economic or political structures, which shape subsequent historical dynamics (Hacker 1998:77). While path

dependence may not explain the origins of a critical juncture, it can describe why a critical juncture's legacy is reproduced.

The particular institutional factors that historical institutionalists appeal to in their analyses vary depending on their theoretical commitments, or, more often, the spatio-temporal context of their analysis. Similarly, the exact nature of the relationship between institutions and other explanatory factors varies. Nonetheless, historical institutionalists regard institutions as critical to explaining divergent policies in different institutional milieus. Indeed, historical institutionalists claim that explanatory factors such as political ideas, public expectations, the influence of organized labour movements, and market forces, are filtered through institutions whose distinct 'logics' or organizational structures are critical to conditioning social and political activity and organization, and thus determining whether and how such factors affect policy change (Hacker 1998; Maioni 1998; Tuohy 1999).

Hacker (1998), Maioni (1998), and Tuohy (1999) assert that, despite geographic, political, and economic similarities between Canada, the UK, and the US,[22] institutional constraints unique to each country have yielded divergent health insurance policies. Two main institutional factors were particularly significant in the shaping of Canadian Medicare: federalism and the structure of the government (Hacker 1998, Maioni 1998). Federalism hinders the adoption of sweeping policy changes, such as the UK's implementation of the National Health Service, since policies must pass through a greater number of veto points prior to being adopted (Hacker 1998). Canada's overall government structure also played a significant role in shaping the opportunities for health insurance policy reform (Hacker 1998; Maioni 1998). Canada's parliamentary system joins the executive and legislative branches and centralizes power in a cohesive cabinet, which promotes strong party discipline at the federal level. As a result, it encourages dissenters to act through third parties (Maioni 1998:24). Moreover, Canada does not have a formal method of ensuring equal representation from all regions in cabinet. As a result, the organization of Canada's parliamentary system as well as regionalism and concerns about ineffective regional

[22] For example, in his classification of the three types of welfare capitalist states, Esping-Anderson's (1989) describes Canada, Australia, and the US, and to a lesser extent the UK, as 'liberal' welfare states, which are characterized by market- and individual- primacy and relatively limited and often means-tested social security and welfare programs.

representation in Ottawa prompted the development of social-democratic third parties in Western provinces; these third parties eventually posed electoral threats and were able to exert influence on federal policy, including by swaying policy decisions in favour of organized labour (Hacker 1998:82; Maioni 1998). Unlike the UK's sweeping post-war reforms, early health insurance reforms originated at sub-national levels as individual provinces (e.g., Saskatchewan, British Columbia, Ontario, and Alberta) debated and implemented several different types of public health insurance. These institutional features also enabled the social-democratic Cooperative Commonwealth Federation (CCF) party, led by Douglas, to pressure the Liberal government into implementing public single-payer health insurance at the federal level (Hacker 1998, Maioni 1998).

Tuohy (1999) emphasizes how opportunities required for radical policy change result from both institutional differences, since the ruling government "must be able to mobilize sufficient authority to overcome vetoes" as well as political will on the part of key political actors, which is required to prioritize health care reform on the broader policy agenda. Opportunities for radical policy change, however, are rare and exist in between long periods of path dependency in which health policy is constrained by the "internal logic"—such as federalism and overall government structures as described by Hacker and Maioni—of each country. Ultimately, these institutional factors constrained the extent to which private health insurance was allowed to develop and the form that private insurance plans took, the initial target of government insurance, and the relative timing of increases in technological sophistication and increased access to care. In turn, they shaped Canada's present-day single-payer, universal health insurance, which covers hospital, medical, and diagnostic services from private purveyors, includes fee-for-service billing, and underwrites expensive technology-intensive facilities (Hacker 1998).

2.2.2.2 The Genesis of Canada's Pharmaceutical Insurance Policy

Canada is unique among countries that offer public health insurance in its persistent exclusion of pharmaceuticals from publicly insured goods. Boothe (2015) sets out to address this policy 'puzzle' by identifying the factors that explain the genesis and trajectory of Canada's pharmaceutical insurance policy, and in particular, why repeated calls for national pharmacare have yielded no significant reform at the national level. Boothe's (2015) analysis builds on the aforementioned analyses to identify factors that explain the genesis of pharmaceutical insurance

policy in Canada, and, in particular, the reasons why repeated calls for national pharmacare have yielded no significant reform at the national level.

According to Boothe (2015), the absence of a national pharmaceutical insurance scheme in Canada is not for lack of consideration. The introduction of broad pharmaceutical insurance has been discussed periodically in Canada at the federal level since the 1940s, yet repeated calls for pharmacare in political circles, the media, and the public have yielded no meaningful policy reform. The recurring interest in pharmacare paired with the lack of meaningful reform have prompted scholars to investigate the factors that have contributed to the genesis of Canada's contemporary pharmaceutical insurance policy and the ongoing impasse concerning pharmacare reform. Boothe argues that a combination of institutional, political, and ideational factors—namely fragmented federal authority, limited electoral motivations, and the lack of principled ideas on the part of politicians—constrained the pace of Canadian health policy change. These barriers limited the scope of pharmaceutical policy reform in Canada and left pharmaceuticals resembling an 'extra' rather than an essential component of health care. The incremental pace of change also contributed to an emphasis on 'fixing what we have' rather than expanding it (Boothe 2017:6). Rather than proceeding with wholesale pharmaceutical policy reform, as in many comparator countries such as Australia or the United Kingdom, Canada promulgated more limited policies focused on price controls and patents to address cost escalation without introducing a mandate for universal pharmaceutical coverage (Boothe 2015).

Boothe (2012; 2013) asserts that institutionalist analyses (Hacker 1998; Maioni 1998; Tuohy 1999) provide incomplete insight into why Canada remains the only industrialized country with health insurance but no comprehensive pharmacare. Comparing the development of health insurance policy in Canada, Australia and the UK, Boothe (2012; 2013; 2015) argues that differences in pharmaceutical policy development are best understood as resulting from distinctive rates of policy change. Thus, similar to historical institutionalists, the timing and path dependence of policy debates remains central to Boothe's (2013:421) thesis, which asserts that policies that develop incrementally constrain subsequent opportunities for expansionary change. Boothe (2013:446) claims that ideational and institutional barriers were complementary in shaping Canada's pharmaceutical insurance policy, but that ideational barriers preceded institutional ones.

Boothe claims that there are three conditions for radical change: "centralized authority as a result of a country's institutional structure, politicians' principled ideas about health policy, and politicians' electoral motivations" (2012:782).[23] When one or more of these factors is absent—as was the case in Canada with its fragmented political authority, lack of principled ideas on the part of the ruling federal party, and relatively low levels of public interest—policy changes occur incrementally and on a smaller scale. As a result, rather than proceeding "as natural or uncontested 'next steps'", later stages in incremental policy reform face the same three conditions required for radical change (Boothe 2017:5). Since Canada's national public health insurance was adopted incrementally, first in several provinces, and then with national hospital and finally medical insurance, pharmacare was left resembling an add-on rather than essential component of health insurance when it resurfaced for consideration in 1964, 1972, 1997, and 2002 (Boothe 2013). Boothe (2013:420) notes that while later "proposals were made under different economic conditions and in the context of different federal-provincial relations […] the ideas expressed by politicians were remarkably consistent and the outcome of these proposals–no policy development–was identical." In particular, Boothe (2017) argues that two main types of ideas hindered pharmacare reform in Canada. First, there was a lack of agreement on a 'big idea' about health insurance policy (such as in the UK's Beveridge Report) during the implementation of Medicare, which limited prospects for radical policy change. As Boothe (2017:6) notes, "action on health was not an ideological imperative, but rather a political compromise" for the ruling federal Liberal governments.[24] Second, federal policy elites shared the belief that national pharmaceutical insurance was unaffordable, and moreover, that it was a distinct policy issue from that of high drug prices, which garnered attention and was addressed through targeted policies. For example, Boothe (2017:14) cites Abby Hoffmann, assistant deputy minister in Health Canada, as explaining that,

> Even if…a universal system would provide more access and be less burdensome on the economy than this fragmented mess that we have today, this is a great example of a terrific academic idea…that is impossible to sell, and it will

[23] Boothe acknowledges the similarity with Tuohy's (1999) assertion that opportunities for policy change require institutional factors (consolidated authority) and political will (a combination of ideational and electoral motivations).

[24] Recall the earlier discussion of the compromise between the Liberal government and the Co-Operative Commonwealth Federation. The latter, under the leadership of Tommy Douglas, could be recognized as having stronger ideological commitments concerning health insurance (Marchildon 2020).

> continue to be impossible to sell as long as costs…go up at the rate they are going up.

Boothe's emphasis on the importance of ideational factors in affecting the opportunities and nature of policy change fits into a broader debate within institutionalism surrounding the importance of ideas in welfare state and policy development. Campbell (1998) and Béland (2005) argue that ideas matter for a number of policy processes, including agenda setting, the articulation of policy alternatives, constraining change through paradigmatic world views, framing policy debates, and in shaping public sentiments or expectations. As such, ideational forces do not preclude the importance of institutions, but rather they can themselves support significant policy change in addition to "reinforcing existing institutional paths through the reproduction of a dominant paradigm and the production of frames justifying existing policy arrangements" (Béland 2005:13). Similarly, institutions themselves can affect how policy frames and ideas affect policy debates by favouring specific ideas (Béland 2005:14).

Boothe's analysis reveals that principled ideas, or lack thereof, played an important role in promoting or constraining pharmacare policy development and adoption by influencing both political actors and the public. Given the importance of ideas in facilitating and constraining policy development, an evaluation and critical analysis of the normative rationales that underpin contemporary pharmacare policy proposals will contribute to understanding the ideas that populate the contemporary debate, and could even help us imagine alternative policy futures, as Jennings and Dawson (2015) have argued.

2.2.3 Media Analysis

Another series of analyses seeks to understand how pharmacare has been framed in Canadian media in recent decades (Daw et al. 2013, Daw et al. 2014). In one study, Daw et al. (2013) conducted a time series analysis to quantify trends in pharmacare coverage in Canadian print media from 1990 to 2010. They draw on a theory of issue-attention cycles, which posits that public attention to certain policy issues operates on a cyclical basis characterized by alternating episodes of interest and disinterest rather than on real-world factors; issues that cycle rapidly do not sustain the public attention needed for policy reform. Three characteristics predispose a policy to such a cyclical pattern of attention: the harms associated with the status quo affect a minority or a less powerful minority (i.e., the minority of Canadians who lack coverage), the

benefits associated the status quo accrue to a powerful minority (i.e., the health insurance and pharmaceutical industries), and the issue is not intrinsically 'exciting'. Canadian pharmacare policy meets these criteria, since a minority of Canadians lack coverage, the current system primarily benefits the health insurance and pharmaceutical industries, which have concentrated interests, and that pharmaceutical financing is complex rather than dramatic. Media coverage of pharmacare policy was generally low and displayed a cyclical pattern; attention peaked significantly in 2002 and 2004 when policy elites considered concrete pharmacare proposals in the context of broader health reforms surrounding the publication of the Kirby and Romanow Commission Reports in 2002 and the 2004 Health Acord, which introduced the National Pharmaceutical Strategy.

Based on the limited media coverage and nature of pharmacare policy, Daw et al. (2013) conclude that pharmacare reform is more likely to be driven by policy elites than by the public. For, without sustained public attention, "a coherent rationale for change will remain underdeveloped within the public consciousness" (Daw et al. 2013:73). In the absence of public engagement, they caution that the pharmacare policy debate risks being defined by stakeholders with defined, niche interests rather than a "principled egalitarian goal for financing needed medicines" (73). They do not cite where this egalitarian goal originates nor exactly what it entails. Similarly, although they recognize that engagement with public values is significant for the legitimacy and sustainability of policy reforms (73), what these values are—and how they feature in the debate—is not analyzed. They acknowledge that further analyses should examine the "narrative content contained within stories on drug financing, focusing on problem framing, presented options, and attributions of responsibility for policy action" (74).

The authors take up the task of narrative analysis in a second media analysis where they quantify and analyze how print media has framed pharmacare policy problems and solutions during the same 20-year period (Daw et al. 2014). Media coverage is taken to play a role in framing how the public understands policy issues based on which facets of an issue are raised or emphasized (297). Daw et al. (2014:299-300) develop three deductive codes to categorize problem frames in the pharmacare policy debate based on academic and grey literature concerning the goals of drug financing: values-related problems (e.g., underinsurance, interprovincial disparities, or misalignment with values), cost-related problems (related to systems-level costs), and other problems (e.g., issues that were not captured by the other two, such as administrative

inefficiencies and problems related to formulary decisions or abuse of medicines). They found that more than 40 percent of articles did not identify problems with the existing pharmaceutical insurance system, while those that did were significantly more likely to raise cost-related problems than values-related ones (302). Conversely, more than 90 percent of articles discussed policy alternatives, with growing interest in catastrophic coverage in the 2000s (304).

Based on the findings of their quantitative analysis, the authors identify three tensions in the media coverage of pharmacare. First, cost-related problem frames are "double-edged" as costs are cited both as barriers to reform and problems facing the existing system that require reform (308). Second, the absence of ideological arguments for or against pharmacare reform represents a "silo of values." While Canada's Medicare system is often framed in value-terms or even characterized as an embodiment of national values and identity, the same values are not commonly extended to framings of pharmacare policy (310). Indeed, Canadian health policy discourse contrasts with that of the United States, which is more ideologically-driven and polarized. Framing pharmacare primarily in terms of cost-related problems in effect silos it off from values-related problems; a silo of values may represent a 'strategic narrative' by proponents of the status quo due to the popularity of Canadian Medicare, which makes it politically unfavourable to explicitly disagree with its underlying values (311). A silo of values means that "nobody publicly stands opposed to a pharmacare system similar to Medicare 'in an ideal world', but that strong narratives about costs make such an ideal world appear unattainable" (Daw et al. 2014:311). Moreover, support for Medicare is also used to argue against pharmacare expansion, which is framed as potentially undermining the fiscal sustainability of the existing system. Third, the dominance of policy elites in driving pharmacare media coverage gives rise to a 'solution-mindedness,' which when paired with cost-related concerns, results in a propensity to take an incremental approach to policy reform by seeking "second-best" policy solutions such as catastrophic coverage (313). Yet, catastrophic coverage represents a retrenchment of existing public pharmaceutical benefit programs offered by provincial and territorial governments (304). Daw et al. (2014:314) conclude that:

> given the lack of a clearly defined rationale for reform, competitive narratives against Medicare, and maintenance of silos of values for prescription medicines versus other health services, an environment has been crated where the potential goals of reform could be more easily manipulated by interest groups and wherein

> policy options that inherently represent retrenchment may have a greater chance of survival.

In effect, and echoing their earlier media analysis (Daw et al. 2013), they emphasize that a pharmacare policy discourse devoid of clear policy objectives and grounded in public values may result in policy reforms that do not reflect the public interest.

Despite highlighting the importance of values, these media analyses do little to unpack or investigate the values that they cite. Further, the second analysis is predicated on a distinction between values and costs that permeates health policy. By selecting analytic codes which are applied deductively to their analysis based on predetermined understandings of policy goals, they render issues related to equity (be it inequities in access as a result of province or residence, insurance status, income, etc.) as values-issues, but treat cost-related issues as distinct from values and thus presumably as being 'neutral' or 'value-free'. They are right to point out that the framing of issues in what they consider to be cost-related terms rather than values ones may represent a strategic choice to deflect attention from or minimize the urgency of reform by proponents of the status quo. Moreover, it may also reflect concerns about the political inexpediency of calling attention to normative issues. However, it is not clear that the cost-related and other problems that they identify are intrinsically neutral or value-free.

Furthermore, several of the issues that they include under 'other' problem frames relate to cost-related ones (e.g., administrative efficiency), but it is unclear as to why they are treated distinctly as the objective of lowering costs or seeking administrative efficiency may be underpinned by similar normative concerns related to efficiency. Daw et al. (2014)'s choice of codes reflects a common tendency in health policy and public policy more generally to dichotomize ethics and economic considerations. However, as I described briefly in the first half of the chapter when discussing the relationship between ethics and public policy, and as I will discuss in the remainder of the dissertation, costs and efficiency also represent normative considerations. Laupacis (2004), for example, recognizes this when noting that, "the benefits and costs of drugs will force us as a society to make some very hard decisions about fundamental human values such as access, equity and affordability." A normative analysis can help make explicit the normative dimensions of these concepts in order to better understand their normative implications as well as to render them open to reasoned analysis, critique, and deliberation and disabuse them of their supposed 'neutrality' or non-normativity.

The studies that I have reviewed so far offer insight into how the Canadian pharmacare policy debate has been studied and understood in published, peer-reviewed policy literature. Although the analyses draw on several analytic approaches and methods, they all point to the importance of normative ideas in the genesis of Canadian Medicare and the evolution of pharmaceutical insurance policy, among other causal factors including political institutions, interests, and the pace and scope of policy change. In particular, the ideas of policy elites played a significant role in policy formation during the establishment of Canadian Medicare (Tuohy 2018b; Marchildon 2020). The adoption of Medicare further shaped Canadians' ideas about national identity and shared values, which in turn have sustained support for the system (Tuohy 2018a). At the same time, these principled ideas did not translate to pharmacare in a way that would motivate reform on the part of policy elites or the electorate; instead concerns about costs prevailed (Daw et al. 2014; Boothe 2015).

While the analyses all point to the importance of normative ideas in understanding the development and evolution of Canadian health and pharmaceutical insurance policy, the normative considerations are rarely unpacked and subjected to further conceptual clarification or critical (and normative) analysis. In the subsequent section, I describe the single, explicitly normative analysis of pharmacare policy in Canada. I conclude by describing how my inquiry proposes to address the dearth of normative policy analysis in the literature concerning the pharmacare policy debate.

2.2.4 Normative Policy Analysis and Pharmacare

The analyses of the pharmacare debate described thus far point to the presence and importance of normative questions and ideas in the Canadian pharmacare debate. Yet, despite identifying and appealing to normative concepts within their analyses, none of the aforementioned studies systemically analyze the normative concepts that they identify. Indeed, normative analysis is neglected within the political science studies of Canadian health insurance policy (O'Neill et al.

2011). To date, there has been only one published academic analysis of the pharmacare policy debate that has an explicit and primary focus on ethics.[25]

MacPherson and Kenny (2009) describe the principles that are invoked explicitly in five policy reports concerning the 2004 National Pharmaceutical Strategy and consider why the identified principles failed to motivate policy change. They identify 16 principles across the five documents; four of the principles (accessibility, effectiveness, equity and safety) are invoked in all four documents.[26] They note that there is significant diversity in the meaning and usage of the principles between the documents. For example, rather than being described in relation to a particular conception of justice, equity is described in the context of two policy issues: equitable access to drugs and equitable health outcomes resulting from access to drugs (29-30). However, MacPherson and Kenny do not further unpack the implications of such observations, nor do they draw connections between the different understandings of individual principles and the policy recommendations within each report.

MacPherson and Kenny (2009: 32) conclude their analysis with a discussion of three reasons for the apparent "impotence" of principles in facilitating the adoption and implementation of the National Pharmaceutical Strategy. They describe how the use of "wooly, undefined" terms which lacked definitional clarity, the absence of criteria for prioritizing between different principles, and the disconnect between the principles and the practical elements of the proposed policy all limited the extent to which the principles could form the basis for consensus or motivate policy reform (33). Morgan et al. (2016) similarly assert that the National Pharmaceutical Strategy failed in part because it lacked a clear vision and policy goals as well as a shared understanding of its overarching purpose among various levels of government. Other studies that have taken a comparably descriptive approach to identifying and analyzing ethical principles in other Canadian health policy reform documents reach similar conclusions about the lack of definitional

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[25] More recently, Da Silva (2017) has argued for the use of Daniels and Sabin's accountability for reasonableness framework to assess whether Medicare, non-insured health benefits and interim federal health programs meet the requirements of procedural justice. Da Silva does not discuss pharmacare in particular.

[26] MacPherson and Kenny (2009:29) identify the following principles (in descending order of their frequency, with the first four appearing in all five documents): accessibility, effectiveness, equity, safety, affordability, transparency, appropriateness, cost-effectiveness, evidence-based decisions, accountability, participation, sustainability, impartiality, inclusiveness, innovation, and patient-centred care.

clarity and confusion about the purpose of policy principles (e.g., Giacomini et al. 2004; Giacomini et al. 2009).

While MacPherson and Kenny (2009:33) acknowledge that definitional clarity is insufficient to motivate policy change, they still note that "having apparent agreement [on guiding principles] from various sources and interests is an essential step." They conclude by arguing that:

> Principles can be powerful motivators for choice and action, and demanding criteria for assessment. There appears to be agreement on the foundational principles for a NPS [accessibility, effectiveness, equity, safety]. However, to date, these principles have done no meaningful work for us, but rather appear to function as we have seen elsewhere—as conventional, politically correct decorations. Collaborative work on robust, coherent and meaningful principles is urgently needed. Such effort may hold the key to real progress on this crucial area of health policy. It is time for all Canadians to use these statements of principle as powerful tools in public and policy discourse. (MacPherson and Kenny 2009: 34)

In that sense, their analysis echoes the policy analyses discussed earlier in identifying the lack of clarity around pharmacare policy goals as one element hindering pharmacare reform.

While MacPherson and Kenny's analysis engages more explicitly with ethics than other analyses of the pharmacare debate, it provides limited indication of which normative positions exist within the debate and how they connect more explicitly with commonly espoused policy arguments. In part, this may be a feature of the documents themselves, which MacPherson and Kenny appear to suggest when they cite that the policy reports fail to describe how the principles are connected to one other or to the proposed policies. However, as I describe in the proceeding chapter where I outline the methodology and methods that guide my inquiry, the difficulty of understanding how principles function within broader policy arguments and proposals is also a feature of a highly descriptive, principles-focused analysis. I describe an alternate approach to analyzing policy documents which enables the analyst to not only identify explicitly cited principles, but also to situate principles within broader policy arguments, which are characterized in terms of their underlying normative rationales. Drawing on such an analytic approach, my inquiry explicitly characterizes and reconstructs arguments in the pharmacare debate in terms of the underlying normative features in order to facilitate a deeper understanding of the similarities and differences in normative positions across the debate, and thus potentially to identify prospects for consensus.

2.3 Summary: Gaps in Knowledge and Implications for My Inquiry

This chapter situates my research in the broader literature concerning the relationship between ethics and public policy as well as existing academic analyses of the pharmacare policy debate in Canada. In the first half of the chapter I discussed the growing recognition in policy studies that that public policies are normative entities and relatedly that policy analysis is a normative enterprise as they require engagement with fundamentally moral and political considerations. Nonetheless, the distinct natures of policy and ethics place certain limitations on normative policy analysis and the contributions of ethicists to the policy making process. As public policies are decision-oriented and emphasize consensus, normative policy analysis is distinct from pure philosophy and instead requires engagement with the real-world policy context as well as a pragmatic consideration of opportunities for consensus building in addition to moral soundness. In other words, normative policy analysis should be engaged and pragmatic rather than primarily theory-driven. Within these parameters, ethics can contribute to policy by aiding in the identification and clarification of policy problems, goals, and evaluative criteria, critical analysis and normative justification, legitimation, and motivation.

2.3.1 Proposed Contributions

It is for these reasons that I set out to conduct an empirical bioethics study of the pharmacare policy debate. As I will discuss in the subsequent chapter, where I outline the study methodology and methods, I take bioethics to be a practically-oriented normative inquiry which is concerned with both the concrete details and contexts of policies as well as the identification and critical analysis of the normative rationales that permeate policy discourse but are often tacit and thus overlooked. Drawing on empirical analytic methods to conduct a documentary analysis of pharmacare policy documents, I engage with the pharmacare policy debate as it is rather than presenting deductive, theory-driven arguments for a particular policy option. Nonetheless, I also draw on theoretical insights to inform my analysis and achieve greater conceptual clarity by more explicitly drawing out the normative features and implications of different policy arguments and proposals.

In the second half of the chapter, I discussed how existing analyses of the Canadian pharmacare policy debate draw on a variety of analytic approaches to examine and explain the genesis of

Canada's health and pharmaceutical insurance policy and, in particular, why there has been limited pharmacare reform. I described how many analyses draw attention to the significance of values and normative ideas in the pharmacare policy debate—especially as they are seen as relating to national identity and values—but few represent an explicitly or primarily normative analysis that address justificatory questions. The dearth of normative policy analysis concerning the pharmacare policy debate is noteworthy both because normative ideas feature within the debate and also because the lack of clarity around and explicit appeals to "values" issues are cited as factors that have contributed to shaping the trajectory of, and even hindering, pharmacare policy reform to date. Given that policy framing can influence the course of policy decision-making, and that policy solutions can define specific policy problems and thus may serve to exert power and influence in policy debates (Campbell 1998; Béland 2008; Stone 2012), assessing discourse in light of ethical values may bolster existing or reveal an alternate framing for pharmacare policy. In turn, a change in framing may have policy implications for the future understanding and uptake of pharmacare in Canada.

If "policies are thus actions which contain goal(s) and the means to achieve them, however well or poorly identified, justified, articulated and formulated," then normative policy analyses can render explicit and critically analyze the normative goals and justificatory rationales operating in policy arguments and across a policy debate (Howlett and Chashore 2014:17). Determining how pharmaceutical policy, as a subset of health policy and ultimately public policy, *ought* to be structured is a normative task that requires a society to identify normative standards for assessing the moral relevance of and justification for policy goals, actions, and processes. Specifying normative criteria to guide pharmacare policy development is necessary as distinct principles have different implications for a variety of considerations including: eligibility for coverage, how insurance ought to be administered, who is responsible for ensuring pharmaceutical coverage, how insurance ought to be financed, how comprehensive drug coverage ought to be, and whether individual or population health or other policy objectives ought to be prioritized.

Accordingly, this inquiry proposes to address the gap in normative policy analysis of the pharmacare policy debate by conducting a systematic normative analysis of pharmacare policy arguments in order to offer conceptual clarity around key principles, arguments, and identify areas of congruence and tension within the debate as well as establish a basis for critiquing the normative arguments within the debate. This analysis, which addresses the descriptive and

analytic aims of my inquiry, is presented in my Findings chapter. It also sets the foundation for a critical and normative analysis of policy arguments and justifications in the debate in the Discussion chapter. Besides contributing to the pharmacare policy literature, this study contributes more broadly to normative health policy analysis where there has been limited attention to how to systematically analyze the normative features of a policy debate. In the following chapter, I describe and justify the methodology and methods that guide my inquiry.

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Chapter 3
Methodology and Methods

> Bioethics does not only require us to argue well; we must also engage with issues that matter and attempt to reach conclusions that are practically normative. This means that we must straddle the conceptual and the empirical. (McMillan 2018:4)

3 Methodology and Methods

This chapter describes the methodological orientation and methods that I adopted to address my research objectives and questions. Research is guided by methodology, which I take to be the "lens through which the researcher views and makes decisions about the study" based on a set of epistemological and ontological commitments, and in the case of normative inquiry, meta-ethical ones; methodology also encompasses methods, which are the specific "procedures or techniques employed in a study" that guide data collection and analysis (Harrison et al. 2017).

In the preceding chapters, I argued that public policy is inherently normative, but that explicit engagement with underlying ethical or political norms is often absent or cursory in public policy discourses and analyses. The contemporary pharmacare policy debate is no exception; few pharmacare policy documents or analyses of the debate have engaged explicitly with normative considerations as such. At the same time, as I recount in the following chapter, philosophers have articulated a range of theoretical accounts that offer thorough justifications for decision-making concerning health insurance policy. What, then, are we to make of these parallel areas of inquiry and their potential relevance to one another?

Bioethics[27] offers a normative mode of inquiry for analyzing public policy discourses that is both practically-oriented and conceptually-informed – bridging moral[28] reasoning with policy and

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[27] My inquiry can also be situated within public health ethics, which focuses on public and population health, or policy ethics. While bioethics is sometimes understood narrowly as concerning medical, clinical, research, and organizational ethics, I embrace its broader and arguably original conception (as per Van Rensselaer Potter use of the term (ten Have 2012; McMillan 2018)), which also encompasses health policy, public health, global health, and ecological health. In other words, bioethics concerns "ethical issues relating to the creation and maintenance of the health of living things" (Dawson 2010:1467).

[28] I use morality to capture both ethics, which concerns standards of the good or the right in the context of private life, as well as political morality, which concerns standards that govern social and political life, including our relationships with others in the public realm as well as between individuals and states or governments (Larmore 2013). Bioethics, as I understand it, spans both ethics and politics (Powers 2005; Pellegrino 2006).

practice. The objective of this thesis is to explore how bioethics, thus understood, can contribute to understanding and informing the pharmacare policy debate.

I posed two research questions to guide my inquiry and address the study objectives:

1. What normative rationales are invoked, explicitly and implicitly, in arguments in the Canadian pharmacare public policy debate?
    a. How are normative concepts used, in what contexts, and to what ends?
    b. Are normative concepts employed consistently? If not, in what ways does their use differ?
2. How can normative and political philosophy contribute to understanding and informing the pharmacare policy debate?
    c. How do philosophical accounts concerning the nature and purpose of health insurance compare with the normative rationales of pharmacare policy identified in question 1?
    d. How can philosophical accounts inform policy arguments in the pharmacare debate?

I conducted an empirical bioethics case study of the Canadian pharmacare debate to address my inquiry's descriptive, analytic, and normative research aims. My first aim, which addresses research question one, is descriptive as I characterize and reconstruct the main arguments in the debate in terms of their underlying normative positions; addressing this descriptive aim was a prerequisite for fulfilling the analytic and normative aims of my inquiry.

My second aim, addressed through research questions one and two, is to analyze the normative landscape of the pharmacare policy debate. I draw on philosophical concepts, theories, and methods of reasoning to identify points of normative convergence and tension and to consider how arguments in the debate compare with the theoretical perspectives outlined in my theory chapter. My analytic aim is explanatory only insofar as I seek to further an understanding of what is *ethically* and *politically* at stake in the pharmacare debate by making the underlying norms explicit and illustrating how distinct policy positions in the debate are associated with particular normative positions. Notably, however, my objective is not explanatory in the sense of seeking to make causal claims concerning the genesis of Canadian pharmaceutical insurance policy or explain why certain norms are invoked or understood in particular ways; nor is my objective generative in the sense of aiming to develop a theory of political change or political discourse.

Finally, my third aim, which is addressed in research question two, is normative; I consider the normative implications of my analysis for the pharmacare policy debate. I should note that my third aim is circumscribed insofar as I confine my analysis to reflecting on the normative implications of my descriptive findings and critical analysis in the particular context of the pharmacare debate. While I am concerned with putting my data and analysis in conversation with theory, it is beyond the scope of this inquiry to develop a robust theoretical account or a full-fledged normative argument concerning the nature and objectives of pharmaceutical insurance or health policy more generally. Instead, I am concerned with raising questions about how my data might speak back to the theories I have employed in my analysis, rather than necessarily answering them.

3.1 Bioethics Methodology

3.1.1 Bioethics as a Normative and Practical Inquiry

Before exploring which methodology is best suited for addressing the bioethical inquiry proposed in this thesis, it is worth reflecting on what bioethics is—its nature and its purpose. At its core, bioethics can be understood as a practically-oriented, or issue-driven, normative inquiry that seeks to provide justified guidance on concrete ethical and political issues (Sheehan and Dunn 2013; McMillan 2018). As McMillan (2018:12) notes, doing bioethics involves "bringing moral reasoning to bear" on practical issues concerning the biosciences and health, broadly understood. It is worth noting that that is *an* account of bioethics and that there are others with distinct methodological implications[29]. As I will discuss in greater detail throughout the chapter, I have adopted this understanding of bioethics not only because it is increasingly common in the field, but also because it is well suited to my research aims, which are both practically-oriented and normative and which concern a specific policy issue and debate, as well as with my understanding of normative policy analysis discussed in the previous chapter.

As a normative inquiry, bioethics is primarily concerned with conceptual clarification, critical assessment of moral argument, and the justification of actions or practices in response to 'ought'

[29] Some argue that bioethics ought to be more philosophical owing to the unique contributions of philosophical analytic methods and theorizing to moral reasoning, conceptualization, and argumentation (Brassington 2013; Häyry 2015; Savulescu 2015).

or ‘should’ questions (Sheehan and Dunn 2013; McMillan 2018). As a practical endeavor, bioethics extends beyond moral or political theorizing, whose primary objectives are to offer comprehensive systems of reasoning and justification in response to fundamental ethical or political questions, and which often use abstract or idealized reasoning to do so; rather, bioethical arguments aim to provide context-specific, practicable, and convincing guidance on particular ethical issues in order to impact practice (Sheehan and Dunn 2013:58). McMillan (2018:28, 40) similarly notes that bioethics aims at being “‘practically normative’ in the sense that it helps us find a way forward with moral issues” or attempts “to improve some aspect of the world.”

Understanding bioethics as a practical, normative endeavor has methodological implications. McMillan (2018:4) contends that good bioethics must be both empirical and ‘Socratic’:

> Bioethics does not only require us to argue well; we must also engage with issues that matter and attempt to reach conclusions that are practically normative. This means that we must straddle the conceptual and the empirical. We must be philosophical in the Socratic sense of posing questions, imagining possibilities, and drawing distinctions, and empiricists in the sense that we either use empirical methods or find some way of grounding our analysis in the issues that matter. Armchair ethics can fail to engage with reality and be practically normative, while meaningful, issue-driven bioethics requires some sophistication in conceptual approaches.

On such accounts[30], bioethics is taken to involve two primary methodological features which reflect its normative nature and practical aims: a *ratio-normative* component and an *experiential* component. Bioethics methodology has a *ratio-normative* component in that it necessitates attending to and engaging in moral reasoning. Rather than prioritizing moral theory as a methodological starting-point or providing an algorithmic method for arriving at moral ‘truths’, moral reasoning focuses on the logic of argumentation and the capacity to make discriminating moral judgements (Arras 2017; McMillan 2018). For example, a variety of analytic strategies or techniques[31] can be used to identify the ethically relevant features of an issue and to reach an

[30] Examples of other authors that I draw on who conceive of bioethics as a practically-oriented, normative enterprise include: Dawson 2009, Sheehan and Dunn 2013, and Ives et al. 2016.

[31] For example, McMillan (2018) describes several techniques to facilitate moral reasoning, including assessing the logic of argumentation (e.g., determining inferential validity through syllogisms), engaging in speculative reasoning (considering ‘what if?’ questions to identify the implications and limits of a position) and drawing distinctions (making values and concepts explicit to distinguish between concepts and identify those of ethical relevance).

ethically justified position on the matter (McMillan 2018). Grounding bioethics in moral reasoning—understood as an activity rather than a specialized body of knowledge—avoids reducing bioethics simply to moral theory (McMillan 2018:4, 107; Sheehan and Dunn 2013; Frith and Draper 2016). Uncoupling method from theory has several advantages, including fostering practical inquiry by promoting contextualized engagement with experience, eschewing the deductive application of theory as a blanket 'solution' to bioethics issues, and leaving open the question of which theories, or even disciplines, are best suited to addressing a particular issue.[32]

Bioethics methodology also has an *experiential* component, which requires what McMillan (2018:35) terms "engagement with experience" or "practical normativity."[33] This feature can be met through formal (usually qualitative) empirical research methods that engage "with the issues that are relevant to those making and impacted by difficult ethical choices"(McMillan 2018:35) in order to develop "a context-specific understanding and explanation of practical ethical issues" (Sheehan and Dunn 2013:64). However, McMillan (2018:39) contends that practical normativity can also be achieved, albeit indirectly, through more conceptual approaches, as long as they facilitate critical reflection or new ways of thinking about normative concepts or common assumptions in a way that contributes to understanding or resolving ethical issues in practice.[34]

While bioethics requires experiential engagement, it remains distinct from sociology, which is concerned with the description, reconstruction, and analysis of the values, beliefs, and practices of people and groups rather than the justification of normative conclusions (Borry et al. 2005:54). This distinction may also be characterized in terms of two differing understandings of

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[32] Moreover, given that moral and political theories remain contested, it would be impractical to wait for philosophers to settle disagreements and select a preferred theory (Dawson 2009; McMillan 2018). With respect to disciplinary contributions, McMillan (2018) claims that the methods of reasoning that form the foundations of philosophy in the Socratic tradition are not solely the tools of philosophy. Similarly, Sheehan and Dunn (2013:62) note that, "ethical considerations […] have purchase as substantive concepts across numerous disciplines, and standard of reasoning are relevant to academic practice beyond philosophy for making convincing arguments of any kind."

[33] Ives (2008) similarly describes requiring "encounters with experience."

[34] McMillan (2018:38-40) cites the example of Judith Jarvis Thomson's thought experiment concerning the famous violinist and the permissibility of abortion. McMillan claims that while the example was removed from experience – and has even faced criticism for being overly contrived – it made significant contributions to the abortion debate by reframing and questioning normative assumptions about the nature of rights conflicts in abortion.

normativity:[35] a philosophical normativity and a sociological normativity. Philosophical normativity is concerned with cogent argumentation aimed at reaching an "ethical position on how [a contested process] *should* occur," or in other words, it concerns justifying evaluative or prescriptive claims to offer guidance on a particular ethical issue (McMillan 2016:30). In contrast, although sociological inquiries may very well be motivated by normative commitments, such as social justice, their primary aim is to understand and explain how norms and practices that groups or societies hold to be valuable, permissible, desirable, or good come into being and are shaped by social structures. Accordingly, sociological normativity may be understood as an epistemic norm insofar as it seeks to complicate or problematize the understanding of social phenomena – including values and norms – by "urging the reader to see a phenomenon its social and political context" (McMillan 2016:30). The distinction reflects the different aims of ethics and sociology; the former aims at a practical normativity, or "guidance about what should be done about an important ethical issue," while the latter concerns critical normativity or, which in a sociology of bioethics involves "critical reflexive analysis of bioethics" (McMillan 2016:68).

Despite perceptions that philosophy and moral theory have a privileged role in bioethics, there is growing recognition that the practical and issue-driven nature of bioethics requires drawing on a variety of disciplines (e.g., sociology, law, policy studies, anthropology, etc.) and research methods in order to facilitate practical moral reasoning (Dawson 2009; Sheehan and Dunn 2013; Arras 2017; McMillan 2018). As answering practical normative questions also often requires addressing what Sheehan and Dunn (2013:59) call 'secondary' questions, such as determining the nature of a particular issue or phenomenon under consideration, the nature of the research question will determine the most appropriate methodology and methods for an inquiry. A corollary is that there is no single 'bioethics methodology'. Indeed, bioethics, and especially the burgeoning area of 'empirical bioethics,' are characterized by a stunning diversity of methodological approaches, which is where I turn my attention next.

[35] There are additional types of norms and normativity, such as legal, aesthetic, and epistemic norms, but they are distinct from ethical or political normativity and are not the focus of my study.

3.1.2 Empirical Bioethics

While bioethics originated in philosophy and theology and drew largely on philosophical methods and theories, it is increasingly turning to qualitative, empirical research methods and theoretical perspectives from other disciplines (Borry et al. 2005). The so-called 'empirical turn'[36] in bioethics arose in part as a response to the 'social science critique' of philosophically-grounded bioethics; this critique asserted that bioethics had historically failed to account for the social contexts and lived experiences of its subjects, and had neglected to acknowledge the social-situatedness of contemporary Western bioethics (Callahan 1999; Haimes 2002; Borry et al. 2005; Hedgecoe 2004; Fox and Swazey 2010). In other words, the social science critique can be understood as alleging that bioethics, understood as "a highly rational, formal, largely deductive mode of argumentation," had failed to meet its experiential methodological requirement, thus undermining its quality and practicability (Fox 1999:8; Hedgecoe 2004). Feminist critiques of bioethics and applied ethics analyses similarly argued that bioethics had failed to engage with and reflect the views, moral commitments, and lived experience of various historically oppressed groups (Young 1990; Lindemann 2001; Scully 2010).

While the soundness of the social science critique is contested,[37] its impact on contemporary bioethics is undeniable as evidenced by the growing interest in, and prevalence of, empirical bioethics inquiries which recognize that bioethics needs "to pay attention to context and to what people actually do and think (and why)" in order to be meaningfully practical (Ives 2017:6). Indeed, this thesis is an example of an empirical bioethics inquiry that makes explicit use of qualitative research methods for the purpose of furthering a practical, normative inquiry.

Empirical bioethics is best understood as a general term that encompasses a variety of approaches to addressing bioethical research questions that combine social science methods for data collection and analysis with philosophical methods of moral reasoning (Davies et al. 2015:1). Indeed, empirical bioethics inquiries can adopt one of a variety of methodologies that

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[36] The 'empirical turn' may be better characterized as an opening, since empirical approaches have broadened the methodological approaches used in bioethics rather than replacing conceptual, normative analyses.

[37] For example, some bioethicists agree with the value of incorporating social science methods and theories into practically-oriented bioethical inquiry, but hold that the 'foundationalist' characterization of bioethics as deductive, theory-driven, decontextualized inquiry is overstated as good bioethics has long required contextual awareness and real-world engagement (e.g., Borry et al. 2005: 64; Herrera 2008; Ives & Draper 2009; Hurst 2010).

integrate social science methods with moral reasoning, but vary in their aims, methods, and epistemological and ontological commitments, depending on the nature of the research objectives (Davies et al. 2015; Ives et al. 2016; Ives et al. 2018). This bears out in practice according to a systematic review of empirical bioethics methodologies, which identified 32 distinct methodologies in the 33 studies reviewed (Davies et al. 2015). The apparent heterogeneity in empirical bioethics is unsurprising given the complexity of integrating empirical and normative inquiries (Ives et al. 2016) as well as the range of possible questions—including what Sheehan and Dunn (2013) refer to as 'secondary questions'— that are of interest in bioethics.

The introduction to a volume on empirical bioethics with contributions from leading scholars in the area describes the characteristics and challenges of empirical bioethics (Ives et al. 2016:5):

> the unique quality of empirical bioethics … is that it aims to be integrative: to combine normative and empirical research practices, and not simply to conduct separate empirical and normative studies in parallel. As such, it has to take seriously, and combine, both normative and empirical epistemologies, and a great deal of intellectual legwork is required in order to be able to tell a coherent theoretical story about how one can combine the empirical and the normative, and how one can obtain both empirically informed and useful normative conclusions that are appropriately justified.

Empirical bioethics aims to be integrative in a way that neither trivializes the role of empirical inquiry and data—by not relegating it to the 'mere' provision of facts—nor reduces bioethics to an empirical inquiry devoid of normative reasoning and force (Hurst 2010; Ives et al. 2016). In other words, integrative empirical bioethics considers empirical inquiry as 'sociology *in* bioethics,' which attempts to break down disciplinary boundaries and use empirical evidence to "directly alter and shape ethical theory" (Frith and Draper 2016:244). In contrast, 'sociology *for* bioethics' maintains disciplinary boundaries and uses empirical methods to generate evidence, which is considered in light of, but does not speak back to ethical theory (Frith and Draper 2016:244).

Adopting an integrative empirical bioethics approach for my analysis of the pharmacare public policy debate is advantageous as it draws on the strengths of both empirical and normative inquiry and thus facilitates the pragmatic and analytic objectives of my investigation. As Ives and Draper (2009:251) note, integrating empirical inquiry into bioethics is important for

achieving a ‘contextual understanding’ and for ‘understanding meaning,’ both of which are important for rigorous, consistent policy or practice-oriented bioethics analyses. Achieving contextual understanding requires having “encounters with experience,” or “positioning oneself so that one can understand, as far as possible, how an ethical problem affects people’s lives, how the problem is constructed and negotiated, and how different resolutions might affect stakeholders in different ways” (Ives and Draper 2009:251). Similarly, understanding meaning involves establishing “how concepts and meanings are used at ‘ground level’ […] to ensure that everyone is talking the same language, and that the theorist is using terminology and concepts that are commensurate with the usage of the stakeholders” (Ives and Draper: 252).

Having a contextual understanding of a policy issue and understanding how stakeholders make sense of key concepts is both of substantive and pragmatic value in policy analysis. In my inquiry, empirical engagement facilitates accounting for morally relevant facts about stakeholder perspectives as they are positioned in public discourse, pharmaceutical insurance policy, and the pharmacare policy debate itself (e.g., the policy goals that stakeholders identify, how different stakeholders frame issues and understand particular normative concepts). Moreover, policy analyses that ground the ethical and political concepts used in an understanding of the perspectives of stakeholders, including those engaged in the public discourse, and policymaking bodies can promote more relevant, effective, and feasible policy guidance (Hedgecoe 2004; Kenny and Giacomini 2005; McMillan 2018). As discussed in the Background Chapter, owing to the pragmatic and problem-driven nature of policy making, normative policy analysis requires attending to questions of political and practical feasibility as well as considering whether opportunities exist to build consensus between stakeholders. An integrative empirical bioethics case study is well suited to the normative and practical aims of my analysis as it facilitates engaging with the contemporary pharmacare policy discourse in order to “identify and clarify the interests that form the basis for common decisions and actions” (Giacomini et al. 2009:67).

Although empirical inquiry is particularly valuable for normative policy analysis, empirical data does not determine the normative conclusions argued for in bioethical analysis; rather, it shapes theorizing, such as by raising relevant pragmatic considerations or by raising additional ethical considerations (McMillan 2018). As described earlier, bioethics extends beyond a sociological description of the values that people espouse by making normative judgements that can serve as the basis for critiquing the goodness or legitimacy of existing systems, practices, beliefs, or

theories, and in the case of my inquiry, existing arguments in the pharmacare debate (Hedgecoe 2004). As Hedgecoe notes, "bioethics without a philosophical input would lack much of the rigour and the 'bite' that modern medical ethics has" (2004:135). Moreover, the critical social sciences have been criticized for failing to adequately explain and justify the normative positions that are largely implicit, yet often fundamental to their analyses (Sayer 2009).

While integrating normative and empirical inquiry is valuable, it is also complex as it requires transcending traditional disciplinary boundaries as well as harmonizing methodological commitments, including their underlying epistemological assumptions and accompanying theoretical frameworks (Ives et al. 2016). Two related concerns are raised with respect to the validity of integrating normative and empirical inquiry: the 'is-ought problem' and the 'fact-value distinction'[38] (de Vries and Gordijn 2009; Ives and Draper 2009; Ives et al. 2016; McMillan 2018). The is-ought problem, which is attributed to David Hume, asserts that normative or prescriptive claims cannot be inferred solely from empirical observations or facts, and inversely, that an empirical observation in and of itself does not imply a prescriptive claim. In other words, an 'ought' cannot be inferred from an 'is', or descriptive facts, including descriptive accounts of prevalent norms, values, and preferences, are insufficient for deducing an ethically justified course of action. Although the is-ought problem may appear to challenge the legitimacy of integrating empirical inquiry with normative inquiry, or even promote skepticism about the grounding of all normative claims, the is-ought problem can also be understood as cautioning that arguments with normative conclusions must have at least one normative premise in order to be valid (Pigden 1989; Ives and Draper 2009; McMillan 2016; McMillan 2018). This logical requirement does not preclude the consideration of facts obtained through empirical inquiry in normative arguments or the analysis of normative concepts. I adopt this understanding of the is-ought problem—as one about the logic of normative argumentation—so I do not make normative claims in the absence of normative premises and arguments, nor do I simply 'derive' my normative conclusions from the findings of my empirical inquiry.

[38] The naturalistic fallacy (particularly G.E. Moore's articulation) is also sometimes cited as a concern and is often erroneously conflated with the is-ought problem (see Ives and Draper 2014:252 for a discussion and examples).

The fact-value distinction holds that statements of fact and value are independent, and thus have distinct epistemic origins; facts are taken to be descriptive and value-free and are knowable through empirical observation, while values are neither dependent nor reducible to facts and are to be discerned through rational, ethical inquiry (Ives et al. 2016). While at first the fact-value distinction appears to challenge the endeavor of empirical bioethics, its soundness is contested (Putnam 2002; de Vries and Gordijn 2009; Ives 2014; McMillan 2016). Drawing on developments in the philosophy of science,[39] pragmatic accounts of bioethics (e.g., Frith 2010; Ives 2014) question the epistemic distinction between facts and values owing to the difficulty—if not practical impossibility—of distinguishing facts and values in practice, while still maintaining that they are semantically, and even ontologically, distinct. Drawing on Putnam (2002), Ives (2014:304) characterizes bioethics as a pragmatic inquiry, which seeks to understand something about the world and is driven by practical or prudential considerations rather than the search for universal, infallible truths:

> Th[e] pragmatic and fallibilist characterization of bioethics replaces any search for '*the solution*' with the search for '*a solution that we can live with, and which goes some way towards resolving the problem we currently have*' [emphasis original]. In this sense, bioethical inquiry becomes a process of 'noble failure' – a never ending attempt to produce 'better' normative accounts, with an acceptance that the constantly changing social and technological landscape will generate new problems that force us to revise the accounts we currently have.

McMillan (2018:5) makes a similar point, noting that the tentative and fallible nature of conclusions in bioethics requires that bioethical inquiry proceed with 'epistemic humility':

> we must be rigorous and build the best case that we can for our ethical positions but, in doing so, be mindful that there is a good chance that we have missed something of importance—that what seems vital today might not be that way tomorrow, and most of all, that the issues we discuss can be deeply important for other people's lives.

Espousing an understanding of bioethics as a pragmatic inquiry—one that yields fallible and provisional conclusions—has implications for my choice of research methodology. Rather than opting for a methodology with epistemological and ontological commitments that fall neatly within positivist, interpretivist/hermeneutic or social constructivist research paradigms (e.g.,

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[39] See, for example, Putnam (2002).

Grounded Theory, ethnography, Foucauldian Discourse Analysis), my methodological commitments can be characterized as approximating critical realism (Bhaskar 1979; Danermark et al. 2002), which has been recognized for its methodological fit with empirical bioethics inquiry (McKeown 2017).

Critical realism holds that ontology cannot be reduced to epistemology. Ontologically, it recognizes the existence of an objective, external reality with 'real' phenomena, but epistemologically, it recognizes that our perception and understanding of reality (the 'empirical') is necessarily interpretive as it is structured by the researcher's interpretations, beliefs, and assumptions (McKeown 2017:193). Accordingly, the analyst has an active role in the analysis and the inquiry is never entirely atheoretical. This contrasts with early positivist, qualitative methodologies, such as Glaser and Strauss's Grounded Theory, which characterize the analytic process as one of discovering pre-existing themes that 'emerge' from the text (Charmaz 2000). As Braun and Clark (2006:80), whose approach I draw on for my thematic analysis, note:

> …an account of themes 'emerging' or being 'discovered' is a passive account of the process of analysis, and it denies the *active* role the research always plays in identifying patterns/themes, selecting which are of interest, and reporting them to the readers.

The virtue of adopting a methodological orientation that approximates critical realism is that it eschews positivist assumptions that researchers can discover 'the objective truth' of reality—a truth that is unencumbered by paradigmatic and theoretical assumptions; at the same time, it endorses the validity of logical, moral reasoning and assessment and avoids devolving into a radical social constructionism that reduces ethical claims into relative matters of opinion (McKeown 2017).

The methodological orientation I adopt has implications for how I understand the relationship between theory and data in my analysis. Rather than 'applying' theory—in the sense of "laying a pre-existing moral framework upon a set of issues"—I use theory to inform the research design and analysis, but not as a determinative arbiter of moral 'truth.' The theoretical framework I describe in my Theoretical Considerations chapter informed the development of my research questions (such as by focusing the analysis on the normative arguments within the debate) as well as the case study design (described in greater detail below). Theory also informed my data interpretation and analysis by providing sensitizing questions and concepts to help tease out the

normative arguments that operate in the debate. The use of a theoretical framework comprised of multiple theoretical perspectives, as described in the Theoretical Considerations chapter, is appropriate for a pragmatic ethics inquiry, since ethical theories can serve as different 'lenses' (Sherwin 1998) or contribute to ethical 'frameworks' that help tease apart the complexities of a moral concept or issue and "aid deliberation by making relevant values explicit" (Dawson 2009:196). Moreover, in keeping with a critical realist and pragmatic orientation, I recognize that empirical analysis can be 'theory challenging,' or speak back to the theoretical claims and accounts used in analysis (Hedgecoe 2004:137; Ives 2014).

3.1.2.1 Quality Standards for Empirical Bioethics Inquiries

The integration of normative and empirical inquiry has implications for assessing the quality and rigour of empirical bioethics inquiries. Broadly speaking, the literature on empirical bioethics, which includes a recently developed consensus statement outlining standards of practice for empirical bioethics research (Ives et al. 2018), commonly identifies at least three interrelated conditions that are taken to be necessary for high-quality, rigorous empirical bioethics research: internal coherence; transparency and reflexivity; and adopting standards of rigour from both normative and empirical disciplines (e.g., Mertz et al. 2014, Davies et al. 2015; Frith and Draper 2016).

Rigorous empirical bioethics requires the purposeful and explicit selection of a methodology in which the methods and epistemological, ontological, and theoretical commitments are both internally coherent and cohere with the research objectives and questions (Davies et al. 2015; Ives et al. 2018). A corollary is that conducting empirical bioethics research requires accounting for how the empirical and normative inquiries—and accordingly facts and values—are integrated and inform each other in the research process (Mertz et al. 2014; Ives et al. 2016: Frith and Draper 2016; Ives et al. 2018).

In addition to explicitly accounting for and justifying the relationship between empirical and normative inquiry, assessing the rigour and quality of empirical bioethics requires adopting appraisal standards from each respective discipline (Hurst 2010; Mertz et al. 2014; Ives et al. 2018). While standards for appraising empirical research methods will vary depending on which particular methodology is adopted, qualitative inquiries share several common foundational standards, as I discuss later in the chapter (Tracy 2010). While good moral reasoning is not

confined to the purview of philosophy, it must meet certain standards. For example, good moral arguments are sound (i.e., based on true premises and are inferentially valid) and present well-justified conclusions (McMillan 2018). Moreover, bioethics draws on philosophical methods of making meaningful distinctions (Sokolowski 1998) in order to identify moral concepts that are clear, thoroughly described, insightful, and relevant (Ives and Draper 2009; McMillan 2018).

In addition, empirical bioethics inquiries should be reflexive (e.g., Hedgecoe 2004; Ives 2014). Reflexivity parallels the requirement for transparency outlined above, in that it requires acknowledging one's ontological, epistemological, and theoretical assumptions; moreover, reflexivity is often considered a standard of methodological soundness in qualitative research (Tracy 2010). Building on the understanding of the active role of the analyst in qualitative analysis and the fallible and revisable nature of bioethics conclusions, reflexivity also facilitates "a willingness to question (and reject if necessary) our existing beliefs, theories, and commitments" as is necessary in pragmatic bioethics (Ives 2014:311).

It is my aim throughout this chapter, both in the preceding and ensuing sections, to provide a thorough and transparent account of the methodological commitments that I espouse and the methods I used in the inquiry. In the subsequent sections I outline the methods used to conduct my case study and develop a rigorous analysis.

3.2 Methods: The Case Study

To inform the empirical component of my inquiry, I opted to conduct a single case study of the Canadian pharmacare policy debate. Bioethics has a long tradition of case-based analysis through casuistry, which employs case analysis and analogical reasoning to develop and justify moral conclusions, as well as other methodological traditions such as pragmatism (Jonsen and Toulmin 1998; Arras 2017). As Hedgecoe (2004:138) notes, Beauchamp and Childress (1989) aptly describe the relationship between theory and practice in bioethics vis-à-vis cases:

> cases provide data for theory and are theory's testing ground as well. Case [sic] leads us to modify and refine embryonic theoretical claims, especially by pointing to inadequacies in or limitations of theories.

I chose to conduct a case study of the Canadian pharmacare policy debate as it allowed me to address my descriptive, analytic, and normative research aims. Characterizing the main

arguments in the debate terms of their underlying normative positions facilitated a practical, normative policy analysis, while the case study also provided a rich context in which to examine the theoretical perspectives that I drew on in my analysis.

I conducted a qualitative, single case study which I adapted based on Yin's method (2014) focusing on the features that are common to case study methods more broadly (Harrison et al. 2017). Yin (2014:16-17) defines a case study as an empirical inquiry that "investigates a contemporary phenomenon (the "case") in depth and within its real-world context, especially when the boundaries between phenomenon and context may not be clearly evident". Yin (2014:2) posits that case studies are desirable when the scope of a study is focused on contemporary, rather than primarily historical, phenomena. Moreover, case studies are well suited to answering explanatory ('how' and 'why') questions and studying phenomena where the researcher has limited or no control over behavioural events, since case studies facilitate comprehensive, in-depth and contextualized understandings of complex phenomena, and longitudinal analyses, rather than evaluating incidence (Yin 2014:16; Harrison et al. 2017).

The Canadian pharmacare debate serves as a valuable case for a bioethical analysis of health policy reform debates for several reasons. Case studies often examine remarkable or anomalous events (Harrison et al. 2017), and Yin (2014:201) notes that exemplary case studies are ones that are "unusual and of general public interest" and where "the underlying issues are nationally important—either in theoretical terms or in policy or practical terms". The Canadian pharmacare debate meets these criteria as it has garnered unprecedented national interest over the past five years (as described in the introduction to the case in the Introduction chapter). Furthermore, were it to be implemented, the introduction of national pharmacare would represent one of, if not the most significant national health policy reform in Canada since the introduction of Medicare in the 1960s. The heightened interest in pharmacare since 2014 has an added, practical benefit in that it has yielded an abundance of policy reports and media coverage that provide diverse and information-rich data sources for a case analysis. The Canadian pharmacare debate also serves as an anomalous and instructive case for the conceptual analysis of normative models of welfare states (Heath 2011) and the division of public and private sectors in the financing and provision of health insurance. Canada is the only country with publicly-funded, universal health insurance that does not include pharmaceutical coverage. Much of the pharmacare debate—even during its

decades-long history[40]—concerns the expansion, rather than retrenchment, of public health insurance within the context of an existing public health insurance system, and one which has an especially strong political and symbolic valence (Maioni 2010; Tuohy 2018). In addition to serving as a case of a health policy reform debate, the pharmacare debate is also instructive as it overlaps with contemporary debates (in Canada and internationally) concerning approaches to pharmaceutical financing and pricing, such as discussions of 'fair pricing' for pharmaceuticals (WHO 2017).

Yin (2014) conceives of case study research as a method, rather than a comprehensive methodology with predetermined methodological and theoretical commitments.[41] In this sense, Yin's method echoes a common feature of qualitative research, which allows a researcher to adopt one of a variety of methodologies and methods without identifying any one as intrinsically more valid. Rather, research quality and rigour is determined by the coherence of the espoused methodology—and its underlying ontological and epistemological commitments—and methods with the research objectives and questions (Caelli et al. 2003; Pratt 2009; Tracy 2010; Kahlke 2014; Davies et al. 2015; Ives et al. 2018). The distinct notion of rigour in qualitative research stems from its aim of facilitating in-depth understanding and analytic generalizability, or transferability, which is characterized by the ability to expand upon, develop, or generalize conceptual or theoretical propositions to new contexts (Halkier 2011; Tracy 2010; Yin 2014). In contrast, quantitative research aims at statistical generalizability, or the generalization of frequencies to other instances. In other words, rather than being "universalizing," analytic generalization can be understood as producing "context-bound typicalities" (Halkier 2011).

Case study research also aims at *analytic* generalizability (Yin 2014; Harrison et al. 2017). Indeed, one of the defining features of a case study is that it benefits from the development of

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[40] The long history of the pharmacare debate facilitates a longitudinal analysis of the debate at distinct time points with reference to changes in the broader historical, political, and economic contexts. Boothe (2015) examines four eras of the debate to develop an explanatory account of the genesis of Canadian pharmaceutical insurance policy.

[41] Yin's (2014:17) method is compatible with various methodological (including epistemological) orientations, which allows the researcher to opt for a methodology that best coheres with their research objectives. That said, Yin's method aligns most closely with realism and post-positivism, which seek to apprehend the nature of reality while recognizing the imperfection of empirical observation and measurement (Harrison 2017). I, however, do not adopt Yin's positivist or post-positivist leanings, such as when he emphasizes the importance of triangulating data to increase accuracy ('construct validity') and rigour of analysis.

theoretical propositions to guide the case study design, data collection, and analysis (Yin 2014:37). Theoretical propositions, or theoretical statements and accounts related to the phenomenon under study, facilitate analytic generalization from a case, either to corroborate, advance, alter, or reject theoretical concepts used in designing the case study or new concepts that arose during or after the course of the study (Yin 2014: 38-41). Accordingly, case study research aligns well with my methodological orientation and overarching objective of conducting an empirical bioethics inquiry that is both informed by a theoretical framework and aims at discerning how bioethics can contribute to the understanding and informing the pharmacare debate.

Yin (2014) describes six steps for conducting case studies. The first step involves designing the case study, which includes determining the research question(s) and identifying relevant propositions (in my case, theoretical propositions) that can inform the study design and analysis, both of which I outlined earlier. I turn to discussing the next step in case study design, the process of 'bounding' the case (Yin 2014:33), before continuing to describe the remaining steps of data collection, analysis, and reporting.

3.2.1 'Bounding' the Case

After selecting research questions and clarifying the nature of the case study, it is necessary to 'bound' or define the scope of the case (Yin 2014:33). The bounded case, defined within a spatial and temporal context, serves as the unit of analysis in the study. I studied the contemporary Canadian pharmacare policy debate as a single case study of a health policy reform debate. The case encompasses the national pharmacare policy debate from 1997 until June 2019, with a particular emphasis on the last six years. Boothe (2015) identifies four seminal moments when pharmacare policy received significant attention prior to the 2010s: 1964, 1972, 1997 and 2002. The publication of the National Forum on Health's (NFH) final report in 1997 serves as an apt starting point for my case study as it was the first government report in recent decades to seriously consider pharmacare. Moreover, it is the first in a series of government policy reports that have defined and motivated sustained interest in pharmacare to this day (Daw et al. 2014; Boothe 2015). Similarly, including the early 2000s in my analysis allowed me to capture the Kirby and Romanow Reports, both of which shaped the health policy landscape in the 2000s and are still referenced in the contemporary debate. Finally, I emphasized the past six

years of the debate in my analysis as this period represents what I consider to be the 'contemporary' pharmacare debate as defined by the resurgence of interest in pharmacare since 2014 as I described in the Introduction chapter. The case concludes in June 2019 with the publication of the final report by the Advisory Council on the Implementation of National Pharmacare, which was convened in by the federal government to conduct public and stakeholder consultations and provide recommendations on how to proceed with implementing national pharmacare. Since the publication of the report, the Liberal government was re-elected as a minority government. In a mandate letter to the new Minister of Health, Prime Minister Justin Trudeau instructed the minister to continue implementing "national universal pharmacare, including the establishment of the Canada Drug Agency, and implementing a national formulary and a rare disease drug strategy to help Canadian families save money on high-cost drugs" (Trudeau 2019). The case has been introduced in Chapter 1, while the timeline summarizing the bounded case with key dates, events, and publications is available in Appendix A.

3.2.2 Data Sources

Once the case is bound, it is necessary to identify the data source(s). Case studies generally recommend using several sources of evidence to facilitate a mutually-informative, in-depth and comprehensive analysis of the concepts under investigation (Yin 2014; Harrison et al. 2017). I used documentary and testimonial data to inform my inquiry as I wished to study how normative concepts are employed in public discourse. I examined two types of publicly available data: documentary data from policy documents (e.g., reports, position papers, and statements) and testimonial data from transcripts from the House of Commons Standing Committee on Health's (HESA) hearings on the development of a national pharmacare program.

The majority of my sources were from grey literature, or policy reports and statements published by governmental and non-governmental sources, including national-level associations (e.g., professional, industry) or public, consumer, or patient interest organizations. I chose policy documents and reports, rather than media publications or social media postings, as my primary data source for several reasons. First, policy reports tend to provide more detailed justifications for the policy goals and proposals they outline, thus providing a richer data source for understanding *how* normative concepts are employed and understood in pharmacare policy

arguments.[42] Second, seminal policy documents often inform and shape the discourse surrounding an issue, including its coverage and reporting in the media; this phenomenon has been observed in the pharmacare debate (Daw et al. 2013). While media can influence how the public conceives of an issue by framing topics in different ways, framing involves representing an issue in understandable and often broad terms, as well as omitting the more detailed justifications offered in policy documents (Iyengar 1991). Moreover, prominent government- or expert-authored policy reports often spur discussion in other venues and may lend credibility to an approach to analyzing or framing an issue, which may in turn amplify the influence of such publications on public opinion through media coverage (Daw et al. 2014).

I also examined testimonial data from the proceedings from the House of Commons Standing Committee on Health's (HESA) hearings on the development of a national pharmacare program held during 2016 and 2017.[43] The documents from the HESA hearings deserve attention for two primary reasons. First, the HESA hearings facilitated my goal of capturing a diverse range of stakeholder and normative positions in the public debate, since they included a variety of stakeholders (e.g., academics, health professionals, patient groups, pharmaceutical industry, private and public payers, and regulatory and government agencies), including some of which had not been well represented in other publicly available documentary data despite being part of the pharmaceutical policy landscape. Furthermore, the hearings offer a source of testimonial data that is also decidedly part of the contemporary, public debate. They present a unique snapshot of the public debate through stakeholder testimonials presented in a single forum where witnesses testify before and are examined by elected officials on the public record and are asked to respond to one another's statements.

3.2.3 Data Collection and Sampling

Purposive sampling is used in qualitative research to strategically select data sources that are relevant to the unique context of a case; it contrasts with random sampling, which aims to reduce bias and enable statistically generalizability (Patton 2002:230). Purposive sampling facilitates in-

[42] Many opinion editorials concerning pharmacare were authored by individuals or stakeholder representatives who had already written detailed policy reports and were now presenting a brief overview of their position for the public.

[43] Details from the HESA hearings and a list of the witnesses and policy briefs are included in Appendices C and D.

depth understanding, and is thus well suited for information-rich case studies of a particular phenomenon (Patton 2002:230). I used two purposive sampling strategies: maximum variation sampling and sampling for politically important cases. Maximum variation sampling "aims at capturing and describing the central themes that cut across a great deal of variation" (Patton 2002:235). Drawing on a diverse array of stakeholder opinions and policy positions through maximum variation sampling enabled me to address my first research question by both identifying the range of distinct normative positions in the pharmacare policy debate as well as capturing the central themes and normative positions indicative of the debate. More specifically, I sought to maximize the variation in the theoretical (normative) positions captured as well as the stakeholders indicative of the range of interests within in the debate.

Additionally, I sampled for politically important cases in order to ensure that I captured publications that had a notable impact on arguments in the debate, as was often the case with (but not limited to) seminal government reports that prompted further discussion (Patton 2002:241). As Patton (2002:242) notes, purposive sampling strategies can be combined to take advantage of the unique purposes that they serve—which is not unusual as research often has multiple aims—as well as in cases when one sampling strategy yields a sample that remains too large and requires further pruning.

To collect my documentary data, I searched academic databases, including ProQuest, Web of Knowledge, and the Canadian Research Index, the search engine Google (including Google Alerts for pharmacare from July 13, 2016 to June 30, 2019), as well as websites of Canadian think tanks[44] using the search terms "pharmacare," "pharmaceutical/drug insurance," "pharmaceutical/drug coverage," "pharmaceutical/drug policy" "Canada," "national," and "report/document/statement". For this study, policy documents include grey literature, or reports, proceedings, background papers, policy statements, and policy campaign materials published through non-commercial publishing streams, including by governments, industry associations, professional bodies, regulatory bodies, patient advocacy groups, and think tanks, as well as white papers. Documents were included in the initial study pool if they were publicly available, discussed national pharmaceutical insurance policy, and were published during the

[44] A list of think tanks consulted is available at: https://mcgill.ca/caps/files/caps/guide_canadianthinktanks.pdf .

case study period (i.e., January 1997 – June 2019). Documents were excluded if they discussed pharmaceutical insurance only in the context of one jurisdiction (province/territory) without discussing national policy implications. To collect my testimonial data, I obtained all of the transcripts and policy brief submissions from the House of Commons Standing Committee on Health's (HESA) hearings on the Development of a National Pharmacare Program from HESA's website.

The initial document pool, which was subjected to close reading, included 118 policy documents as well as 22 transcripts and 31 policy brief submissions from the HESA hearings. The final study sample, which served as the basis for the in-depth case analysis and coding, was selected using the purposive sampling case criteria outlined earlier in order to capture politically important documents as well as a variety of stakeholders and policy positions. Additionally, I emphasized including more documents from the contemporary debate. Key sampling decisions are listed in Appendix B. The final study sample included 72 documents in total:

- 15 transcripts from the HESA hearings (with each hearing having 3-4 witnesses) [Appendix C]
- 11 policy brief submissions from the HESA hearings [Appendix D]
- 46 policy documents [Appendix E], including 14 governmental publications, 10 non-governmental policy documents from 1997 to 2012, and 22 policy documents from the contemporary debate (2013-2019)

3.2.4 Data Analysis

While health-related qualitative research often adopts a 'branded' methodology that has accompanying methods with explicitly described analytic strategies, it is not unusual for researchers in the social sciences to conduct studies that fall outside of established methodologies to combine methods to serve their research needs (Caelli, Ray and Mill 2003; Kahlke 2014). Kahlke (2014:47) describes such a researcher as a "bricoleur, a research artist capable of playing within and without a methodology in order to meet research needs and build new genres," further noting that *bricolage* is in keeping with the spirit of qualitative research as it allows for "new fields of research, new theoretical perspectives, new questions, or new approaches to old research problems." I have opted for an analytic *bricolage* of my own, since my inquiry does not 'fit' neatly within an existing methodology and Yin (2014) provides limited

analytic direction applicable to my research aims.[45] I developed an analytic strategy that addressed my descriptive, analytic, and normative research aims, and which coheres with the methodological commitments of an empirical bioethics case study. I adapted a general strategy for thematic analysis to: identify the main policy arguments within the debate; characterize the policy arguments in terms of their underlying normative positions; and analyze the points of normative tension and congruence across the arguments in the debate, including across time. Thus, the unit of analysis for my thematic analysis was the normative rationale underlying a policy argument, rather than individual principles within a policy document.

Before turning to the methods I adopted to analyze my data, it is worth noting that although the pharmacare policy debate is amenable to a critical discourse analysis, I have instead opted to conduct an empirical bioethics case study as it is better suited to addressing my descriptive and analytic research aims. Cheek describes discourse analysis as being "concerned with the way in which texts themselves have been constructed in terms of their social and historical 'situatedness'" (2004:1144). Cheek (2004: 1147) further emphasizes that the text, rather than its content, is the object of study in discourse analysis:

> …text *is the data*, and the approach is therefore not about exploring "the" content or meaning of the text. Rather, it is about explaining how certain things came to be said or done, and what has enabled and/or constrained what can be spoke or written in a particular context.

Given that the text is not the object of my analysis and I do not aim to theorize the nature and function of discourse in the pharmacare policy debate, a critical discourse analysis is not well suited for my inquiry. Instead, and as will become apparent in the following sections where I describe my analytic strategy, I am interested in the content of the text, namely the normative concepts and rationales employed in policy arguments. Similarly, I am not conducting an

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[45] Yin (2014) describes four general strategies and five specific techniques to guide the analysis of case study evidence, where the choice of strategy and technique depends on the nature and objectives of the particular case study. One analytic strategy involves drawing on theoretical propositions to guide analysis and delineate analytic priorities by sensitizing the analyst to relevant theoretical—in my case, normative—concepts (Yin 2014:136). Yin recommends using this strategy when theory has shaped the study objectives and literature review, as it has in my inquiry; moreover, this strategy suits my research aims of describing and analyzing the normative logics in the pharmacare debate. The five analytic techniques that Yin (2014) describes do not fit well with my research objective as they are better suited for explanatory, generative, or experimental and evaluative analyses; however, he himself acknowledges that they are non-exhaustive.

externalist critique of the normative dimensions of the debate, or in other words, I am not constructing a "genealogy of ethics" or a sociological account of "the social processes, meanings and institutions that frame and produce 'ethics' and ethical problems" (Haimes 2002:110).

3.2.4.1 Analyzing the Normative Discourse in a Policy Debate

My first research aim was to identify and describe the main policy arguments in the pharmacare debate in terms of their underlying *normative rationales*. Normative rationales can be understood as the normative features of a policy argument, or the arrangements of normative concepts such as principles, values, etc. that underpin and serve various discursive purposes in a policy argument. A normative rationale is a relational account that describes both the relationship between normative concepts within an argument and the relationship between normative concepts and the features of the proposed policy. My inquiry focuses on describing normative rationales, rather than enumerating individual principles, since policy reports often appeal to multiple principles that serve a variety of justificatory purposes.[46] Comprehensive normative arguments are rarely explicitly articulated in policy documents. It is for this reason, as Giacomini et al. (2004:22) note, that the relationships between normative concepts, and the relationships between norms and proposed policies, are of interest in policy analysis:

> 'Values talk' [in health policy] is, paradoxically, both very important and ambiguous in its meaning. To understand what is really being said, analysts must read critically between the lines. Declared values can be powerful imperatives or toothless platitudes, honestly guiding or strategically misleading. Undeclared values can be either crucial or irrelevant, and in either case, it matters to know. Context shapes the meaning of declared values. In particular, the importance and the impact of a specific value will be attenuated by the other values against which it is 'balanced' as a tradeoff or 'tied' to as part of a package deal.

As the unit of analysis in my inquiry was the normative argument within a text rather than individual principles,[47] I required an analytic approach that allowed me to capture the

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[46] For example, Giacomini et al. (2009:61) characterize policy values (i.e., normative concepts) based on their function: "*terminal* values (goals or objectives), *procedural* values (means and process for achieving the goal), or *substantive* values (criteria for justifying decisions and actions for goal achievement)." These distinctions can help discern how values relate to each other and to policy.

[47] I reached this conclusion after having already coded and analyzed my data to identify a list of decontextualized normative concepts, which provided insufficient indication of how the concepts related to one another, or of the dominant normative logics within the debate. Changing one's research method to better suit one's research aims is not uncommon in qualitative research and reflects its iterative and reflexive nature (Evans 2000).

relationships between normative concepts within their indigenous discursive context. To do so, I adapted a general method of thematic analysis to suit my study aims.

3.2.4.2 Thematic Analysis

In keeping with my descriptive and analytic research aims, I sought to understand how the policy arguments and their underlying normative rationales within texts related to one another and functioned *across* the case, that is, across the debate. To do so, I looked to thematic analysis, which is a method for identifying "repeated patterns of meaning" across a data set, interpreting or theorizing themes to make sense of their significance and implications within a broader context, and reporting themes in rich detail (Braun and Clarke 2006:86). Thematic analyses can be either inductive or theoretical, where a theoretical analysis is driven by the researcher's theoretical or analytic interests and involves coding for a specific research question (Braun and Clarke 2006:84).

I adapted Braun and Clarke's (2006) approach for identifying, analyzing, and reporting themes within data to conduct a theoretical thematic analysis, which is commonly used in qualitative health research. While Braun and Clarke's method is compatible with various methodologies[48], including my own critical realist, empirical bioethics approach, it requires that methodological commitments be internally coherent and clearly acknowledged "*as* decisions" (Braun and Clarke 2006:80-81 emphasis original). Furthermore, their method is interpretive insofar as it recognizes that the analyst plays an active role in identifying themes, rather than passively discovering themes that 'emerge' from data (Braun and Clarke 2006:80). An understanding of the researcher as an active participant in the analytic process is consistent with the methodological commitments of a critical realist, pragmatic empirical bioethics inquiry.

Braun and Clarke (2006:87) describe six steps for thematic analysis: 1. Familiarizing oneself with the data sample; 2. Developing initial codes in a systematic fashion to capture interesting features of the data related to the research question(s); 3. Aggregating related codes into potential

[48] Braun and Clarke (2006:81) describe how thematic analysis is compatible with methodologies spanning from realism to interpretivism; however, they do not endorse a "naïve realist" or strictly positivist epistemological orientation as they recognize that the researcher "cannot free themselves of their theoretical and epistemological commitments" (2006: 81, 86).

themes and sub-themes, where a theme "captures something important about the data in relation to the research question, and represents some level of patterned response or meaning within the data set" (Braun and Clarke 2006: 82); 4. Comparing the preliminary themes with the coded extracts, and the entire data set, and developing a thematic map of the analysis to conceptualize patterns and relationships (including commonalities, tensions, and inconsistencies) between the themes (Braun and Clarke 2006:89); 5. Refining, naming and defining the themes and overall narrative of the analysis; 6. Writing up the analysis, incorporating exemplary excerpts from the data, and clearly relating the analysis to the research question and broader literature. The importance of being transparent about analytic choices in the context of analysis extends to the process of writing up results as well, such as by being explicit about how and when theory is used in the interpretation and analysis of data (Braun and Clarke 2006; Tracy 2010).

I adapted Braun and Clarke's method in order to address the particular aims of my inquiry and engage with the theoretical framework described in the proceeding (Theoretical Considerations) chapter. Recall that my first research question concerns the main normative rationales in the pharmacare debate, which requires attending to both the relationship between normative concepts within an argument and the relationship between normative concepts and the features of the proposed policy. My second research question asks how normative and political philosophy can contribute to understanding and informing the pharmacare policy debate, and thus calls for a theoretically-informed analysis. In other words, I was not searching for just any sort of theme or pattern across the data set. Rather, I sought to identify the main policy arguments in the debate, characterize them in terms of their underlying normative positions, and then to identify themes across the discursive landscape of the debate. Below I describe how I adapted Braun and Clarke's analytic approach to address my inquiry's aims.

3.2.4.2.1 A Misguided First Attempt: Decontextualized Principles

The need to adapt Braun and Clarke's approach for thematic analysis arose from a misguided first attempt at analysis inspired by a series of publications that descriptively enumerate ethical principles and values identified in health policy reports and frameworks.[49] Originally, I 'tagged'

[49] I drew on four articles: a survey and analysis of the types of entities health policy decision-makers believe "values" to be and how they use value-concepts in 36 Canadian health reform documents (Giacomini et al. 2004); an outline of the role of values in health policy and a call for the establishment of a field of health policy ethics within

relevant segments of the text using *in vivo* codes (i.e., using the language used in the texts) in a data management software (QSR NVivo 11).[50] My codes focused on identifying broad normative concepts and the final analytic codes were enumerated as principles in a table [Appendix F]. I categorized each principle in terms of its function as a terminal, substantive, or procedural principle. However, this process resembled a "code-and-retrieve" exercise similar to Tesch's notion of coding as a process of "decontextualization and recontextualization" (Coffey and Atkinson 1996); my initial codes decontextualized the normative concepts from their indigenous discursive context, while I attempted to recontextualize the principles as I wrote up my findings. Yet, the process of identifying individual, decontextualized principles did not facilitate articulating a coherent account of how the principles related to one another or to the broader policy arguments. Accordingly, I sought to adopt a different analytic strategy which would capture the discursive context for the normative concepts that I identified. Changing one's analytic strategy to better suit one's research aims is not uncommon and reflects the iterative and reflexive nature of qualitative research (Evans 2000).

3.2.4.2.2 From Decontextualization to an Adapted Thematic Analysis of Policy Arguments and Normative Rationales

The tendency to fragment and decontextualize data through coding in qualitative data analysis can be distinguished from the *Gestalt* principle, or the notion that the whole is greater than the sum of its constituent parts (Hollway and Jefferson 2000:57). In the context of my analysis, the *Gestalt* principle suggests that understanding argumentative rationales and interpreting individual normative concepts requires considering the discursive context and logical form of the entire policy argument, since "parts are defined by their relation to the system as a whole in which they are functioning" (Hollway and Jefferson 2000:57). Accordingly, I developed an analytic strategy that retained an emphasis on analyzing data sources as a whole and on logical chronology to capture the form or logic of normative policy arguments within a text, even if their

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policy analysis (Kenny and Giacomini 2005); an investigation into the nature and use of 24 explicit ethics frameworks that are components of strategic health policy documents and an articulation of preliminary guidelines for evaluating health policy ethics frameworks (Giacomini, Kenny, and DeJean 2009); and an analysis of the principles invoked in 6 documents pertaining to a National Pharmaceutical Strategy (MacPherson and Kenny 2009).

[50] NVivo served as a data management tool, which enabled me to retrieve codes, as well as their surrounding text in later stages of the analysis. However, I identified and labelled all the codes manually in NVivo.

underlying normative rationales were not always explicit, and then across texts and arguments in the debate. Accordingly, I ended up reanalyzing my data in 3 main stages through an adapted thematic analysis, where the main 'themes' that I sought to identify included the main policy arguments, their underlying normative rationales, and the normative tensions and congruencies between the different arguments and normative positions in the debate:

1. **Identifying the main policy arguments in the debate**: I first sought to identify the main pharmacare policy arguments across the whole debate, which involved:
    a. Reading each document while paying attention to the policy problems, proposed policy solutions, and arguments offered in support of the proposal(s), *within* each individual text. At this stage, I focused on identifying the types of policies being advocated for (e.g., related to the financing, organization, scope, comprehensiveness, etc. of the proposed pharmacare programs).
    b. Next, I compared the arguments across the whole study sample to identify the main policy proposals or arguments within the debate. I identified three main proposals: public, single-payer, mixed, multi-payer, and catastrophic coverage. Additionally, I noted a fourth category of arguments that opposed or questioned the need for pharmacare reform (which had some overlap with the mixed, multi-payer arguments).
2. **Characterizing the main policy arguments in terms of their underlying normative rationales**: Having identified three main pharmacare proposals, I sought to characterize them in terms of their underlying normative rationales. To do so:
    a. I returned to analyzing individual documents to identify how each document *framed* and *justified* its policy arguments *normatively*. I searched for normative concepts, including principles or values, that were cited explicitly (e.g., such as concepts I had identified in original principles-focused analysis, see Appendix F) and considered how they are used in relation to one another and to the proposed policy objectives and processes. I also examined the implicit normative rationales, which I identified by paying attention to what the documents identified as policy goals or problems and what they proposed as potential solutions; this analysis was aided by the theoretical framework described in the following chapter where I survey representative theoretical accounts of whether, when, and why, as a matter of justice, health

insurance ought to be considered a matter of public or private concern and responsibility.

   b. Then, I compiled the normative rationales within each of the three main pharmacare policy arguments in order to identify the main normative rationales offered in support of the different pharmacare proposals across all of the texts. For example, for single-payer pharmacare, I identified three main normative rationales (equity, community, and efficiency) as well as several sub-categories of arguments within each of these, and I collected exemplary segments of text under each heading and sub-heading.

3. **Identifying normative discursive themes across within the debate**: Once I had characterized each main proposal in terms of its main normative rationales, I compared the normative rationales between the arguments in the debate (i.e., public single-payer vs. mixed multi-payer vs. catastrophic) and across time during the case study period.
   a. I sought to identify and characterized the main areas of normative tension or congruence between the policy arguments and their accompanying normative rationales in the debate. For example, I asked questions such as: do they frame policy problems differently, do they justify their positions with reference to similar or distinct principles, do they understand the same principles in different ways, or do they understand the normative purpose of pharmaceutical insurance distinctly?
   b. This stage yielded my two main findings, which recount the progression of normative justifications across the debate in time and identify the points of normative congruence and tension between the main policy arguments. I identified a form of relative agreement about universalizing insurance, but disagreement about the way it ought to be financed and organized, which was underpinned by distinct normative positions concerning the normative nature and purpose of pharmaceutical insurance.
4. **Writing up the findings**: Finally, I wrote up the analysis, incorporating exemplary excerpts from the data, and clearly related the analysis to my research questions and the theoretical literature that had informed my analysis.

3.2.5 Assessing Research Quality and Reflexivity

The analysis of my findings yielded a descriptive account of how implicit and explicit normative propositions contribute to and are situated in pharmacare policy arguments across the pharmacare debate; I did not measure the frequency with which particular concepts or rationales

are employed in a text. As I described earlier, both qualitative research and empirical bioethics allow a researcher to adopt one of a variety of methodologies and methods without identifying any one as intrinsically more valid. Research quality is determined by the coherence of the espoused methodology—and its underlying ontological and epistemological commitments—and proposed methods with the research objectives and questions (Tracy 2010; Kahlke 2009; Davies et al. 2015; Ives et al. 2018).

The emphasis on transparency about methodological commitments and analytic choices shifts the focus of quality assessment from the *process* to the *outcome*, or substance, of the analysis (Eakin 2003; Stenvoll and Svensson 2011). Accordingly, it is necessary to be transparent about analytic choices. Moreover, the importance of transparency about analytic choices extends to the process of writing up results, such as by being explicit about how and when theory was used in analysis and interpretation of the data (Sandelowski 1993). I recognize that my analysis is necessarily an interpretation of the original texts. In keeping with good qualitative research, I aimed to be trustworthy in my description of the themes I identified by providing rich detail, using the language from the documents in my descriptions, and noting exemplary quotations when describing normative concepts in order to stay close to the text and maintain "continuous dialogue with empirical data" when developing concepts later in the analysis (Becker 1998:109; Coffey and Atkinson 1992; Tracy 2010).

Reflexivity also contributes to the methodological soundness of qualitative research as well as empirical bioethics methodology (Hedgecoe 2004). Reflexivity refers to the process of acknowledging one's ontological, epistemological, and other assumptions in relation to one's inquiry and analysis (Tracy 2010). Accordingly, I have aimed to be reflexive while conducting my research by recording my experiences and impressions of acquiring and engaging with the data throughout the analysis as well as by being explicit about my methodological commitments as described earlier in my discussion of empirical bioethics. These reflections contributed to the "audit trail," or reflexive account of my emerging reasoning and analytic decisions and interpretations (Tracy 2010:842), prompted me to remain cognizant of my methodological and theoretical assumptions and my *active* role in the analysis and interpretation of data.

As discussed in this chapter as well as preceding ones, I am approaching this study from a bioethics, but more precisely public health ethics perspective, which emphasizes the importance

of population-level analysis as well as a consideration of how social and structural factors contribute to or limit population health (Thompson et al. 2013). Moreover, a public health ethics perspective raises the notion of 'public good' and, by focusing on population-level dynamics and policies, draws attention to norms that operate at meso- and macro- political and social levels—norms that have been identified as distinct from those commonly identified with clinical- and research-focused bioethics (Lee 2012). Accordingly, the theoretical framework that I describe in the following chapter draws primarily on political philosophy and public health ethics rather than normative philosophy which is concerned primarily with individual conduct. These theories recognize that normativity in public health and public policy is *political*, in that it occurs in the context of a political community. Moreover, as I describe in the following chapter, I draw on a range of theoretical accounts—many of which fall broadly within a liberal political tradition, which I see as facilitating an internal rather than an externalist critique.

As I discuss in the following chapter, I also recognize that there is a tendency in general public discourse and political philosophy to presume that political or state activity and incursion on individual freedoms or in the market economy requires special justification, but I follow Coggon (2012:117) in asserting that both state involvement and noninvolvement require normative justification. While I have aimed to remain open with respect to my own normative commitments, I recognize that I am working in a public health ethics tradition that recognizes the value of population health and that impact of social and structural factors on health, and thus largely contrasts with the commitments of the libertarian philosophy I discuss in the next chapter.

Public health ethics recognizes that norms are shaped by and operate in a social, historical, and political context. Moreover, as a subset of applied ethics, it holds that facts alone are not prescriptive, and that evidence, practices, and actions are value-laden—a notion that is gaining recognition in policy analysis, as described in the preceding Background chapter. Consequently, a fundamental assumption in my analysis is norms underlie and motivate practices and policy instruments (sometimes explicitly and often implicitly). Moreover, institutions such as markets or technical concepts that are commonly invoked as non-normative, such as economic or scientific rationales, are also underpinned by normative assumptions. As for my meta-ethical commitments, building on the notion of bioethics as a normative and pragmatic discipline, I presume that normative theory can inform or speak to policy and practice and vice versa.

Finally, I also recognized that I was studying a policy debate within the broader debate concerning Canadian Medicare, and that Medicare itself is an institution with which I have lived experience and which influences my life and the life of those around me. For example, each encounter with the health care system prompted reflection on the impact on existing and absent policies on myself, my family and friends, and others around me—both those who are similarly and differently situated.

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Chapter 4
Theoretical Considerations

4 Theoretical Considerations

Central questions in the Canadian pharmacare policy debate include whether societies have obligations to provide universal health insurance to their members, and if so, which goods and services ought to be covered and under what conditions. As discussed in my review of the literature on the normativity of public policy, public policies commonly raise these sorts of moral and political questions concerning just policy ends, means, processes, and obligations. While it is then unsurprising that normative concepts feature prominently in public policy debates such as the pharmacare debate, they are seldom explained in detail. There are various practical reasons why policymakers and analysts tasked with developing and improving policy do not engage in deeper normative analyses (Kingdon 2002). However, as a bioethics[51] analysis, my analysis *is* concerned with the normative rationales that underlie policy arguments in the pharmacare debate. Accordingly, I draw on theories in political philosophy and public health ethics to further my analytic and normative objectives. Rather than exhaustively reviewing the entirety of the normative literature on health insurance, I survey representative accounts within four major theoretical orientations in contemporary Anglo-American political philosophy—communitarianism, egalitarianism, public economics, and classical liberalism and libertarianism—which illustrate how each position justifies whether, when, and why, as a matter of justice, health insurance ought to be considered a matter of public or private concern and responsibility.

This chapter provides a typology or framework of four major normative accounts of the division between public and private in the financing and delivery of health insurance. I draw on this typology to inform the descriptive, analytic, and normative analysis in my findings and discussion chapters. As will become evident throughout my analysis of the findings, elements of these normative accounts are reflected to varying degrees, and often in combination, across the

[51] I explained how I frame the scope of bioethics in the previous chapter. Briefly, while my inquiry may be more appropriately located within public health ethics—owing to the focus on population health and health policy—I take bioethics to extend beyond narrow clinical and institutional concerns.

pharmacare debate. However, and as I described in greater detail in the preceding chapter (Methodology and Methods), the theoretical accounts that I describe provide a conceptual grounding and language, but not *a priori* analytic codes, to facilitate analyzing the normative discourse in the documentary data from the pharmacare debate. Moreover, while policy arguments often appeal to unelaborated normative concepts, I analyze the justificatory role and policy implications of particular concepts by considering them in relation to other concepts within an argument as well as broader theories, or well-developed systems of reasoning, which offer richer normative justifications for particular forms of political and social organization.

I proceed by first introducing the political and philosophical tradition of liberalism, which provides the political context for the pharmacare debate and helps differentiate the theoretical accounts that I describe. I then introduce libertarianism and classical liberalism, which advocate for the narrowest conception of the state and a public-private division that does not resemble that of any contemporary welfare state. The remaining three accounts that I discuss justify more expansive state involvement in health insurance, albeit to different extents and for different reasons. I selected these four theoretical orientations to inform my analysis based on a survey of philosophical literature, including other works that review and characterize normative accounts of welfare states or health insurance mechanisms (e.g., Goodin 1988; Shapiro 2007; Heath 2011) and in response to preliminary engagement with the data sources and other analyses of the pharmacare policy debate (e.g., as described in the Background Chapter), which provided early indications that the selected theories were pertinent to or reflected in some way in the pharmacare public policy discourse. My aim in this chapter is not to argue that a particular theory provides a superior account of the normative importance of insurance or the legitimate scope of the public and private sectors in health insurance. Rather, I characterize concepts from these theories to construct a theoretical framework which I can then draw on to inform the analysis of arguments in the pharmacare debate. In addition, I put my findings into conversation with the theories presented in this chapter in the Discussion Chapter.

4.1 An Introductory Note on Liberalism

Before proceeding, it is worth locating the theoretical accounts that I describe in relation to the broader philosophical and political tradition of liberalism. The liberal tradition includes a spectrum of positions—such as libertarianism, classical liberalism, and liberal egalitarianism—

which vary in how they conceptualize and accord normative weight to liberty, and as a corollary, how they conceive of the legitimate role and scope of the public and private. While there is much heterogeneity across liberal accounts, they share two foundational normative commitments that shape how they understand justified political authority and the aims of political justice: a commitment to the priority of individual liberty as a political norm for shaping interpersonal interactions, and a commitment to the equality of all people, such that each individual has equal, intrinsic worth and bears certain basic (fundamental and inalienable) rights (Freeman 2001). How they understand individual liberty or what they take to be basic or fundamental liberties and rights is where the accounts diverge and why they arrive at different conclusions about political responsibility and just institutions.

The broad umbrella of liberalism includes positions ranging from 'comprehensive' philosophical theories with particular value, metaphysical, and epistemological commitments to 'politically' liberal positions, which concern normative principles that justify systems of social and political institutions but do not pronounce on questions of fundamental (e.g., moral or religious) values or ends (Freeman 2001; Gaus 2004).[52] In other words, while comprehensive liberal accounts concern normative ideals or a conception of the good life, politically liberal accounts focus on identifying political principles to guide social and political interactions without committing to a particular account of fundamental values (Waldron 2004).

The attention to principles rather than ideals or fundamental values on politically liberal accounts is motivated by what John Rawls characterizes as the fact of 'reasonable pluralism,' or that within a society, people tend to espouse various reasonable, yet often irreconcilable, conceptions of the good or the ultimate ends of life (Kymlicka 2002; Waldron 2004; Heath et al. 2010). Paired with the understanding of people as being free and equal, reasonable pluralism motivates the principle of liberal 'neutrality.' Liberal neutrality, or the notion that *political* justifications and decisions ought to be neutral with respect to questions of fundamental values and conceptions of the good life, asserts that it would be unjust to structure political and social life in

[52] While some draw a sharp distinction between political and comprehensive liberal accounts (e.g., Rawls, especially in later works, e.g., 1985), others have argued that the distinction is not strict and that liberal positions may be better understood as existing on a spectrum (Gaus 2004). Both political and comprehensive liberalism are heterogeneous in terms of the commitments and justificatory strategies that they employ (Waldron 2004). For further discussion of this distinction, refer to Gaus 2004; Waldron 2004.

service of a particular conception of the good (Waldron 2004). As such, political liberalism contrasts with perfectionist theories or societies which structure political activity to promote a specific conception of the good life (Kymlicka 2002; Heath et al. 2010). In contrast, communitarianism can be considered perfectionist insofar as it advocates for a particular conception of the good—the 'common good'—towards which the state and its members should be oriented.

The principle of neutrality has institutional implications. As Heath et al. (2010:434) note, liberal societies tend to structure their social and political institutions according to mid-level principles rather than foundational values or ideals in order to respect neutrality:[53]

> From this perspective, a large part of the success of the market, electoral democracy and rights-based legal regimes is that they are all institutional arrangements that are neutral with respect to individual goals, and thereby permit concerted collective action despite an underlying heterogeneity of preference. Political philosophers have invested considerable time and energy debating the normative principles underlying these institutions, in an attempt to articulate principles that might reasonably claim to be neutral in the requisite sense. The principles of efficiency, equality and liberty have emerged from these debates as particularly privileged, because each is thought to allow for a persuasive ranking of aggregate outcomes without anyone having to judge the value of the particular projects that individuals are pursuing.

Accordingly, liberal political systems tend to share a number of key institutional features that aim to support principles such as liberty and equality, including: recognizing people's equal rights to basic liberties; upholding equal opportunity of entry into social and political positions; recognizing the role of markets in promoting allocative efficiency; recognizing the role of governments in the provision of public goods; and understanding political power as public rather than private power (Freeman 2001). Comprehensive liberal theories, which prioritize liberty as a fundamental value, offer but one way of justifying liberal political institutions (Freeman 2001). Indeed, various political theories—including egalitarianism, welfarism, and libertarianism—espouse liberal neutrality despite disagreeing on how it is best instantiated (Heath et al. 2010).

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[53] Similarly, Beauchamp and Childress' principles of biomedical ethics (autonomy, beneficence, non-maleficence, and justice), which have had broad appeal (to the point of being seemingly ubiquitous) in bioethics, were articulated as mid-level principles that could offer guidance for addressing ethical dilemmas in medicine in a pluralistic liberal society (Arras 2017).

Canada's social and political institutions reflect features of liberal political systems and its constitution protects basic liberties (e.g., freedom of conscience, freedom of speech, freedom of association, and freedoms protecting bodily and psychological integrity) that are valued in the liberal tradition. As such, the pharmacare public policy debate operates within a political context that invokes liberal democratic ideals.[54] Similarly, arguments in the pharmacare debate presume some form of the existing liberal political order and its associated institutions as a background condition.

Liberalism is a dominant political position in many industrialized countries; moreover, there is a tendency in general public discourse and political philosophy to presume that political or state activity and incursion on individual freedoms or in the market economy requires special justification (e.g., as noted by Dawson 2009, Heath 2011, Coggon 2012). Articulated more formally, public and political discourse often follows the 'fundamental liberal principle,' or the notion that "freedom is normatively basic, and so the onus of justification is on those who use coercion to limit freedom" (Gaus 2018). In practice, this often extends to a presumption that the onus of justification rests with political positions deemed more 'intrusive' than libertarianism or classical liberalism (Coggon 2012:152), and accordingly, a presumption in favour of liberty-promoting policies and institutional arrangements. While the market is commonly invoked as the premier liberty-promoting institution, how liberals conceptualize liberty impacts their understandings of which institutions do in fact promote liberty (e.g., those who value substantive equality of opportunity tend to argue for greater state involvement in securing the social and economic conditions necessary for effective opportunity). I follow Coggon (2012:117) in asserting that both state involvement and noninvolvement require normative justification on any

[54] It is worth noting that states which claim to espouse liberal ideals can nonetheless fail to uphold them or may uphold them to varying degrees. Here I am not assessing Canada's status as a liberal democracy and whether it lives up to its ideals, but rather noting that the normative ideals that are invoked as rationales for Canada's political order fall within the liberal tradition. Moreover, this discussion of liberalism may evoke the concept of 'neoliberalism,' which is increasingly used in academic scholarship and public discourse to describe ideologies, macro-economic doctrines, the Foucauldian notion of 'governmentality,' and particular types of policies, programs, and government reforms (Steger and Roy 2010; Bell and Green 2016). While Canadian health policy has been characterized as being neoliberal (e.g., Whiteside 2009), my analysis does not engage directly with the literature on neoliberalism for several reasons. As neoliberalism is primarily used as a sociological, or descriptive term, rather than as a defined political theory, it does not serve my aim of outlining normative theories or accounts of what the division between public and private *ought* to be. Moreover, neoliberalism is often invoked when characterizing post-1970s politics and economics—and in contrast with post-war Keynesianism (Steger and Roy 2010)—yet many industrialized countries still had politically liberal institutions and some form of liberal political discourse prior to the 1970s.

political account that recognizes a political community and state, however minimal its scope. In this sense, libertarianism, private institutions, and the absence of regulation are not privileged as the primary political position or as natural social arrangements which do not require justification.

In addition to providing the political context for the case study in my analysis, liberalism forms a common thread that weaves together and helps distinguish the four theoretical orientations that I outline in this chapter. Libertarianism and classical liberalism, public economics, and liberal egalitarianism all share liberal commitments, but vary in how they conceptualize liberty and its political and institutional implications. Communitarianism can be distinguished from—and is often articulated in contrast with—liberal accounts that are normatively individualist, since it holds that communities, rather than individuals, are the primary object of political analysis.[55]

As the proceeding sections will illustrate, liberal accounts vary in how they conceptualize liberty, which has distinct implications for how they conceive of the legitimate role of public and private institutions in matters of health. One key feature that distinguishes liberal accounts is whether they conceive of liberty primarily in negative or positive terms (Berlin 1969; Taylor 1979). As noted earlier, a shared tenet of liberal theories is an understanding of people as being moral equals who bear certain basic rights. Indeed, all liberal accounts are concerned with equality of some kind, but they differ precisely in what they consider to be the equalisandum—or that which is deemed morally important, be it opportunity, wealth, freedoms, rights, or otherwise (Sen 1995; Kymlicka 2002). For example, proponents of negative liberty consider the job of justice to be securing formal equality, usually in the form of equal protection of basic civil and political liberties. Conversely, proponents of positive liberty view justice as securing substantive equality of opportunity or some other prerequisite for self-determination or self-realization such as wellbeing or capabilities. Put differently, negative liberty is *freedom from* coercion or interference to act upon one's choices, and is thus seen as limiting the role of states to protecting basic civil and political liberties from external constraints (Goodin 1988). Conversely, proponents of positive liberty argue that a formal conception of equality fails to acknowledge that people who are disadvantaged (either naturally or socially) face constraints that greatly limit

[55] As I discuss in the context of communitarianism, some communitarians straddle or aim to reconcile certain facets of both liberalism and communitarianism.

their capacity to exercise their basic liberties and thus, in effect, limit their effective opportunity (Taylor 1979). Accordingly, positive liberty can be understood as *freedom to*, or the ability to act upon or pursue one's interests and goals (Berlin 1969); it is often regarded as underpinning a political imperative to organize the social and political institutions in society so that everyone has the material conditions required to exercise their liberty (Goodin 1988).[56] A third form of liberty, which has been developed in the republican tradition, sees political liberty as freedom from domination or arbitrary political interference (Pettit 1997). While republican liberty is a negative form of liberty in the sense that it rests on the absence of domination by others, it is more demanding than negative liberty, since it also calls for the absence of 'capacities for arbitrary interference,' including material dependency on others (Pettit 1997:85). Republican liberty calls for a form of substantive equality, but one that is structural rather than strictly material, which enables people to stand as equals in their enjoyment of non-domination (Pettit 1997:113). The implications of these distinct conceptualizations of liberty for the role public and private actors and institutions in the provision of health insurance will become more evident throughout the chapter.

In addition to different underlying normative commitments and conceptualizations of key normative principles such as liberty, different political orientations also vary in how they understand other politically-salient ideas such as the nature of moral psychology (e.g., the nature of motivation and reasoning) and social ontology (e.g., the nature of persons, interpersonal relationships, and relationships between individuals and collectives) (Pettit 2006). In turn, different understandings of moral psychology and social ontology impact how each political position conceives of the morally-salient empirical 'facts' which they invoke as assumptions or premises when arguing that an issue, such as health insurance, ought to be a matter of private or public concern and policy intervention.[57]

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[56] However, substantive equality of opportunity does not necessarily require equal outcomes as people can vary in terms of natural talent, ability, and also in effort and motivation.

[57] This is akin to what Mack and Gaus (2004) refer to as the "empirical generalizations about how the world works (or fails to work)" which, in addition to normative principles, comprise the 'doctrinal' features of a particular political tradition.

Rather than providing a comprehensive overview of each theoretical account that I outline, I survey the defining characteristics of each position in terms of its implications for understanding the normative significance of health justifying whether, why, and to what extent societies ought to treat health insurance as a matter of public or private concern and responsibility.

4.2 Libertarianism and Classical Liberalism: The Residual State

Of the liberal philosophies, libertarianism and classical liberalism can be understood as existing within the same intellectual tradition—the 'liberty tradition'—or as having strong doctrinal and political resemblances (Mack and Gaus 2004); for example, they are normatively individualist, regard liberty as the fundamental political norm, and advocate for a very limited role for the state in social and economic life, including in matters of health (with the classical liberalism allowing for a slightly greater role than libertarianism), since they regard the state as being the primary threat to individual liberty.[58] As a result, they share more commitments with one another than they do with other liberal positions such as liberal egalitarianism. Owing to their shared commitment to the primacy of individual liberty, I discuss them as falling within the same philosophical tradition, but I also describe their distinct features, which come to light especially in the policy context.

4.2.1 Libertarianism: The Minimal State

Libertarianism prioritizes respect for individual liberty as the primary political principle,[59] which defines what claims one can legitimately make towards others as a matter of right, and as a corollary, demands considerable protection as a matter of justice (Mack and Gaus 2004). Libertarians tend to adopt a negative conception of liberty as autonomy or freedom from coercion or external constraints. Accordingly, curtailing individual liberties is justified only for the purposes of preventing (or redressing) the violation of others' basic liberties and harm to

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[58] It is beyond the scope of this chapter to discuss all the varieties of libertarian and classical liberal accounts. A broad sketch of the central tenets of these normative positions is sufficient to highlight the normative commitments that are pertinent to public policy discourse. I also leave aside 'left libertarian' accounts, which argue for a greater egalitarian-redistributive role for the state (for an overview, see Mack and Gaus 2004), since they are less commonly invoked in the philosophical literature pertaining to health insurance and are less commonly associated with libertarianism in public discourse.

[59] Libertarian accounts vary in terms of the fundamental values (e.g., freedom, equality) they appeal to in order to justify the primacy of liberty as a political norm (Kymlicka 2002).

others, and not for the purposes of benefiting the individual (paternalism) nor for promoting the good of others or society at large (e.g., in the service of common good or efficiency) (Mack and Gaus 2004). Accordingly, libertarians emphasize the importance of consensual and voluntary action as a prerequisite for political authority, as well as individual responsibility, since the latter is seen as taking ownership for, rather than (non-consensually) imposing the costs of one's decisions onto others.

Libertarians tend to consider a narrow set of basic liberties or rights as normatively basic, such as rights to personal liberty and security and rights of ownership (including self-ownership and property rights) (Mack and Gaus 2004). For example, on some accounts, people are taken to have a basic right of self-ownership or autonomy over themselves as well as rights of ownership (including for the use and transfer of extra-personal property) for property or resources that they have acquired through their own labour, as long as they have not done so by infringing on others' equal liberties (e.g., Nozick [1974] 2013). On such an account, rights of ownership are considered preconditions for freedom as they enable individuals to act upon their own conceptions of the good life, as well as for institutions such as the free market.

The libertarian commitment to the primacy of individual liberty as requiring protection from coercion and external influence has institutional and distributive implications. Libertarianism advocates for the narrowest conception of the state—often referred to as a 'minimal' or 'small' state, depending on its proposed scope (Mack and Gaus 2004). In its minimal form, the state's role is limited to protecting the narrow set of liberties that are fundamental on the libertarian account, such as rights to security and property, and on some accounts, enforcing contracts into which private parties have entered voluntarily. Taxation is justified only insofar as it necessary for financing these limited state activities (e.g., police and justice systems) of which the individual tax-payer is taken to be a beneficiary. Redistributive taxation, such as to finance social welfare programs to assist the disadvantaged, is considered tantamount to theft or even 'forced labor' as it is coercive (Nozick [1974] 2013:169);[60] instead, justified forms of assistance are

[60] In *Anarchy, State, and Utopia, Nozick ([1974] 2013)* envisions a minimal or 'night-watchman state' that is far more limited in its scope of activity than any modern welfare state. Nozick does not even consider taxation to be justified, and instead sees the state as having a legitimate monopoly (insofar as it arises naturally) on the provision of protective services, which it sells to people who are presumed to have an interest in voluntarily purchasing them.

voluntary, such as through acts of charity financed through voluntary contributions. Accordingly, just distributions are those that result from voluntary or free exchanges between individuals. Libertarians see a free-market economy as the primary institution to facilitate cooperative action, since it promotes free exchange and respects individual choices as it is neutral vis-à-vis individual preferences and does not presuppose final ends (Kymlicka 2002). Accordingly, they tend to be averse to government regulation. Similar arguments about the overreach and illegitimacy of government regulation (e.g., concerning drug safety and pricing by the US Food and Drug Administration) have been raised on the grounds that it is paternalistic and coercive as it limits individual choices and access to medications and directly contributing to the deaths of patients by delaying or restricting access to potentially life-saving treatments (Flanigan 2014; 2017).

In addition to principled defenses of the free market, libertarians also advocate for free markets based on empirical beliefs they espouse concerning psychology and social organization. For example, the free-market is considered to be more efficient at generating economic welfare as it is seen as transmitting information about individual preferences more effectively than central planning—largely owing to limitations in individual epistemic capabilities—as well as holding people responsible for their decisions, and thus providing an "economically and socially desirable incentive structure" (Mack and Gaus 2004:21). For similar reasons, libertarians tend to question the limits of expertise and expert evaluation (e.g., see discussion in Coggon 2012). Libertarians also tend to reject the egalitarian imperative of correcting for unequal circumstances in practice as they call into question the feasibility of determining whether individual differences are the result of choices or circumstances (Kymlicka 2002:154).

Tristram Engelhardt (1996; 1997) develops a libertarian account of bioethics, including of health insurance. However, rather than presupposing the fundamental moral primacy of liberty, he takes a political principle of individual liberty (or in his case, a 'principle of permission') to be a necessary corollary of living in a secular, pluralist democratic society in which there are multiple, intractable accounts of the good and the right (Engelhardt 1996). Accordingly, he asserts that bioethics and health policy ought to be guided by a procedural morality grounded in the principle of permission, since agreement amongst voluntarily consenting adults is the sole condition that legitimates political or collective action in matters of health (1997:193). It is for this reason, he asserts, that "the paradigm moral activities of secular morality are the free market,

contract formation, and the establishment of limited democracies" (193). In contrast, policies or actions that are grounded on substantive principles, such as the principle of beneficence, are justified only if they occur through mutual understanding between the beneficiary and benefactor in accordance with the principle of permission and in accordance with the beneficiary's own conception of the good (1996:112).[61]

Engelhardt takes issue with grounding a 'welfare right to health care' on egalitarian grounds, since he asserts that it would require endorsing "one among a number of competing concrete moralities of life, death, and equality" (1997:189). As he sees secular morality as procedural and political authority being legitimized through "the consent of the governed" (1996:177), he asserts that, "the provision of any general protection against morbidity and mortality is best offered as a limited insurance against losses in the natural and social lotteries" (1997:194). In other words, he claims that a market-based or private tier of medicine is "morally unavoidable" as "people are free to purchase the health care they can buy and to provide the health care others wish to give or sell" (1996:402-403). He explicitly calls out Canada's single-tier Medicare system as "morally impermissible because it violates fundamental principles of secular morality" as it mandates a universal set of health care services while barring individuals from procuring better quality basic or luxury care (1996:403). Nonetheless, Engelhardt acknowledges that a basic package of public insurance funded through common resources[62] may (but need not) be offered for the poor or disadvantaged through a voucher system or medical savings accounts which individuals could use to procure basic health care from an insurance and care provider of their choice (1996; 1997).

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[61] Engelhardt acknowledges that beneficence can "suggest that it would be good to benefit persons in need" and support "the concrete moral goals to which medicine ought to be directed," but that it does not justify compelling someone to act in such a manner unless they are contractually obligated to (1996:107-108). Moreover, he asserts that an individual who rejects beneficence loses all claims of beneficence (or 'mutual sympathies') from others; however, reciprocal claims of beneficence are not universal and can only exist within a particular community (1996:111).

[62] Engelhardt (1996:160) asserts that, "communal or societal ownership legitimately comes into existence only insofar as individuals enter into a joint endeavor with a view to creating a common fund for communal undertakings." For his argument concerning communal ownership, see Engelhardt (1996:158-161).

4.2.2 Classical Liberalism: The Residual State

Classical liberals share commitments to individual liberty and free-markets with libertarians. However, they tend to allow for a greater role for the state than libertarians do, albeit still as a 'small' state. Classical liberals see the role of the state as legitimately extending to the provision of economic public goods, including ones extending beyond basic protective services, and in certain cases, to the provision of minimal social welfare programs (Mack & Gaus 2004). Economic public goods are goods that are both non-rivalrous and non-excludable, and are thus prone to free-riding. The state's provision of public goods is justified on account of the market's failure to provide these goods efficiently, since private institutions lack the authority to use coercive force to compel individuals to pay their 'fair share' and not free ride (Mack & Gaus 2004). However, the state provision of public goods does not presuppose a common good or shared concerns, nor does it see the state as redistributive; rather, the state is seen as orchestrating a Pareto improvement (a term borrowed from economics), or a change in allocations that leaves at least one individual better off by providing them with a service that they would have procured through the market were it available at a cost-effective price without worsening anyone else's position (Mack & Gaus 2004). Ultimately, just distributions are tied to satisfying individual preferences as far as possible through private mechanisms, while the state plays a residual role in correcting market failures.

While classical liberals acknowledge that the state can legitimately provide a greater range of goods than merely enforcing the protection of individual rights and liberties, as on the libertarian account, they still hold that only a narrow range of goods qualify as true public goods, and accordingly, that the state's role is relatively limited. In some cases, the provision of a social minimum of welfare services, such as to eliminate poverty, is also justified with an appeal to public goods, or if it seen as redistributive, is seen as residual (Mack & Gaus 2004).

Public goods-based arguments have been articulated in the context of public health by scholars on the libertarian-classical liberal spectrum in an effort to (re)define the parameters or legitimate scope of government intervention (and coercion) in matters of health (e.g., Epstein 2004; Anomaly 2011). They argue that public health activities ought to be limited to securing health-related public goods both in order to respect individual liberty as well as deliver certain types of goods that markets fail to deliver efficiently. Moreover, these accounts contrast with, and in part

respond to, assertions that the origins and moral foundations of public health concern social justice (e.g., Beauchamp 1976, Powers and Faden 2006, Daniels 2008, Thompson et al. 2013), which they see as extending beyond the legitimate scope of public, and thus state, intervention.

Richard Epstein (2003; 2004) argues for a return to the 'old' public health, which is limited to activities such as communicable disease control and regulating certain activities that generate health-impacting externalities such as pollution. Epstein asserts that a limited range of health-related public goods can be justifiably delivered by states as they are not delivered efficiently by markets, nor privately through tort law, and are compatible with individual rights.[63] Indeed, he suggest that "only a knave" would dispute the use of taxation to support the provision of goods such as sewers (2004:1445). Epstein argues that the 'new' public health has unjustifiably broadened its scope to include address "any topic of widespread public importance," which has led to increased government regulation of areas of life that are now deemed to be matters of public health (e.g., obesity).[64] He argues that, as a result, increased regulation has reduced "overall social wealth and freedom," such as by increasing prices or delaying innovation of care and treatment or through moral hazard, since people are less inclined to take efforts to improve their health or stop the spread of infectious diseases.[65] Regulations are thus seen as reducing wealth creation as well as diverting resources from the 'old' public health's core activities.

Jonathan Anomaly develops a public goods-based account of public health which is distinct from, although "potentially complementary" with Epstein's (2011:258). Similar to Epstein, he sets out to define the legitimate scope of activities that should be considered matters of *public health* in response to what he characterizes as an "identity crisis" in the field associated with its increased attention to promoting human rights and social justice (2011:251); he sees the latter as more appropriately falling under the purview of other discipline such as social work. Anomaly argues that public health activity should be restricted to what he characterizes as its original and

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[63] For example, he frames regulating negative externalities as liberty-protecting as they aim to mitigate "public bads [which] are inflicted upon others without their consent, as are communicable diseases and pollution" (2004:1246).

[64] For a critique of Epstein's argument, including his dichotomization of the 'old' and 'new' public health, see Gostin and Bloche (2003).

[65] For example, he suggests that regulations have contributed to increased prices and reduced research and development of new vaccines and pharmaceuticals (2004:1469), or similarly, that regulations limiting health insurance providers' ability to engage in risk rating or exclude individuals with pre-existing conditions contribute to moral hazard and thus higher health care costs as well as lower overall population health (2004:1463).

more circumscribed mission of promoting the health of populations by providing health-related (economic) public goods "for which there is significant demand, or *would be* significant demand if potential consumers of the good had accurate information about the likely costs and benefits (both moral and monetary) of providing the relevant public good" (2011:256).[66] Accordingly, he argues that government intervention should be restricted to the provision of goods and services which cannot be provided efficiently by private entities.[67] Like Epstein, he considers the range of health-related goods that are pure public goods to be relatively narrow. In addition to appealing to its efficiency-promoting features, Anomaly claims that limiting the scope of government intervention in matters of health to securing economic public goods is further justified as it avoids paternalism and respects liberal neutrality and is thus less politically divisive. He also calls into question the 'new' public health's emphasis on addressing the social determinants of health, which he considers to be determinants of "*private* welfare [rather] than *public* health," and hence as outside justified collective action aimed at promoting *population* health (2011:257). Moreover, he asserts that policy objectives such as "equalizing resources and maximizing aggregate welfare are fiercely contested social goals" and which are tied to egalitarian or utilitarian aims that ought not to be presupposed in the core agenda of public health (2011:257).

I have described how libertarianism and classical liberalism envision at most a narrow role for state involvement in health and health care—one that is limited to the provision of public goods. They argue that health insurance ought to be provided by the market (or at least must include a private tier), since it is both more efficient and respects individual choices in purchasing and offering care. In contrast, the normative accounts that I outline in the rest of the chapter argue for an expanded role for the state in the financing and organization of health insurance (although each offers a distinct normative rationale).

4.3 Public Economics: The Efficient State

As discussed above, classical liberals assert that the state should be limited to providing a narrow set of public goods which markets fail to provide efficiently. An alternative account of the

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[66] He asserts that the legitimacy of *public* health intervention increases "as the public good and the size of the population to which it applies increase" (2011:251).

[67] Anomaly allows for non-governmental entities to provide population health-related goods that are not pure economic public goods; however, these entities lack the coercive power of the state to enforce their policies.

division between public and private institutions similarly sees the role of the state as correcting market failures; however, it asserts that the range of activities where public intervention is justified extends beyond the provision of pure economic public goods to a broad range of market failures or collective action problems, and as a result, the state itself plays a significant role in advancing efficiency by promoting certain types of cooperation (Moss 2002; Heath 2006; Heath 2011; Horne 2019). Fittingly, it is referred to as a 'market failures' approach (Heath 2014; Horne 2019), or alternatively, as a 'public economic' or 'public goods'[68] model of the welfare state (Heath 2011:23-25). A prominent example of the market failures approach has been developed by Joseph Heath in business ethics (2014) and with respect to welfare states (2006; 2011), and which has been extended to health insurance and public health by L. Chad Horne (2016; 2019).

According to the market failures approach, the appropriate division between public and private institutions ought to be determined based on which institutional mechanisms secure a particular cooperative benefit (by resolving a collective action problem) more efficiently. The market failures approach adopts the principle of Pareto efficiency as its central principle;[69] it considers efficiency as a political principle akin to equity or liberty, rather than a value-free, technical measure as is often presumed in economics (Heath 2011; 2014). As introduced earlier in the context of classical liberalism, a Pareto efficient improvement is one in which goods or services are allocated in such a way that at least one individual's welfare (or preference satisfaction) is improved without reducing that of anyone else. In that sense, a commitment to Pareto efficiency may also be characterized as advocating for the elimination of 'gratuitous suffering,' since it aims to address inefficient outcomes which can be understood as 'lose-lose' transformations (or changes in social states where all parties are left worse off or no better off) (Heath 2011:24).

Despite centering on efficiency, Heath (2014) characterizes the market failures approach as operating within a liberal and contractualist tradition rather than being a consequentialist or utilitarian account aimed at maximizing aggregate welfare. This is because Heath's (2014:146-

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[68] Again, in a broader sense of public good than on the classical liberal account, since it looks to any area in which the state is more effective than markets at reducing transaction costs.

[69] Nonetheless, Heath recognizes that additional principles such as equality are pertinent to political decision making. For example, while he cites efficiency as justifying the delineation between public and private institutions, he argues that equality can be relevant to determining how a particular program is financed (Heath 2011:41).

171) characterization of Pareto efficiency can be understood as one of constrained maximization, since he notes that efficiency maximizing transformations are limited by deontic considerations that arise from the cooperative arrangements that people enter (or would agree to) in order to more efficiently pursue their own objectives. The public economic account suggests that liberal democracies arrange their institutions to provide a structure of reciprocity (e.g., by creating positive externalities, or benefits to third parties, and minimizing negative externalities, or harmful effects to third parties) in order to motivate individuals to produce cooperative benefits which enable them to better aid each other in achieving their goals, whatever they may be (Heath 2006:315). Institutions secure cooperative benefits (or Pareto-efficiency gains) that increase total welfare by helping resolve collective action problems. Collective action problems arise in situations where individuals pursuing their preferences in a narrowly self-interested or instrumental manner result in a collectively worse outcome that leaves everyone worse off than if they had cooperated and limited rather than attempted to strictly maximize their individual self-interest.[70] It is for this reason that Heath (2014:175) suggests that Pareto efficiency "serves as a genuine constraint on the pursuit of individual self-interest" and, moreover, is not simply an instrumental or prudential value as in the 'engineering' sense of efficiency which aims at maximizing outputs for a given set of inputs (Heath 2001). In contrast, recall how libertarians hold that individual liberty is primary, so collective action that is efficient but not voluntarily chosen or consented to by individuals is considered unjustified and illegitimate.

While the public economic account looks to economics for its central normative principle, it does not necessarily favour private institutional arrangements *a priori*. Rather, it suggests that social and economic institutions should be structured using a variety of organizational mechanisms (e.g., markets, corporations, and governments) depending on which goods they promote most efficiently. Contemporary economics and social contract theory suffer from what Heath (2006) calls a "catallactic bias," which is that they privilege gains from trade (i.e., gains achieved through market exchange or the division of labour) as the primary mechanism of cooperative benefit. Welfare economic theory consider market allocations to be most efficient (i.e., Pareto-optimal), but only if specific conditions are satisfied. As outlined by the First Optimality

[70] Prisoner's Dilemmas are collective action problem. For a more detailed discussion of collective action problems, see Heath 2006; Heath 2014.

Theorem, the conditions required to satisfy a competitive equilibrium include price transparency, a full and accurate understanding of the intrinsic properties of rival products, costless entry and exit of producers, no increasing returns for production and distribution, and the absence of monopolies (Arrow 1963; Reinhardt 2001; Reinhardt 2007). Markets tend to be well suited for addressing scarcity and organizing the exchange of private, medium-sized dry goods, since they are sensitive to changing consumer needs for material goods and the conditions for free market exchange of such goods are relatively attainable (Heath 2001:126).[71] However, when the conditions for free market exchange are not met, markets are prone to failure; where markets fail, certain goods and services may be secured more efficiently through non-market mechanisms (Heath 2006). By privileging gains, and the market as the most efficient institutional arrangement for securing them, the catallactic bias discounts the other institutional mechanisms—and especially the welfare state—which are necessary to attaining the plurality of goods that important for human welfare (Heath 2006:316-317). In addition to gains from trade, Heath (2006) describes four other cooperative mechanisms—economies of scale, risk pooling, self-binding, and information transmission—which yield a variety of distinct cooperative benefits through public and private non-market institutional arrangements.[72]

4.3.1 Insurance as a Mechanism for Risk Pooling

On the market failures account, discerning how health insurance ought to be structured requires understanding what cooperative purpose(s) insurance serves and whether the resulting benefits are delivered more efficiently through private or public means. On this account, health insurance is primarily understood as a risk pooling mechanism that generates efficiency gains by reducing the uncertainty associated with meeting future health care needs (Heath 2006; Horne 2016; Horne 2017). The market failures account advocates for publicly-mandated universal health insurance, which it considers most efficient as it is able to avoid particular types of market failures associated with health insurance markets.

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[71] As Heath (2006:322) notes, however, markets are also not exempt from collective action problems as free-rider strategies such as theft and fraud threaten the efficiency gains achieved through market exchange.

[72] For a detailed description of these mechanisms, see Heath 2006.

Health and health care are replete with uncertainty. Risk pooling is taken to generate efficiency by attenuating subjective uncertainty and risk (i.e. risk to the individual), even when objective risk remains constant, since spreading risks across a larger pool yields statistical stability and reduces variance (Heath 2006:322; Horne 2016). Risk pooling can be understood as increasing utility for all in the pool as a reduction in variance serves to preserve expectations and facilitate planning and decision-making, and further increases utility for risk-averse individuals who would willingly seek reductions in subjective risk and thus benefit from not having to deliberate about costs during already arduous periods of illness or injury (Flood 2000; Heath 2006:323; Horne 2016:594). It is in this sense that risk pooling schemes offer a source of collective benefit which is distinct from the gains from trade attained through market exchange of health insurance and services.

Health insurance markets suffer from well-documented inefficiencies and are prone to market failures owing to the uncertainties and information asymmetries inherent in health and healthcare (Arrow 1963; Reinhardt 2001; Reinhardt 2007; Heath 2006; Horne 2017). Uncertainty and information asymmetries in health insurance markets give rise to the free rider strategies of adverse selection and moral hazard (described below) which undermine market mechanisms for delivering efficiency gains through risk pooling (Flood 2000; Heath 2006; Horne 2017).[73] When imperfect market conditions prevail, non-market institutional arrangements may prove more efficient, as is the case with public provision of goods that have a high variability in returns, such as health insurance (Heath 2006). The government's legitimacy, paired with its coercive and punitive powers, enables it to address free riding and collective action problems such as moral hazard and adverse selection, which otherwise curtail the gains achieved through risk pooling strategies in unregulated health insurance markets (Heath 2006; 2011).

Health insurers often have insufficient information to charge actuarially fair premiums, or premiums that reflect each policyholder's actual risk of becoming ill and expected treatment costs (Grootendorst 2013). Adverse selection arises in private health insurance markets as high

[73] Health care markets suffer from an insufficiency of information owing to the uncertainties associated with the incidence of disease and the safety and effectiveness of treatment (which affect future use). Asymmetries arise because relevant information, including a patient's health status and history and medical knowledge, are not equally accessible to patients, clinicians, and insurers.

risk individuals have greater incentives to purchase comprehensive insurance policies, while insurers are unable to distinguish between high risk individuals and risk-averse individuals who also desire comprehensive policies (Akerlof 1970).[74] Since insurers are unable to charge actuarially fair premiums, or premiums which accurately reflect the risks that an individual contributes to the insurance pool, low risk individuals end up subsidizing the premiums of high risk individuals and thus may leave the insurance scheme due to excessive premiums. Their departure is compensated for by increasing the premiums of the remaining policyholders, which may result in further departures by lower-risk individuals. Thus, private insurance schemes are often left with a disproportionately large percentage of high risk individuals paying very high premiums or limited-to-no coverage for known high risk individual such as those with pre-existing conditions, chronic illnesses, and the elderly (Flood 2000). Universal insurance schemes eliminate the potential for adverse selection by removing selection altogether, which serves to ensure the sustainability of the insurance (Horne 2017). Horne (2016; 2017) argues that a public economic argument offers a superior justification for universal public health insurance than egalitarian ones (discussed in the following section), since the government's ability to eliminate free riding by mandating universal enrollment in the insurance pool produces considerable cooperative benefits in the form of a sustainable health insurance, or risk pooling, mechanism. Moreover, an efficiency-based account is taken have the virtue of avoiding an appeal to paternalism (Horne 2016:595) and of respecting liberal neutrality (Heath et al. 2010).

Another collective action problem associated with insurance is moral hazard (Flood 2000; Grootendorst 2013).[75] *Ex ante* moral hazard describes the phenomenon where individuals who are insured against a specific risk have a reduced incentive to avoid the harm, and thus inadvertently increase their objective risk of incurring a loss (Heath 2006). *Ex post* moral hazard

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[74] Insurers do try to identify high risk users through community rating (assessing premiums on the basis of average risk for a community) or by general risk rating (estimating an individual's risk based on proxies such as employment, gender, or age) (Flood 2000). However, some risk rating practices have been restricted or outlawed, even in the US (Shapiro 2007:43-45).

[75] The extent to which moral hazard (especially *ex ante*) occurs in health care is contested. While insured patients will use more health services than those who are uninsured given that the purpose of health insurance is to assure one's ability to access care when required, moral hazard concerns usage that *exceeds* medical need. Although there is limited evidence that health insurance is correlated with increased consumption and costs of health services, moral hazard can be mitigated through measures such as price regulation, cost-sharing, nationalization of insurance, monopsony bargaining, and managed care (Flood 2000).

arises when patients (and clinicians) are indifferent to costs and request or prescribe additional or more expensive diagnostics, medications, or treatments (usually based on perceived effectiveness or ease of use) than if the patient were to pay out-of-pocket (Flood 2000).[76] Private and public insurers tend to approach moral hazard in distinct ways. Private insurance tends to address ex ante and ex post moral hazard through cost-sharing mechanisms (co-pays, deductibles, etc.) which are designed to incentivize individual patients to limit their use of insured goods or services. Meanwhile, prior-authorization schemes which require physicians to justify prescribing a more expensive drug in lieu of a cheaper alternative target prescriber behaviour. Insurers are also increasingly using behaviour-based monitoring programs to incentivize patients to limit their ex ante moral hazard through adopting changes in health behaviours, such as by offering lower premiums to those who quit smoking or exercise consistently. Public insurers, on the other hand, tend to approach moral hazard through less individually-targeted mechanisms. While some public insurers, as in Canada, still include some cost-sharing mechanisms, they also draw on cost-effectiveness considerations to shape prescribing practices by offering coverage only for treatments or medications that are deemed cost-effective and truly 'medically necessary' (e.g., through the use of drug formularies or reference-based pricing). Reimbursing only for medically necessary care is one way of limiting moral hazard (Horne 2016:595).

As a mechanism for pooling risks, health insurance is considered redistributive only insofar as *all* forms of insurance transfer insured goods from those who do not suffer a loss to those who do (Heath 2011; Horne 2016).[77] This is because insurance distributes insured goods according to need—that is, based on whether someone has incurred an insured loss—in keeping with its purpose as a risk pooling mechanism aimed at reducing people's uncertainty associated with future health needs (Horne 2016:595). It is only insofar as insurance is then *also* financed progressively (e.g., through progressive income taxes or premiums), or is financed through

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[76] Moral hazard is exacerbated by the information asymmetries between physicians and both patients and providers, which stem from physicians' specialized medical knowledge and prescribing privileges. Patients are less likely to question the effectiveness of prescribed treatments, and when paired with fee-for-service payments, information asymmetries may even incentivize physicians to prescribe more than necessary (Flood 2000).

[77] Libertarians can take issue with the inherently redistributive nature of insurance on the grounds that it constitutes illegitimate cross-subsidization and redistribution of resources, which is why they tend to advocate for financing mechanisms that limit or do not involve cross-subsidization, such as individual medical savings accounts (Shapiro 2007).

contributions that are not ‘actuarially fair,’ that it will also involve redistribution from the wealthier and the healthier to those with lower incomes or poorer health—features which are often associated with ‘social’ insurance. It is for this reason, Horne (2016:588) argues, that ‘the medical need principle,’ or distribution according medical need, is better understood as concerning ‘indemnity’ or following an assurential or ‘insurance logic’ rather than as an egalitarian principle.[78]

Accordingly, Heath (2011) and Horne (2016; 2017) argue that although public health insurance is often justified on the grounds that it is as a redistributive or altruistic tool for achieving equality or community (as on egalitarian or communitarian accounts discussed below), the normative justification for publicly-financed insurance is more accurately understood in terms of its contributions to efficiency (through reducing the variability of returns and mitigating free rider strategies that undermine health insurance markets).[79] Moreover, by justifying state intervention in health insurance on the basis of efficiency, the public economic argument avoids perpetuating the catallactic bias (Heath 2006; 2011); as such, it contrasts with libertarian and classical liberal accounts, which consider state activity to be primarily redistributive, and thus illegitimate, or as playing only a residual role in promoting efficiency through securing the legal and regulatory conditions required to maximize market efficiency.

4.4 Egalitarianism: The Redistributive State

The libertarian and public economic accounts justified the role of the state in social and economic life in terms of its ability to address market failures, despite disagreeing over the extent to which states ought to play a role alongside markets. Arguably, however, most arguments for universal health coverage in philosophical literature take the form of an egalitarian argument or appeal to considerations of fairness or social justice. While liberalism takes the *moral* equality of

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[78] Horne (2016:588) concedes that “the medical need principle has some egalitarian implications; it entails, for example, that no one should be denied care due to inability to pay” and argues elsewhere (2017) that an egalitarian argument can be made for why societies ought to protect their members against health risks owing to the moral importance of protecting future expectations for self-determination.

[79] In his survey of normative justifications for welfare states, Goodin (1988:4) suggests that market failures-type reasoning was invoked by certain early proponents of broad welfare programs, such as in the UK: “New Liberals such as Beveridge put the emphasis upon the state’s duty to remedy market failures. Accordingly, they suppose the core of the welfare state to be “social insurance” – paradigmatically, workmen’s compensation, health and unemployment insurance, but extending also to old-age pensions, perhaps.”

persons as a fundamental commitment, liberal egalitarians take equality to be a central political principle and often a key distributive principle; they argue that people should be treated as equal in some respect of life prospects or self-determination (e.g., opportunity, wellbeing, or capabilities). Egalitarians can be distinguished between those who are primarily concerned with *distributive* equality and justice (e.g., of resources, opportunities, welfare, or final results) and those who are primarily focused on *relational* equality and justice (e.g., equality of status or respect) which they recognize may in turn carry certain distributive implications for social and economic institutions and practices (Goodin 1988:52; Shapiro 2007; Nielsen and Landes 2016).[80]

Egalitarians are concerned with unjust inequalities, or inequities, and require an account of what makes an inequality morally concerning such that it warrants possible incursion into an individual's liberties, including through state intervention and redistribution of resources. Broadly speaking, egalitarians tend to distinguish between inequalities that arise from circumstances beyond a person's control and those that result from voluntary choices; inequalities arising from socially modifiable circumstances beyond an individual's control are unjust, while those arising from freely made decisions are not (Shapiro 2007). Moreover, they consider advantages stemming from circumstances (such as through chance or natural talents) as being undeserved or unearned, which makes redistribution of unearned advantages legitimate (Kymlicka 2012). However, the extent to which egalitarians ascribe moral saliency to choice and individual responsibility in determining injustices various across accounts.

Luck egalitarianism offers one prominent account of justice which emphasizes the role of luck and individual responsibility. Luck egalitarians view the job of justice as one of rectifying instances where inequalities in life prospects are the result of bad luck (Segall 2010). In particular, they distinguish between 'bad brute luck,' where chance occurrences contributing to inequalities are not reasonably foreseeable or modifiable, or which occur as a result of decisions made under coercion; and 'bad option luck,' where inequalities arise from voluntary decisions in circumstances where poor outcomes were reasonably foreseeable (Segall 2010). Luck

[80] While relational egalitarian accounts can be considered egalitarian, they also share a concern for relational equality with communitarians, which I discuss in the subsequent section (Shapiro 2007). Insofar as relational egalitarians value relational equality as a prerequisite for something like democratic citizenship or community, I discuss them in the context of communitarianism.

egalitarians consider it reasonable to hold individuals responsible for bad option luck, and thus do not see such inequalities as warranting intervention, while inequalities arising from bad brute luck can justify redistributive policies.

Egalitarians consider equality to be intrinsically valuable (Shapiro 2007:12). Most often, egalitarians are concerned with substantive equality of some sort (e.g., of opportunities, access, capabilities, well-being), which in turn translates into a form of concern for substantive material equality, rather than the formal equality which libertarians and classical liberals ascribe to. Indeed, egalitarians see libertarianism and classical liberalism as failing to take into account the unequal circumstances or background conditions that shape people's opportunities or capabilities to exercise their individual freedoms, and thus see the job of justice as one of securing equality in some such respect and as concerning social justice, or a fair distribution of benefits and burdens in society (Kymlicka 2002). While many egalitarians espouse liberal tenets, they see redistributions to compensate the naturally and socially disadvantaged as legitimate insofar as they aim to equalize some aspect of people's natural or social circumstances, rather than the outcomes of their individual choices (Kymlikca 2002). In contrast, libertarians permit inequalities that arise from undeserved circumstances such as chance or natural talents (Kymlicka 2002).

While, for example, the public economic account takes efficiency as its guiding normative principle, efficiency offers limited guidance on how the benefits of cooperation ought to be distributed. On the libertarian or classical liberal accounts, distributions are taken to arise through choice according to individual interests or preferences, which, for example are expressed through the willingness to pay and free exchange or otherwise voluntary acts of charity. On this account, the state's only legitimate role is that of protecting individuals' liberties so as to facilitate individual choice rather than redistributing resources, which violates liberty. While egalitarians acknowledge a role for markets in generating (and maximizing) wealth,[81] they see states as redistributive, or as tasked with remedying the social inequalities that arise through market exchange as well as natural inequalities that stem from bad luck (Goodin 1988; Heath

[81] For example, Heath (2014:175) notes that Rawls recognizes Pareto efficiency as a principle of justice; indeed, Rawls's (1971) theory is concerned with both maximization and fairness, but he grants justice lexical priority over efficiency and welfare.

2011). In other words, egalitarians see states and markets as having different 'normative logics:' states promote equality, while markets maximize efficiency (Heath 2011:17). Admittedly, many of these egalitarians are primarily concerned with distributive equality. Relational egalitarians, rather, see the state not as primarily redistributive (although arguably its underlying activity remains redistribution), but as facilitating the equal standing amongst citizens or within a 'community of insureds' (Landes and Néron 2015:148).[82]

When understood broadly, egalitarianism includes approaches with different distributive patterns. Recall that true egalitarians value equality intrinsically. In practice, however, many egalitarians avoid endorsing a principle of strict equality as it is liable to this leveling down objection, which is often considered an undesirable and perverse outcome (Shapiro 2007). For, pursuing strict equality as an ultimate end can justify reducing the situation of the best- or better-off (even if they are below a threshold of sufficiency), rather than necessarily raising the situation of the worst off in order to achieve equality. Some seek to avoid the leveling down objection by appealing to the related, albeit normatively distinct, principles of sufficiency or priority.[83] Sufficientarians consider the aim of justice as being to secure a sufficient level of a particular desideratum (opportunity, wellbeing, etc.) for everyone, above which obligations to provide further benefits are diminished or inequalities are not considered unjust and in need of remedying (Powers and Faden 2006; Fourie 2016). Meanwhile, prioritarians emphasize the moral significance of bettering the situation of the worst off. However, unlike egalitarians, who are concerned with reducing the relative situation between the best and worst off, prioritarians and sufficientarians are concerned with "the absolute (meaning noncomparative) levels of the currency of justice"— be it improving the absolute position of the worst off in the case of the former or meeting an absolute threshold of sufficiency in the latter (Fourie 2016:15).

4.4.1 Daniels's *Just Health*

There are many egalitarian theories of justice, but perhaps the most influential (at least insofar as it has served as a touchstone in the contemporary Anglo-American political philosophy) is John

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[82] As noted earlier, arguably such positions may be better understood as having a communitarian bent, so I revisit them in the subsequent section.

[83] Although related, sufficientarianism and prioritarianism are not technically egalitarian as they consider equality instrumentally rather than intrinsically valuable (Parfit 1997).

Rawls's (1971) social contract theory of justice as fairness, which argues that the basic structure of society should be organized in such a way as to promote fair equality of opportunity[84] through the equal distribution of social goods, or where inequalities are to be permitted only if they advantage the most disadvantaged. While Rawls did not discuss health insurance as a social primary good which would be subject to distribution by social institutions guided by his principles of justice, Norman Daniels furthers the Rawlsian project in the context of health and health care. In *Just Health*, Daniels (2008) modifies and builds on Rawls's theory of justice as fairness by extending the scope of Rawls's principle of fair equality of opportunity to also include considerations of distributive justice in health and health care insofar as health is instrumentally valuable for achieving a persons' life plan. Moreover, Daniels contends, that while health may be a natural good, its distribution within a population is "to a large extent socially determined" as should thus be subject to considerations of social justice (2008:14).

Daniels's (2008:11) inquiry is guided by a 'Fundamental Question:' "As a matter of justice, what do we owe each other to promote and protect health in a population and to assist people when they are ill or disabled?" Daniels develops his argument in response to this question in stages by addressing three 'Focal Questions.' First, he sets out to articulate an account of the moral importance of health in order to explain why we have certain types of moral obligations concerning the distribution of health which we do not necessarily bear with respect to other goods. Drawing on Boorse's definition of health, Daniels (2008:37) understands health as the absence of pathology, or as normal, 'species-typical' functioning (e.g., for an appropriate reference class). In a departure from Rawls, who did not include health in assessments of opportunity, Daniels (2008) argues that health is *morally special* as it is required for achieving fair equality of opportunity, since the presence of significant pathology reduces the range of opportunities a person can reasonably exercise in shaping their life plans.

Daniels (2008:79) notes, however, that the moral importance of health does not in and of itself indicate whether inequalities in health are unjust in the way that inequalities of opportunity are.

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[84] Rawls's fair equality of opportunity is substantive and can be distinguished from formal equality of opportunity. While the former requires that individuals, including the disadvantaged, have (and be enabled to have) opportunities to develop their talents, the latter only requires that opportunities, such as for employment or public office, be open to all applicants and be assessed on their merits (Daniels 2008). This distinction echoes that of positive and negative liberty discussed earlier.

Here, Daniels (2008:79-102) turns to addressing his second focal question of determining which inequalities in health (across social or demographic groups) are unjust and, accordingly, warrant remedying as a matter of social justice. He argues that health inequalities arising from the unjust distribution of socially controllable factors, which include not only access across the life course to medical care or public health interventions, but also various social determinants of health such as wealth and education, can be considered inequities. Drawing on Rawls's argument about justice as fairness, Daniels (2008) argues that insofar as we are concerned with protecting a fair range of opportunities for all as a matter of social justice, it is necessary to seek a just distribution of the various socially controllable factors that contribute to restoring, maintaining, or promoting normal functioning.[85]

Daniels (2008) considers reasonable access to care which is effective relative to other interventions to be one such factor that impacts health. He argues that access to care which is considered essential for promoting opportunities, which can be understood as effective opportunities rather than simply unconstrained individual liberty, ought to be universal and can be offered through a mix of public or private insurance (2008:143). Moreover, he does not preclude 'tiering' insurance such that people can procure care exceeding the basic level which is offered universally. What constitutes reasonable care is determined based on its contributions to protecting or restoring normal functioning and opportunity across the life course. For example, not only does he emphasize the importance of preventive care and limit universal coverage to providing for health needs, rather than enhancements, he takes age as a relevant (albeit not absolute) consideration in determining the provision of health care services.[86] In emphasizing preventive care (2008:140-141), he also points to the importance of "measures aimed at the equitable distribution of the risks of disease," including of the social determinants of health, and not solely the provision of acute health services.

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[85] Horne (2017) argues that an egalitarian justification for the in-kind provision of health insurance cannot be grounded on the basis of the 'moral importance of health' as on Daniels's account. Rather, Horne suggests that access to health needs ought to be secured universally because health needs are unpredictable and thus pose challenges for individuals' future expectations and capacities for self-determination.

[86] Daniels (2008:178-180) appeals to a 'Prudential Lifespan Account' in arguing that it would be rational for persons to agree to ration certain expensive treatments and forms of care by age so as to prioritize resources for the young, and thus increase the chances that people live a normal life span despite decreasing the chances that they live longer than normal ones.

While Daniels (2008) calls for universal health coverage, he acknowledges that resource constraints will necessarily require setting priorities when allocating limited resources such that not all health needs can be satisfied. Moreover, he suggests that it is to be expected that people will reasonably disagree over how limited resources should be allocated. Daniels (2008:103-139**)** turns to his third focal question to consider how limited resources should be allocated to meet health needs fairly and legitimately (e.g., deciding which goods and services to cover through health insurance). Daniels (2008:3) suggests that an appeal to a substantive principle of justice such as fair equality of opportunity will underdetermine decisions concerning "unresolved rationing problems," and that instead, just priority setting ought to be guided by considerations of procedural justice. Drawing on his previous work with James Sabin, he identifies an approach to procedural justice known as 'accountability for reasonableness' as a candidate. Accountability for reasonableness delineates a set of four procedural norms to guide decision-making under conditions of reasonable disagreement amongst fair-minded people: that decisions should be publicly accessible, relevant, revisable based on new evidence or arguments and subject to appeal, and enforceable. Considerations of fair equality of opportunity constrain the range of possible decisions reached through the process of accountability for reasonableness (e.g., they must respect non-discrimination).

Daniels and Sabin (2001) comment directly on Canadian pharmaceutical insurance policy in response to a study of the discordance between provincial pharmaceutical formularies.[87] They argue that the observed discordance between provincial formularies, especially with respect to inclusion and exclusion decisions for 'me too' drugs, is not in and of itself indicative of inequity (i.e., an unjust inequality). Given the uncertainty around relative benefits and cost-worthiness of 'me too' drugs, "reasonable people using the same general criteria are likely to disagree about how to weigh the value of modest differences and significant costs" (313). Rather than requiring equal outcomes, justice requires the consistent use of fair decision-making processes (i.e., ones that meet conditions of publicity, relevance, and revisability). Accordingly, they conclude that neither a centralized nor decentralized approach to formulary decision-making is necessarily more just as long as they both involve fair processes, but rather "they involve placing different

[87] For an analysis of the Canadian Medicare and the Interim Federal Health Program, and the Non-Insured Health Benefits Program using Daniels and Sabin's accountability for reasonableness framework, see Da Silva (2017).

moral and political weights on the importance of local decision-making and consistency in outcomes" (314). Moreover, they note the importance of accounting for patient preferences and responses to 'me too' drugs, such as by reimbursing for more expensive alternatives if a patient does not respond well to a less costly option. Elsewhere, Daniels and Sabin (1997) argue that the decisions of private (including for-profit) institutions engaged in limit setting for insurance benefits also ought to meet standards of procedural justice in order to be considered legitimate and fair, including having publicly accessible rationales, indicating how decisions meet the medical needs of covered populations under acceptable resource constraints, and appeals mechanisms.

4.4.2 Powers and Faden's *Social Justice*

Like Daniels and Segall, Madison Powers and Ruth Faden (2006) are interested in identifying unjust inequalities in health as well as articulating and justifying the political implications of inequities for health policy, public health, and health care. In *Social Justice: The Foundations of Public Health and Health Policy,* they argue that the aim of justice is to secure a sufficiency of achievement of six essential dimensions of human well-being (of which health is only one); they identify this as the 'positive aim' of their theory (2006:9). Additionally, they assert that their theory has a 'remedial aim' (2006:9) of improving social arrangements which contribute to systematic patterns of disadvantage that compromise the development and attainment of the essential dimensions of well-being (usually of particular socially situated groups). In that sense, Powers and Faden's account (2006:36) differ from Daniels's in that they see health as an intrinsically (albeit not uniquely) valuable dimension of wellbeing, rather than as a being morally important owing to its contributions to opportunity. Moreover, unlike Daniels, who proceeds from ideal theory and in the social contract tradition, they intentionally develop a non-ideal theory in which justice-based obligations for social institutions and practices arise from, and are discerned within, real-world contexts.

Powers and Faden's (2006:3) central aim is to determine "which inequalities matter most" as a matter of social justice. They ground their analysis in an account of human wellbeing which consists of six "plural, irreducible dimensions, each of which represents something of independent moral significance:" health, personal security, reasoning, respect, attachment, and self-determination (2006:15). They claim that each of these dimensions of well-being is pertinent

to social justice as they are "*characteristically* present within a decent life" and are significant to everyone, whatever their life plans may be (2006:15 emphasis original).[88] Furthermore, they see the dimensions of well-being as interrelated and hold that public health policy must not only attend to health, but also the other dimensions of well-being. For example, they justify a social obligation to secure universal access to health care with an appeal to health as well as moral respect (as a precondition for "being respected as a moral equal").

Powers and Faden (2006:50) characterize their account as "broadly egalitarian," in that it is concerned with the moral justification of inequalities, but that it parts way with strict egalitarian accounts, which render justice an intrinsically relational concept (e.g., as concerning one's status in some measure of equality relative to others), and which consider equality intrinsically valuable. Rather, they adopt a sufficiency approach, characterizing justice as attaining a sufficiency of well-being across the six aforementioned dimensions, while also acknowledging that in certain dimensions, sufficiency will in fact require equality (e.g., with regards to the dimension of respect). They consider their sufficientarian approach to be advantageous as it avoids the leveling down objection launched against strict egalitarianism and captures the prioritiarian intuition about the moral importance of improving the absolute wellbeing of the worst-off, while also recognizing that securing a decent minimum ought to be a central aim of justice (2006:52-56).

While Powers and Faden (2006) stress the importance of looking beyond medical care to public health and the other determinants of inequalities in health, and contend that considerations of justice in health are not removed from those in other spheres (e.g., in contrast with views such as that of Walzer's *Spheres of Justice* discussed below), they advocate for guaranteeing the continuous provision of universal health insurance. They in part justify their position with an appeal to the market failures (adverse selection and moral hazard) associated with private health insurance markets, as on the public economic account; however, while they acknowledge the role of efficiency, they do not identify it as being of primary moral concern. Rather, they

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[88] Powers and Faden (2006:29-30) describe their position as one of "moderate essentialism" which serves a theoretical purpose for assessing social institutions and practices rather than a metaphysical one which holds the necessity of meeting a certain threshold in each dimension for well-being or a moral one which judges whether a life is worth living. Moreover, they see it as compatible with a commitment to liberal neutrality as it does not online a comprehensive conception of the good and emphasizes the value of respect and self-determination (2006:44).

(2006:100-141) are concerned with the characteristic responses to market failure, including exclusionary underwriting, high premiums, cost-sharing mechanisms, and underinsurance, which they consider to be unjust insofar as they undermine policies and institutions required to secure a sufficiency of health and respect and which exacerbate existing patterns of systematic disadvantage (such as by threatening the developmental trajectory of childhood cognitive skills, which impacts well-being throughout life).

4.5 Communitarianism: The Civic State

Despite their differences, the theoretical accounts that I have described so far all reside under the broad umbrella of liberalism by upholding the normative primacy of the individual and describing the role of the state as facilitating social cooperation or redistribution between generally self-interested individuals. Communitarianism is a theoretical tradition which includes a variety of accounts that emphasize the importance of giving due normative weight to the community as an independent moral consideration, and thus see the aim of the state as not merely promoting instrumental cooperation, but also the common good.[89] Ontologically, communitarians also tend to see individuals not as primarily self-interested, but as relational beings whose identities, aims, and values are shaped or even constituted by their contexts (Jennings 2007b). Communitarianism is often contrasted with liberalism, which it sees as having 'neglected' the value (and constitutive nature) of community in its understandings of individuals and political morality and discourse, including in health care and public health (Beauchamp 1985). However, the division between communitarianism and liberalism is not entirely strict as some accounts attend to normative concerns from both camps in some form of 'liberal communitarianism' (e.g., Emanuel 1993, Jennings 2015, see discussion in Kymlicka 2002:228-268).[90]

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[89] I distinguish between public goods and the common good. Public goods, which I discussed earlier in the context of classical liberalism and public economics, are identified as goods which are non-excludable and non-rivalrous and thus cannot be attained through the narrow pursuit of self-interest, while I take the common good to denote shared interests between co-citizens or members of a political community.

[90] While communitarianism is often associated with the 'left,' or statist positions, communitarian positions also exist within the 'romantic right' (Goodin 1988:70) or neoconservative political positions, which also recognize the value of community, but claim that it is best instantiated in local communities characterized by shared traditional, religious, or cultural ties and values (see discussion in Kymlicka 2002:271-272). For a recent example of a conservative critique of American economic liberalism, see Deneen 2018. For a historical analysis that argues that the welfare state dismantled local community ties and fraternal bonds by replacing institutions of voluntary

Kymlicka (2002:209-210) characterizes communitarianism as including three types of accounts: ones which see community as supplanting justice, and two which see community as modifying justice, either by regarding community as the source of justice, or by giving more normative weight to the common good when specifying the content or aims of justice. Within the latter, communitarian positions can be characterized as those that include 'thicker' conceptions of the common good or community—understanding it as 'more-than-the-sum-of-its-parts'—and in that sense, as contrasting with liberalism, or those that advocate giving due consideration to the common good, but without reifying 'the public' as an entity apart from the individuals it comprises (Coggon 2012:183-188).

Community can be understood as both a descriptive concept as well as normative (or evaluative) standard (Jennings 2007a:543). Broadly, a community is a social group characterized by a shared sense of identity, values, goals, or 'the common good' and a sense of how life in common is to be lived, as well as a sense of solidarity, togetherness, or 'fellow-feeling' (Goodin 1988:72; Shapiro 2007:29-30; Jennings 2007b:36). Normatively, community recognizes the value of 'the common good,' or of shared interests which transcend an aggregate of individual interests or preferences, as well as a sense of mutual obligation (Jennings 2007a:543). Accordingly, communitarians tend to see individual and public interests as conflicting less often than liberals do (Jennings 2007a). While communitarian accounts invoke other principles such as equality and liberty, they tend to conceptualize or value them differently than liberals (Shapiro 2007; Cohen 2009). For example, they may value equality insofar as it sustains a sense of solidarity or community membership, rather than seeing it as intrinsically valuable.

Communitarians also tend to differ from liberals in that they take issue with 'individualism' or the ontology of the liberal self and individual self-determination (Kymlicka 2002). For example, some accounts critique the liberal conception of self-determination as underestimating the social preconditions required for meaningful self-determination (Nedelsky 1989; McLeod and Sherwin 2000). Similarly, they criticize the liberal notion of the self as being 'prior to' rather than 'embedded' in social practices and relationships that necessarily shape the capacity for and give

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reciprocity and mutual aid which were offered through private, community-based fraternal organizations or mutual aid societies, see Beito 2000. I set aside 'right' communitarian accounts in my overview.

meaning to self-determination (Kymlicka 2002:221).[91] As Jennings (2007a:547) suggests, "the liberal self seeks expression and affirmation *through* but not *in* social relations, which are at best instrumentally useful for the satisfaction of subjectively defined interests, and at worst confining" while communitarianism sees "self-realization in – as well as through – relations of shared purpose with others."

The communitarian commitment to the intrinsic value of community has implications for the justified division between public and private life and institutions. Communitarians value the institutions and policies of welfare states, including universal health insurance, either because they are implications of valuing community or because they contribute to a sense of community membership or solidarity.[92] Generally, communitarians tend to prefer social and institutional arrangements that promote a "single-status moral community" which unifies benefactors and beneficiaries (Goodin 1988:74). Rather than primarily being concerned with just distributions (as on liberal egalitarian accounts), communitarians tend to emphasize the importance of right relationships and see justice as pertaining to relational liberty or equality of status or respect; accordingly they see the former as contributing to and being made possible by the latter (Goodin 1988:71; Jennings 2015). Universal rather than targeted welfare programs are seen as creating the relational and material conditions so that people are regarded as equals within a community (e.g., Goodin 1988:74; Walzer 1983; Shapiro 2007). A community of moral equals is itself seen as more likely to give rise to just distributions (e.g., through processes of democratic participation) (Emanuel 1993; Jennings 2007b). Concern for just relationships or relational equality can also motivate an aversion to the commodification of certain goods if market-based distribution is seen as giving rise to relationships of dependency or domination which undermine a morally-significant aspect of equality between members of a community (e.g., Walzer 1983); further, communitarians can be wary of commodification if they regard it as valuing a good or a

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[91] For a discussion of three grounds on which different communitarian accounts take issue with the liberal notion of the self, see Kymlicka 2002:221-228.

[92] Further, the relationships between community and welfare entitlements can be ones of logical implication (e.g., "having welfare rights is just what it is to be a member of the community") or empirical observation (e.g., "welfare entitlements are empirically conducive to the feelings of community attachment") (Goodin 1988:81). Goodin (1988:70-118) examines four models of community-based justification for the welfare state (based on the matrix of logical and empirical relationships and logical or causal connection between welfare entitlements and community membership). He argues that all fail to demonstrate that the welfare state is either necessary or sufficient for achieving the communitarian ideal, nor do they show that communitarianism uniquely justifies the welfare state.

domain of interaction 'in the wrong way,' or contrary to a commonly shared understandings of the moral ends it ought to serve (e.g., Sandel 2012, also see discussion in Heath 2011:18-20).

Communitarians see political responsibility as being collective or shared, and hold that social and political institutions should reflect a sense of mutual obligation, which ought to extend to the provision of welfare services for members who are unable to secure them themselves (Shapiro 2007). Relatedly, and building on the ontological distinction discussed above, communitarians offer a distinct account of moral motivation from liberals based on a sensibility of solidarity or 'mutuality of civic concern and support' for others (Jennings 2015). They see mutual aid as a form of "reciprocal altruism" rather than a merely instrumental form of collective action or voluntary cooperation between self-interested individuals (Goodin 1988:76; Jennings and Dawson 2015). Accordingly, when it comes to the various forms of social insurance offered by welfare states, communitarians tend to regard them as more than just assurential mechanisms aimed at securing assistance should it be required in the future:

> Talk of "mutuality" and "reciprocity" rather suggests […] that the reason that one person helps others is to secure assistance from them tomorrow. Communitarians see no role of any such cynical "insurance" or "investment" logic in their mutual-aid arrangements. What motivates members of a true community to render assistance to a neighbor in distress, they would say, is not any expectation of future return on their investment but rather a genuine, empathetic concern for their plight of the needy neighbor. (Goodin 1988:77-78)

Public provision is thus seen as preferable as it is motivated by reciprocal altruism or civic-mindedness rather than the self-regarding or pecuniary motives associated with the market (Heath 2011).

Some communitarians also emphasize the importance of participatory and deliberative democracy and democratic political institutions that are responsive to their citizens' concerns (Emanuel 1993; Shapiro 2007). Some, especially when drawing on the civic republican tradition, advocate that citizens ought to cultivate civic virtues in order to further the common good and contribute to legitimate or welfare-enhancing democratic institutions (Jennings 2007b; Kymlicka 2002).

4.5.1 Walzer's *Spheres of Justice*

In *Spheres of Justice,* Michael Walzer (1983) develops a communitarian theory of justice grounded in the notion of 'complex equality,' which aims at protecting individuals against, and preventing social goods as being used as means to, tyranny or domination. Walzer's theory of justice is communitarian insofar as he sees justice as particular to—and moreover, defined by the social understandings of— the political community to which it applies. He argues that distributive justice is concerned with 'social goods,' or goods that have shared meanings (e.g., about the purpose(s) a good serves or how and why it is valued) within a particular political community (1983:6-7). Further, Walzer asserts that different social goods have distinct shared meanings, which in turn give rise to different 'spheres' of distribution with their own distinct distributive principles (1983:7-10). In other words, a just distributive criterion is dictated by the nature of a social good: "if we understand what [a social good] is, what it means to those for whom it is a good, we understand how, by whom, and for what reasons it ought to be distributed" (Walzer 1983:9). Hence, rather than being universal, principles of justice are particular to both a community and a distributive sphere. It is in this sense that Walzer's theory is an example of a communitarian account which posits community as the source of the principles of justice (Kymlicka 2002:210-211).

Rather than aiming at equalizing opportunities as a whole, Walzer takes complex equality as meaning that, "no citizen's standing in one sphere or with regard to one social good can be undercut by his standing in some other sphere, with regard to some other good" (1983:19). For example, while the market may inevitably lead to inequalities in certain goods stemming from distributions according to one's ability to pay, these inequalities ought not affect distributions, and an individual's standing, in other spheres where the ability to pay does not constitute a just distributive principle (e.g., in the provision of security and welfare, of which medical care is an example, and which ought to be distributed according to need; or in awarding honours or punishments, which ought to be distributed according to desert or merit).

Walzer (1983:64-65) describes political communities as forming first and foremost to assure security and welfare, which they achieve through collective provision of socially recognized needs. Within the 'sphere of security and welfare' (1983:65), all goods which are socially recognized as necessary to common life constitute needs that ought to be provided communally,

universally, and distributed according to need.[93] Communal provision is taken to promote equality of membership within a community (78). Further, once a good is recognized as warranting communal provision, everyone has a shared duty to "bear the necessary burdens" of realizing it, such as through taxation (68).

Walzer claims that longevity is now widely considered one such socially recognized need, since considerable efforts are made to ensure that it is "widely and equally distributed, that every citizen has an equal chance at a long and healthy life" (1983:87). According to Walzer, the distributive logic of medical care—"that care should be proportionate to illness and not to wealth"— fits that of socially recognized needs (86). Where it is considered a socially recognized need, a minimally decent level of medical care must be provided communally and according to need, and accordingly, it must be removed from the distributive sphere of the market (e.g., by banning private insurance or privately employed clinicians) as it is necessary to "block any other distributive procedure that doesn't attend to need" (89). Moreover, medical care must be provided universally, since "once communal provision begins […] it must provide what is 'wanted' equally to all the members of the community" (87). For, Walzer contends, where free enterprise remains, "wealth will be dominant" and "individuals will be cared for in proportion to their ability to pay and not to their need for care" (89).

Walzer's argument is emblematic of an "anti-commodification intuition" in communitarian models of the welfare state (Heath 2011:20), since it argues for limiting the scope of the market in the provision of medical insurance and care on the basis that markets value medical care, and socially recognized needs more broadly, in the wrong way—not as needs but as commodities[94] to be bought and sold based on desires and tastes.[95] Other communitarians similarly take issue with

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[93] "Once the community undertakes to provide some needed good, it must provide it to all the members who need it in proportion to their needs. The actual distribution will be limited by the available resources but all other criteria, beyond need itself, are experienced as distortions and not as limitations of the distributive process" (1983:75).

[94] As Walzer remarks, "commodities, even when they are primitive and simple, are above all commodious; they are a source of comfort, warmth, and security. Things are our anchors in the world. But while we all need to be anchored, we don't all need the same anchor. We are differently attached; we have different tastes and desires […]" (1983:104).

[95] Indeed, Walzer (1983:90) states that, "needed goods are not commodities […] they can be bought and sold only insofar as they are available above and beyond whatever level of provision is fixed by democratic decision making (and only insofar as the buying and selling doesn't distort distributions below that level)."

the commodification of certain goods or services and hold that limits ought to be imposed on markets if market provision involves valuing a good in a morally inappropriate way (e.g., Sandel 2012). The anti-commodification justification for public provision provides communitarians with an explanation for why states ought to provide needed goods in kind rather than offering cash transfers which can be used to acquire needed goods through the market; as discussed earlier, in kind provision is a feature of welfare state programs which egalitarian accounts sometimes struggle to adequately justify on the basis of redistribution alone (Heath 2011:21; Horne 2017).

4.5.2 Jennings on Civic Republicanism and Solidarity

Civic republicanism bridges aspects of liberalism and communitarianism by invoking a relational concept of liberty as non-domination and advocating for the importance of civic virtue in promoting a sense of social unity or community belonging and sustaining democratic institutions.[96] Bruce Jennings (2007a; 2009; 2015) has written widely on civic republicanism and relational liberty in the context of public health ethics, and others have also argued that it may offer a normative foundation for public health (Nielsen and Landes 2016; Weinstock 2016).

Civic republicanism holds that liberty—understood as freedom as non-domination or independence from arbitrary power or authority—is the primary political value (Pettit 1997; Jennings 2015:10). Republican liberty is concerned with protecting individuals from arbitrary power exercised not only by political authorities, but also private entities, including the rich and the powerful, and thus sees the state as playing a legitimate role in protecting individuals from domination. Jennings introduces a similar concept of relational liberty, which he describes as:

> freedom through transactions and relationships of interdependency with others […] a practice of freedom that constitutes—and is constituted by—membership, by which I mean participatory parity and equality of civic respect, and solidarity, by which I mean mutuality of civic concern and support. (2015:10; emphasis original)

[96] Not everyone considers civic republicanism to be communitarian (e.g., Lovett 2018). However, as Kymlicka (2002:257) suggests, it can be considered communitarian at least insofar as it "take[s] seriously the need for liberal democracies to develop and sustain a sense of ethical community." Moreover, Jennings (2015:9), whose work I primarily discuss here, describes himself as adopting a "communitarian strand of liberalism" in his work.

Here Jennings echoes an aim of civic republicanism to redefine the relationship between the individual liberty and the common good as not being innately at odds; he suggests relational liberty contains "within itself the basis for its own moral limitation" (2015:9). Further, Jennings takes issue with the liberal ontology of *individualism*, which he sees as overlooking the mutual interdependence and social embeddedness of people, but he distinguishes it from *individuality*, which he recognizes as serving a "fundamental safeguard of human rights and dignity" (2007a:547). As such, Jennings aims to tread a delicate balance between not invoking a 'thick' conception of the common good that gives rise to collectivism and is incompatible with pluralism or 'reifying' a sense of 'the public'—that is, treating it as if it were a natural rather than socially constructed entity with rights, obligations, and interests separate from those of the individuals that constitute it—and simply invoking a 'thin' conception of the common good that devolves into a liberal understanding of the public as an aggregate of individuals with no intrinsic significance as a collective (2007b:54).[97] In that sense, he sees "the republican conception of the public as a middle way between a political imagination too thin and one too thick" (2007b:53). Rather than suggesting that the common good outweighs individual interests, Jennings suggests that it:

> internaliz[es] this tension and dualism within the political and moral agent himself or herself. The true tension is not between the reified interests of something called the public and the localized interests of individuals. The tension is within the objective situation and the motivational structure (conscience) of each citizen. We are all torn between our private wills and our civic wills, between our interests as isolated individuals or consumers and our moral interests and commitments as members of a community of shared purpose broader than ourselves. (2007b:55; emphasis original)

When something becomes a public matter, it is recognized as pertaining to a shared purpose or concern rather than an overlapping concern that affects many individuals, even though shared concerns still affect people as individuals (Jennings 2007b:48; Coggon 2012:100).

Jennings (2007b; 2009) suggests that civic republicanism offers public health—with its focus on population health and public policy and programs—with a more effective mode of justification

[97] Recall, for example, the public goods which are seen as justifying state and public health activity to ensure the efficient provision of goods or services to satisfy individual preference in classical liberalism and public economics.

and normative legitimacy than the dominant liberal, 'Millian paradigm,' since it does not necessarily pit the interests of the individual against those of the public and recognizes the impact of social contexts on health. Furthermore, civic republicanism calls for political institutions that are subject to democratic control and which support people's status as citizens of equal standing or full members of a democratic community. Relatedly, and in a departure from liberalism, civic republicanism also places certain obligations on citizens by encouraging members of a community to cultivate certain types of moral traits or *civic virtues*—or ways "of living and being in the political world"—in service of the common good and in order to sustain the democratic aims of the community (Kymlicka 2002; Jennings 2007b:46; 2009). Indeed, Jennings suggests that civic virtues, as well as sensibilities such as solidarity, are required to secure the normative legitimacy and trust needed for the successful implementation of various public health policies and programs which not only require limiting individual liberties but also at times the active involvement of individuals (2009; 2015:7).[98] As such, citizens are motivated not only by self-interest, but also by civic virtue and a disposition of solidarity.

Emanuel (1993) similarly articulates a vision of a liberal communitarian alternative to liberalism, which he sees as failing to provide an adequate ethical framework to guide decision-making concerning the allocation of health care resources and the design of just health care system. He asserts that citizens ought to engage in deliberative practices to define a common goal that can guide decisions concerning the distribution of health care resources, not only at the level of clinical decision-making, but also in determining which resources ought to be provided for in the first place.[99] Accordingly, public deliberation and democratic participation contribute not only to creating the conditions for equal standing or membership, but also serve as a means to define the

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[98] Jennings (2007b:43) even draws a connection between the origins of American public health and the civic republican movement, suggesting that the shift towards utilitarian thinking coincided with the fields' growing focus on technical and methodological questions.

[99] For example, Emanuel (1993:178-244) suggests that a liberal communitarian polity in the US would consist of thousands of community health programs (CHPs) comprised of several thousand citizen-members. The CHPs would be responsible for guaranteeing and organizing care for their members in line with their objectives, which would be ascertained through deliberative processes involving the membership. The CHPs would be financed through vouchers which a federal board (operating a national health care trust fund) would provide to each person or family in the value of five-years' worth of payments (with the aim of dissociating access to insurance from employment and the ability to pay); however CHPs could decide to offer services that would carry additional fees.

common good (or aims) of the community vis-à-vis health care, which can be used to guide decisions about insurance design and priority setting.

4.6 Conclusion

In this chapter, I outlined four theoretical orientations from political philosophy that offer distinct accounts and justifications for the legitimate role of public and private institutions, including in the financing and/or provision of health insurance. Libertarian and classical liberal theories advocate for a minimal or residual state with similarly limited involvement in matters of health. Public economic, egalitarian, and communitarian accounts all assert that states are justified in taking on a greater role in the financing or provision of health insurance, but do so for distinct normative reasons (appealing to the state's efficiency-promoting, redistributive, or civic features respectively). The normative rationales and concepts that I have outlined from each respective theory contribute to a theoretical framework which I draw on to inform the analysis of arguments in the pharmacare policy debate in the following chapter. As will become evident throughout my analysis of the findings, components of these normative accounts are reflected to varying degrees, and often in combination, in arguments within the pharmacare debate. As described in the previous chapter, this theoretical framework offers a conceptual grounding and language, but not *a priori* analytic codes, to facilitate my interpretation and analysis of normative rationales that underpin policy arguments presented in the documentary and testimonial data in my case study. Additionally, I put my findings in conversation with the theories presented here in my discussion.

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Chapter 5
Findings

> Whether they are improved access, more equal coverage or greater system efficiency, what are the principles that should guide us in considering national approaches to pharmacare? Are we focusing sufficiently, not only on availability of pharmaceuticals, but also on the best type of treatments, on proper outcomes?
> – Minister of Health Allan Rock, Conference on National Approaches to Pharmacare (Health Canada 1998:61)

> It's time to close the gap between our values and our reality. It's time for universal single-payer public pharmacare.
> – Advisory Council for the Implementation of National Pharmacare (Health Canada 2019:114)

5 Findings

This chapter presents the findings from my analysis of documentary and testimonial evidence from the Canadian pharmacare policy debate from 1997 to 2019 [Appendices C-E]. I describe the discursive[100] landscape of the debate by characterizing the main pharmacare policy arguments in terms of the underlying normative positions that they appeal to. While I devote more attention in my analysis to the contemporary pharmacare debate, I also describe how the debate has evolved since the National Forum on Health released its final recommendations in 1997. By characterizing the discursive landscape of the pharmacare debate with reference to the normative models of health insurance described in my theory chapter, I address the two research questions that have guided my inquiry. As they are largely descriptive, my findings primarily address my first research question, which asks what normative concepts are invoked (explicitly and implicitly) in arguments in the Canadian pharmacare policy debate; however, insofar as I draw on my theoretical framework to identify normative concepts invoked in the debate, my findings are also analytic and interpretive, and thus also begin to address my second research question, which asks how normative and political philosophy contribute to understanding and informing the debate. My findings are thus an interpretation of the debate, which reflects the

[100] I use 'discourse' in a descriptive sense, i.e., pertaining to the arguments and reasoning in the documents that I analyze. I do not use it in a methodological sense, such as in reference to critical or Foucauldian discourse analysis, which regard discourses as "ways of thinking and speaking about aspects of reality" and as "a set of common assumptions that sometimes, indeed often, may be so taken for granted as to be invisible or assumed," and which constrain or facilitate the production of knowledge (Cheek 2004:1142).

interpretive nature of normative policy analysis, which requires appealing to theoretical and normative frameworks to interpret and make sense of social reality. I build upon the descriptive analysis of my findings in the discussion chapter to further address my second research question through more explicit engagement with theory and normative analysis.

My inquiry yielded two main findings. First, the findings indicate that the main areas of tension in the debate are normative, not solely technical or evidentiary. In particular, I describe how arguments for the two main policy proposals under consideration in the contemporary pharmacare debate—universal public, single-payer insurance and universal mixed 'fill in the gaps' insurance—appealed to different underlying normative rationales. These distinct normative positions in turn shaped different framings of three central policy problems—access, costs, and appropriateness—and ideas about the purpose of pharmaceutical insurance and who ought to be responsible for realizing it.

Proponents of public pharmacare envisioned pharmaceutical insurance as a form of insurance which not only efficiently pooled risks, but was also redistributive and solidary (on the grounds that it was financed through progressive means such as taxation), did not hold individuals financially responsible for their health risks, and was administered as a right of Canadian citizenship (or residency). They emphasized the importance of expanding access to medically necessary medications by universalizing coverage and eliminating financial barriers, of reducing costs associated with a fragmented insurance landscape, as well as the importance of assessing and promoting the prescribing and use of appropriate medications, or those with evidence demonstrating safety, effectiveness, and cost-effectiveness. They argued that political responsibility for the financing and organization of pharmaceutical insurance was communal and lay primarily at the meso- and macro-levels with governments, public institutions (e.g., a national drug agency), or independent expert bodies, and thus would be best realized through universal, public, single-payer insurance.

Conversely, proponents of a multi-payer pharmacare model, which would build on the existing mix of public and private insurance to fill gaps in coverage, saw pharmaceutical insurance as a mechanism for pooling risks associated with unpredictable, significant drug costs, and one arising primarily through voluntary relationships, such as through employer-employee interactions. They also acknowledged a role for a residual public pharmacare program targeted

towards providing sufficient coverage for those with particularly great financial needs, including as a result of rare diseases requiring expensive medications. They tended to frame issues of access and financing as matters of individual preferences or choices. Accordingly, they advocated for access to a greater range of medications and saw public policies such as public formularies or regulations that delayed access to new medications as restricting individual liberties insofar as choice and access are limited. With respect to costs, some proponents of mixed pharmacare echoed concerns about high drug prices, but they countered that cost-savings and efficiency gains would be best achieved through public-private collaboration with the added benefit of not reducing coverage for individuals with existing employer-based pharmaceutical insurance plans. Other proponents of mixed pharmacare were reticent about promoting price reductions owing to concerns about drug shortages, reduced market availability of drugs, and disincentivizing innovation; instead, they advocated for the use of cost-sharing mechanisms to encourage patients to be accountable for and judicious in their drug use. Similarly, they claimed that medically necessary drug use was best determined in the context of the individual clinical encounter. Proponents of mixed pharmacare held that the responsibility for financing and organizing pharmaceutical insurance was personal and resided primarily with individuals or in the context of individual relationships between employees and employers or patients and physicians. The role of the public sector was limited to securing a sufficient level of coverage for those with limited financial means or especially high medication expenses.

My second main finding concerns the evolution of arguments in the debate during the case study period from 1997 until 2019. I assert that the contemporary pharmacare debate[101] is characterized by convergence around the goal of expanding and universalizing pharmaceutical coverage, which is paired with disagreement about the form that universal coverage ought to take (e.g., how it ought to be financed and administered and what the terms and scope of coverage ought to be). While public single-payer pharmacare had long been touted as a policy ideal in government reports and recommendations, it was often regarded as not being immediately feasible. My findings suggest that the growing support for and belief in the feasibility—and even necessity—of adopting public single-payer pharmacare in the contemporary debate was motivated by

[101] As discussed in the case description, I identify 2013-2014 as the early stages of the ‘contemporary’ pharmacare debate owing to the notable increase in policy publications, media coverage, and political interest in the topic.

strengthened and more explicit arguments in favour of its efficiency-promoting, rather than solely (albeit still in addition to) its equity and community-promoting features.

5.1 Normative, Not Just Evidentiary Tensions

My findings indicate that tensions in the pharmacare debate centred on normative considerations and disagreements and not only empirical or evidentiary ones. That is, rather than solely being evidentiary, scientific, or economic disputes, key areas of disagreement were underpinned by differing appeals to and characterizations of normative principles—including equity, efficiency, and liberty—and conceptualizations of the central problems of access, costs, and appropriateness, and thus differing positions on the locus of political responsibility vis-à-vis matters of health.

5.1.1 How ‘Values’ Were Discussed

Policy documents seldom explicitly identified issues as pertaining to ethics, values, or distinct normative positions. When they did, they often invoked them in reference to foundational policy objectives or principles. For example, they described the guiding objectives and principles outlined in the *Canada Health Act (CHA)* as ‘Canadian values’ or “the core values of Canadian medicare” (Morgan et al. 2015), or invoked values such as equity and solidarity as being “the core values on which our health care system is premised” (Commission on the Future of Health Care in Canada 2002: xvi). For the most part, only a narrow set of issues were explicitly identified as concerning values or ethics: questions pertaining to resource allocation—often under conditions of evidentiary uncertainty, such as with expensive drugs for rare diseases for which there was limited evidence of safety and effectiveness—issues of professional or scientific integrity, and characterizations of Medicare as being tied to national values.

> Anticipated outcomes [of the National Pharmaceutical Strategy] include: […] an open and transparent framework for ethical resource allocation that balances both population and individual health outcomes. (Federal/Provincial /Territorial Ministerial Task Force on the National Pharmaceuticals Strategy 2006:24)

> You brought up an extremely important challenge and ethical dilemma when you're looking at a pan-Canadian pharmaceutical type program. You mentioned value for money. Of course, you brought up Solaris, the big one in the room. My question to you would be this. If Canada implements this type of program, however it lands, who would decide on which drugs are covered? It's an extremely difficult question, because if you're one of the patients who would

> really benefit from a drug that's out there and you'd really want to have access to that drug but you have a system that won't allow you access, how would you suggest to this committee that a program could get around that problem? - Mr. Colin Carrie, MP Oshawa, Conservative Party of Canada (HESA-33 2016:9)

Moreover, when mentioned, ethics- or values-issues were often explicitly contrasted with economic or cost-related ones. Although efficiency was often identified as a policy objective, it was often cited in contrast with so-called 'values' concepts such as equity. For example, Morgan et al. (2014:13) identified access, financial equity, and system efficiency as the three fundamental objectives of pharmaceutical financing systems. When discussing financial equity, they wrote, "considerations of financial equity are, of course, normative. However, there is reasonable consensus in the literature — and observational evidence from health system designs around the world — that health care system financing should protect patients from financial burdens associated with illness." Conversely, they did not identify system efficiency as normative or value-laden, nor did they provide justification for invoking it as they did with financial equity. In another example, the 'rightness' of a decision was distinguished from financial considerations: "Improving patient safety through better prescribing is both the right thing to do and a smart financial move" (Health Council of Canada 2009:14). Similarly, Medicare was characterized as being seen as "a moral enterprise, not a business venture" (Commission on the Future of Health Care in Canada 2002:xx).

While not commonly acknowledged as such, economic and cost-related issues, as well as determinations of medical necessity, were framed as being objective and answerable through economic or scientific analysis, and implicitly as having self-evident persuasive force. In contrast, values-related issues were often invoked in the context of evidentiary uncertainty, and were framed as subjective and contested. However, as I describe in this chapter, normative disagreements underpinned not only distinct ideas about just distribution and access, but also distinct conceptualizations of what constituted efficient insurance and appropriate drug use, and thus contributed to differing conclusions about preferred pharmacare policy solutions.

5.1.2 Explicit and Implicit Normative Concepts

My central claim in this chapter is that the pharmacare debate is characterized by tacit normative disagreements, even if they were seldom explicitly identified as such. Accordingly, it is worth specifying how I understood normative concepts in my analysis. Normative concepts that were

invoked explicitly include evaluative concepts such as principles or values, or when issues were explicitly described as being 'moral,' 'ethical' or 'political' in nature. Normative concerns were also invoked implicitly in prescriptive or evaluative claims concerning policy objectives, problems, solutions, or processes. As will become apparent, normative concepts were appealed to frequently, but they were often implicit or, when used explicitly, were often left undefined.

Although pharmacare proposals and arguments invoked a variety of normative concepts when identifying policy problems and justifying policy goals and means, they did not present robust, systematic normative accounts of the nature and purpose of pharmaceutical insurance resembling those outlined in the theoretical background. Rather, pharmacare policy arguments appealed to combinations of ethical and political principles that were often left undefined. Nonetheless, the context and ways in which normative concepts were employed in policy arguments could be analyzed to identify distinct normative conceptualizations of what the nature and purpose of health and pharmaceutical insurance ought to be.[102] Similarly, issues identified as warranting policy intervention were indicative of underlying normative positions, since the identification of an issue as a policy 'problem' involves evaluating it against a normative standard. As a result, it was possible to characterize the major policy positions in the pharmacare debate in reference to features of the normative accounts of health insurance described in the theoretical background, while also recognizing that policy arguments did not adopt normative accounts in their entirety and often appealed to features of more than one account.[103]

5.1.3 A Trio of Policy Problems

Since the 1990s, recurring interest and public debate about the introduction of national pharmacare—or some form of federal or pan-Canadian pharmaceutical insurance—has largely been motivated by a trio of interrelated policy issues that have been identified in the context of

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[102] For example, normative concepts can be categorized according to their function in arguments, such as in being "*terminal* values (goals or objectives), *procedural* values (means and process for achieving the goal), or *substantive* values (criteria for justifying decisions and actions for goal achievement)" (Giacomini et al. 2009:61).

[103] As I discussed in my methodology and theory chapters, I drew on the theoretical positions outlined in my theoretical background to provide sensitizing concepts, although not *a priori* codes, for analyzing and framing my findings. While my epistemological orientation most closely resembles critical realism, my findings are necessarily *an* interpretation of the documents and transcripts that I analyzed. Moreover, in the discussion chapter, I develop my own normative account of what I take to be the most justified model of pharmacare.

Canada's existing pharmaceutical insurance landscape: access (to pharmaceuticals and insurance coverage), costs (to individuals as well as public and private payers), and appropriateness (of prescribing and drug use). These three issues remained at the centre of the contemporary debate, as was highlighted in a discussion paper prepared for the Advisory Council for the Implementation of National Pharmacare's (Advisory Council) public and stakeholder consultations (Health Canada 2018). The discussion paper identified access and costs as motivating policy problems as well as three issues that required addressing: who is covered and under what circumstances, which spoke to the membership or inclusiveness of the insurance program; which drugs are covered, which spoke to the parameters for determining the scope of drugs covered; and who pays, which concerned the responsibility for financing and administering insurance (e.g., through taxation, employer contributions, premiums, co-payments, deductibles, etc.). As will become apparent throughout the chapter, the issues of access, costs, and appropriateness were conceptualized and used in different ways depending on the stakeholder's policy objectives and underlying normative position, which in turn motivated them to recommend different pharmacare policy solutions.

Finally, the nature and purpose of pharmaceutical insurance was contested in the debate. Accordingly, when I refer to health or pharmaceutical insurance, I use the term 'insurance' in a broad sense to capture various financing and administrative models (e.g., public insurance systems funded through general tax revenues, social insurance systems funded through mandatory contributions, private not-for-profit insurance, and private for-profit insurance) rather than limiting its use to a single conception such as private, for-profit 'actuarially fair' insurance[104].

5.1.4 Convergence in the Contemporary Debate

The majority of the policy reports published early on in the contemporary pharmacare debate critiqued the status quo of the Canadian pharmaceutical insurance landscape—which was often described as a 'patchwork' of pharmaceutical insurance programs—and advocated for universal,

[104] Terms such as 'medicare' and 'pharmacare' may have multiple, evolving meanings. For example, Marchildon (2012) notes how the meaning of 'medicare' has evolved. While it had originated as a shorthand for 'medical care insurance' when public coverage for physician services was first introduced in Canada the 1960s, he uses it in its broader and now commonly-used sense as denoting "*universally* provided public health-care services" (5).

publicly-funded, single-payer pharmaceutical insurance. As pharmacare garnered wider interest, a variety of stakeholder positions emerged; most acknowledged the need for reform, but they disagreed on the extent and nature of the reforms required. By the time the Standing Committee on Health (HESA) had set out to study the development of a national pharmacare program in 2016, the pharmacare debate had largely shifted to considering how, rather than whether, universal pharmaceutical coverage should be achieved. Following two years of consultations, HESA observed this convergence in its final report, as did some witnesses before the committee:

> For these reasons, there was unanimous agreement among stakeholders appearing before the Committee, including patient groups, health care providers, the private insurance industry, innovative drug manufacturers, unions, employers and academics that the gap in prescription drug coverage in Canada and the inequity that it creates among Canadians needs to be addressed. While witnesses differed on whether gaps in coverage should be addressed through the expansion of current programs, or the creation of a targeted program, the vast majority agreed that they should be addressed through the development of a national universal pharmacare program. (Standing Committee on Health 2018:43)

> The issue, then, is *not* whether to institute national pharmacare, but *how*. (Matthew Herder's Policy Brief, quoted in Standing Committee on Health 2018:66)

As noted by HESA's summary, the contemporary pharmacare debate was characterized by convergence, albeit not outright agreement,[105] around a core policy objective: expanding and universalizing pharmaceutical coverage so that all Canadian residents[106] would have some form of coverage. As a result, the contemporary debate largely focused on determining how best to implement universal pharmaceutical coverage, and in particular, how to finance, administer, and determine the terms of coverage, including which drugs to cover.

Within this context, two policy options received serious consideration: universal publicly-financed, single-payer drug coverage and a 'fill in the gaps' model that would build on the

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[105] Only a minority of stakeholders (e.g., Fraser Institute 2015) opposed or questioned the need for universal pharmaceutical insurance such as by noting that all provinces already offered some form of pharmaceutical coverage for low-income individuals and that a single, national policy could limit policy innovation.

[106] Most policies do not specify who qualifies as 'Canadian'; policies that do often adopt criteria from existing public health insurance programs, which provide coverage on the basis of residency status rather than citizenship. I also use the term Canadian in reference to residency status. Moreover, I recognize that the scope of public health insurance coverage is also contested (e.g., whether to offer coverage for refugee claimants or non-residents).

existing mix of public and private insurance to provide universal coverage. A third option, universal catastrophic coverage, which would offer protection against high drug costs, received serious consideration in the early 2000s. Although catastrophic coverage received less attention in the contemporary debate, concerns about financial burdens associated with highly expensive drugs remained salient and were often raised in reference to expensive drugs for rare diseases. HESA identified the public single-payer and mixed 'fill in the gaps' models as the two primary pharmacare options raised by witnesses before the committee (Standing Committee on Health 2018:2). Similarly, the Advisory Council identified these two models following its public and stakeholder consultations, with the addition of a third model offering targeted coverage for expensive drugs (Health Canada 2019:3).

I now turn to describing the normative justifications offered in support of the pharmacare options under consideration in the debate. First, I describe how pharmacare proposals justified universalizing pharmaceutical insurance. Then I proceed by characterizing the three main pharmacare proposals that have been considered since 1997—public single-payer, mixed 'fill in the gaps', and catastrophic coverage—in terms of their underlying normative justifications. I endeavor to demonstrate how different policy positions appealed to different normative justifications, which in turn shaped how they characterized, and consequently accorded political responsibility for and proposed to address the problems of access, costs, and appropriateness.

5.2 Universal Coverage

The area of greatest convergence in positions in the contemporary pharmacare debate concerned expanding the scope of pharmaceutical insurance to provide some form of pharmaceutical coverage for all Canadians. Proponents of universal pharmacare appealed to several types of normative justifications, often in combination, to justify universalizing pharmaceutical coverage. Most commonly, calls for universal coverage invoked the medical necessity of pharmaceuticals as a foundational premise. However, the normative implications they ascribed to medical need differed. In its basic form, an appeal to medical need reflected the distributive logic inherent in all insurance. Yet explicit appeals to the medical necessity of pharmaceuticals were also often made in the context of egalitarian and communitarian justifications of universal, and especially universal *public single-payer* pharmacare, which would offer equal *comprehensive* coverage of medically necessary medications for all Canadians. Meanwhile, proponents of universal mixed

'fill-in-the-gaps' coverage made fewer, if any, explicitly egalitarian or communitarian appeals and did not regard medical need as necessitating public coverage. Rather, they tended to frame universal coverage as operating at a threshold of sufficiency (e.g., through an essential medicines list that would offer a minimum breadth of coverage) or priority (e.g., in having public coverage prioritize offering coverage for those most in need, either financially, or, for example, by virtue of having a rare disease that required highly expensive medication).

5.2.1 Medical Need

Most proposals for universal pharmaceutical coverage began with the observation that pharmaceuticals are medically necessary, or hold a key therapeutic role in modern medical care; they noted that without access to medically necessary drugs, people could incur a variety of harms, including pain, suffering, worsened quality of life, exacerbated illness, and premature death, which could also have further systemic ramifications including exacerbating health inequities, lost productivity, and increased downstream health care costs.

> Pharmaceuticals are important to the health of Canadians. For many patients prescription drugs and vaccines have prevented serious disease, reduced hospital stays, replaced surgical treatment and improved their capacity to function productively in the community, while at the same time often offsetting other potential health care costs. (The Coalition for a Canadian Pharmaceutical Strategy 2006:1)

A common justification offered in favour of universal coverage was that access to and utilization of pharmaceuticals should be determined on the basis of clinical criteria—that is, medical need—and thus ought to be universally available on that basis rather than on criteria such as income, age, employment status, care setting or province of residence. This view was often captured with an appeal to a variant of the phrase, 'access based on need, not ability to pay.' Furthermore, it was often made in reference to the *Canada Health Act* (1985:1), which identifies facilitating "reasonable access to health services without financial or other barriers" as one of two primary objectives of Canadian health care policy, and which posits that publicly insured services[107] ought to be provided on a universal basis.

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[107] Publicly insured services include 'medically necessary' hospital services, 'medically required' physician services, and 'medically or dentally required surgical-dental procedures performed by a dentist in a hospital.'

> The goal of a Canadian pharmaceutical strategy should be to ensure that every Canadian has timely access to safe and effective prescription drugs, and that no Canadian is deprived of needed prescription drugs because of inability to pay. (The Coalition for a Canadian Pharmaceutical Strategy 2006:2)

> Canadians are rightly proud of the principle that our universal public health care system should base access to care on need rather than ability to pay. Until we deal with the lack of national pharmacare in this country, I am sorry to say that I don't believe we are living up to that principle. – Dr. Danielle Martin, Women's College Hospital (HESA-7 2016:5)

While not exclusively the case, many proponents of universal insurance who invoked medical need as the primary distributive principle for determining access to pharmaceuticals saw the medical necessity of drugs not only as justifying universal coverage, but also as being intimately linked with public financing and administration. I will expand on the normative justifications offered in favour of public universal coverage shortly. However, it is worth noting that not all proponents of universal coverage saw medical need and universality as necessarily linked to public financing and provision, making commitments to universal coverage *in general* a more broadly (albeit not necessarily universally) held view. In that sense, it is possible to distinguish between the basic assurential logic of insurance, which distributes insured benefits according to need, and a more overtly egalitarian logic that ties the value of satisfying health needs to something like equality of opportunity or a communitarian logic which holds that certain basic needs ought to be secured universally as they are the prerequisites for forming right relationships (e.g., of equality and non-domination) amongst members of a community (Goodin 1988; Heath 2011; Horne 2016).

5.2.2 Equity

Proponents of universal pharmaceutical coverage frequently appealed to notions of fairness, equality, or equity in justifying the expansion of pharmaceutical coverage. However, equity-based justifications for universal coverage took two main forms: those that provided greater indication as to why equity was morally significant in the context of pharmaceutical insurance (usually in the form of egalitarian appeals to fair equality of opportunity or another form of life-prospects or wellbeing), and which tended to be promoted by stakeholders advocating for public pharmacare or in some cases catastrophic coverage, and those that appealed to equity in particular contexts, such as in making more sufficientarian claims for universal access to a

minimal level of coverage, and which tended to come from stakeholders advocating for mixed ‘fill in the gaps’ pharmacare.

The medical necessity or therapeutic value of pharmaceuticals was generally uncontested, even among those who were ambivalent toward or questioned the need for universal pharmaceutical insurance. Proponents of universal pharmacare who adopted egalitarian-like justifications held that medical necessity imparts a positive moral valence on pharmaceutical coverage, which justified implementing universal pharmaceutical coverage owing to its contributions to improving health outcomes and supporting some form of wellbeing or life-prospects, such as equality of opportunity. In particular, equity-based arguments identified two key equity-promoting features of universal pharmaceutical insurance: ensuring equitable access to medically necessary drugs, which contributed to improved health outcomes, as well as equitable security and financial protection by ensuring that Canadians would not face undue financial burdens when procuring medically necessary medications (e.g., whether due to sudden illness, unemployment and loss of employer-provided coverage, or otherwise).

A few proponents of universal pharmaceutical coverage explicitly specified that the equitable access to medications and financial protection was important for the egalitarian commitment to fair equality of opportunity or related notions such as facilitating a ‘level playing field’ or equitable health outcomes. Although largely unspecified, health outcomes were either regarded as intrinsically valuable, insofar as health was a dimension of wellbeing, or more commonly, as instrumentally valuable as they impacted productivity or opportunity, as was specified by the National Forum on Health:

> Equality of access was one of the most important values consistently advocated. Canadians should have equal opportunity to achieve health and well-being and to receive health services according to their needs. The health care system allows all of us to share in the costs of health care on the basis of our ability to pay, through income and other taxes. The system is equitable and simple and reinforces an abiding sense of the fairness of equality in opportunity. (National Forum on Health 1997)

> The founders of Medicare a half-century ago established the principle of equity of access to hospitals and doctors' services for all Canadians. First Ministers agree that no Canadians should suffer undue financial hardship in accessing needed drug therapies. Affordable access to drugs is fundamental to equitable health outcomes for all our citizens. (Government of Canada 2004)

> This patchwork of different [public pharmaceutical benefit] initiatives across the country also means that not all Canadians have the same advantages. The intent of the National Pharmaceuticals Strategy is to level the playing field for all Canadians, regardless of where they live. (Health Council of Canada 2009:1)

The National Forum on Health, which included a 'Values Working Group' dedicated to studying the principles and values that Canadians espoused with respect to health and health care, explicitly identified equal access to health care—including the security and stability conferred through insurance—as an egalitarian commitment; moreover, equitable health outcomes were taken to be important owing to the special impact of health on opportunity, enabling "a fair chance at success," or quality of life:

> Many people readily acknowledged that their commitment to egalitarianism is restricted to health care and that they are not troubled by wide discrepancies based on ability to pay or status in other areas of society. They have no trouble isolating health care in this way because they see it as something of a completely different character from housing or automobiles or vacations. It is also clear that many, perhaps most, believe that they, personally, might be worse off should the system evolve into two tiers.
>
> One of the ways in which equality in health care is different stems from the fact that being as healthy as possible is seen to be fundamental to the quality of life that is part of being Canadian. […] Equality of access is also seen to be essential to opportunity. Variances in income could be the end result of the market economy, but being physically healthy is seen as a precondition for having a fair chance at success. If there is to be equality of opportunity, then as far as possible everyone should start from a position of good health.
>
> Finally, many saw our health system as a smart investment on the part of our country - one that gives us some comparative economic advantages and makes society more stable. (National Forum on Health 1997)

In addition to highlighting an egalitarian commitment to fair equality of opportunity, this passage alluded to another strand of egalitarian reasoning which was echoed in several other proposals that appealed to notions of equality in justifying universal insurance. As discussed in the theoretical background, egalitarians are usually not concerned with inequalities as such, but rather with *unjust* inequalities, or inequities—which are usually (and especially on a luck egalitarian account) taken to encompass inequalities that arise from involuntary or unchosen circumstances or actions for which people cannot be reasonably held responsible (Shapiro 2007; Segall 2010). These include inequalities that arise from bad brute luck (i.e., where chance occurrences are not reasonably foreseeable or modifiable, such as genetic predisposition) or as a result of decisions or actions that are taken under coercion, rather than those that are freely

chosen (Shapiro 2007). [108] For example, the notion cited in the above quote that inequalities in income or lifestyles were tolerable as they reflected the choices that individuals make while participating in the market economy can be taken as indicative of this sort of egalitarian reasoning. A similar line of reasoning was visible in the following quotation, which asserted that someone who had contributed their fair share (and was thus deserving[109] or, alternatively, had contributed their share to a reciprocal scheme) ought not be reasonably expected to shoulder the financial burdens associated with high drug costs:

> The burden of a loved one being sick in front of you and going down with dementia, is enough. Last year we were $6,000 in debt with drug bills. Now we are faced with losing our home. We both worked hard all our lives, and I don't think that's right. - Gretta Ross, Sarnia, Ontario (Canadian Centre for Policy Alternatives and Canadian Health Coalition 2008:12)

The challenge, however, arises in determining which inequalities arise from voluntary or chosen actions—for which people can reasonably be held responsible—and which are the result of involuntary or unchosen circumstances and decisions, for which they cannot. As I expand on later in the chapter, this distinction had implications for how stakeholders conceived of the purpose of pharmaceutical insurance and what they envisioned as an appropriate policy response, including whether they advocated for charging 'actuarially fair' premiums.

Some stakeholders, and especially proponents of public single-payer pharmacare, further justified the need to universalize coverage in reference to the fact that those currently lacking insurance (e.g., because they neither qualified for public programs targeted at social assistance recipients nor employer-sponsored plans) tended to be disproportionately 'vulnerable' (e.g., precariously employed, working poor, self-employed) and already faced financial insecurities.

> The chaotic blend of existing public and private plans is therefore a major source of inequity. It is often the most vulnerable and financially fragile who are the least protected. (Gagnon and Hébert 2010:21)

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[108] Most egalitarians do not consider compensating for the effects of good brute luck, such as natural talents or positive genetic predispositions, as an essential aim of justice (Shapiro 2007:20), whereas communitarians might.

[109] Luck egalitarianism differs from accounts of equality that appeal to an ideal of desert. The latter hold just distributions to reflect levels of deservingness, such as in virtue of good conduct, which means that an undeserved equality can be considered unjust. Luck egalitarians, such as Segall, are not concerned with deservingness per se, or with penalizing 'undeserved' equalities, but rather with remedying inequalities that stem from differential luck where persons are worse off for no fault of their own (Segall 2010: 16-19).

> It's the poor 25%, the most vulnerable of our population that have no insurance at all, who are losing [by not benefiting from negotiated lower prices]. That is a tragedy. – Dr. Anne Holbrook, McMaster University, as an individual (HESA-8 2016:10)

Financial burdens associated with drug costs could also be seen as compounding barriers to opportunity or wellbeing for those who were systemically disadvantaged.

While many proponents of universal pharmacare who appealed to equity stressed the importance of equitable access to medically necessary medicines and financial protection, and thus called for universal *first-dollar* coverage, the Kirby Report emphasized the importance of securing Canadians equitably against undue financial hardship based on its understanding of the two overarching objectives of federal health care policy outlined in the *Canada Health Act.*[110]

> […] the Committee strongly supports the view that no Canadian should suffer undue financial hardship as a result of having to pay health care bills. This basic principle at the root of Canadian health care policy should be applied to prescription drug expenses. (Standing Senate Committee on Social Affairs, Science and Technology 2002:125-126)

In emphasizing the primacy of providing equitable protection against undue financial burdens, the Kirby Report recommended implementing a universal insurance program that would protect against catastrophic drug costs rather than offering first-dollar coverage. It is worth noting that some other stakeholders countered that while universal catastrophic coverage could formally provide universal financial protection, it would not necessarily ensure universal access and financial protection in practice, since even smaller out-of-pocket drug costs could pose barriers to access and be unduly burdensome for some individuals.

> For people who can't afford those catastrophic deductibles of 3%, 5%, 10%, or 12% of their income, having access to catastrophic drug coverage is equivalent to not having any drug coverage at all. – Dr. Danielle Martin, Women's College Hospital (HESA-7 2016:4)

Although the Romanow Report identified universal, public pharmaceutical coverage as the ultimate goal of pharmacare reform, it also recommended establishing a universal catastrophic

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[110] The Kirby Report (2002:308) identified the two objectives as being: "To ensure that every Canadian has timely access to all medically necessary health services regardless of his or her ability to pay for those services" and "to ensure that no Canadian suffers undue financial hardship as a result of having to pay health care bills."

drug program, similar to the Kirby Report. Romanow saw catastrophic coverage as a first step towards integrating drugs into Canada's existing public single-payer Medicare system, which offers comprehensive, first-dollar coverage. Romanow also appealed to egalitarian reasoning in justifying universal catastrophic coverage, such as when invoking concerns about the inequities that arose when some Canadians were "expected to shoulder a considerable financial burden simply because they were born with a serious illness" (which is framed as something beyond the person's, or their parents' or caregivers', control) or were "struck by an illness at some point during their lives" (which suggests a sudden or unpredictable and thus reasonably unforeseeable event)—concerns that were further exacerbated by interprovincial differences in public drug coverage (Commission on the Future of Health Care in Canada 2002:197).

Interprovincial differences in coverage were cited as a major source of inequity as they tied access to residency and resulted in people with the same condition incurring different costs.

> Based on what we know about Canadians' values, people's access to necessary prescription drugs should not be determined by where they live. (Commission on the Future of Health Care in Canada 2002:197)

> If delivered regionally, then pharmaceutical care must be portable throughout the country and national standards are required to ensure equity for all Canadians, no matter where they live. (Best Medicines Coalition 2017:2)

Moreover, interprovincial differences in coverage were taken to be concerning as they could limit Canadians' choice of residence.

> "I will not be able to retire in this province. I have to look at where my costs for diabetes are covered," Thoen told the hearings. "… I live in Canada and I want to stay in Saskatchewan if that is my choice." (Canadian Centre for Policy Alternatives and Canadian Health Coalition 2008:21)

Addressing interprovincial inequities in access was often tied to the establishment of a common national formulary, which would facilitate portability of coverage:

> The intent of a common national formulary is to ensure that Canadians who receive government funding for their prescriptions could move anywhere in Canada and receive the same medications. (Health Council of Canada 2009:15)

Indeed, despite differing recommendations with respect to the details of pharmacare, and in particular whether it ought to be publicly or privately financed and administered or offer comprehensive or catastrophic coverage, many proposals endorsed the need for a common,

national formulary to inform prescribing, ensure equitable access (at least at a threshold of sufficiency), and to harmonize cost-effectiveness assessments and reimbursement decisions.

> The development of a comprehensive national formulary to guide the minimum listing decisions of public and private plans is a critical building block to improve equitable access. (Canadian Pharmacists Association 2017:9)

However, as I discuss later in the chapter, the development of a national formulary was criticized by some stakeholders on the grounds that it would restrict access to or choice of medications and thus represented a levelling-down for those who already had broader coverage

Similar to interprovincial differences in coverage, proponents of universal insurance noted that limiting universal coverage to the inpatient hospital setting unjustifiably–and inequitably–tied coverage to the care setting rather than medical need.

> Le Rapport [Demers] souligne « l'incohérence et le paradoxe de la gratuité des médicaments, qui est totale lorsque le patient est hospitalisé, mais inexistante lorsque le même citoyen passe à un autre statut » même si son état de santé demeure grave et précaire. (La Coalition Solidarité Santé 2005:12)

> Yet our goal is – or should be in a system created to provide for patients – to fund the service or product the patient needs, and not the institution. There is no logical or equitable reason why drug costs should be transferred to the individual from the institution. Patients at home have no opportunity to bulk purchase the drug and negotiate prices accordingly, so it is a greater burden to the system to send the patient home without the ongoing discounts provided to the institution. (Best Medicines Coalition 2006:20)

As the second quote suggests, the existing system, which limits universal drug coverage to hospital settings, was seen as contributing to further inequities as patients paying for drugs out of pocket were exposed to higher drug prices than those with public or private insurance that are able to secure lower drug prices through price negotiations and bulk purchasing.

5.2.3 Community

Proponents of universal pharmacare, particularly those advocating for public single-payer or in some cases catastrophic coverage, also appealed to notions of community and often invoked them in concert with equity to justify universal coverage. As discussed in the theoretical background, community-based appeals draw attention to the common good, as well as a shared sense of identity (where community membership is constitutive of individual identity), solidarity,

and a sense of mutual responsibility or reciprocity (Shapiro 2007:30). Arguments appealing to principles of community support institutional arrangements that promote the common good or solidarity between members of a community; for example, universal insurance programs are often seen as promoting solidarity as they promote mutual responsibility and treat everyone as a full member of the community (Goodin 1988; Shapiro 2007). While on egalitarian accounts equity emphasizes a concern for unjust inequalities between individuals and understands justice as aiming at achieving substantive equality of some measure of wellbeing or opportunity, community-based appeals can place limits on certain types of inequalities that egalitarians may otherwise permit, such as aiming to compensate for advantages rather than primarily focusing on addressing disadvantages resulting from unchosen and unforeseeable circumstances (Cohen 2009). In the context of the pharmacare debate, community-based claims tended to arise more sporadically than egalitarian ones; moreover, they primarily took the form of appeals to notions of shared (national) identity and values or mutual responsibility, more so than focusing on compensating for inequalities that arise from unearned advantages.

Most often, community-based arguments framed Canada's existing universal Medicare system—and the values or principles that it was taken to embody (usually equity and solidarity)—as a defining feature of national identity. As a result, many of the arguments classified here as appeals to "community" had clear nationalist overtones. Indeed, the Medicare system was often invoked as a national symbol that characterized "Canadians as a people" and, furthermore, as one that distinguished Canadians from Americans:

> People also told us that the health care system had a special importance to them as Canadians: "...it's a basic fundamental tenet of being Canadian." Many agreed that the universality of the system helped distinguish Canada from the United States in a way that showed us to be a more generous and compassionate society. Others said that they derived a sense of pride with the quality of the system. People feel they are very fortunate to have benefited from such a good system. Accessibility and quality are described as the twin pillars of the health care system, with accessibility being somewhat more important for the majority. We take pride that both rich and poor have access to the same quality of health services in Canada. (National Forum on Health 1997)

The Romanow Report similarly identified equity and community-based notions such as solidarity as underpinning the existing Medicare system and as being defining features of what it meant to be a Canadian citizen:

> In their discussions with me, Canadians have been clear that they still strongly support the core values on which our health care system is premised – equity, fairness and solidarity. These values are tied to their understanding of citizenship. Canadians consider equal and timely access to medically necessary health care services on the basis of need as a right of citizenship, not a privilege of status or wealth. (Commission on the Future of Health Care in Canada 2002:xvi)

Furthermore, equity-based appeals referencing the *Canada Health Act* took on a community-based character when they were framed as significant for promoting a shared, national identity or as shared, Canadian values. Indeed, the principles of the *Canada Health Act* and the commonly cited refrain of 'access based on need, not ability to pay' were sometimes framed as *the* fundamental Canadian values, such as when then Ontario Minister of Health and Long-Term Care Dr. Eric Hoskins, who would go on to chair the Advisory Council, wrote, "[a]s citizens, we believe that every person must have access to health care regardless of their ability to pay. There may simply be no more Canadian a value" (Hoskins 2014). The Advisory Council's final report also framed notions of fairness, mutual responsibility, and solidarity as "uniquely Canadian values" that ought to guide the development and implementation of national pharmacare:

> Be bold, Canadians told us. Be brave, they appealed to us. But most of all, they reminded us to heed those uniquely Canadian values: looking out for one another, supporting neighbours and communities through tough times and treating each other with fairness. They told us if we could harness that intangible thing—what it means to be Canadian—we might just make pharmacare happen. (Health Canada 2019:8)

Echoing appeals to national identity cited above, the report also framed the implementation of national pharmacare as an exercise in nation-building and strengthening a shared commitment to each other:

> For the first time in more than 50 years, Canada would be introducing a new pillar to its universal health care system. This is nation building, strengthening the social contract that bonds us, and reinforcing our sense of what it means to be Canadian. And although it will be a challenging transformation—all great national projects are—it will give Canadians and future generations a public prescription drug plan that is effective, fair and sustainable; one that shares the cherished Canadian values that are embedded in universal health care. (Health Canada 2019: 107)

With the positive moral valence ascribed to the existing Medicare system, universal (and especially public) pharmacare was often dubbed the 'missing piece' or 'unfinished business' of

Medicare—a logical next step in completing the original equity- and community-based objectives of the existing Medicare system:

> We conclude that Canadians want to preserve the fundamental principles of medicare. We must, therefore, complete the job of building medicare. […] It makes little sense to guarantee public coverage when services are provided in hospitals, yet provide partial or no coverage at all for the same services out of hospital. (National Forum on Health 1997)

> At Canadian Doctors for Medicare, we're of course proud of our system; it's why we work tirelessly, not only to defend the principles on which it was based and on which it was founded, but also to find ways to improve it. […] When we talk about pharmacare, we talk about it as one such program. We talk about it as the unfinished business of medicare. – Dr. Danyaal Raza, Canadian Doctors for Medicare (HESA-74 2017:5)

As evidenced by some of the previous quotations, proponents of universal, and especially public single-payer pharmaceutical coverage often jointly invoked principles of equity and community in justifying universal coverage on the basis that it would both be equitable and sustain a sense of shared identity and mutual responsibility. For example, following its discussion of universal health coverage as being tied to an egalitarian commitment to equality of opportunity, which I cited earlier, the NFH (1997) continued by noting that Medicare was regarded as an entitlement "as a matter of citizenship," "emblematic of a commitment to compassion" (which it had explicitly tied to solidarity, common good, and mutual dependency elsewhere in its report), and as providing "a sense of community" and "common purpose."

> An overwhelming majority of participants stated that medicare was, and is, an essential part of their national identity. […] Canadian underpinnings of the health care system include the premise that it ought to be government run and not for profit, that money is not the primary consideration and that all are entitled - as a matter of citizenship - to equal access to quality care. This typically Canadian approach is, for many people, emblematic of a commitment to compassion, to equality of opportunity, to a sense of community and to a common purpose. (National Forum on Health 1997)

Indeed, mixed egalitarian and communitarian appeals were often invoked to support the implementation of universal pharmacare, and, as I expand on in the following section, *public* universal pharmacare in particular. For example, the above cited concern regarding the commodification of pharmaceuticals and health insurance is emblematic of a particular type of

communitarian reasoning, which holds that pharmaceuticals and health insurance ought to be distributed and provided through public means as they were common goods.

5.2.4 Realizing Universal Coverage

As I have described, egalitarian and communitarian-based appeals were most often invoked when explicitly arguing for a universal pharmaceutical insurance program that would ensure access to pharmaceuticals on the basis of medical need and provide equitable financial protection. Moreover, pharmacare—envisioned as an extension of Medicare—was taken to be emblematic of understandings of Canadian identity or 'shared values' and commitments to mutual responsibility or solidarity. Proponents of public single-payer pharmacare, as well as some proponents of catastrophic coverage who saw it as an incremental step towards public single-payer coverage (e.g., Romanow), tended to more explicitly invoke equity- and community-based justifications when calling for universal coverage. Finally, and as I describe further in the context of arguments presented in favour of mixed 'fill in the gaps' pharmacare, only a minority of stakeholders questioned the need for universal pharmaceutical coverage; however, they still tended to focus their efforts and dissent in arguing for mixed or private universal coverage and especially *against* public single-payer pharmacare.

For the most part, proponents of mixed pharmacare made more overtly sufficientarian appeals by calling for a minimum level of coverage for all. It is worth noting, however, that the egalitarian-like arguments invoked most often by proponents of public pharmacare were, in effect, also sufficientarian in the sense that no one argued for universal coverage of *all* available medications. However, and as I expand on in greater detail throughout the chapter, proponents of public pharmacare tended to use a more narrowly defined concept of 'medically necessity' or 'appropriate' medications—usually denoting medications with good evidence indicating their safety, effectiveness, *and* cost-effectiveness—than proponents of mixed pharmacare. So while the former could invoke comprehensive coverage in reference to all (or most) of the drugs that they deemed medically necessary, the latter considered a larger number of drugs to be medically necessary, and thus a formulary covering fewer drugs would represent only a minimal or minimally sufficient (rather than comprehensive) threshold of coverage on their account.

With the majority of stakeholders having advocated for or at least tacitly conceded the objective of universalizing pharmaceutical coverage, the focus of the debate turned to determining how

best to finance and administer universal pharmacare. It was at this stage of the debate where differences in reasoning and policy options diverged more markedly, both in terms of their understandings of whether pharmacare financing and provision ought to be public, private, or a mix of both, and whether it ought to offer comprehensive, first-dollar or catastrophic coverage. I now turn to outlining the three main pharmacare options considered in the debate: public single-payer, mixed 'fill in the gaps', and catastrophic. I describe how they each prioritized distinct aspects of the problems of access, costs, and appropriateness, which in turn shaped how they conceptualized political responsibility when advocating for their preferred pharmacare model.

5.3 Public Single-Payer Pharmacare

As I alluded to in the preceding section, many proponents of universal pharmacare saw universal coverage as necessarily linked with public financing, usually through single-payer insurance resembling Canada's existing Medicare, which is guided by the objectives and principles outlined in the *Canada Health Act* and offers comprehensive, first-dollar[111] coverage for insured services. Public single-payer pharmacare was often framed not only as the most equitable, but also the most efficient way of achieving universal coverage and addressing issues related to access, costs, and appropriateness. While equity and community-based arguments did most of the work in justifying the overarching objective of universal coverage, efficiency donned a significant (albeit not exclusive) justificatory role in supporting universal *public single-payer* pharmaceutical insurance in particular. Before describing how public single-payer pharmacare was justified with appeals to equity, community, and efficiency, I outline the historical progression of policy ideas about public single-payer pharmacare. I suggest that in the contemporary debate, proponents of public pharmacare were successful in making their case, at least insofar as it was reflected in the HESA and the Advisory Council recommendations, due to

[111] While most proponents of first-dollar coverage used the term 'first-dollar' and often described it as representing coverage for the total cost of a drug (starting from the first-dollar), many conceded that a pharmacare plan with no premiums, deductibles, or co-pays may not be politically or practically feasible; in such cases, they emphasized the importance of keeping co-pays to a minimum, especially for low-income individuals, so as not to deter necessary medication use. For example, Steve Morgan (HESA-07) referred to such a program as offering 'first-prescription' coverage, as it would provide coverage, albeit with a co-pay, from the very first prescription. In contrast, plans with deductibles or those offering catastrophic coverage (which in effect amounts to a large deductible) offer coverage only after a person's out-of-pocket spending has exceeded the value of the deductible.

how they framed their arguments and used evidence demonstrating that public single-payer pharmacare offered the most efficient way of financing and organizing universal coverage.

5.3.1 Evolving Ideas about Public Pharmacare

Since the start of the case study period, universal public pharmacare was often identified as the ultimate objective of Canadian pharmaceutical policy owing to its equity-, efficiency-, and community-promoting features, even if it was not regarded as being immediately feasible.

> The National Forum on Health believes that the way to improve appropriate access to, and utilization of drugs, and to control the growth of drug expenditures, is to ensure that medically necessary prescription drugs are made available to all Canadian residents, without deductibles or co-payments. International experience has shown that this is best accomplished under a publicly financed and regulated system, which in Canada would, of course, be administered by the provinces with arrangements for portability of benefits - within reasonable constraints - throughout the country. In essence, that requires finding a mechanism to transfer private health expenditures to governments so that they can be managed publicly. This is the ideal the Forum advocates for the long term. (National Forum on Health 1997)

> In an ideal world, were the slate clean and money not a factor, few would doubt that a first-dollar, publicly-funded, single-payer universal system would be the best outcome. It would be the least expensive to society as a whole. And it would be the most fair. […] But, we do not, of course, live in an ideal world, with that clean slate and unlimited money. Which brings me to the phrase 'long-term'. With resources -- provincial and federal -- being what they are, and very real competing demands on them, it seems improbable to me that there would be sufficient consensus in the near term to move immediately to the kind of full-blown system I have just described. – Minister of Health, Allan Rock (Health Canada 1998:58-59)

> However, the immediate integration of all prescription drugs into a revised Canada Health Act has significant implications, not the least of which would be substantial costs. Therefore, the goal should be to move in a gradual but deliberate and dedicated way to integrate prescription drugs more fully into the continuum of care. Over time, these proposals will raise the floor for prescription drug coverage across Canada and lay the groundwork for the ultimate objective of bringing prescription drugs under the Canada Health Act. (Commission on the Future of Health Care in Canada 2002:190)

Many reports in the late 1990s and early 2000s saw escalating drug costs and the shift in costs from the private to the public sector (despite overall cost savings) as barriers to the immediate

feasibility of universal public pharmacare, and instead recommended more circumscribed and incremental reforms in the form of universal catastrophic coverage.

Although similar concerns were raised about public single-payer pharmacare in the contemporary debate, I would argue that its reputation changed to significant effect. Early on in the contemporary debate, advocates of public pharmacare developed and leveraged economic costing models, which estimated that the efficiency-gains associated with shifting to a public single-payer system would save several billion dollars annually for Canadians as a whole, in arguing for the feasibility and necessity of implementing public pharmacare (e.g., Gagnon and Hébert 2010, Gagnon 2014, Morgan et al. 2015).

> In this report, we will demonstrate that a public and universal drug insurance plan covering all prescription drug costs, based on first-dollar coverage, is economically possible and socially desirable in terms of equity and drug safety. We will also demonstrate that, in an appropriate institutional environment, it would be the most economically efficient drug insurance plan for the country's citizens. (Gagnon and Hébert 2010:15)

A study by the Parliamentary Budget Office (PBO),[112] which was commissioned by HESA as a part of its hearings on the development of national pharmacare, similarly found that the public pharmacare model it was asked to evaluate would result in systems-level savings in the order of $4 billion dollars annually (PBO 2017). Accordingly, I suggest that public pharmacare received serious consideration in the contemporary debate—including featuring as the preferred model in both HESA's and the Advisory Council's final recommendations—owing at least in part to the success with which proponents of public pharmacare shifted the discourse towards an argument that it would offer both the most equitable *and* efficient model of universal pharmacare. Not only did many stakeholders who argued in favour of public pharmacare draw on this line of reasoning and cite the aforementioned economic analyses as supporting evidence, HESA and the Advisory Council drew directly on these economic models and their authors' testimonies as well:

> The Committee believes that the best way to move forward in establishing a universal single-payer public prescription drug coverage program is by expanding the *Canada Health Act* to include prescription drugs dispensed outside of hospitals as an insured service under the Act. A study by the Office

[112] The PBO conducts nonpartisan economic analyses for the federal government.

> of the Parliamentary Budget Officer, which was commissioned by the Committee, examined this approach and found that it has the potential to reduce total annual prescription pharmaceutical expenditures by $4.2 billion, based upon prudent estimates. Such an approach would also ensure that all Canadians have equitable and affordable access to life saving prescription drugs. In short, it will save money and lives. The Committee has concluded that merely addressing coverage gaps will not lead to better health outcomes or better cost control. In the words of Dr. Marc-André Gagnon, Associate Professor, School of Public Policy and Administration, Carleton University, "In trying to preserve the fragmented system while filling the gaps, we end up thinking of the public system as some sort of trash can for bad risks." (Standing Committee on Health 2018:2)
>
> To help the council better understand national pharmacare's fiscal implications and its likely impact on spending for prescriptions, we had a drug spending model developed that builds on the methodologies of the Parliamentary Budget Officer (2017) and Dr. Steve Morgan et al. (2015). (Health Canada 2019:86)

The Advisory Council explicitly identified public single-payer pharmacare not only as a policy ideal, but also precisely as the most feasible way of realizing universal pharmaceutical coverage:

> The council deliberated the merits of these two [catastrophic and multi-payer] models as stepping stones toward the creation of a universal, single-payer, public pharmacare plan. In the final analysis, the council felt that any advantages presented by these models—either because they already exist in some form in Canada or because they might initially entail a lower level of public investment—were outweighed by the longer-term efficiency and sustainability of a single-payer model. (Health Canada 2019:167)

Even Roy Romanow, who had recommended implementing universal catastrophic coverage as the chair of the Royal Commission on the Future of Health Care in Canada, testified before HESA that were he to write his report today, he would have recommended implementing a public single-payer program based on considerations of both costs and 'values.' He cited new evidence, including Marc-André Gagnon's testimony and costing models, in support of the feasibility of adopting public single-payer pharmacare:

> In the years since that time [when the Romanow Report was published in 2002], I would argue that the numbers—which are set out in one of the documents I presented to you as a model of what to follow—indicate in effect that 13 or 14 countries have followed a universal pharmacare program, which means that it has to have worked. Why do I say that? Because it is accepted by the governments and by the public both on a cost basis and within a values structure. […] I think the evidence, with some little discrepancies here and there, which are important to consider, overwhelmingly indicates that a single pharmacare

> plan complements our program. To me, it fits with our values, and it fits with the evidence that is there. Fourteen years ago, we didn't have nearly the numbers we have today. – Roy Romanow, Commissioner, Commission on the Future of Health Care in Canada, as an individual (HESA-14 2016:11)

While efficiency-based arguments took on particular salience and justificatory power in supporting public single-payer pharmacare in the contemporary debate, my analysis in the remainder of the chapter suggests that what was considered efficient was nonetheless contested.

I now turn to describing the equity, community, and efficiency-based arguments that were commonly invoked to justify implementing universal *public* pharmacare. Most proponents of public pharmacare called for a single-payer system that would offer comprehensive, first-dollar coverage for medically necessary medications included on a national formulary—features which were taken to promote the most equitable and efficient form of universal coverage and best address gaps in access, contain drug costs, and promote appropriate prescribing and drug use.

5.3.2 Equity

As described earlier, equity contributed significantly to arguments in favour of universal pharmaceutical insurance. The role of equity in justifying public universal pharmacare in particular tended to be less explicitly articulated. That is, while it was commonly cited that universal public pharmacare would be more equitable than the status quo, fewer documents explicitly specified why a universal public single-payer model would be more equitable than a mixed multi-payer one. Nonetheless, documents that described the equity-promoting features of a public model did so primarily on two grounds: first, it would best support equality of opportunity or wellbeing by facilitating equitable access to drugs and financial protection through comprehensive first-dollar coverage, and second, that it would promote a fair system of financing for drugs and insurance.

Public pharmacare was often framed as the most equitable way of securing universal access to drugs and financial protection through comprehensive first-dollar coverage, which would cover the total cost of a drug without a co-pay or deductible, or at least offer coverage from the first prescription. In contrast, catastrophic or private insurance were cited as posing barriers to access due to premiums, co-pays, and deductibles as well as often restricting eligibility for individuals

with pre-existing medical conditions (which were presumably seen as ‘unchosen’ and thus not something people could be reasonably held responsible for) in the case of private insurance.

> Bill Swan of Halifax has suffered from severe asthma for most of his life. He told the hearings that he was spending $150 to $200 a month for medications over 20 years ago. When he went to an insurance company to see if he could purchase a plan that would help defray the costs, he was denied because he had a “pre-existing condition” – asthma. “I got so angry that I stopped taking the drugs and then I had to be admitted to hospital,” he told the hearings. “We need Pharmacare because people like me will never be able to get drug coverage through private insurance plans,” Swan said. (Canadian Centre for Policy Alternatives and Canadian Health Coalition 2008:15)

First-dollar coverage was seen as promoting equity as it would eliminate financial barriers, especially for lower-income individuals who were disproportionately impacted by cost-sharing mechanisms, owing to evidence indicating that even minimal co-pays could deter people from accessing medically necessary medications.

> It is really important to understand how unhelpful catastrophic drug coverage is for the patients in my practice and practices across the country: people living with diabetes, high blood pressure, asthma, chronic heart disease, and chronic lung disease. To give you an example, in Ontario, where I live, on an income of $20,000 annually, a patient would need to spend $800 out of pocket before her coverage would kick in. This requires an upfront cash outlay that a person living on $20,000 a year simply can't afford, so what happens is that people just don't fill their prescriptions. – Dr. Danielle Martin, Women's College Hospital (HESA-07 2016:4)

Indeed, cost-sharing mechanisms often used in private insurance, such as co-pays and deductibles, were cited as presenting individuals, and especially those with lower incomes, with ‘impossible’ choices where they had to forgo either medications or other essentials such as food or shelter, and thus were not faced with truly free choices concerning their medication use.

> Les aînées à faible revenu, les personnes assistées sociales, mais aussi les travailleuses et travailleurs à faible salaire et les prestataires de l’assurance emploi ne devraient pas avoir à payer pour l’achat d’un bien aussi indispensable que les médicaments. On les place présentement devant des choix impossibles : choisir entre les médicaments, la nourriture, le loyer et autres dépenses essentielles et s’exposer à des impacts néfastes sur leur santé et à une utilisation accrue des services de santé. (La Coalition Solidarité Santé 2005:3)

The Advisory Council drew on egalitarian reasoning even more explicitly in its justification of a universal public drug program, citing that it would most effectively reduce inequities associated

with a ‘myriad’ of characteristics (including many of which are social determinants of health) that both impacted people’s propensity to develop certain diseases and illnesses as well as how they accessed and experienced health services and government programs:

> A person’s risk of developing certain diseases and illnesses, and how well they respond to medication, is influenced by sex, race and age, among other factors. Socio-economic status, isolation, discrimination, environmental factors, how Canadians self-identify and a myriad of other characteristics and behaviours can have a significant influence on health and illness and response to treatment. Each of these factors can also affect how people access health services, and how they experience government programs. The council believes a universal public drug insurance plan with a comprehensive formulary and minimal copayments is the best model for reducing inequities. (Health Canada 2019:58-59)

This line of reasoning, and in particular the reference to characteristics which constitute social determinants of health, could be taken as reflecting an egalitarian concern about reducing inequities stemming from unchosen factors or circumstances as well as a broader concern for social justice. Accordingly, a universal public program offering comprehensive first-dollar coverage was portrayed as most effectively facilitating access to medically necessary medications and financial protection to support equitable health outcomes and, more broadly, some desiderata of equality such as fair equality of opportunity.

In addition to ensuring equitable access to drugs and financial protection, some explicitly framed public pharmacare as the most equitable way of financing pharmaceutical insurance. For example, a universal pharmacare program that was publicly financed through progressive taxation was cited as not only tying access to medical need, but also as a mechanism for redistributing wealth by making financial contributions proportionate to income.

> A public drug insurance plan should form an integral part of a country's pharmaceutical policies. The plan must tie together social programs designed to provide a minimum of well-being for all citizens, health policies designed to optimize public health, industrial policies aimed at attracting foreign investment, intellectual property policies, and tax policies designed to ensure greater fairness in redistributing wealth. (Gagnon and Hébert 2010:5)

The notion that a universal public insurance system ought to be redistributive—including across income brackets as well as different health statuses—was seen as placing greater financial responsibility on those with greater income or advantages and, as I discuss in the next section**,** also drew on notions of solidarity.

> These systems [in Australia, New Zealand and the United Kingdom] are all financed through general tax revenues. Through their progressive taxation systems, the cost of care is shared among all members of society according to their means—the wealthy help to pay for services for the poor, and the healthy help to pay for the care of those who are ill. (Health Canada 2019:54)

In contrast, the existing approach to financing pharmaceutical insurance was cited as being regressive as it granted significant tax subsidies to those with private or employer-based insurance, which offered the greatest benefits to higher-income individuals contrary to an egalitarian conception of just institutions as aiming at reducing inequalities or bettering the conditions of the least well-off.

> It's that public subsidization of private insurance as it is done in Canada is inherently inequitable because people with higher incomes receive a larger subsidy than people with lower incomes. In effect, it's a regressive subsidy that goes against the general principle that government-financed programs are generally either universal or preferentially support those with lower incomes. – Dr. Irfan Dhalla, Health Quality Ontario (HESA-08 2016:5)

Furthermore, a universal public system that negotiates drug prices nationally was seen as enhancing fairness or equity as it would facilitate consistent drug pricing across the country. In contrast, the present system was cited as unfair, since individuals paying for drugs out-of-pocket paid higher prices (the list price) for the same drug than what public or private payers paid following confidential price negotiations with manufacturers. However, and as I will discuss in the context of mixed pharmacare, other stakeholders contended that fair drug pricing could be achieved in a multi-payer system if private payers joined public payers in price negotiations.

5.3.3 Community

As when justifying universal pharmacare, proponents of public pharmacare appealed to communitarian concepts in addition to, albeit less frequently than equity. Two main types of community-based justifications were offered in favour of public pharmacare: appeals to solidarity, mutual responsibility, and shared identity and an argument based on the nature of pharmaceuticals and health care as common goods.

Similar to the community-based justifications cited in favour of universal coverage more broadly, some argued that a universal public program in particular was emblematic of a shared national project that would reflect shared Canadian values. Appeals to shared endeavors,

identity, or values were also invoked alongside notions of mutual responsibility or solidarity. For example, as described earlier in the context of equity-based justifications for public pharmacare, public financing through progressive taxation was seen both as redistributive and as a mechanism for sharing financial responsibilities. Moreover, public universal pharmacare was framed as embodying a shared national commitment, which extended even to future generations.

> The time for universal, single-payer, public pharmacare has come. This is our generation's national project: better access to the medicines we need, improved health outcomes and a fairer and more sustainable prescription medicine system. Let's complete the business of universal health care. That can be our promise, and our legacy, to each other and to all future generations. (Health Canada 2019:3)

In contrast, Quebec's existing system of universal multi-payer insurance was cited as 'dismantling' social solidarity because it created silos between contributors and beneficiaries as well as between public and private insurance pools:

> […] the social solidarity between segments of the population has been completely dismantled. The system is not forward-looking, contrary to what people may think and contrary to what a public insurance system should be. People who contribute to a private system their entire lives receive no warning when they are removed from the system and are insured by public insurance as soon as they turn 65 years old. There is no inter-funding between the private and public portions of the system, and the coverage terms and conditions vary a great deal between the public and the private portions. – Dr. Marie-Claude Prémont, École nationale d'administration publique, as an individual (HESA-7 2016:6)

Some proponents of public pharmacare also invoked common goods-like arguments to justify the public financing and provision of pharmaceutical insurance. They argued that because pharmaceuticals are medically necessary, they ought to be regarded as common goods rather than commodities, which could be the subjects of individual preferences. Accordingly, as common goods, drugs ought to be financed and provided through collective (public) means, which were considered best suited to distributing drugs universally according to the logic of need. In contrast, private insurance was cited as an inappropriate mechanism for distributing drugs as it operated according to the distributive logic of the market—on the basis of market prices and in the pursuit of profit—and treated drugs as consumer goods which would be available based on willingness and ability to pay. Market-based and profit-driven distribution were taken to be concerning as they did not allocate drugs solely according to need—both under-

allocating drugs in cases where patients lacked the ability to pay and over-allocating resources to drugs that were not necessarily appropriate but were profitable.

> The fifth and final element of a well-designed pharmacare program is an emphasis on reducing over-prescribing and improving quality and safety. This critical job cannot be left to private insurance companies or to pharmaceutical companies, which neither are accountable to the public nor have any kind of incentive to decrease rather than increase prescribing. – Dr. Danielle Martin, Women's College Hospital (HESA-07 2016:5)

Moreover, the commodification of drugs and the profit-motive were portrayed as distorting the incentives of pharmaceutical manufacturers in drug research, development, and marketing, such as by encouraging ‘ever-greening’ and the development of ‘me-too’ drugs rather than truly innovative ones that would serve the public interest. Furthermore, commodification and the profit-motive were cited as motivating aggressive marketing, regardless of a drug’s safety or cost-effectiveness, which distorted prices and contributed to inappropriate prescribing and drug use and thus to harm and waste.

> That drugs are as much a part of "medically necessary" care as are the services of physicians and of hospitals, seems now too obvious to deserve discussion. But this raises an issue that runs deeper than questions of access, appropriateness, and equity. In a fundamental sense, it implies that we do not wish to treat drugs as a "commodity", on a par with shoes and ships and sealing wax, and that it is irrational and inconsistent with our broader objectives to do so. In the ordinary marketplace, sellers of commodities market their products to anyone who can be persuaded to buy. But "medically necessary" services are of value when, and only when, provided to those who can benefit from them. Providing services to others is not only useless but may be actually harmful. Hospitals and physicians are not expected or professionally encouraged to "market" their services; rather they are expected to meet the needs of patients, and to refrain from providing, indeed to withhold, services that are not appropriate. Drugs, on the other hand, are marketed with great energy and skill, by firms whose managements are responsible for maximizing their profits. Increasing sales - that is, escalating drug costs - and continuing concerns about over-prescribing are not a "side-effect", but the direct and natural consequence of this behaviour. […] Consistent application to drugs of the principles that apply in the hospital and physicians' services sectors would imply "de-commodification" of drugs, and in particular active discouragement of drug marketing through both regulatory and purchasing policies. This would lead both to lower prices, and to more appropriate prescribing. (National Forum on Health 1997)

> [Pharmaceuticals] can be viewed as commodities to be developed, advertised and bought and sold like other goods. However, they can also be viewed partly

> as "public goods" (like hospitals) whose use should be carefully planned and distributed. Reconciling public and private sector elements will be difficult because of the different objectives, priorities and perspectives inherent in these sectors. (Health Canada 1998:18)

> The drug companies claim that research costs are high, but they spend three times more on advertising and promoting drugs than they do on research. […] According to Health Canada, only 15% of newly approved drugs are an improvement or a breakthrough over existing drugs. The other 85% are “me-too” drugs, just a different version of what already exists, but at a higher price and with monopoly price protection for 20 years. Massive advertising and promotion campaigns then create a demand for the “new” drug. [...] The issue is not just the cost of particular drugs, but also the wide prescribing of drugs to healthy people. (Canadian Centre for Policy Alternatives and Canadian Health Coalition 2008:9)

> Pharmaceutical companies are private profit-making businesses, not a public service. Indeed, they are very successful businesses in that the profits they make are extraordinarily high. […] Until we start to discuss producing drugs for the public good with public non-profit drug manufacturers, the best option open to us is to expand our public plans to cover the whole population. A national public plan would then have the strength to negotiate reduced prices with the pharmaceutical companies, as so many other countries have already done. (Canadian Health Coalition 2016:4)

Of the common goods-type arguments invoked in the contemporary debate, fewer explicitly identified pharmaceuticals or health insurance as common goods. Instead, they emphasized how the profit motive distorted incentives for research, development, and marketing of drugs, in addition to distorting the incentives of private insurers in reimbursement practices. However, as I will show, proponents of public pharmacare in the contemporary debate placed even greater emphasis on the efficiency-promoting features of public single-payer insurance.

5.3.4 Efficiency

While efficiency was mentioned in passing in arguments presented in support of universal pharmaceutical insurance, it played a significant role in justifying public pharmacare in particular, and as mentioned earlier, took on an especially prominent role in arguments in the contemporary debate. Proponents of public pharmacare argued that a public single-payer system offered the most efficient way of achieving universal coverage. Indeed, once public pharmacare was framed as more efficient than piecemeal or incremental reforms narrowly aimed at cost-containment or filling coverage gaps, the main argument in support of public insurance took the

form of: how could you *not* implement universal public coverage when doing so would expand access to medically necessary drugs, save lives, and also save billions of dollars?

> The lack of political enthusiasm for Pharmacare can mainly be explained by fears of the escalating costs such a plan is expected to entail. But this argument, which also predominates in the media, is completely lacking in substance. The sound economic analysis included in this report shows that the rational implementation of universal Pharmacare, with first-dollar coverage for all prescription drugs, would not only make access to medicines more equitable in Canada and improve health outcomes, but also generate savings for all Canadians of up to $10.7 billion in prescription drugs. Canadians cannot afford not to have universal Pharmacare. (Gagnon and Hébert 2010:5)

> Canadians have been waiting for pharmacare since it was first recommended in the 1960s. Evidence suggests that decisions not to implement universal public pharmacare is costing us billions of dollars, and worst of all, hundreds of lives every year. – Dr. Steven Morgan, University of British Columbia, as an individual (HESA-07 2016:2)

Public insurance was considered more efficient than the current patchwork of public and private insurance plans or alternative catastrophic or mixed 'fill in the gaps' programs for several reasons. A centralized, single-payer public insurance system (and the associated public institutional infrastructure, such as a national drug agency) was seen as most effectively: (1) reducing costs to Canadians as a whole by exercising countervailing power in drug price negotiations and realizing economies of scale through reduced administrative costs; (2) promoting the solvency and sustainability of insurance by pooling risks more broadly; and (3) guarding against harms and waste associated with inappropriate prescribing and drug use by transmitting credible information concerning drug safety and effectiveness to inform reimbursement decisions and prescribing practises.

Efficiency-based arguments for pharmacare drew on two senses of efficiency: efficiency understood as maximizing value for payers (e.g., achieving the greatest value for money, being guided by cost-effectiveness, or reducing total drug spending), or efficiency understood in the Pareto sense, which endorses improving welfare when doing so does not worsen others' welfare, and generally aims at minimizing harms, waste , or 'gratuitous suffering,' especially in the context of addressing the market failures that health insurance markets are prone to (Heath 2011:24). The two, however, were rarely explicitly distinguished.

5.3.4.1 Countervailing Power, Economies of Scale, and Systems Integration

The most common argument concerning the efficiency of public single-payer pharmacare highlighted the cost savings that Canadians could achieve, as a whole, by bulk purchasing drugs and negotiating drug prices. Joint price negotiations were seen as a legitimate and necessary exercise of purchasing power (or countervailing power) against drug manufacturers who operated in a highly concentrated industry. A public single-payer system was considered more efficient than a multi-payer one as it could concentrate purchasing power to negotiate lower drug prices in order to maximize value for payers. Although it was not explicitly characterized as such, negotiating lower prices could also be understood as redistributing economic 'rents' to payers from manufacturers who had misused the patent system by developing 'me-too' or 'ever-greened' rather than truly innovative or more cost-effective drugs.

> Given the complex and fragmented nature of the Canadian pharmaceuticals marketplace, there is a strong case for a collaborative national approach to achieve the Pricing and Purchasing mandate. Multiple payers, competing incentives, priorities and interests characterize the Canadian pharmaceuticals market. This fragmentation benefits the pharmaceutical industry, which uses the current market structure to leverage one jurisdiction against another for access and to obtain product listings. This fragmented market also allows for the maximization of profit margins, at a level which would not otherwise be realized in a single/unified market. To date there has been limited price or purchasing coordination among FPT drug plans, and this lack of collaboration means public plans potentially under-utilize their significant purchasing power and allow industry to command higher prices. (Federal/Provincial /Territorial Ministerial Task Force on the National Pharmaceuticals Strategy 2006:39)

> Each province is now doing a job of bargaining for price, and each one of them offers a certain market size to a supplier. The larger the market size, the more pressure they can bring to bear on the supplier for a volume discount. […] If the provinces aggregated their needs and involved the federal government, without necessarily placing the federal government in charge but through a partnership that is contractual in nature, we would then have an aggregated national requirement that could be supplied in a single transaction—or maybe two or three, a small number. Plain economic theory says we're going to get a better deal doing that. – Dr. Amir Attaran, University of Ottawa, as an individual (HESA-43 2017:12)

Additionally, they argued that public single-payer insurance was more efficient as it was associated with lower administrative fees, owing both to economies of scale as well as the fact

that insofar as it was universal, it would incur lower expenses associated with determining eligibility for reimbursements.

> The administration of private drug plans is an enormous expense. Millions of workers are making claims for themselves and their families, and the plan at every work place differs with regard to eligibility, deductibles, co-payments and prescription coverage. (Canadian Health Coalition 2007:19)

> Single-payer systems reduce or eliminate duplication of legal, technical, and administrative costs associated with rebate negotiation, monitoring, and enforcement in multi-payer systems. (Morgan et al. 2013:16)

Furthermore, proponents of public single-payer insurance argued that integrating such a program into the existing public Medicare system would be most efficient for the system as a whole, since systems- and population-level objectives could be incentivized and pursued more consistently.

> There is also a risk of wider inefficiencies if the financing of medicines is separated from the financing of other forms of healthcare. If managers are only concerned about controlling the cost to the drug plan – private or public – and not related costs elsewhere in the system, the result can be inefficient from a healthcare system perspective. An example of system-level inefficiency occurs when prescribers are entirely isolated from the financial consequences of their prescribing choices. (Morgan et al. 2013:16)

> In our research we found a report by Express Scripts Canada that says $5 billion is paid out every year by employers and unions in order to cover poor drug choices and unnecessarily expensive pharmacy services, but individual businesses and employee groups are not in the best position to rein in these costs. One of the problems with our system is that private insurance for drugs and public insurance for medical care creates a silo between the management of those critical parts of our health care system. It would be more efficient for the costs of medically necessary prescription drugs to be managed along with the budgets for other forms of care. In the Canadian context, that means it makes the most sense for those costs to be managed by provincial governments, in co-operation with each other and with the federal government. – Ms. Anita Huberman, Surrey Board of Trade (HESA-10 2016:1-2)

A public single-payer system was also seen as best being able to address the inefficiencies arising from the perverse incentives that arose in the existing patchwork system, such as when low-income individuals could be better off remaining on social assistance than seeking employment in situations where the latter would entail losing public drug coverage and being required to cover significant drug costs out-of-pocket.

> John Cox lives in Halifax. At one point in his life he had to choose between taking a job to support himself, and obtaining his medications; he couldn't have both. How did this happen? Cox has a disability that requires anti-psychotic medications. They were covered when he was receiving social assistance, but when he decided to go to work, he had to pay for the medications himself. Since he couldn't afford them, he stopped taking them and suffered severe consequences. (Canadian Centre for Policy Alternatives and Canadian Health Coalition 2008:13)

> While income-based exemptions are commonly used in the provision of social benefits in Canada, they also run the risk of creating significant discontinuities between eligible and non-eligible income brackets—sometimes referred to as "income cliffs." Income cliffs can create perverse incentives by penalizing individuals for improving their financial prospects, such as by obtaining a new job or going off social assistance, because doing so will mean they must begin paying a deductible before receiving the coverage they rely on. (Health Canada 2019:166)

Similarly, some argued for public universal pharmacare owing to the fact that it could increase Canadians' mobility and range of choices in the labour market as it would no longer tie pharmaceutical coverage to the particular set of pharmaceutical benefits offered by an employer.

> Now the fact that many people depend on those employer-based drug plans also causes problems in the job market. A parent whose child has diabetes or whose spouse has cancer cannot afford to lose his or her employer-based insurance, and that traps people in jobs that may not be right for them. Importantly, many Canadians who are working—the self-employed, people who work on contract, people who work part-time, and people who work in small businesses—do not have private coverage. It isn't only the working poor. – Dr. Danielle Martin, Women's College Hospital (HESA-07 2016:4)

> Again, I think a recurring refrain from us is patchwork, that private plans also have inconsistent coverage, inconsistent levels of copayment. For instance, people are very vulnerable in making a job change if their current plan covers their devices, supplies, and medications [for managing type 1 and 2 diabetes]. They may be reluctant to shift to a company that provides a better opportunity for them but doesn't offer the coverage they need. – Dr. Jan Hux, Canadian Diabetes Association (HESA-19 2016:15)

Public pharmacare was seen as addressing the failure of private insurance to offer adequate insurance, which created perverse incentives that restricted the range of meaningful choices available to Canadians when navigating employment opportunities.

5.3.4.2 Insurance Sustainability

While invoked less frequently than assertions about price negotiations and administrative costs, proponents of public single-payer insurance also pointed to the efficiency gains that could be achieved through pooling risks across a large population. Proponents of public pharmacare pointed to the challenges that the increasing number of high-cost drugs posed to the solvency and sustainability of private insurance plans, especially those offered by small- and medium-sized businesses. They noted that businesses were now less likely to offer insurance benefits or private plans were increasingly looking for ways to limit coverage either by reducing eligibility (e.g., for retirees) or by reducing coverage and shifting costs to individuals through increased premiums, co-pays, or deductibles or more stringent annual or lifetime insurance caps.

> In fact, a survey of 200 employers found that four out of five (83%) drug plan sponsors reported expensive new drugs coming to market are jeopardizing the sustainability of these plans. (Canadian Labor Congress 2016:4)

Although seldom stated explicitly, concerns around the sustainability of private insurance plans can be taken as suggestive of the reasoning that pooling risks across larger populations—as is done in single-payer insurance—lowers the subjective risk of each claimant and enables insurers to better weather fluctuations in reimbursement demands and maintain long-term sustainability.

> The pharmaceutical industry is in transition from the era of the blockbuster drug – those developed and sold at moderate costs for large segments of the population – to the era of the niche-buster drug – those developed and sold at very high costs for specific population groups, often those with serious unmet health needs. […] Incorporating these drug therapies into the healthcare system will require careful evaluation and management of the technologies themselves as well as a system of financing that pools the related financial risks across the broadest possible population. (Morgan et al. 2013:4)

Indeed, some stakeholders representing small-and medium-sized business (e.g., the Surrey Board of Trade) and unions (e.g., the Canadian Union of Public Employees, Canadian Labour Congress) noted that their members were facing challenges associated with the provision of pharmaceutical insurance owing to the volatility associated with reimbursements for high cost drugs. They also questioned the appropriateness of having employers, rather than healthcare professionals, determine the extent of pharmaceutical coverage given that employer-based insurance plans were increasingly subject to negotiations concerning the comprehensiveness of coverage rather than offering open formulary plans, which cover all market-approved drugs.

> Employers are pressing to contain costs, and health care benefits have become a major source of contention between unions and employers. (Canadian Centre for Policy Alternatives and Canadian Health Coalition 2008:10)

> There are strains on all businesses. Costs are high and uncontrolled for those who do offer drug coverage. Costs are an impediment for some companies to offer any coverage. There are concerns that a catastrophic public drug plan like B.C.'s still places a major burden on sponsors of private plans. Businesses are also very concerned about government passing a law that would make private insurance mandatory, as in Quebec. […] Businesses know better than anyone else how important it is to focus on core competency and to maximize the efficiencies of those processes. Canadian businesses are therefore concerned that the fragmented nature of drug coverage in Canada results in excess administrative costs, reduced purchasing power, and a silo mentality that may limit the overall efficiency of Canada's medicare system. […]The high price of medications today, many of which now come to market at prices of tens of thousands of dollars per patient per year, require coverage and cost-control policies out of the reach of the private sector in Canada. – Ms. Anita Huberman, Surrey Board of Trade (HESA-10 2016:1)

> Unions are reporting that health and drug benefits are increasingly being negotiated at the bargaining table with employers. Employers and unions are unfairly put in the position of deciding the extent of availability of and access to prescriptions drugs for workers – a process based on affordability of the insurance plans rather than an evidence-based public system that is based on workers' medical needs. (Canadian Labour Congress 2016:6)

> In my experience, employers want out from dealing with drug plans for employees. They wonder, as I do, why employers who are running businesses making paper or automobiles, or employers who are managing municipal and provincial public services, are making decisions about the provision of prescription drugs. Why do we have this absurd situation in which employers, and in some cases unions, are determining health issues around prescription drugs? Would this not be better in the hands of medical professionals and medical researchers? – Ms. Julie White, Canadian Health Coalition (HESA-11 2016:5)

Furthermore, proponents of public single-payer insurance cited Quebec's universal but multi-payer pharmaceutical insurance system as an example of a universal pharmaceutical insurance model that ought *not* to be replicated nationally because it was neither equitable nor efficient. Many highlighted that Quebec's system was ineffective at controlling costs for individuals as well as private and public payers—resulting in Quebec having the highest per capita pharmaceutical expenditure in Canada—owing to the fragmentation of its multi-payer system.

> The public plan [in Quebec] is not really income based; this means that single person earning as little as $8,114 has to pay the maximum premium amount ($640 per year). With private group insurance plans, on the other hand, the premium payable is based on the risk posed by the health status of all employees in the same office. Unlike public plans, however, no class of persons insured under a private plan gets free medication, not even minor children; a 9% sales tax is applied to the group insurance premiums and employees pay taxes on their employer's contribution to the group insurance plan. In addition to these inequalities, there is another serious issue with the current hybrid pharmacare program: the inability to effectively control costs. Consequently, the measures undertaken by Quebec's health insurance plan (RAMQ) to control costs affect only those insured, without solving the problems, yet we have witnessed an explosive rise in spending in private insurance plans. (Union des Consommateurs 2016:2)

> In the past 20 years [in Quebec], we have seen a gradual increase in private sector premiums to the extent that more and more people are leaving the private plans to seek refuge in the public system, which is heavily subsidized. Only the public part of the system is regulated, because people could not afford what the system truly costs without substantial subsidies. – Dr. Marie-Claude Prémont, École nationale d'administration publique, as an individual (HESA-07 2016:5)

> If we are trying to think of solutions based on the current fragmented system, we end up thinking that the public system is some sort of trash can for bad risks. This means that, if private plans are not able to handle something, the public system will get it. The Canadian government should therefore look after those without coverage and perhaps provide coverage for expensive treatments or for some more problematic drugs that private systems are not able to cover, such as those related to oncology. If we do that, the public system is based on the commercial needs of private plans, not on the health needs of Canadians. The typical example is the Quebec model, which is sometimes held up as a model. That should not be the case because the Quebec model simply makes the ineffective structure of private plans mandatory for everyone. It institutionalizes a system that is defined by its ineffectiveness in containing costs. When all is said and done, it is not surprising that, if we compare the costs per capita in Quebec to the costs per capita in the rest of Canada, Quebec spends on average 20% more per capita than in the rest of Canada. – Dr. Marc-André Gagnon, Carleton University, as an individual (HESA-07 2016:6)

Accordingly, proponents of public pharmacare argued that adopting a universal mixed multi-payer system, such as the one already in place in Quebec, would not address concerns about the inefficiency of employer-sponsored private insurance schemes.

5.3.4.3 Information Transmission

In addition to concerns about the impact of a fragmented pharmaceutical insurance system on drug costs and the sustainability of insurance programs, proponents of a public single-payer plan touted the efficiency-promoting features of centralized, public institutions and mechanisms for information transmission. That is, public institutions and mechanisms were framed as being able to more efficiently collect, analyze, and transmit credible information concerning drug safety, effectiveness, and cost-effectiveness to inform reimbursement decisions as well as appropriate pharmaceutical prescribing and use. Accordingly, many proposals—both historically (e.g., the National Forum on Health, the Romanow and Kirby Commissions, and the National Pharmaceutical Strategy) and in the contemporary debate (e.g., the Standing Committee on Health and the Advisory Council)—recommended reforming mechanisms for drug procurement and price negotiations, a national formulary, post-market surveillance, and drug safety and cost-effectiveness evaluation as a part of a broader national pharmaceutical strategy. Many also recommended developing a national drug agency which could coordinate these various responsibilities (e.g., the National Forum on Health, Romanow Commission, Standing Committee on Health, and the Advisory Council). These reforms were often framed as complementary or even necessary to realizing and sustaining universal pharmaceutical coverage by helping guide decision-making about safe and cost-effective medication prescribing, use, and reimbursement. Indeed, of the three main pharmacare policy options under consideration, proponents of public single-payer pharmacare most adamantly identified appropriate prescribing and drug use to guard against harms and waste as key policy objectives of pharmacare.

As I expand on in subsequent sections, the Romanow and Kirby Commissions and the National Pharmaceutical Strategy, which had all recommended universal catastrophic insurance, also envisioned a greater role for the public sector in improving the quality and availability of evidence concerning pharmaceuticals to inform reimbursement decisions and prescribing practices, thus distinguishing the question of public vs. private sector jurisdiction in financing from information transmission. Proponents of public single-payer pharmacare invoked two interrelated efficiency arguments with respect to information transmission: one concerning inefficiencies associated with current intellectual property protections and incentives for pharmaceutical research and development, and another concerning the efficiency of centralized,

public institutions and mechanisms in the regulation, collection and dissemination of credible information concerning drug safety and cost-effectiveness.

Proponents of public single-payer pharmacare highlighted inefficiencies associated with existing intellectual property regulations and cited mechanisms such as a national formulary not only as reducing regional inequities in coverage, but also as potential ways of reducing the waste and harms associated with existing pharmaceutical research, development, and marketing practices. Patents are meant to generate efficiencies by protecting intellectual property in order to incentivize research and development of innovative medications (i.e., medications offering patients significant benefits in terms of safety, effectiveness, or costs). Yet proponents of public pharmacare asserted that pharmaceutical manufactures regularly failed to develop truly innovative medications, and instead focused on developing 'me-too' drugs, which offered only marginal benefits over existing medications but were lucrative as they bore new patents that granted market exclusivity. Similarly, the practice of 'ever-greening,' where a drug's indications are expanded or dosage is modified to extend the patent term and delay market entry of generic versions, was cited as a common but perverse outcome of existing intellectual property regimes.

> Finally, public investment in, and promotion of, research by multinational firms, does not necessarily provide the greatest return for Canadians. Research efforts in Canada focus on two areas: variations of existing drugs that provide moderate or no therapeutic improvement over existing medicines ("me-too" drugs); and line extensions (usually a new strength) of existing medicines. (National Forum on Health 1997)

> The federal government should immediately review the pharmaceutical industry practices related to patent protection, specifically, the practices of *evergreening* and the notice of compliance regulations. (Commission on the Future of Health Care in Canada 2002: 208)

> The point I would make is that [an evidence-based formulary which is responsive to post-market surveillance data] could also elevate the standards for demonstrating improvement over existing therapies. What we see right now, unfortunately, is that a lot of new medications aren't terribly important for advancing care and health care outcomes. They are me-too drugs, and so on. I think this kind of body could encourage greater innovation that is in line with improved health care outcomes. – Professor Matthew Herder, Dalhousie University, as an individual (HESA-12 2016:8)

Public institutions and regulatory mechanisms, such as an evidence-based formulary that would reimburse for cost-effective medication, were cited as potential ways of incentivizing research and development into truly innovative medications.

Proponents of public single-payer insurance also voiced concern about the role of pharmaceutical manufacturers in the development and transmission of information concerning pharmaceutical safety and effectiveness. For example, they asserted that drug manufacturers had a propensity to invest significant financial resources into aggressive marketing of new medications, including me-too or ever-greened medications to generate demand from physicians (e.g., through detailing) and patients (e.g., through direct-to-consumer advertising or sponsorship of patient advocacy groups). Drug manufacturers were seen as disseminating information which was motivated by profit, rather than primarily being based on impartial assessments of safety, effectiveness, and cost-effectiveness, which would serve population health, the public interest, and patients' best interests. This was seen as contributing to the overuse and inappropriate use of drugs, including driving demand for new pharmaceuticals, which rather than being truly innovative, were often more expensive than existing ones, and thus resulted in waste and even harm. Moreover, advertising could also be regarded as distorting the physician's fiduciary duty to act and prescribe in the patient's best interests.

> The dynamics of the pharmaceutical sector are such that the players are in fierce competition with one another to establish brand-name recognition of their products by physicians, to build consumer allegiance, and to garner profits from the sale of these products. After reflection upon the sums of money spent on advertising and the extent of detailing (informational visits to physicians) by company sales representatives, we have concluded that these activities to promote products and increase sales do not always reflect what is in the patient's best interest. Many doctors have neither the time nor the familiarity with pharmaceuticals to compare and contrast information they receive from manufacturers. If salesmen could be expected to provide objective information on alternative drug and healing interventions, their interaction with doctors could be most beneficial. But such an expectation would be naive. A salesman's job is to sell, and only to sell; that is what s/he is paid for. (National Forum on Health 1997)
>
> There is no doubt that the public wants more information about drugs and their effectiveness. Rather than leave this to pharmaceutical companies, the National Drug Agency could meet this need by providing balanced, objective information in an accessible manner. This is a much better approach than direct-to-consumer advertising in place in the United States. This type of advertising is a major

> business in the United States and it has been shown to affect patients' requests for drugs. (Commission on the Future of Health Care in Canada 2002:203)

> I think part of it is also the capacity to bring pharmaceutical companies under control. They have huge profits. They are going to our doctors and talking to them about what drugs they should be carrying. They are providing conferences to doctors. We need the kind of independent information to doctors that is provided in some of these fully public drug plans, as in Australia and the U.K., where information is independently given to doctors about what drugs they should be prescribing. – Ms. Julie White, Canadian Health Coalition (HESA-11 2016:17)

Similarly with respect to industrial policies aimed at attracting investment, proponents of public single-payer pharmacare noted that drug manufacturers had failed to spend a proportionate amount on research and development in order to justify high drug prices, since spending on research and development was consistently declining in Canada at the same time that drug prices were increasing. Moreover, rather than reinvesting profits into high-value activities such as research for innovative drugs, they focused on marketing which was seen as a low-value and ineffective method of disseminating information about drug safety and effectiveness.

> The drug companies claim that research costs are high, but they spend three times more on advertising and promoting drugs than they do on research. (Canadian Centre for Policy Alternatives and Canadian Health Coalition 2008:9)

> It's estimated that about 80% of new drugs that arrive on the market have no therapeutic benefit over existing drugs. Yet if our system agrees to cover everything at any price, companies would end up engaging in major promotional campaigns to convince doctors to always prescribe the newest, more expensive, patent-protected drug. So we end up with marketing-based medicine, not evidence-based medicine. – Dr. Marc-André Gagnon, Carleton University, as an individual (HESA-07 2016:12)

In addition to concerns about inefficiencies associated with existing patent schemes, proponents of public single-payer pharmacare cautioned about the need to encourage appropriate prescribing and drug use to guard against harms (e.g., adverse events) and waste (e.g., increased costs) associated with the overuse, underuse, and unsafe use of drugs. A public single-payer system was cited as being more efficient than a mixed multi-payer one at securing and disseminating credible information for this purpose, both in terms of economies of scale (e.g., through centralized information systems such as would exist in a national drug agency) as well as information transmission (e.g., by ensuring the collection and dissemination of credible evidence

concerning safety, effectiveness, cost-effectiveness, and post-market use rather than relying on physician detailing and direct-to-consumer advertising to inform reimbursement policies).

> While there is strong evidence to suggest that many drug expenditures represent money well spent, considerable evidence also points to significant waste, driven by inappropriate prescribing and use. When drugs are not prescribed or used appropriately, the quality of care is reduced, unnecessary costs are incurred and patients can be seriously injured. […] Inappropriate prescribing and/or drug utilization have been identified as key factors in rising drug expenditures and overall health costs. (Federal/Provincial /Territorial Ministerial Task Force on the National Pharmaceuticals Strategy 2006:46)

Rather than relying on pharmaceutical manufacturers to collect and disseminate information to physician and patients, proponents of single-payer pharmacare advocated for the establishment of independent institutions (e.g., a national drug agency) and tools (e.g., a national formulary) to generate and disseminate impartial, credible information concerning drug safety, effectiveness, and cost-effectiveness. They argued for the development of a national formulary developed by an independent body of experts and based on impartial evidence that would limit reimbursement to cost-effective medications unless otherwise justified through a fair appeals process. As such, they framed a national formulary as not only effective for reducing inequities in coverage and for cost-containment, but also for informing and incentivizing appropriate prescribing. Indeed, rather than being seen as restrictive, the formulary was framed as guarding against harms and waste.

> Governments, physicians, pharmacists and patients are important decision-makers in the management and appropriate use of safe and effective drug treatments. Improper drug selection, inappropriate dosage, adverse drug reactions, drug interactions, therapeutic duplication, and patient non-compliance threaten the health outcomes of Canadians and add to system costs. It is therefore critical that decision-makers have access to accurate, unbiased and up-to-date information about a drug's effectiveness and impacts in different contexts and populations. (Federal/Provincial /Territorial Ministerial Task Force on the National Pharmaceuticals Strategy 2006:30)

> Drug research, the drug approval process and the prescribing practices of doctors are all influenced by funding and promotion from pharmaceutical companies. A public Pharmacare plan must include an independent agency to approve drugs on a more rigorous basis, set research standards and ensure that research findings are available to health care professionals and to the public. Post-marketing safety must also be strictly monitored. Drug company advertising and promotion to the public and to health care professionals must be replaced with more reliable and independent information. Pharmacare would make it possible for doctors and

> patients to get objective and up-to-date information about proper prescribing and use of drugs. (Canadian Health Coalition 2007:5)

> We need to set up a system that is structurally built around evidence-based data in order to maximize the therapeutic value of each dollar spent. […] A universal public prescription drug system could be built on the same basis. We could have a depoliticized independent agency that would rely on evidence. For instance, we could merge the Canadian Agency for Drugs and Technologies in Health and the pan-Canadian Pharmaceutical Alliance. This agency could manage the national formulary, meaning the list of covered drugs, but always with a view to maximizing the therapeutic value of each dollar spent. People might think that a national formulary of this kind would reduce the choices for patients, but that is not at all the case, because waste would be reduced. If patients still wanted treatment that is not based on evidence in terms of its effectiveness or if they wanted more expensive treatments when a less expensive alternative was available, they could do so by paying out of their own pockets. – Dr. Marc-André Gagnon, Carleton University, as an individual (HESA-07 2016:7)

Proponents of a national formulary also cautioned about the harms and waste associated with open formularies, which are common in private plans. They questioned the purported benefits of reimbursing for all new medications on the grounds that many were either me-too or ever-greened medications that offered little to no benefits over existing ones despite being significantly more expensive.

> As a physician, if I write a prescription for a patient, their private plan will nearly always cover it. Now that might sound good to you. I know it sounds good and you will probably hear people present to your committee over the coming days who will try to convince you that it is good, but in fact, it's not. It's not good for health, and it's not good for the economy. Why? Such open formulary plans give licence to doctors and other providers to prescribe more expensive medicines when less expensive ones are just as good or even better. This results in high costs for no reason and is one of the many drivers for the high costs that you've heard described by Steve [Morgan] and others. Eventually, of course, those costs are passed on to Canadians, either directly or indirectly. Open formulary plans also encourage what's known as off-label prescribing, which leads to doctors writing prescriptions for cases where the drugs are not medically proven to work, and they fail to provide any guidance to patients or to prescribers about what the most appropriate drug choice is for a given condition. This leads to a culture of over-prescribing and inappropriate prescribing that has real effects on the health of Canadians every day and leads to statistics of the kind we know. […] Indeed, private insurance plans have no incentive to reduce inappropriate prescribing. In fact, the incentive is just the opposite, because the more prescriptions we write, the more money they make. – Dr. Danielle Martin, Women's College Hospital (HESA-07 2016:3)

Moreover, some noted that in a mixed system, the tendency for private insurers to offer coverage for a wider array of medications–including higher cost, but not more effective medications–could also contribute to higher costs and waste for individuals paying out-of-pocket or receiving coverage through public plans, since physicians tended to prescribe based on habit:

> The prescribing decisions for patients with private insurance may influence prescribing decisions for those with public coverage. That sounds like a hypothesis, but we actually have evidence that this happens. […] Because this is in the public plan, clearly the costs of what we might call low-value prescribing are borne by all of us. – Dr. Irfan Dhalla, Health Quality Ontario (HESA-08 2016:5)

In addition to informing prescribing, a national formulary consisting of cost-effective medications was touted as potentially incentivizing research and development into innovative drugs, which would offer significant benefits over existing ones (e.g., Gagnon and Hébert 2010:36).

Proponents of public pharmacare also pointed to features of medication use—including information asymmetries and that they were non-elastic goods—that distinguished drugs from ordinary consumer goods in arguing for why public first-dollar coverage would offer the most efficient form of pharmacare and one that would uphold the government's fiduciary obligations to promote public health by facilitating patient medication adherence. Namely, they suggested that population health could be improved and health systems costs could be reduced by mitigating the *underuse* of medications, which occurred when individuals were deterred (often by a co-pay) from filling prescriptions for medications used in preventive care or for chronic ailments, but which did not yield immediately visible benefits. Accordingly, they regarded efforts to reduce drug costs and adjudicate appropriate prescribing as primarily as matters of collective or expert rather than individual patient responsibility.

> There is a broader economic case to be made for providing unfettered access to medicines proven value in the healthcare system. Many medicines deliver benefits by reducing the statistical risk of a future illness – the actual benefits of which cannot be immediately felt or known by patients. Particularly in such classes of medicines, the low-cost provision of prescription drugs can improve health system efficiency by increasing medication adherence and consequently averting costly consequences of untreated illness. (Morgan et al. 2013:11)

> It's important that we understand that patients don't act the way that we as managers of a health care system might wish them to act. If you put a $10 charge

> on a prescription drug for a patient, many will look at that drug and think that it's a preventative thing, that it's for their cholesterol, or for their hypertension, or for managing their blood sugars because they're a type 2 diabetic. They'll say, "I don't think I will fill that prescription. I'll just get by without it, because I don't feel there's a benefit." That personal choice by the individual, which is quite rational to an individual, ends up costing our health care system money in the long run. It's those very drugs, those preventative drugs, that patients stop taking and then end up in the hospital, where it costs us far more money than we will have saved in the long run by asking them to pay the copayment. – Dr. Steven Morgan, University of British Columbia, as an individual (HESA-07 2016:12)

Proponents of public single-payer pharmacare were adamant about the importance of promoting appropriate drug use in order to guard against harms and waste associated with the prescribing and use of drugs that were unsafe or not cost-effective and claimed that public institutions and regulatory mechanisms would best facilitate efficient information transmission. Conversely, they saw the private sector as lacking incentives to promote appropriate drug use and prescribing. However, as will become apparent in the following section, what constitutes appropriate or medically necessary drug use was contested. Moreover, as I alluded to previously and will expand on in the context of catastrophic coverage, not all stakeholders saw a public single-payer system of pharmaceutical insurance financing as necessarily linked to the establishment of public institutions and regulatory mechanisms to support the efficient transmission of credible evidence to inform and incentivize appropriate prescribing and drug use.

5.3.5 Summary and Implications

As I have described, proponents of universal public single-payer pharmacare argued that single-payer insurance offering comprehensive, first-dollar coverage for medically necessary drugs included on a national formulary would provide the most just and efficient form of universal pharmaceutical coverage. Particular understandings of equity, efficiency, and to a lesser extent community, shaped how they framed the issues of access, cost, and appropriateness, and as a corollary, who they considered responsible for addressing insurance financing, organization, and evidence gathering. They saw pharmacare largely as a matter of collective responsibility which would be best met through public institutions and mechanisms. They saw governments as being responsible for ensuring universal access to medically necessary medications and financial protection, as well as for containing costs and facilitating appropriate prescribing through intervention at the macro- and meso- levels, such as through joint price negotiation, the use of

formularies based on evidence and expert committee recommendations, and the development of institutions and mechanisms for the dissemination of credible information.

Proponents of public single-payer pharmacare tended to frame the issue of access as concerning gaps in pharmaceutical coverage as well as financial barriers to access and thus focused on ensuring that all Canadians had access to medically necessary pharmaceuticals as well as financial protection through insurance, which were seen as important for promoting fair equality of opportunity or some other form of wellbeing or life-prospects. They tended to see securing the conditions for good health—and opportunity more broadly—as matters of shared rather than primarily individual responsibility. Moreover, they suggested that it was the responsibility of higher-income and healthier individuals to help subsidize insurance costs for those with lower incomes or particularly high drug costs.

With respect to costs, proponents of public single-payer pharmacare tended to identify high drug prices, which they attributed to the fragmented pharmaceutical insurance landscape, as a primary source of high drug costs in Canada. They asserted that the decentralized insurance landscape not only resulted in higher administrative costs and threatened the sustainability of private insurance, but also limited the ability of payers to negotiate drug prices with manufacturers, which contributed to higher drug prices and costs to Canadians as a whole. Moreover, they claimed that manufacturers charged prices that did not reflect the true value of pharmaceutical research and development, but rather treated payers as 'price-takers,' included exorbitant advertising costs, and pitted public payers (including different provincial governments) against one another. Accordingly, they claimed that it was the responsibility of governments to contain drug costs on behalf of the public, and advocated for policy intervention at the national level in the form of single-payer public insurance owing to its efficiency-promoting features.

While proponents of public pharmacare primarily saw high costs as being a function of the decentralized insurance system, they acknowledged that the volume of drug use impacted overall spending as well. They noted that it was the responsibility of public payers and medical professionals to promote 'appropriate' drug use—or the use of medications that were comparatively more effective and cost-effective on the basis of epidemiological evaluations—in order to contain costs and limit waste. A corollary of framing the responsibility for limiting inappropriate drug use as a public or professional responsibility was that proponents of public

pharmacare advocated for the use of an evidence-based formulary to promote appropriate drug use. Conversely, they advised against using cost-sharing mechanisms aimed at encouraging individual patients to limit their drug use, which they saw as posing barriers to access.

> Research has shown that even small copayments deter the use of essential medications; the deterrent effect of making people pay the full cost is all the greater, and this will fall disproportionately on vulnerable populations. (Registered Nurses' Association of Ontario 2016:3)

Proponents of public pharmaceutical insurance tended to frame medical necessity as imparting a particular moral valence to pharmaceuticals (e.g., as significant for equality of opportunity), which served as the rallying cry (‘access based on need, not ability to pay’) for universalizing insurance as well as allocating medically necessary medications. They stressed the importance of covering drugs that were ‘appropriate,’ or offered demonstrable benefits in terms of safety, effectiveness, and costs to patients, often tying medical necessity to appropriateness.

> Not only can a pharmacare system give Canadians the best health possible, but a pharmacare system could give them much better health care than they currently get. To me it's incredibly important that this message come across clearly in this afternoon's discussion, that giving everybody access to every drug all the time is not good health care. It leads to inappropriate prescribing, which causes real harm to people's health. What we need is to push ourselves and to push Canadians to understand that what they need access to, what they deserve access to, are drugs for which there is good, solid medical evidence. [...].What goes on the formulary should be the drugs for which there is solid evidence, and then there should be a transparent and fair appeals process. – Dr. Martin Danielle, Women's College Hospital (HESA-07 2016:9)

Furthermore, determining and promoting the prescribing and use of medications that had demonstrable comparative benefits in terms of safety, effectiveness, and costs was taken to be a responsibility of public institutions as well independent bodies comprised of experts and professionals; they were seen as being in the best position to regulate and maintain independent systems for the collection and dissemination of credible evidence to inform formulary and clinical practice recommendations. Even in the face of difficult resource allocation decisions for expensive medications with limited evidence, proponents of public pharmacare suggested that public institutions would be best suited to making difficult decisions concerning the fair allocation of limited resources independently and in the public interest.

> I see a public body as more able to strive towards key goals around fairness and access such that these really tough decisions.... Many of them will be challenging decisions. If you are a patient without any treatment options, you are going to consider that medicine essential, but the evidence base at that point in time and the price at that point in time may make coverage prohibitive. – Professor Matthew Herder, Dalhousie University, as an individual (HESA-12 2016:15)

The particular ways in which proponents of public single-payer pharmacare framed and justified the issues of access, costs, and appropriateness underpinned a distinct understanding of the nature and purpose of pharmaceutical insurance. They tended to frame pharmaceutical insurance not only as a mechanism for pooling financial risks associated with high-cost and unpredictable medication use, but also as a mechanism for redistributing responsibility for financing equitably (from higher-income and healthier to lower-income and sicker individuals rather than reflecting their individual health risks). They also saw it as promoting appropriate drug use by ensuring access to medically necessary medications through first-dollar coverage for medications with demonstrated safety and cost-effectiveness profiles, including for routine and chronic medications, and not just catastrophic or high cost drugs. Moreover, they envisioned pharmacare as a constitutive feature of national identity, community, and certain shared values rather than as arising from contingent or private relationships such as between individual employees and employers. In sum, they saw the responsibility for securing access, containing costs, and assessing and promoting appropriate drug use primarily as matters of public, professional (expert), and collective responsibility best dispensed through a public universal, single-payer insurance system.

5.4 Mixed, Multi-Payer ‘Fill-in-the-gaps’ Pharmacare

While public single-payer pharmacare garnered significant attention and support in the contemporary debate, many other stakeholders supported an alternate model of universal pharmacare that would fill gaps in coverage in the existing landscape of multi-payer public and private insurance. Two main types of arguments were presented in favour of a mixed, multi-payer ‘fill in the gaps’ model: one embracing many of the similar objectives as in public pharmacare—including an emphasis on expanding access, containing costs, and ensuring system sustainability—but which argued that a multi-payer model offered the most efficient means of achieving these objectives, and another, which placed greater emphasis on the importance on liberty-based considerations, including ensuring timely access to and choice of a full range of

medications and coverage options, and which was accordingly more critical of centralized mechanisms for financing, negotiating prices, and regulating reimbursement and prescribing practices as they were seen as restricting choice or delaying access to new medications.

5.4.1 Efficiency through Multi-Payer Insurance

While some proponents (e.g., the health insurance industry) of mixed multi-payer pharmacare emphasized many of the same objectives as the proponents of public pharmacare—including calling for expanding access to achieve universal coverage, more equitable drug pricing, and more efficient mechanisms for containing costs and ensuring sustainability—they contested the assertion that a public single-payer system offered the most efficient means for realizing these objectives. In particular, they claimed that the same efficiency gains that could be achieved through a public single-payer model (such as through joint price negotiations, bulk purchasing, and risk pooling for expensive drugs for rare diseases) could also be achieved through cooperation between public and private payers, while also avoiding reductions in coverage for those with existing private insurance coverage and costly upheaval of the existing system. They emphasized that unlike a public, single-payer system, a mixed system would expand access, contain costs, and promote system sustainability without levelling-down or worsening coverage for those with existing private insurance. Furthermore, they contested assertions related to the potential savings on administrative costs in a single-payer system and cautioned about the fiscal challenges associated with shifting costs to the public sector.

> The prescription drug system in Canada must be fundamentally reformed if it is to serve Canadians well in the long-term. The current system is inequitable both in terms of access and price. It is also increasingly being challenged from a financial perspective by the ongoing growth in drug costs which, ultimately, must be paid by plan sponsors, typically employers, or ordinary workers who pay for their prescription drugs through co-payments or directly out-of-pocket. Rising drug costs, particularly related to the increasing incidence of rare but very high cost drugs, undermines the ability of employers to continue to offer drug coverage benefits to employees. […] A pullback on drug coverage by employers would have dramatic implications, not only for individuals, but also for governments who are themselves struggling with rising healthcare costs. Any long-term solution to these challenges will require both public and private payers to make adjustments to their programs and to work more collaboratively going forward. (Canadian Life and Health Insurance Association 2014:i)

> The best solution for Canadians will be the one that leverages the strengths of both the public and private sectors and brings them together in a coordinated

> way. […] Broadly, we believe there are two major issues that need to be addressed. The first relates to putting the system on a more sustainable path financially, and the second relates to greater equity around access. – Mr. Frank Swedlove, Canadian Life and Health Insurance Association (HESA-10 2016: 3)

> Sustainability and access are in all our best interests. Better use of drugs leads to a less expensive healthcare system, and healthier and more productive Canadians. Improvements are within our grasp if we work together – we need more than an evolution, but not full-blown revolution to ensure these changes are made. (Moore and Walters 2017:4)

The health insurance industry and several other stakeholders expressed significant concerns about the sustainability of the existing, fragmented pharmaceutical insurance system, especially given the increasing use of expensive drugs for rare diseases (EDRDs) which posed challenges for the solvency of private insurance plans, and especially those with smaller memberships. However, they argued that if private payers could join public payers in negotiating drug prices, such as by joining the Pan-Canadian Pharmaceutical Alliance, as well as work on a joint strategy for financing EDRDs or 'orphan drugs', the cost savings and efficiency gains to be achieved through centralized price negotiations and risk pooling could be achieved in a multi-payer system with the added benefit of not reducing coverage for those with existing private plans. They noted that the private insurance industry had started to adopt joint risk pooling, especially for small and medium sized insurance pools, in order to maintain sustainability in the face of reimbursements for expensive drugs for rare diseases. However, they also noted the current anti-competition laws prevented private insurers from engaging in joint price negotiations amongst themselves (CLHIA 2014:17). They also suggested that joint price negotiations and avoiding shifting costs to the public sector would help the sustainability of drug expenditure in the public sector as well. Furthermore, although not always stated explicitly, they tacitly invoked liberty-based claims when characterizing employer insurance contributions as advantageous as they were voluntary, unlike the compulsory contributions required for public insurance.

> If the growing burden of high cost drugs, in particular, is not addressed there is a real risk that employers will take steps to restrict their drug coverage. […] Any significant reduction in coverage by employers would have dramatic implications, not only for individuals, but governments as well. (Canadian Life and Health Insurance Association 2014:2)

> With respect to very rare drugs, or "orphan drugs", we equally believe that governments and private insurers need to work together to develop a common approach to providing access to these medications. If there is one area where a

> common approach is critical, it is for those drugs that have very small patient populations, yet have very significant costs associated with them. – Mr. Frank Swedlove, Canadian Life and Health Insurance Association (HESA-10 2016:3)

> […] 8. Leverage the buying power of the full Canadian drug system to negotiate lower prices and create a competitive market mechanism to set prices for inter-changeable drugs for all payers.
> 9. Implement government-funded programs which creatively combine with private medical plans to ensure that all Canadians have appropriate coverage and yet retain the voluntary contribution from private payers.
> 10. It is critical to keep the $11B of private voluntary contributions flowing into the system. There are ways to redesign the system that keeps this source of funding while ensuring coverage for all. (Moore and Walters 2017:4)

> Expensive specialty drugs have greatly improved the lives of patients, but at significant and growing cost to all. As greater numbers of specialty drugs enter the market or new indications are approved for specialty drugs they will become an increasing financial burden that may not be sustainable. It becomes important to manage these costs and to spread the risk as broadly as possible. (West 2016:10)

Moreover, they argued that the main cost savings and efficiencies that could be achieved through a centralized, single-payer system were tied to price negotiations and bulk purchasing, while they contested that a public single-payer system would offer further efficiency gains in the form of lower administrative costs.

> Mr. Frank Swedlove: […] The governments turn to our industry [private health insurance] to provide that [administrative] work because we do it more effectively and more efficiently than the governments can do it.
> Ms. Rachael Harder: Let me pick up on that, because I think you make a good point. Other presenters, include the other one who is here with us today, Anita, have mentioned that they feel that government could do it more efficiently and with less cost. Can you comment on that for me?
> Mr. Frank Swedlove: I think the basis of that thinking is the fact they can negotiate a lower price because they would be using the entire Canadian market. That is an important factor, and that's why we say if we are able to join with the provinces to negotiate a price that reflected the entire market of Canada, then we would all share in those lower costs. That's where you save the money. (HESA-10 2016:9)

> Insurance companies are in general, effective drug plan administrators and claims adjudicators with low profit charges on low risk large drug plans. National insurers have complex payment systems and awareness of provincial variations that could assist in development of an effective integrated drug payment system while maintaining a broad drug formulary to serve employers well. (West 2016:11)

In addition to promoting cost-savings, joint price negotiations were seen as promoting fair pricing as they could secure the same drug prices for all payers, rather than having Canadians paying out-of-pocket or through private insurance pay higher drug prices than those with public coverage, as is presently the case (Canadian Life and Health Insurance Association 2014:3).

As noted earlier, proponents of mixed multi-payer insurance argued that a distinct efficiency-promoting advantage of such a model was that it would avoid reducing coverage for many Canadians with existing private coverage. As private plans tended to offer more comprehensive coverage than public plans, 'fill in the gaps' pharmacare would focus on improving overall access rather than reducing or levelling-down coverage. They asserted that a mixed system would maintain access to a broader range of medications as well as insurance options, which could be tailored to the needs of individual organizations and offered additional benefits in the form of services such as case management.

> First of all, private insurers generally provide Canadians with access to far more drugs than public plans, and we allow access to new drugs much more quickly than public plans. This is a critical point because, contrary to what many advocates for reform suggest, nationalizing prescription drug coverage will result in a material pullback in coverage for the majority of Canadians. Second, Canada's insurers have also introduced some of the most important patient-centred innovations over the past several years. […] A good example of that is what we refer to as case management. – Mr. Frank Swedlove, Canadian Life and Health Insurance Association (HESA-10 2016:12)

> The majority of Canadians are covered by private plans, and many are satisfied with their current plan. They hear stories about moving to a public plan that would cover everybody and that there might be a reduction in the benefits they receive. Roughly three-quarters of Canadians were concerned that moving to a national first-dollar public plan would actually result in lower coverage for themselves. – Mr. Perry Eisenschmid, Canadian Pharmacists Association (HESA-11 2016:13)

Indeed, when it came to the comprehensiveness of coverage, proponents of a mixed system argued that the broader or open formularies offered through private insurance granted patients access to a wider range of medically necessary medications than public plans. They argued that controlling costs by restricting access could impact patient health outcomes and welfare as well as physician choice of medication, as they claimed had happened in other jurisdictions.

> I think the bottom line is that the way you tend to control cost is by restricting access. [...] We're getting some interesting data around cancer survival rates in

> the U.K., which are slipping and falling behind, and they've been slower than other countries to approve new cancer drugs. There's a link there, to the point that the government in the U.K. has just had to introduce a completely new program to start re-funding cancer drugs again so that they can do a catch-up. They may have overreached there. New Zealand is a very low-cost environment but has an extremely restricted formulary. Polling of doctors there suggests that 75% of them in the last year have wanted to prescribe a drug that they've been unable to prescribe because it's not on their closed formulary. So this is a trade-off. We could design a system in Canada that would be very cheap, but it would come at the expense of access. That has outcome consequences and implications for patients. – Mr. Stephen Frank, Canadian Life and Health Insurance Association (HESA-10 2016:6)

In this sense, they framed the concern around reducing or levelling down coverage primarily as one of efficiency—as they emphasized the potential harms to patient health and welfare that would result from reduced coverage or restricted access—rather than solely a liberty-based concern pertaining to patient and prescriber choice.

The health insurance industry and some other proponents of multi-payer pharmacare, including the Canadian Pharmacists Association, recommended creating a common formulary to establish a national minimum threshold of coverage. They saw a national formulary as promoting both equitable access (at least at a threshold of sufficiency) as well as efficiency, since it would reduce costs associated with fragmentation; however, they did not see it as necessarily requiring a public single-payer program.

> Low spending and a comprehensive formulary do not require a single payer model. Use of a single payer model requires the tremendous upheaval of both provincial and private insurance. Consideration should be given to a more targeted approach, at least as a starting point, to benefit about 10% of Canadians with inadequate or no drug insurance. (Bonnett 2017:2)

> The industry supports the establishment of a common national minimum formulary. Such a national minimum formulary would ensure a baseline of coverage for all Canadians and would reduce some of the existing complexity in the system. This approach would still allow those provinces, plan sponsors, or individuals who want additional coverage to have it. – Mr. Frank Swedlove, Canadian Life and Health Insurance Association (HESA-10 2016:3)

While the health insurance industry primarily appealed to efficiency, and to a lesser extent, equity- and liberty-based arguments in advocating for multi-payer pharmacare, efficiency and liberty-based arguments were not always clearly distinguished and were often invoked in tandem as I discuss in the next section.

5.4.2 Maintaining Choice through a Multi-Payer System

A second type of argument commonly offered in favour of multi-payer insurance placed greater emphasis on liberty-based concerns. Some stakeholders, such as certain patient groups (including the Best Medicines Coalition, which is a coalition of patient groups, Canadian Cancer Survivor Network, and Mood Disorders Society of Canada), brand name pharmaceutical manufacturers, and free-market-oriented think-tanks, also advocated for a mixed multi-payer model, but framed their concerns more explicitly in terms of liberty-based considerations in addition to some of the efficiency concerns cited above. For example, they emphasized the importance of patient and prescriber choice and ensuring access to a full range of drugs and insurance options in a timely manner. These types of arguments still acknowledged expanding access and coverage as a pharmacare policy objective, but they largely focused their attention on expressing concerns that commonly recommended cost-containment strategies, such as formularies or joint price negotiations, would restrict patient choice and timely access to a full range of medically necessary medications. Moreover, they framed the policy issue of access as primarily concerning timely access to new medications and access to a full range of medications. They wanted patients to have access to medications unrestricted by government regulation or other administrative bodies as they considered patients and clinicians best able to assess and account for the unique circumstances and medical needs of individual patients when selecting medications.

These stakeholders also cautioned against adopting pharmaceutical insurance that would level down or worsen coverage for those with existing private plans, which offered more comprehensive coverage than would likely be available through a public single-payer plan.

> I think our industry [research-based or brand name pharmaceutical manufacturers] would take the position that it would be a willing partner at the table with any government decision to move forward in this area [the creation of a national formulary]. Our main concern would be that we would move from a status quo position that would improve access for everybody and not require decreased access for any Canadian. – Mr. Brett Skinner, Innovative Medicines Canada (HESA-14 2016:8)

> The focus of Canadian pharmacare discussion should be to extend and improve coverage to those within adequate coverage, not weaken the drug benefits of the large majority of Canadians that currently have good coverage. – Mr. W. Neil Palmer, PDCI Market Access (HESA-09 2016:5)

Moreover, they emphasized the need to have an insurance program which neither delayed nor restricted access to new medications (including on the basis of cost-effectiveness), since they viewed such restrictions as both limiting choice as well as potentially harming patients and costing the health care system more, which is framed as a dual concern for liberty and efficiency.

> This makes it very difficult to treat mental illness if the correct drug is not available because it has not been approved for use, because it has not been made available on either a provincial or federal formulary, because it is too expensive for patients, or because there is a cap on mental illness drugs covered by a public pharmacare program. A national pharmacare program must take into account new and innovative medicines that are able to treat patients better and allow them to truly recover full functionality from their illness. After all, simply keeping the symptoms at bay will cost Canada more in the long run. (Mood Disorders Society of Canada 2016:7)

> The implementation of a publicly-funded national pharmacare program combined with other cost containment initiatives (such as reference pricing, therapeutic substitution, preferred drug lists, etc.) may limit the choice of medicines for physicians and patients if their preferred therapy (or the most effective therapy) is not covered. This may negatively impact patients, and ultimately prevent the initiative from reducing overall expenditures. Given that patients react differently to different medicines in terms of both benefits and side effects, changes in therapies may have negative health impacts for patients or increase the disability burden of disease. Private costs might also increase if patients choose to remain on their preferred medicine and are forced to fully cover the cost or pay the price differential between their preferred medicine and the one covered by the national program. Furthermore, the lack of access may play out in other ways too: through the delayed introduction of new innovative medicines and delayed introduction of low-cost generics. Each of these can lead to poorer health outcomes, additional expenditures on non-pharmaceutical forms of care, and avoidable prescription costs. (Acri 2018:33)

Furthermore, they cautioned that cost-containment methods such as price negotiations and tendering—which the insurance industry had supported—could result in harmful consequences such as contributing to drug shortages and threatening a sustainable supply of medications (e.g., if a tendering process results in relying on single drug manufacturer to produce a medication) or disincentivizing pharmaceutical manufacturers from investing into research and development of innovative medications.

> At the same time, no such plan should put patient access at risk by making drug supplies dependent on a few manufacturers, or limiting treatment options by favouring one manufacturer over another. Greater pharmaceutical and other health manufacturers' investment in Canada would encourage increased choice,

> innovation, cost-effectiveness, and availability. (Best Medicines Coalition 2006:21)
>
> Bulk Purchasing agreements have been shown to consistently generate cost savings. Those savings are sometimes passed along to consumers, potentially encouraging adherence to prescribed drug regimens. However, these policies may also limit choice for patients and physicians whose preferred drug is left out of the agreement, may lead to monopolistic supply conditions, and may lead to increased prices for other drugs in exchange for the lower price on the negotiated drug. (Esmail and Barua 2015:35)
>
> The cost to the federal purse must be balanced with the need to maintain an environment that allows for the industry to remain competitive and innovative so that patients are able to choose their care. (Mood Disorders Society of Canada 2016:9)
>
> A model national formulary must recognize the need for new innovative medicines and allow for individualized patient care. As a starting point, drug plans could focus on harmonizing listing decisions for new therapies to increase treatment options. And while a national formulary would help ensure increased equity across the country, every effort should be made to avoid the risks associated with using this formulary to achieve excessive price reductions that could lead to more limited access (for example drug shortages), and without consideration of how this would impact the overall system. (Canadian Pharmacists Association 2017:9)

Similarly, many of these stakeholders also voiced reservations about strategies aimed at informing prescribing, such as the use of a national formulary, which were accepted by the health insurance industry. The use of formularies was often framed as worrisome both on efficiency- and liberty-based grounds, since formularies were seen as aiming primarily at cost-containment and thus restricting patient and provider access to and choice of medications as well as potentially worsening health outcomes:

> The group also concluded that the solution of creating a prescriptive list of medicines to be provided across Canada was not a best practice. While it might enhance coverage for some, it may well reduce or limit coverage for others. The result of any health policy change should not be to create a floor but a best practice for all. (Canadian Cancer Survivor Network 2016:2)
>
> I guess the concern is, what are you getting in terms of health outcomes by making that shift [to public insurance]? You're simply moving all the dollars and costs over, and everybody has the same plan. It may address that equity question, but it's certainly not improving the health outcomes generally for the people who already have coverage. – Mr. W. Neil Palmer, PDCI Market Access (HESA-09 2016:15)

Unlike proponents of public single-payer insurance, these stakeholders did not emphasize, or in most cases, even discuss 'appropriate' medication use; instead, they emphasized the importance of patients and prescribers having access to and choice of a full range of medications, including to new medications. Accordingly, the range of medications they deemed to be 'medically necessary' was broader than that which proponents of public pharmacare considered to be 'appropriate'. Proponents of mixed pharmacare tended to emphasize the importance of timely access—largely understood as access unencumbered by regulatory delays—to new medications. They saw public plans as restricting and delaying access to innovative medications as, on average, they required longer to approve new drugs for reimbursement, usually owing to cost-effectiveness evaluations. These positions could also be understood as anti-paternalist as they saw regulations as limiting the freedom of patients and clinicians to determine whether a drug's safety, effectiveness, and cost profile suited the individual's medical needs and preferences.

> Pharmaceuticals are a fundamental component of any well-functioning health care system. Research has consistently shown that the consumption of prescription drugs (and, in particular, newer prescription drugs) is related to better health outcomes and increased longevity. (Esmail and Barua 2015:33)

> First, our first priority is patient access to necessary medicines to meet diverse patient needs; second, we believe that maintaining the prescriber-patient relationship and choice are both critical and fundamental rights; third, we must address the gaps in care and access to treatment for the uninsured and those who cannot afford it; fourth, we believe in direct public funding for those most in need; fifth, the economic and societal benefits of medicines and vaccines must be considered; sixth, Canada's health care system must support innovation and the adoption of groundbreaking science and technologies to improve health outcomes; and seventh, any program must provide the best standard of care for all Canadians, not simply cost-containment driven solutions. Programs focused on cost-containment often mean reduced access to medicines, the exact opposite of what we would hope for Canadians. – Mr. Glenn Monteith, Innovative Medicines Canada (HESA-14 2016:5)

In addition to restricting access to medically necessary medications, some argued that a uniform, national pharmaceutical insurance program would limit provinces and territories from tailoring their pharmaceutical benefit programs according to different population needs and fiscal circumstances (Esmail and Barua 2015:10).

Some also voiced concerns about shifting costs from private to public payers on liberty-based grounds, as single-payer insurance restricted choice in insurance, as well as on efficiency grounds, such as by citing efficiency-losses associated with increased taxation.

> It is critical to account for this deadweight loss of taxation, and to recognize the important ways in which this contrasts with insurance premiums. Insurance premiums are sometime mischaracterized as "hidden taxes." The fact is, these premiums do not impose the deadweight loss on society that income taxes do. The efficiency gains and cost savings generated by insurance premiums, relative to tax revenues raised through income taxes, must be recognized and appreciated. (Acri 2018:25)

Similarly, some raised liberty-related concerns about increased taxation, which was seen as restricting patient choice in how to spend their money and echoed aforementioned distinctions between voluntary and compulsory insurance contributions. Conversely, the subsidization of insurance for low-income individuals within a multi-payer mixed or private insurance system was framed as promoting choice (Esmail and Barua 2015:54).

> Since the 1970s, provincial governments have taken away from Canadians a great deal of their freedom to choose the prescription drugs they use. Provincial drug-benefit plans now account for almost half of the country's prescription spending, forcing Canadians to trade off an easily measured burden on taxpayers with benefits to patients that are not well measured. (Graham and Tabler 2005:1)

Indeed, proponents of mixed multi-payer insurance tended to frame pharmaceutical insurance as a voluntary (or arising from voluntary, private employee-employer relationships) mechanism to pool risks for unpredictable, high drug costs which would be financed through 'actuarially-fair' premiums, which reflected an individual's health risks.

> An insurance plan that functioned well would take on the liability of catastrophic expenses for relatively unpredictable and otherwise unmanageable diseases while keeping patients financially liable for diseases relatively more predictable and less costly to treat. (Graham and Tabler 2005:15)

However, many proponents of mixed multi-payer insurance envisioned a role for private insurance payers in offering coverage for lower-cost, routine drugs while also involving the public payer to provide coverage for highly expensive drugs. Patient groups were particularly adamant about including coverage for routine, lower-cost drugs. However, proponents of mixed multi-payer insurance tended to place greater responsibility on individual patients in contributing to routine drug costs through co-pays or deductibles. They saw cost-sharing mechanisms as ways

to limit inappropriate or unnecessary drug use and moral hazard; some even cautioned that low co-pays were insufficient for incentivizing patients to manage their consumption of medications.

> Asking patients to take responsibility from the first dollar of coverage does not deny choice between medicines, it simply increases patients' motivation to make the appropriate trade-off between taking a medicine and all the other goods and services upon which they can spend their money. (Graham and Tabler 2005:10)

Finally, it is worth noting that no stakeholders in the contemporary debate argued explicitly against *universal* pharmaceutical coverage, although some approached it with tacit skepticism. They tended to argue against public single-payer pharmacare in particular by drawing on the liberty and efficiency-based arguments discussed above, as well as by calling into question commonly-invoked evidence about gaps in coverage in the current insurance landscape. The few stakeholders who approached universal pharmacare with skepticism called into question evidence concerning the existing levels of cost-related non-adherence and underinsurance, noting that commonly-reported statistics were unreliable or overestimated the extent to which people were actually un- or under-insured. Indeed, they pointed out that most Canadians were insured, even if they were perhaps unaware of or had not accessed their coverage (e.g., in the case of catastrophic coverage offered by some provincial public plans), and thus argued that the impetus for significant pharmaceutical insurance reform was lacking.

> However, the comprehensive analysis undertaken in this report reveals that the majority of Canadians have access to drug insurance through private or public plans, or even both. In addition, the research estimated 4.1 million Canadians (or 11.3 per cent) are not enrolled for either public or private coverage, despite being eligible. The number of non-enrolled varies widely and for different reasons across provinces. Survey results can provide some context, including the potential role of lack of awareness of public programs, lack of need, or out-of-pocket costs and premiums, as possible reasons for non-enrolment. (Conference Board of Canada 2017:iii)

Similarly, they questioned the extent to which pharmaceutical coverage required expansion by arguing that all provinces and territories already offered public pharmaceutical coverage, including catastrophic coverage, for individuals on social assistance (who could be considered 'priority' populations on a prioritarian account of justice as they were the least well off).

> Similarly disingenuous, when it comes to Canada's vulnerable citizens, are claims of a lack of access to prescription medications … Analysis of existing drug coverage shows that, in every single province, Canadians on social

> assistance receive coverage for drugs at very low or no cost to the patient, and that lower income Canadians across the country receive, at a minimum, catastrophic insurance for prescription drugs. A national drug plan would add little to such existing levels of coverage. (Esmail and Barua 2015:ii)

5.4.3 Dissent within the Standing Committee on Health

While the Standing Committee on Health's (HESA) final recommendations called for the introduction of public single-payer insurance, a minority of MPs, representing all of the committee members from the Conservative Party of Canada, published a dissenting statement appended to the report; they voiced efficiency- and liberty-based concerns in response to the call for public single-payer insurance (Standing Committee on Health 2018:117-120). In their statement, the CPC MPs referenced the testimony of industry and patient group representatives who advocated for mixed multi-payer insurance more often than had been referenced in HESA's main report, which placed greater emphasis on the testimony of academic and medical experts and other proponents of public single-payer insurance.

The dissenting statement voiced three main concerns: that the cost-savings predicted in the PBO's costing model were uncertain owing to a number of factors which had been assumed, were unaccounted for, or were based on uncertain or contested evidence; that reducing high per-capita drug costs ought to be prioritized prior to expanding coverage, and which could be done through a variety of policy mechanisms that did not require a public pharmacare program; and that public pharmacare would reduce coverage for those with existing private insurance as well as result in job losses in the private insurance sector.

> Another important consideration is the willingness of Canadians who are currently covered by private insurance plans to transition to a mandatory public program, which in most cases, will provide less coverage than they are currently receiving. It is anticipated that many of the unions who have fought for what are considered excellent coverage plans may be unwilling to convert to a public plan, and that there may be court challenges on that front. The shifting of coverage from private plans to a public plan is not fully understood and more needs to be done to inform the public of any proposed changes. (Standing Committee on Health 2018:119)

Moreover, they called into question the federal government's ability to efficiently manage a complex national program and data management system by referencing past failures in implementing national information systems (e.g., Phoenix) (Standing Committee on Health

2018:118-119). Accordingly, they invoked a long-standing refrain in Canadian pharmaceutical policy by calling for incremental reforms, which would first aim to contain drug costs in order to make expanded access and universal coverage feasible in the future.

> The Consumer Products Association provided the Committee with information that [changing certain prescription medications to over-the-counter drugs] would save billions of dollars in prescription drug costs; moving only the top three relevant prescriptions to over the counter would save $1 Billion. These savings, along with any savings that could be realized from generic price leveraging, volume leveraging, or from better drug selection […] could be applied to find the funds needed to ensure all Canadians have coverage. (Standing Committee on Health 2018:120)

5.4.4 Summary and Implications

Proponents of mixed, multi-payer insurance argued that a multi-payer insurance scheme that would fill gaps in coverage in the existing multi-payer insurance landscape would offer the most efficient and liberty-preserving approach to universal pharmaceutical coverage. As with arguments for public insurance, the particular normative justifications invoked by proponents of mixed pharmacare had implications for how they framed the issues of access, costs, and appropriateness, as well as how they conceived of the purpose of pharmaceutical insurance. Many proponents of mixed public-private or private models framed the policy objectives of pharmacare as primarily the responsibility of individuals or arising from private relationships (e.g., between employees and employers), and accordingly saw the appropriate level of policy intervention as residing at the micro-level, or as arising in the context of the individual patient-clinician encounter or employee-employer relationship.

With respect to access, proponents of a mixed system acknowledged the need to expand and even universalize drug coverage to address financial barriers to access, but they also tended to emphasize barriers to access associated with government regulation. For example, they saw attempts to regulate access to medications through a national formulary—which they framed as a tool for cost-containment rather than promoting equitable or appropriate drug use—as restricting patient access to drugs, since formularies both delayed the time required to approve a drug for reimbursement as well as restricted the range of drugs that were covered or even marketed. Proponents of mixed pharmacare framed the responsibility for ensuring access to pharmaceutical insurance primarily as a responsibility of individuals, or as arising through private relationships,

such as between employees and employers. Nonetheless, they often conceded that there was a public obligation to extend support to low-income individuals or those with extremely high drug costs. For example, even those who questioned the need for universal pharmacare often argued that significant reforms and programmatic expansion were not required as public programs already offered coverage for certain priority populations, such as individuals on social assistance.

As with access, proponents of mixed multi-payer pharmacare who advocated for a greater role for the private insurance sector framed cost-related issues in a different manner than proponents of public pharmacare. Proponents of a mixed system who argued for the need to improve the efficiency of the system and to reduce costs, such as by having public and private payers engage in joint price negotiations, also saw high drug prices as a concern. However, others focused more on the impact of the use of medications, or restricted access to new medications, as contributing to high costs. Unlike proponents of public single-payer pharmacare who were largely adamant about the need to encourage appropriate prescribing and drug use through the use of a formulary for cost-effective medications, proponents of mixed pharmacare tended to see the responsibility for containing costs and limiting inappropriate or wasteful drug use as lying with individual patients and prescribers. Moreover, rather than seeing co-pays or deductibles as posing barriers to access, they framed them as incentives that encouraged individuals to manage their consumption of drugs in line with their overall priorities and preferences, and thus limiting unnecessary drug use and limiting moral hazard. Some also voiced concerns that efforts to reduce drug prices would harm patients by restricting market access of existing medications or discourage research into novel therapies.

Finally, proponents of mixed multi-payer pharmaceutical coverage argued that appropriate drug use was best determined in the course of the individual patient-clinician encounter on the basis of the unique characteristics and circumstances of the patient. They claimed that top-down, population-level approaches for determining prescribing, such as through a national formulary, lacked the sensitivity to attend to the individual medical needs of individual patients and thus restricted access for patients with unique health needs. Moreover, they saw public mechanisms as either motivated by cost-containment, rather than the patient's best interests, or as paternalistic if they purported to protect patients from inappropriate drug by restricting or delaying access on the basis of a drug's safety or effectiveness profile. Accordingly, they considered a broader range of medications as being medically necessary or appropriate than proponents of public

pharmacare had advocated to include on a national formulary, and asserted that patients and clinicians ought to have timely access to and choice of a full range of medications.

As with arguments for public pharmacare, the ways in which proponents of mixed pharmacare framed the problems of access, costs, and appropriateness underpinned a particular conception of the purpose of pharmaceutical insurance; in this case, they saw pharmaceutical insurance as a voluntary mechanism for pooling risks with the addition of a residual public subsidy for low-income individuals or individuals with particularly high drug costs. Many proponents of mixed public-private or private models saw the financing, organization, and decision-making concerning the prescribing and use of medications as primarily being the responsibility of individuals or arising the context of private relationships. Moreover, they advocated for charging premiums that reflected the actuarial risk that an individual or group of individuals presented to an insurance pool. They considered a mixed multi-payer system to be the most efficient and liberty-preserving mechanism to offer such insurance as it avoided levelling down or worsening coverage for those with existing private insurance. The concern about levelling-down stemmed from their assertion that only individual patients and clinicians could and ought to be responsible for adjudicating medical necessity and appropriate drug use. Limiting coverage to drugs on a government formulary that only reimbursed for medications deemed appropriate by an expert or government panel was seen as overly restrictive and as a blunt tool that would not account for the unique needs and preference of individual patients.

5.5 Catastrophic Coverage

Universal catastrophic coverage, which would offer all Canadians financial protection against undue financial burdens associated with the use of chronic or expensive medications, was also considered as a pharmacare policy option[113]. As I alluded to throughout the chapter, catastrophic coverage received serious attention in the early 2000s; it was recommended in both the Romanow and Kirby Reports and was a component of the National Pharmaceutical Strategy. For example, the Romanow Report recommended introducing universal catastrophic coverage as a

[113] Catastrophic coverage is presently the most commonly offered form of public pharmaceutical coverage in Canada; seven provinces offer catastrophic coverage, albeit with varying eligibility and financing arrangements (Health Canada 2019).

first step towards the eventual integration of pharmaceuticals into Canada's existing public single-payer Medicare system, which offers comprehensive, first-dollar coverage; others (e.g., Kirby), however, did not explicitly frame catastrophic coverage as an incremental reform. While there was limited discussion of catastrophic coverage (as such) in the contemporary debate, many stakeholders, including proponents of public or mixed pharmacare programs discussed above, called for a dedicated strategy to address the financing of 'orphan' drugs, or expensive drugs used to treat rare diseases. For example, the Advisory Council called for a dedicated strategy for expensive drugs for rare diseases and the 2019 federal budget proposed to invest over a billion dollars for this explicit purpose.

Proposals for catastrophic drug coverage usually recommended implementing catastrophic coverage within the context of the existing multi-payer insurance landscape, but through a public plan offering universal catastrophic coverage for annual drug costs exceeding a fixed amount (e.g., Romanow and Kirby both suggested $1,500) or percentage of a household's income. In other words, a public catastrophic insurance plan financed by the federal government would serve as the insurer of last resort for existing public and private plans, as well as for individuals without any coverage, to limit out-of-pocket spending on drugs for all Canadians.

Universal catastrophic coverage was justified on the grounds that it would both offer equitable financial protection for high drug costs and it would be secure the sustainability of private, but also public, insurance plans by pooling risks associated with high drug costs.

> In developing its proposal to expand the federal government's role in health care to include protection against the impact of severe or "catastrophic" prescription drug expenses, the Committee has sought to accomplish two objectives. First, and foremost, the Committee wants to make sure that no Canadian individual or family is exposed to undue financial hardship as a result of having to pay all, or even a significant fraction, of the costs of extremely expensive and/or prolonged prescription drug treatments. This is entirely consistent with the basic public policy objectives underpinning the system of public health care insurance in Canada. Second, the Committee wants to create the conditions for long-term sustainability of current prescription drug coverage programs, both provincial public and private supplementary drug insurance plans, in the face of escalating prescription drug costs and the anticipated introduction of increasingly expensive and effective drug therapies. (Standing Senate Committee on Social Affairs, Science and Technology 2002:137)

Where catastrophic coverage differed from universal public coverage was that it prioritized securing financial protection for high drug costs while still leaving individuals responsible for routine or smaller drug costs. Many arguments for universal catastrophic coverage echoed arguments for public first-dollar coverage about ensuring that Canadians had consistent and equitable protection from the uncertainty and financial risks associated with illness owing to the importance of financial security for fair equality of opportunity or as a fundamental tenet of Canadian Medicare and identity.

> Drugs, once a small portion of total health costs, are now escalating and among the highest costs in the system. The expense associated with some drug therapies or of providing extended home care for a seriously ill family member can be financially devastating. It can bankrupt a family. This is incompatible with the philosophy and values upon which medicare was built. (Commission on the Future of Health Care in Canada 2002:xvii)

There was a sense that individuals ought not to be held responsible for covering high drug costs, whether they occurred as a result of chronic medication use or acute high cost therapies, in contrast with 'modest' costs that could be considered reasonably foreseeable and budgeted for.

> Two percent of Canadians (some 600,000 individuals) have no prescription drug coverage whatsoever and must assume full personal financial exposure in the event they require expensive prescription drugs. (Standing Senate Committee on Social Affairs, Science and Technology 2002:133)

In that sense, proponents of catastrophic coverage espoused an understanding of pharmaceutical insurance as primarily a mechanism for pooling reasonably uncertain risks.

Proponents of universal catastrophic coverage also invoked the efficiencies associated with risk pooling to justify universal catastrophic coverage. As with arguments for public single-payer and mixed insurance, proponents of catastrophic coverage voiced concerns about the solvency of individual drug insurance plans given the increasing use of expensive drugs for rare diseases (EDRDs). A catastrophic drug plan where the federal government would cover drug costs exceeding a certain threshold for all Canadians, irrespective of whether they had public, private, or no supplementary coverage, would in effect render the federal government an underwriter for other insurance plans and would pool the risks associated with high cost drugs nationally, rather than keeping them siloed within thousands of individual pharmaceutical insurance plans. For example, the Kirby Report proposed that the federal government would assume 90% of

catastrophic drug costs for claimants with annual expenses exceeding $1,500 or 3% of household income, whichever amounted to the lesser expense, irrespective of their other insurance coverage, and would thus stabilize the pharmaceutical insurance market by reducing the subjective uncertainty associated with expensive drugs and incentivize employers to offer competitive benefit plans (Standing Senate Committee on Social Affairs, Science and Technology 2002:141).

In the contemporary debate, documents tended to call for a dedicated strategy for EDRDs rather than universal catastrophic coverage. They noted that EDRDs, which resulted in unpredictable but sizeable costs, were a special case in which a centralized system of public financing and cost-sharing was required to ensure the solvency and sustainability of drug insurance programs.

> One element of employer drug plans likely to have profound financial implications to governments, employers and patients alike is insurance drug pooling unsustainability. As employers reach their affordability threshold, public plans or patients will assume the financial burden for specialty and moderately priced drugs. The risk of this happening is high and rapidly increasing as savings from generic drug reform and the patent cliff diminish. (West 2016:10)

Proponents of catastrophic pharmacare pointed to other challenges facing Canadians in the absence of financial protection from high drug costs, including consequences ranging from harms associated with discontinuing or not starting medication use, higher health care costs, perverse incentives to remain on social assistance, and the unsustainability or deterioration of private insurance plans (Standing Senate Committee on Social Affairs, Science and Technology 2002:133).

Most proponents of catastrophic insurance also cited the need to develop a broader pharmaceutical strategy, which would include institutions and mechanisms such as a national drug agency, a national formulary, and a cooperative drug purchasing strategy, to address issues of costs, access, and appropriateness in an equitable and efficient (both through economies of scale and information transmission) manner, as had been argued for by various proponents of public single-payer and even mixed multi-payer pharmacare .

Proposals for catastrophic coverage often appealed to similar arguments as offered for public pharmacare, which is not surprising given that they saw the public payer as an insurer of last

resort for high drug costs. However, catastrophic coverage would leave individuals responsible for lower or routine drug costs, and would not address the different cost burdens faced by individuals with public, private, or no coverage (as in practice, only individuals without additional insurance would remain personally responsible for paying for their routine drug costs).

5.6 Conclusion

In this chapter, I characterized the main policy arguments in the contemporary pharmacare debate in terms of their underlying normative positions. My major finding is that the tensions at the centre of the debate were normative and not only evidentiary in nature. While there was convergence around the objective of expanding and universalizing pharmaceutical coverage, proponents of public or mixed pharmacare appealed to different normative models of health insurance to frame the issues of access, costs, and appropriateness in distinct ways. As a result, proponents of public pharmacare saw addressing the problems of access, costs, and appropriateness primarily as matters of public, professional (expert), and collective or shared (and in this case, national) responsibility, while proponents of mixed pharmacare saw them as arising primarily in the context of private relationships between individual patients, clinicians, employers, or insurers.

I also described how the tenor of the debate has changed over time. Historically, the pharmacare debate has been characterized by arguments against the status quo—primarily in the form of calls for universal public pharmacare—yet early reports often considered public pharmacare as a long-term ideal rather than an immediately realizable one. The contemporary debate saw convergence around the objective of universalizing coverage, so the debate centered primarily on determining whether universal coverage should take the form of public single-payer or a mixed multi-payer insurance. I suggest that proponents of public single-payer pharmacare were successful in promoting their position and transforming the narrative about public pharmacare, at least insofar as it was eventually adopted as the preferred model in both the Standing Committee on Health's and Advisory Council's final recommendations, owing to their ability to marshal evidence and shift the focus of the debate to efficiency-based arguments rather than primarily equity or communitarian ones. Nonetheless, not all stakeholders shared the same conceptualization of efficiency. Proponents of mixed, multi-payer pharmacare saw proposals to limit coverage to pharmaceuticals listed on a national formulary, and in some cases to negotiate drug prices, as

worsening or restricting access to medically necessary medications. Thus, even understandings of concepts that were seemingly technical or value-free, including medical necessity and efficiency, were contested based on stakeholder's differing underlying normative positions.

Upon reflecting on the points of tension in the contemporary pharmacare debate, several outstanding questions remain: What purpose ought pharmacare fulfill?; What constitutes medically necessary and appropriate drug use and who can legitimately adjudicate it?; How ought principles such as community, efficiency, equity, and liberty be understood in the context of pharmacare?; What are the implications of framing pharmacare as a politically normative debate? In the following chapter, I turn to exploring these questions in greater depth while discussing the findings presented in this chapter in light of material presented earlier in chapters 2 and 4.

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Chapter 6
Discussion

> The welfare state is, first and foremost, a political artefact. As such, it is a product of historical accretion and political compromise. Different bits have been added, over the years, by different people with different purposes in mind. It is today supported by many diverse groups, for many diverse reasons. (Goodin 1988:3)

6 Discussion

This thesis set out to articulate how a bioethics analysis can contribute to understanding and informing the contemporary pharmacare policy debate in Canada. In the preceding chapter, I analyzed documentary and testimonial data from the pharmacare policy debate. Drawing on theoretical perspectives from political philosophy and public health ethics, I characterized the main policy arguments in the debate in terms of their underlying normative positions, which served to address the descriptive aim of my inquiry. I described two primary findings: first, that different pharmacare policy proposals appealed to different underlying normative positions, which in turn shaped distinct framings of issues related to access, costs, and appropriateness, and accordingly, ideas about the purpose of pharmaceutical insurance and who ought to be responsible for realizing it; second, I described the progression of arguments and normative justifications in the debate since 1997, noting that the contemporary debate can be characterized by agreement around universalizing access (in some form), and that public single-payer pharmacare has attracted greater attention on the basis of not only its equity- or community-promoting, but especially its efficiency-promoting features. However, what is deemed efficient and fair is disputed between different stakeholder groups, often as a result of distinct understandings of the purpose of insurance, and accordingly, prioritizations and appeals to medically necessary or appropriate pharmaceutical prescribing and use.

Accordingly, my inquiry suggests that tensions in the pharmacare debate are characterized largely by disputes over normative (political) objectives—what the purpose(s) of pharmacare ought to be—rather than solely or primarily about empirical or technical disagreements concerning which model of pharmacare can best deliver on a particular objective. The key issue, then, which remains unresolved and leaves pharmacare policy at a discursive impasse is what the purpose of pharmaceutical insurance *ought* to be.

This chapter builds on the findings presented in the preceding chapter in order to address the analytic and normative aims of my inquiry addressed in my second research question; I consider how normative and political philosophy can contribute to understanding and informing the pharmacare policy debate. The chapter consists of three main sections. First, I analyze the normative disagreements at the centre of the debate, which concern the purpose of pharmacare policy. Second, I discuss certain implications of framing the pharmacare debate as a politically normative debate. Third, I address the normative aim of my inquiry by critically analyzing the normative arguments and rationales to identify normative tensions that require resolving in order to move forward with the design and implementation of a pharmacare program.

6.1 Pharmacare as Politically Normative Debate

As I described in my findings, the central disagreement over whether universal pharmacare ought to be realized through a public single-payer or mixed multi-payer system is a fundamentally political dispute, which is underpinned by largely tacit normative disagreements, rather than technical or evidentiary ones. Pharmacare policy proposals appeal to different normative positions, which not only conceptualize and prioritize principles such as equity, efficiency, and liberty differently, but also appeal to distinct meanings of seemingly technical concepts, such as medical necessity, and ultimately, promote different policy objectives and ideas concerning political responsibility and health. In this section, I consider what it means for pharmacare to be a politically normative debate and I discuss the implications of framing pharmacare as such.

6.1.1 The Purpose of Pharmacare

Based on the findings articulated in the preceding chapter, I contend that the Canadian pharmacare policy debate is a fundamentally normative debate, which is underpinned by distinct moral and political stances and ultimately, different pharmacare objectives. In this section I consider the ways in which the two main arguments in the debate differ in how they frame what the purpose of pharmacare ought to be. Understanding the purpose of pharmacare requires addressing at least three main moral and political questions: first, what does society owe its members with respect to securing and meeting their (health) needs?; second, how ought society prioritize health needs (including when it cannot meet all needs), which in turn requires asking what health needs are, or in other words, which needs are ‘medically necessary’?; and third,

which method of organizing, financing, and delivering pharmaceutical insurance best meets these obligations?

I contend that the ways in which 'medical necessity' is conceptualized in arguments in the debate is indicative of the ways in which different positions address these three questions and envision what the objective(s) of pharmacare policy ought to be. While medical necessity is considered a clinical term, its use in policy discourse has moral and political dimensions as well and, as such, it is a contested term in the same way that normative principles are. Indeed, how 'medical necessity' is conceptualized or framed in pharmacare arguments has distinct implications for which system of administering, financing, and delivering pharmaceutical insurance is considered to be fair and efficient, and thus legitimate and preferable. My findings echo others' findings about the malleable nature and multiple meanings of 'medical necessity' in health and Canadian Medicare policy, where distinct meanings of medical need are shaped by different yet largely implicit stakeholder values (Charles et al. 1997). Without clarity and agreement about what role medical necessity ought to play in pharmacare policy, and most importantly, which health policy goal(s) it ought to serve, "the concept of medical necessity carries a heavy policy load for which it is ill equipped" (Charles et al. 1997:388).

6.1.2 Relations of Responsibility

As I described in the findings, the pharmacare policy debate can be characterized as a dispute between two main political positions which appeal to different normative principles and frame the policy problems—access, costs, and appropriateness—and their attendant solutions in distinct ways. In this section, I consider how the ways in which arguments for public single-payer and mixed multi-payer pharmacare use 'medical necessity' is indicative of the different ways in which they address the question of what society owes its members with respect to securing and meeting health needs, as well as attendant considerations of whose responsibility it is it meet these needs. [114]

[114] I use need to denote a concept akin to 'basic' needs that ought to be met and give rise to certain types of obligations, while necessity is an evaluation of whether something qualifies as a need (and is itself contested).

For some time now, there has been a broad consensus in the health policy and the philosophical literature that "there is (at least) a right to a decent minimum of health care" or that societies ought to offer universal health coverage for the essential health needs of their members (Powers and Faden 2000; Buchanan 2009:17; WHO 2019). Similarly, my findings suggest that there is at least some form of agreement about the requirement to expand and universalize pharmaceutical coverage in Canada, which was recognized in the final reports of the Standing Committee on Health (2018) and Advisory Council on the Implementation of National Pharmacare (Health Canada 2019). However, disagreement remains concerning the form that universal coverage ought to take, including the level of coverage that ought to be guaranteed as well as a related concern about who ought to be able to determine the extent and form of coverage offered. The differences in how proponents of public single-payer and mixed multi-payer pharmacare address these questions are most apparent when one considers how they frame and make use of the concept of 'medical necessity' in their arguments. Indeed, medical necessity takes on multiple meanings in the pharmacare debate, including with respect to justifying universal coverage and as a criterion for priority setting. I suggest that the different framings of medical necessity can help us understand the different normative rationales that underpin distinct pharmacare policy proposals, including the two distinct visions of the purpose of pharmacare.

Consider how medical need is invoked by proponents of public single-payer pharmacare with reference to the phrase 'access based on need, not ability to pay.' This commonly invoked phrase is often an expression of the claim that pharmaceuticals are a basic need that ought to be guaranteed for all Canadian residents such that they can access pharmaceuticals when needed. This reflects what Marchildon (2014:364) refers to as a 'strong' form of universality where citizens are covered on uniform terms and conditions (and in the case of Medicare, under a single tier). Furthermore, a Medicare system that adheres to this principle is also framed as expressing solidarity or mutual responsibility and support (e.g., Commission on the Future of Health Care in Canada 2002:xvi; Health Canada 2019:8). The characterization of Canada's existing Medicare system as solidary is echoed in bioethics literature:

> Canada's [Medicare] system can be said to exhibit a high degree of solidarity in its single tier design, and its normative grounding is explicitly solidaristic—i.e., the desire to share the best standard of medical care possible with all members of the community. (Reid 2017:115).

It is worth unpacking in what sense health insurance can be understood as solidary, since public single-payer and mixed multi-payer pharmacare can be understood as expressing distinct relations of solidarity.

Lehtonen and Liukko (2015:162) outline three forms of solidarity embodied in insurance: *chance*, *risk*, and *income* solidarity. All insurance involves *chance solidarity*, or "the basic sharing of responsibility in the face of uncertainty" concerning who the future beneficiaries will be. Chance solidarity stems from the very nature of insurance as a risk pooling mechanism, where the spreading (and thus sharing) of material risk generates collective benefit by reducing the subjective uncertainty of each insured individual concerning the quantity of resources that they must reserve for their future needs (159). This observation echoes claims about the efficiency-generating properties of insurance made in public economic accounts of health insurance, as discussed in chapter 4 (e.g., Heath 2006; Horne 2017). Moreover, it is worth noting that chance solidarity is inherent to the insurance mechanism and is not intrinsically redistributive in an egalitarian sense (Landes 2013; Horne 2017). Although insurance involves a material transfer from those who have a greater need for the insured good or service (in this case, health care) from those who have fewer needs, whether insurance *also* involves a net material transfer from those who are wealthier or those whose contributions exceed their relative risk depends on whether it also embodies *risk* or *income* solidarity.

Risk solidarity concerns the equalization of risk premiums, such that contributions to the insurance pool track a criterion (such as equality) other than the relative risk that each insured contributes to the pool (Lehtonen and Liukko 2015:162). In this sense, risk solidarity contravenes actuarial fairness, or the notion that premiums ought to reflect the relative risk of the insured individual. Income solidarity refers to the equalization of contributions according to income or economic resources (e.g., financing through progressive taxation or premiums) (160). The extent to which an insurance system embodies risk or income solidarity, which may be taken as expressing egalitarian or communitarian considerations, is a distinctly moral and political decision.

Lehtonen and Liukko's taxonomy of different forms of insurance solidarity offers a helpful way of understanding the ways in which different insurance systems are solidary, and accordingly, shape different moral relationships between co-insureds. As a public, single-payer system that is

financed through progressive taxation, Medicare exhibits all three forms of chance, risk, and income solidarity. Proponents of public single-payer pharmacare can thus be understood as advocating for a morally comparable system of pharmaceutical insurance, which, as a matter of justice, not only offers a universal mechanism for securing against health and related financial risks, but is financed progressively—and thus fairly on an egalitarian account of social justice—and without regard for preexisting health risks, which again echoes social and luck egalitarian accounts of justice. In the pharmacare debate, the appeal to 'access based on need, rather than ability to pay' unites all three forms of insurance solidarity. In its most basic form, the 'medical need principle', or the notion that health care ought to be distributed on the basis of need, is indicative of a concern for the efficiency-gains associated with chance solidarity, which is inherent to all insurance rather than being intrinsically egalitarian (Horne 2016). However, the concern for universal coverage and financial protection that is offered regardless of financial means or health risk reflects additional egalitarian concerns for risk and income solidarity. Moreover, certain arguments for public pharmacare also exhibit a concern for relational justice or communitarian concern for fostering relationships of equality and mutual interdependence or responsibility. Landes and Néron (2015), for example, assert that public insurance may be better understood as expressing relational rather than redistributive justice, as it creates a 'community of insureds' that fosters relationships of moral equality, since every member is regarded as both a contributor to and beneficiary of the system.[115]

In contrast, while proponents of mixed multi-payer pharmacare agree with the need to expand coverage, they advocate for a narrower understanding of universality which guarantees everyone some form of coverage but not on uniform terms and conditions. Such a system can be understood as exhibiting more limited forms of solidarity, which do not span the community (or in this case, province or territory). Rather, members of individual insurance plans, such as employees of the same company, constitute limited risk pools within which they exhibit chance solidarity. They may also exhibit risk or income solidarity within their individual insurance pool if premiums are not risk-rated rated and are relative to income. Yet on the 'fill in the gaps' account of pharmacare, the public system—which is in effect the pharmacare program—is

[115] Landes and Néron (2015) adopt the notion of 'communities of insureds' from Stone's (1999) discussion of insurance as creating 'moral opportunity' rather than moral hazard.

considered a supplementary or residual system of coverage for those who lack private coverage. Insofar as beneficiaries of the public program are seen as not contributing to it (whether or not that is actually the case, since all members will nonetheless be 'taxpayers' in at least some sense), the residual system resembles a system of charity, which is predicated on an imbalanced relationship between benefactors and beneficiaries, more than it does a system of solidarity characterized by relationships of reciprocity and equality (Landes and Néron 2015).

Accordingly, arguments for public single-payer and mixed multi-payer pharmacare can be understood as delineating the responsibility for meeting and securing pharmaceutical needs in distinct ways. Moreover, each system embodies different forms of solidarity and creates different relationships of responsibility between the co-insureds. Although in both cases the public payer is expected to fill gaps in coverage for those without existing coverage, in public single-payer pharmacare it is considered a mutual and collective responsibility, which is not contingent on considerations of risk or income. Meanwhile, a residual public program within a multi-payer system silos responsibilities, such that all those who can procure insurance individually are expected to be responsible for securing their own needs and those of the members of their insurance pool; they share a more limited collective responsibility for helping meet the needs of those who cannot meet their own needs, whether due to low income or high health costs.

What remains an open question is whether insurance does, as a matter of fact, shape relationships and expectations concerning responsibilities for health and, relatedly, whether health—or pharmaceutical—insurance is an institution in which we ought to value and seek to create relations of mutual interdependence. Lehtonen and Liukko (2015:156) assert that insurance is a social technology, which not only creates different types of relationships of solidarity, inequality, and exclusion, but also in turn conditions "the ways in which related moral and political concepts are perceived." While it is beyond the scope of this inquiry to conclusively assess the possibility for insurance to act in this way, I revisit these questions later in the chapter where I critically assess the rationales for different forms of insurance. Nonetheless, it is worth acknowledging Tuohy's (2018) assertion that the implementation of Medicare predates its rise to the status of a national 'icon' that has shaped Canadians' ideas and expectations about national identity and values.

6.1.3 Medical Necessity and Priority Setting

A second difference between the two main positions in the pharmacare debate concerns how they approach the question of how society ought to prioritize health (pharmaceutical) needs, and relatedly, which pharmaceuticals ought to be deemed 'medically necessary.' Once again, the ways in which medical necessity is framed are indicative of different moral and political stances and objectives. As described in the findings, proponents of public single-payer pharmacare advocate for universal drug coverage, but more precisely, comprehensive coverage for 'appropriate' medications included on a national formulary on the basis of safety, effectiveness, and cost-effectiveness. Accordingly, they see a public single-payer system as being fairer (ensuring comprehensive coverage for everyone through a system of progressive financing) and more efficient (expanding access without reducing access to appropriate drugs, and moreover, limiting inappropriate drug use, as well as facilitating information transmission about drug safety and effectiveness to prescribers and patients). In contrast, proponents of mixed multi-payer pharmacare contend that a public single-payer system would reduce or delay access to a full range of medically necessary medications for those with private coverage and thus worsen their access, health, and wellbeing. Consequently, they argue that a mixed multi-payer system which ensures a minimum level of coverage would be fairer (as it would expand access without leveling down coverage and would retain 'individual choice') and more efficient (as it would not leave people with private coverage worse off by limiting access to a full range of medications and that it would avoid shifting costs to the public sector).

The distinct appeals to appropriateness or medical necessity are indicative of differing policy objectives. Appeals to appropriate care are invoked in arguments that emphasize the importance of improving and preserving population health, while medical necessity is invoked to justify a system in which people with private coverage can maximize their individual health and those on a public (residual) formulary are given access to a minimally sufficient threshold of coverage. Relatedly, the two positions differ in where they locate the responsibility for adjudicating medical necessity and priority setting. On the one hand, appropriateness incites priority setting at the population level, which necessitates pharmaco-epidemiological evaluations of safety and effectiveness as well as considerations of cost-effectiveness. It is thus largely portrayed as being the responsibility of experts, reliant on procedural forms of justice, and subsequently a consideration of the unique circumstances of the patient during the clinical encounter.

Conversely, arguments that emphasize access to a full range of medically necessary drugs locate the assessment of necessity at the clinical level of the prescriber and individual patient (if they have comprehensive insurance); meanwhile, formularies of the residual public system are framed as being set by third parties and as further limiting prescribing choices and timely access to new medications. While the first instance of priority setting is often (pejoratively) referred to as the 'rationing' of care, the latter constitutes a form of rationing as well. However, it shifts the locus of priority setting from the qualities of medications (appropriate vs. inappropriate) to the people who are covered (those with private insurance vs. those without). In the case of a mixed system, limit setting occurs by excluding people without private coverage or those who cannot pay actuarially fair premiums that reflect their medical risk due to low income or preexisting medical conditions which require treatment with many and/or expensive medications. Arguments for mixed multi-payer pharmacare suggest that only those on public insurance receive 'rationed' care.

However, the framing of public insurance as one encumbered by rationing in contrast with a generous private system not only obscures the shift of the locus of priority setting (from drugs to people), but also fails to acknowledge that all systems of insurance require some form of priority or limit setting (or 'rationing') (Sreenivasan 2012; Lehtonen and Liukko 2015; Reid 2017). Sreenivasan (2012:143), for example, argues that, as a matter of justice, all health care systems that have a universal entitlement to care (however they are administered) must have at least a "readiness to ration" entitlements to beneficial and effective care, and on a stronger account, must ration care. Rationing is required when the cost of all medically necessary (in a strictly scientific science of all possibly beneficial and effective) care exceeds that of the limit of justifiable health care spending, which is determined by the need to conserve resources in recognition of the fact that health is not the only good that requires and merits social expenditure (144-145). Moreover, when one also recognizes that health care is but one determinant of health amongst a broader range of social factors, the requirements of justice may place even greater demands on rationing care—that is, capping health care spending—in order to leave sufficient resources to address other determinants.

However, limit setting should not only be understood as a requirement of justice (which is contested), but rather, as a basic feature of insurance. Every insurance system must set limits insofar as all of the members in the pool share an interest in having the insurance be able to meet

both the present needs of individuals who have incurred a loss as well as sustain the future needs of others in the pool by limiting moral hazard (Lehtonen and Liukko 2015:164). Indeed, systems of insurance that pay out indiscriminately incur rising premiums, as has been observed in the US which has the highest per capita health care costs (Bentley et al. 2008). Moreover, as noted in the findings, the increasing number of expensive medications entering the market has prompted private insurance plans in Canada to increase premiums, co-pays, or deductibles, add more stringent annual or lifetime insurance caps, or to move away from offering coverage for all market drugs in order to remain solvent, which reflects this underlying principle of insurance (Daw et al. 2013; Daw et al. 2014). Accordingly, it is disingenuous to claim that a public system concerned with 'appropriate' drug use represents a system of rationing while claiming that a private system that provides access to medically necessary medications avoids setting limits. In both cases, however, decisions of how to set limits, and in particular, how broad a range of resources ought to be dedicated to a particular end such as pharmaceutical insurance, represents an evaluative decision about priorities and desired ends, rather than being a technical inevitability.

Nonetheless, even if one recognizes that priority setting is a feature of any system of insurance, the question still remains whether it is preferable to set limits across a population or between separate public and private tiers. Reid (2017:132) aptly describes different questions that arise in the context of priority setting in a single- or two-tier health care system:

> A universal or single tier system need occupy itself with only one question: what is the best care we can afford for all patients, given these resources? A multi-tier system must face at least two questions: what is the minimum care we should provide to everyone, and then, in addition, what is the medically responsible and financial sustainable care that we should offer beyond that minimal care to those who deserve better care because they can pay more?

These are questions that I revisit later in the chapter when I critically analyze the rationales offered for the main arguments in the pharmacare debate. For now, however, it is worth recognizing that there are two related sites of tension when it comes to addressing the question of how a society ought to prioritize pharmaceutical needs and which pharmaceuticals ought to be considered medically necessary: (1) whether the 'basic' level of universal coverage ought to be comprehensive or minimal and (2) who ought to be responsible for adjudicating or determining which drugs are 'medically necessary' and merit inclusion on a formulary or reimbursement.

6.1.4 The Many Faces of 'Medical Necessity'

What I have shown thus far is that the distinct conceptions of medical necessity identified in my findings are indicative of different pharmacare policy objectives. Accordingly, rather than simply being a technical or value-neutral criterion, medical need is a contested and evaluative term with multiple meanings and normative implications. My findings echo Sharpe's (1997:337) observation that the use of the terms 'appropriate' and 'necessary':

> inevitably presupposes, expresses, and potentially reinforces complex normative and political assumptions. … about what ends should guide health care decisions … [and] about the location and distribution of power in the matrix of health care decision making, in other words, who is making health care decisions.

Moreover, my findings echo observations about the multiple and changing meanings and uses of 'necessity' and 'appropriateness' in health insurance policy (Sharpe 1997; Charles et al. 1997). For example, Sharpe describes how prior to the 1970s, appropriateness was restricted to the notion of clinical appropriateness, which was determined in the encounter between the individual patient and physician on the basis of professional judgement and in service of the individual patient's interests. At the time, Sharpe notes, there was a sense of perceived abundance of resources, such that all health care deemed to be clinically appropriate by a physician was reimbursed *if* the patient had insurance. In the 1980s, however, the tides changed as the economic landscape turned to one of perceived scarcity, thus requiring the management (or rationing) of care. In this context, the locus of decision-making shifted towards a third party and was driven by considerations of cost-worthiness or "appropriateness within a resource nexus" on the basis of the "interests of all patients in [the] resource nexus" and, in the case of for-profit insurance, the interests of stockholders (Sharpe 1997:338).

The Canadian pharmacare debate reflects the changing history of appropriateness. Proponents of a mixed model make appeals to medical necessity that reflect an era before the introduction of evidence-based medicine and resist shifting the locus of decision-making away from individual prescribers and patients, and which continue to operate in a perceived environment of abundance. Yet, as I discussed in the findings and I will further discuss later in the chapter, private insurance has more recently shown indications of faltering as exemplified by industry appeals to government to step in with the financing of highly expensive drugs and their desire to join the Pan-Canadian Pharmaceutical Alliance. Proponents of public pharmacare, meanwhile,

emphasize the importance of using evidence to inform determinations of effectiveness and taking into account societal interests, or the interests and wellbeing of all members in the insurance pool (or in this case, all residents), and determining appropriateness within the context of a universal budget. Moreover, as I discussed earlier, it is not clear that any insurance system is limitless, for each insured member has an interest in ensuring that others do not inappropriately overuse insurance for which they will also incur the costs.

In the Canadian context, Charles et al. (1997) have conducted a similar analysis of the changing meanings and uses of the term 'medical necessity.' They note that 'medical necessity' plays a central role as a policy tool in Canadian health policy as the *Canada Health Act* stipulates that publicly insured goods and services include all medically necessary hospital and physician services. The authors identify four distinct eras and understandings of medical necessity. When Medicare was first introduced, 'medically necessary' was taken to mean "what physicians and hospitals do," which served to establish a "minimum *federal* floor for publicly funded services" in order to expand public coverage (1997:370).[116] In the 1980s, provincial governments began assuming greater health care costs as the *Canada Health Act* banned physician extra-billing and federal health transfers were restricted. Under these conditions, medical necessity took on the meaning of "the maximum we can afford," which made the federal floor the provincial ceiling for coverage in order to control costs (375). Next, the advent of evidence-based medicine in the 1980s and 1990s shifted the locus of medical decision-making away from individual physicians to emphasize the importance of decision-making based on the best available evidence from clinical trials and practice guidelines (378). In this context, medical necessity took on the meaning of "what is scientifically justified" in an effort to improve the quality of care. Finally, a fourth meaning surfaced in the 1990s, which equated medical necessity with "what is consistently funded across all provinces" in order to "promote equity in entitlements and access" in the context of establishing or renegotiating a consistent package of publicly funded services across provinces and territories (370, 382).

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[116] Sreenivasan (2012) asserts that medical necessity is arbitrarily defined in administrative rather than scientific terms in Canada, where services listed in the *Canada Health Act* are deemed necessary whereas those that are excluded, such as pharmaceuticals, are not. Charles et al.'s findings suggest that even the administrative sense of the term has evolved.

These two examples demonstrate how the concepts of medical necessity and appropriateness have taken on new meanings depending on the social, political, and economic contexts of policy making, and in response to new policy objectives in recent decades. Similarly, I have described how distinct appeals to medical necessity and appropriateness motivate different accounts of which model of pharmacare is efficient and fair, and that these determinations are indicative of different understandings about the normative nature of pharmaceutical insurance and political responsibility, or the extent to which it ought to be a 'public' concern. As Verweij and Dawson (2007) note, there are at least two senses of 'public' in public health: that it concerns the health of the public, or the health of populations, and the extent to which public health interventions are collective efforts. Arguments for public single-payer pharmacare can be understood as appealing to a stronger sense of collective action grounded in notions of reciprocity and solidarity with an orientation towards securing and promoting population health, while arguments for mixed multi-payer pharmacare limit the extent to which pharmacare is seen as a collective effort and primarily emphasize the health of individuals.

Adjudicating between different policy objectives ultimately requires making a political decision—a decision about competing normative commitments and objectives. As such, the pharmacare policy debate can be considered a subset of broader debates about health insurance, including in the origins of Canada's existing health insurance. My findings resonate with Marchildon's (2012:6) observations that the history of Canadian Medicare is not only a policy history, but also a political history characterized by "a profound, value-laden conflict involving two disparate visions of public health care and the role of the state." It is not my aim to resolve this tension by arguing for a preferred view, but rather to bring it to the surface. In the next section, I discuss the implications of framing the pharmacare debate as a political debate. Afterwards, I revisit and critically analyze the normative arguments in the pharmacare policy debate in light of their normative coherence with the objective of implementing a system of universal pharmacare.

6.2 Implications of Framing Pharmacare as a Political Debate

In the preceding sections I argued that the distinct conceptualizations and uses of medical necessity by different stakeholders in the pharmacare debate are indicative of two distinct normative accounts of the purpose of pharmacare. Here, I consider the implications of framing

the pharmacare policy debate as not only a policy debate, but also as a politically normative one, which is characterized by different moral and political stances. First, I contend that cost-related issues in the debate should be conceived of as normative, rather than purely technical, neutral, or objective considerations. As such, they are not fundamentally distinct from 'values' issues, which are often restricted to considerations of equity, but are one of several key *normative* issues at the heart of the debate. Doing so allows us to further unpack what is meant by (i.e., the normative concerns that underpin) the cost-related concerns that have persisted throughout the long history of the pharmacare debate. Indeed, unlike the commonly invoked 'equity-efficiency trade-off,' it is not a simple of matter of equity and efficiency being at odds in pharmacare policy. Rather, the normative tension centres on competing understandings of fairness or justice.

6.2.1 Not Costs *versus* Values, but Costs *as* Values Issues

One way to frame the pharmacare policy debate is to consider it as a dispute between competing political visions, rather than as, for example, a debate between 'values' and 'costs,' or normative and economic issues. It is common for health policy literature to distinguish between ethics and economics, and to frame issues pertaining to 'values' as primarily tied to considerations of equity, fairness, and justice, while cost-related issues are restricted to value-free economic evaluations. As I discussed in the findings, the distinction between values and costs is echoed in the pharmacare debate itself, such as in pronouncements about pharmacare being both the 'right' thing to do and an economically sound policy. Similarly, in an analysis of the media framing of pharmacare, Daw et al. (2014) distinguish between 'values' and 'cost'-related problems when suggesting that pharmacare has been strategically framed in terms of costs—as being economically unviable—as a tacit way to support the status quo and stymie pharmacare reform, rather than as a 'values' issue concerning equitable access or coverage. Moreover, they observe that the framing of the Canadian pharmacare debate is not characterized by strong ideological differences, in contrast with health care reform debates in the United States. The distinction between costs and values leads to an oft-cited sentiment that the goals of pharmacare are clear, but that ideational barriers—especially concerns about affordability— present obstacles to policy reform:

> …Canadians know *what* to do about pharmacare – the harms caused by a lack of broad public pharmaceutical coverage are well understood, and there is a reasonable degree of expert consensus on the type of program [sic] could

> mitigate these harms and realize important benefits in terms of lower drug prices and costs, more equitable access to necessary therapies, and better health outcomes for Canadians. The difficulty is in knowing *how* to do it […]. The first lesson is that to achieve changes to Canada's limited and fragmented pharmacare programs, reformers must address ideational and electoral barriers to change, as well as (and perhaps before) institutional barriers. Over time, the idea that pharmacare is prohibitively expensive and subject to uncontrollable costs has become an article of faith with elites, an idea that is not supported by evidence. Communicating new ideas about pharmacare to the public is essential, because one way to generate the political will for change among elites is to demonstrate a public appetite for it. (Boothe 2017:18)

My findings lend support to the observation that Canadian pharmacare policy discourse is less overtly ideological than health care debates in the US, in the sense that normative disagreements are largely tacit and proponents of the status quo appear reticent to explicitly oppose universal pharmaceutical coverage. Nonetheless, my findings suggest that there is also a normative struggle over '*what* to do about pharmacare' as tacit normative disagreements about the purpose(s) of pharmacare persist and motivate different framings of the key policy problems of access, costs, and appropriateness and related policy solutions.

Here, I suggest that the normative disagreements at the centre of the debate are less overt in part because they are framed as primarily economic, and thus technical and non-normative concerns, despite the fact that issues of costs and affordability have normative implications. Unpacking the normative considerations that underpin concerns about costs further suggests that the dispute is not merely one of determining which pharmacare policy option will be most efficient, but rather one about competing ideas about justice, which in turn underpin divergent ideas about the legitimate role of the state, including in the financing and provision of health insurance.

Framing 'costs' as economic concerns rather than as normative ones presupposes that they are purely technical and value-free. However, even seemingly technical issues, such as medical necessity and efficiency, warrant consideration as normative issues.[117] Earlier, I discussed how medical necessity is a contested and evaluative concept within the pharmacare debate and in health policy. Similarly, to consider cost-related issues as normative invites an explicit

[117] Economists distinguish between positive and normative economics, where the latter involves making normative judgements about economic policy.

consideration of what their normative features and implications are—such as by asking what makes costs a policy 'problem'—and moreover, to recognize that costs are not inevitably problems, but rather, become particular sorts of problems through decisions or evaluations in relation to a desired policy objective, standard, or underlying policy principle. In other words, costs represent a measure of some form of value. Thus, framing cost-related concerns as 'values'—or more aptly, as normative—issues allows us to unpack what underlies concerns about costs and affordability and thus to evaluate whether these concerns are warranted and justified with respect to desirable policy objectives. In contrast, much of the discourse concerning costs or affordability treats costs as inevitably unjustified or undesirable, but inadequately explains *why* costs associated with pharmacare, and especially the shifting of costs from private to public payers, would be *unjustified*.

Understanding costs as a normative consideration allows us to see that these concerns are proxies for normative positions and thus renders the underlying normative rationales open to critique, rather than leaving them to operate as tacit trumps against which 'values' concerns must be justified. Consider, for example, how costs and concerns about affordability by the public sector have long been cited as barriers to implementing national pharmacare, and publicly-funded pharmacare in particular (Daw et al. 2014; Boothe 2015; Boothe 2017). The *idea* that public pharmacare would be costly has long persisted on the part of policy makers and has hindered pharmacare reform in the past (Boothe 2017). My findings support this observation, especially in the 1990s and 2000s when costs were commonly cited as practical barriers to public pharmacare, even by those who identified universal public pharmacare as an ultimate policy goal (e.g., Commission on the Future of Health Care in Canada 2002). This echoes broader concerns about neoliberal calls for 'small government' and the need to limit public spending in an era of perceived economic scarcity, such as which prompted changes in the meaning of 'appropriateness' and 'medical necessity' in health policy (Sharpe 1997; Charles et al. 1997). Yet, decisions about public spending reflect or express decisions about societal priorities (Bayertz 1998; Kotalik 2005). As an economist who is referred to as the 'the architect of US Medicare' noted, our willingness to bear certain costs can serve as a barometer of values:

> …the federal budget is not only an economic but a social document through which [our shared] values are expressed. The expenditure and revenue numbers in the budget represent our collective decision about program and priorities. (Fein 1986:220 quoted in Emanuel 2002)

My findings suggest that the discourse in the contemporary debate has shifted to emphasize the efficiency of public single-payer pharmacare. Yet, despite this discursive shift, proponents of mixed multi-payer pharmacare dispute the primacy of public pharmacare for two main reasons: a denial of the relative cost-effectiveness or efficiency of public single-payer pharmacare, and a second, more tacit argument grounded in liberty. In other words, my findings suggest that the dispute at the centre of the contemporary pharmacare debate is not one simply of values versus costs, or equity versus efficiency, but rather a dispute over which costs are justified and on what grounds.

Indeed, if the cost-related concerns are distilled to their normative cores, we can observe two main normative tensions. First, there is a dispute about which form of pharmacare will be most cost-effective. Proponents of public pharmacare argue that a single-payer system would be the most effective at reducing costs to Canadians as a whole by facilitating joint drug price negotiations, realizing economies of scale through reduced administrative costs, and guarding against the harms and waste associated with inappropriate prescribing. As discussed earlier, their understanding of efficiency is shaped by the concern for universal coverage and population health, as well as appeals to appropriate drug use; they do not see the shift to a single-payer system offering coverage for drugs listed on a formulary as an instance of leveling down or worsening coverage, but rather, as a way to limit inappropriate and harmful drug use. Meanwhile, proponents of mixed multi-payer pharmacare counter that a multi-payer system would be most cost-effective for the public payer, reduce deadweight losses associated with increased taxation, and as some proponents such as the insurance industry argued, that joint price negotiations and bulk purchasing could still be achieved through joint collaboration with governments in a multi-payer system.

Yet, there is a second set of cost-related issues that motivate opposition to public single-payer pharmacare, which manifest as opposition to shifting drug costs and control over insurance to the government. These concerns are not primarily related to efficiency, but more to liberty. Admittedly, there are pragmatic or institutional concerns related to the costs (monetary and otherwise) of the political processes required to realize such far-reaching reforms in the Canadian federation where sub-national governments have jurisdiction over the delivery of health care (e.g., debate over the division of responsibility for financing). Yet many arguments against public single-payer pharmacare draw on ideational rather than, or in addition to,

institutional concerns. Ideational concerns appear to take two forms: one about cost shifting and another about agency in medical decision-making. First, a public single-payer system would shift costs to the public payer, which can represent a tacit concern about an enforced system of collectivized financing that institutionalizes income and risk solidarity, or a form of coerced and illegitimate cross-subsidization, where individuals' contributions would subsidize the costs of people with low incomes, poor health, or 'risky' behaviours. Similarly, it can represent a broader concern about incursion on individual liberty through higher taxation and even as limiting individuals' decisions to acquire insurance to begin with. A second and more cited concern is that of the removal of control or agency over insurance financing and decision-making for those with existing private insurance that is expected to occur with a shift to public financing and rationing through a national formulary.

Thus, examining cost-related issues as normative issues rather than purely economic ones helps reveal that not all of the cost-related issues are purely matters of efficiency as one might first expect. Moreover, even efficiency concerns are contested based on different understandings of health policy objectives. What we see, rather, is that appeals to efficiency in health policy often mask concerns about liberty, and in particular, concerns about *negative* liberty, or freedom from government coercion or restriction

In this sense, I would again agree with Daw et al. (2014)'s observation that framing pharmacare in terms of costs creates a silo of values that may limit prospects for reform. Yet, I would further add that it is not the framing of costs in itself that is a limiting factor, but rather an understanding of costs in purely (positivist) economic rather than normative terms. If costs and related terms such as efficiency are understood as contested, normative concepts, they may no longer function as *de facto* trumps in public policy discourse. For example, in the introductory chapter, I noted how Ontario expanded its public pharmaceutical coverage to include all individuals 24 years and younger in January 2018, but that the plan, OHIP +, was partially repealed with the change in government that June. Within three weeks of being elected, the Conservative government announced that it would only maintain OHIP+ coverage for individuals who did not previously have private coverage. OHIP+ now resembles a mixed multi-payer pharmacare plan that fills gaps in coverage for Ontarians 24 years and younger. Notably, the decision to partially repeal OHIP+ was framed and justified by the government with reference to efficiency:

> it would be more efficient, saving the taxpayers money and dedicating resources to the people who need it most. Even more importantly, it would continue to guarantee that children and youth still receive the prescription drugs they need. Since insurance plans can cover thousands more drugs than the 4,400 currently available through OHIP+, children and youth would still have access to more medications than under the current program. [...] Premier Ford promised the people he would find efficiencies without compromising service or jobs, and we are delivering. (Christine Elliott, Minister of Health and Long-Term Care, June 30, 2018)

In this case, efficiency is framed primarily in terms of limiting the scope of state activity, or the government spending of taxpayer money, as well as redressing concerns about levelling down or reductions in coverage for those with private insurance. However, what these efficiencies were, and for whom they represented cost-savings or improvements is not as clear cut.

The framing of the pharmacare debate as being one between values and cost-related ideas may obscure that equity and efficiency are not necessarily at odds. My findings show this most clearly in the context of the contemporary debate, where proponents of pharmacare have explicitly argued that the efficiency of a single-payer system is key to being able to afford and sustain an equitable system of universal coverage. While they also contested the efficiency of a public system, proponents of mixed multi-payer pharmacare have doubled down on liberty-based arguments. By arguing that the medical necessity of drugs ought to be determined in the context of the clinical encounter between the patient and the prescriber, they see attempts to implement a formulary based on considerations of cost-effectiveness as restricting patient and provider choice of and access to a broader range of medications on the basis of an individual's unique circumstances. Instead, the tension over costs in the debate may be better characterized as being underpinned by opposing ideas of fairness: an egalitarian sense of fairness or justice, where inequities are eliminated or are in service of the worst off or a communitarian one that seeks an equality of status, versus a libertarian or liberal one in which fairness is determined by latitude in and responsibility over financial, medical, and other decisions. In other words, it is not so much a contest between values and costs, but rather between the principles that shape whether and when certain costs are deemed to be just and who is deemed to have a legitimate role in making such determinations and on the basis of what kind of evidence.

6.3 Taking Stock: Revisiting Arguments in the Pharmacare Policy Debate

Thus far, I have characterized arguments in the pharmacare policy debate in terms of their normative underpinnings rather than primarily critiquing or endorsing them. In the preceding section, I argued that the pharmacare policy debate is characterized by a fundamental, albeit largely tacit, moral and political disagreement about the objectives of pharmacare policy and legitimate role of public and private institutions in health care. I identified several sites of normative tensions that require addressing in order to move forward with pharmacare policy reform. In this section, I analyze whether the normative claims and rationales that stakeholders appeal to cohere, underdetermine or overlook key moral considerations concerning the pharmacare policy solutions they espouse. I argue that if a central objective of Canadian health insurance policy is to secure and promote the health of Canadians as well as to offer financial protection against health care costs, a public single-payer system that uses reference-based pricing and allows for supplementary private coverage is most likely to offer an efficient system of insurance. Such a system takes into account both considerations of equity, including access to a comprehensive list of medicines that is financed progressively, and liberty, by allowing individuals to purchase medications excluded from formularies and to procure supplementary coverage.

6.3.1 Starting Premises about Pharmacare Policy Objectives

My analysis proceeds by granting the premise that Canadians are interested in implementing some form of universal pharmacare, which my findings suggest is largely accepted in the contemporary pharmacare public policy debate, is supported in public opinion polling (Abacus Data 2015, Angus Reid 2015, Ipsos 2019, Angus Reid 2020), and is broadly supported in philosophical literature from various theoretical traditions (with the exception of libertarianism, which advocates for much narrower state involvement than is present in Canada or any other modern welfare state). Additionally, it is worth recalling the objective of Canadian health policy as stated in the *Canada Health Act* (1985:5):

> It is hereby declared that the primary objective of Canadian health care policy is to protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers.

This objective can be understood as having two components: facilitating affordable and timely access to medically necessary health care services and securing financial protection from undue financial burdens associated with accessing needed care for all residents (Standing Senate Committee on Social Affairs, Science and Technology 2002:308). Notably, these features resonate with what Buchanan (2009:92) characterizes as the 'core' of a just health care system from a diversity of philosophical accounts: "1. universal access 2. to an 'adequate level' of care 3. without excessive burdens", where burdens include financial costs as well as factors such as discrimination, geographic inaccessibility, or excessive wait times.

Similarly, it is worth noting that following the end of the case study period, which is marked by the publication of the Advisory Council on the Implementation of National Pharmacare's final report in June 2019, and following a federal election in October of the same year, the federal government identified the implementation of national universal pharmacare as one of its health policy objectives. So far, it has specified its intent in pursuing the establishment of a National Drug Agency and the development of a national formulary and a strategy for financing expensive drugs for rare diseases (Trudeau 2019).

Here, I consider whether the normative arguments that proponents of distinct pharmacare policies present cohere with the underlying normative principles and rationales they espouse, and moreover, consider which of the proposed systems of financing, organizing, and delivering pharmaceutical insurance may be best poised to meet Canadian health policy objectives.

6.3.2 Equitable Coverage

In my findings, I outlined how proponents of public, single-payer pharmacare justified their position by appealing to a combination of equity-, community-, and efficiency-based rationales. Here I begin by considering the equity-based arguments and implications of egalitarian commitments for health insurance. Equity is frequently cited as justifying the implementation of universal pharmaceutical insurance as well as public, single-payer pharmacare in particular. It is worth unpacking the implications of egalitarian commitments for pharmaceutical insurance and whether they necessitate a public, single-payer plan in particular. Egalitarians tend to support universal health coverage that is comprehensive and meets a threshold of sufficient or adequate (rather than strictly equal) coverage in accordance with a preferred equalisandum, whether it be at the level required to attain 'species-typical' functioning (Daniels 2008) or stabilize future

expectations (Horne 2017) to protect capacities for self-determination, or at a threshold required to achieve a sufficiency in each of several essential dimensions of wellbeing (Powers and Faden 2006).[118] Moreover, they tend to endorse forms of risk and income solidarity for similar reasons, such that insurance financing is neither risk-rated and is financed progressively insofar as necessary to meet broader requirements of justice—features that are often invoked when referring to the egalitarian commitments of Canadian health care (e.g., Martin et al. 2018).

Conversely, catastrophic coverage alone is unlikely to meet egalitarian commitments, since in the absence of comprehensive coverage, individuals without private coverage for first-dollar or first-prescription coverage may face greater financial barriers to accessing basic pharmaceuticals, which can disproportionately burden individuals with low incomes or expensive health needs. For example, even small cost disincentives for drug consumption result in increased cost-related non-adherence of both non-essential and essential drugs across all income groups, but especially in low income groups (Goldman et al. 2007). Similarly, one in five Canadian households with an income below $20,000 reported cost-related non-adherence as compared to one in twenty in households with an income exceeding $80,000 (Bolatova and Law 2019). Moreover, inequities in first-prescription coverage can further contribute to inequities in access to and utilization of otherwise universal, publicly funded health services.[119] The provision of coverage for routine care rather than only catastrophic costs also offers population-level health benefits as it can promote the use of routine and preventive care. While this offers efficiency benefits, such as by reducing future morbidity (e.g., Piette et al. 2004; Egede et al. 2014) and health care costs due to increased hospitalizations and emergency department visits (Anis et al. 2005; Goldman et al. 2007), it also contributes to equity insofar as those lacking private coverage and thus forgoing care are much more likely to be of lower socio-economic status (Bolatova and Law 2019).[120]

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[118] Egalitarian objectives can still be met without requiring total equality in health care, since health is not the only good required to achieve equity in a more fundamental ends such as capacity for self-determination or wellbeing, or even in health outcomes.

[119] For example, evidence suggests that in Ontario, physician utilization (or visits to both general practitioners and specialists) is higher among individuals with prescription drug insurance and that individuals without insurance may be deterred from otherwise funded care due to the expected cost of medications (Allin and Hurley 2009). Despite higher physician utilization among high income individuals, the presence of a public coverage for individuals on social insurance demonstrated a pro-poor effect.

[120] In Ontario, differences in health outcomes and mortality for patients with diabetes mellitus are correlated with socio-economic status, but diminish after the age of 65, which is when the Ontario Drug Benefit Program offering

Egalitarian accounts also require a consideration of appropriateness in determining how to distribute the benefits and burdens associated with health care financing within health care as well as more broadly. Resources spent on medications could otherwise be spent on other health care services (e.g., in areas that are currently recognized as being underfunded such as mental health, dental care, home and long-term care, etc.) or in other public policy areas that could impact self-determination or wellbeing. This becomes all the more evident if one recognizes that various factors beyond health care—the social determinants of health—have a significant impact on health status and outcomes, and thus also warrant policy attention and resources to address other determinants of health and other inequities. Notably, the *Canada Health Act* is not exhaustive and frames its objective as facilitating 'reasonable' access to care.

Moreover, although economic methods such as cost-utility analysis, which aggregates diverse benefits into a common measure in order to calculate how to maximize value per dollar at the societal level, offer direction on how to maximize public resources within the health care budget, they offer no direction on competing claims about fairness concerning how benefits and burdens ought to be redistributed (Powers and Faden 2006). Any system of priority setting will be tasked with making a number of trade-offs, including: determining whether life-saving treatment is morally unique; whether the size of a benefit holds moral significance (e.g., whether numerous small benefits are to be prioritized over fewer large health benefits); whether the rule of rescue is to be heeded (e.g., where greater resources are directed towards benefiting an identifiable person rather than towards a greater number of 'statistical' lives); and to what extent those who are worst off ought to be prioritized (Powers and Faden 2006:142-177). In the context of pharmaceuticals, these questions are particularly acute with respect to high cost medications and therapies and in the case of 'orphan' drugs or drugs for diseases that are rare and also often chronic and life-altering, and which tend not to have alternative therapy options (Largent and Pearson 2012; Roberts et al. 2015).

While egalitarian commitments may support universal coverage for a comprehensive range of appropriate pharmaceuticals, does a concern for distributive justice necessarily *only* support a

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pharmaceutical insurance offering comprehensive coverage for seniors kicks in (Lipscombe et al. 2009; Booth et al. 2012).

public, *single-payer* plan? Egalitarians argue for public pharmaceutical coverage primarily on two grounds: first, that it would best support equality of opportunity or wellbeing by facilitating equitable access to drugs and financial protection through comprehensive first-dollar coverage, and second, that it would promote a fair system of financing, or in other words, one that exhibits risk and income solidarity. Yet, it is not clear that a single-payer system that offers coverage on strictly uniform terms and conditions is necessarily linked to broader equity outcomes, or even health equity given the impact of the social determinants of health.[121] It is possible, for example, to design a sufficiently well-regulated mixed multi-payer insurance system that would deliver universal comprehensive coverage. For example, it could offer progressively financed public insurance for those without private coverage, include regulations limiting cream-skimming or risk-rating, and set a floor for coverage requiring that all plans offer a comprehensive list of medicines included on a national formulary or essential medicines list. Countries such as Germany and the Netherlands operate universal health insurance systems that consist of multiple private payers, but are publicly subsidized and heavily regulated to meet equity objectives (Fierlbeck 2012). While it remains an empirical question how effective such a system would be at attaining equity objectives (e.g., whether the existence of private coverage undermines willingness to finance the public system), it is plausible in theory. It would, however, require greater regulation and public financing than is currently present in the private insurance landscape in Canada.

If public pharmacare is not inherently more equitable than a comparable multi-payer system that offers progressively financed coverage for a comprehensive list of appropriate medications, what might justify public pharmacare in particular? As described in the findings, proponents of public pharmacare increasingly emphasize that a public single-payer system offers efficiency advantages over a mixed multi-payer system. While a mixed system could in theory be carefully orchestrated to offer desired levels of coverage and subsidies for those with lower incomes or more expensive health needs, including through progressive financing mechanisms, it would not

[121] For example, Sreenivasan (2007) has argued that equality of opportunity does not justify universal health care as a concern for fair equality of opportunity would be better served by directing greater resources to addressing the social determinants of health. For a response to Sreenivasan, see Reid (2016).

benefit from the efficiency-promoting features of a single-payer system, as was noted by the Advisory Council (Health Canada 2019:167).

6.3.3 The Efficiency of Single-Payer Pharmacare

Proponents of public pharmacare argue that a single-payer system would offer the most efficient form of pharmacare as it could reduce the cost of pharmaceutical coverage to Canadians as a whole by negotiating lower drug prices, realizing economies of scale through reduced administrative costs, promoting the solvency and sustainability of insurance by pooling risks more broadly, and limiting inappropriate prescribing and drug use by transmitting credible information concerning drug safety and effectiveness. Proponents of mixed pharmacare question or deny the relative efficiency of a public single-payer system (e.g., citing deadweight losses or denying savings associated with administrative efficiencies) and claim that other cost savings could be achieved through public-private collaboration.

Economic evidence suggests that single-payer systems offer cost savings advantages, including through administrative efficiencies (e.g., Law et al. 2014; Galvani et al. 2020; Himmelstein et al. 2020). However, where the case for mixed pharmacare arguably falters most markedly concerns its ability to serve as an efficient risk pooling mechanism. As discussed in the findings, the increasing number of high-cost drugs is challenging the solvency of private insurance plans, especially those offered by small- and medium-sized businesses. As a result, businesses are now less likely to offer insurance benefits or are looking for ways to limit coverage either by reducing eligibility or by reducing coverage and shifting costs to individuals through increased premiums, co-pays, or deductibles or more stringent annual or lifetime insurance caps. Although the private insurance industry has adopted certain strategies to increase its risk pooling abilities, it is also openly seeking the government to step in to aid with the financing of expensive drugs. Yet, this very admission suggests that private insurers are struggling to meet their basic function as *insurance—that is risk pooling—mechanisms.*

Moreover, while the insurance industry is looking to government to step in as an insurer of last resort, they still seek to retain coverage for more routine costs, despite the fact that the most basic ‘insurance’ logic—restricted to chance solidarity—would involve insuring against risks associated with unpredictable, significant drug costs. Concerns about the very solvency of private insurance plans lends credence to the idea that a single-payer system would be more

efficient, since a larger risk pool can better mitigate the volatility associated with high cost medications as well as prevent adverse selection, which can lead to insurance 'death spirals' (Hussey and Anderson 2003). As such, it is unsurprising that pharmacare has received sustained attention—and that the efficiency-based rationale for single-payer pharmacare has gained traction—at a time when public and private payers alike are struggling with containing drug costs internationally given the notable shift towards the development of specialized, often highly expensive medications.

It is also worth noting that while proponents of mixed multi-payer pharmacare caution against government incursion in insurance and pharmaceutical regulation, they also argue that governments ought to retain tax exemptions for employer-sponsored plans, which amount to $2,605 million in 2016 (PBO 2017). [122] Yet, these exemptions amount to regressive subsides, since they offer greater advantages to those with higher incomes and higher marginal tax rates, which contravenes egalitarian commitments to policies that favour the worse off. Moreover, evidence indicates that nearly 80% of households with incomes exceeding $100,000 have private coverage while fewer than 50% earning between $40,000 and 59,999 and fewer than 30% earning less than $39,999 have private coverage (Health Canada 2019). Accordingly, these subsidies disproportionately advantage a greater number of individuals who already have the greatest ability to pay for drugs. These same benefits, however, are not extended universally.

Besides contravening egalitarian commitments, these tax subsidies also distort health insurance markets as it is estimated that the elimination of such subsidies would result in an approximately 20% reduction in employee-sponsored health insurance plans (Stabile 2001; Finkelstein 2001) and up to 50% in smaller firms (Stabile 2002). This can be considered a form of inefficiency as the true cost of insurance is underpriced and has been externalized to others, or in this case, the general public. Insofar as private, employer-sponsored plans offer more 'generous' pharmaceutical formularies as they have fewer incentives to require the utilization of cost-effective care, access to a broader range of medications in the private sector is being publicly subsidized, while basic universal coverage remains unrealized for the general population. Thus,

[122] Employer-sponsored health care benefits are not counted as taxable income by the federal government and thus indirectly functions as a subsidy as employees receive benefits for which they would otherwise be taxed.

tax exemptions for employer-sponsored insurance not only raise equity concerns, but also further call into question the efficiency of multi-payer private pharmaceutical insurance.

Ultimately, the advantage of the single-payer plan is that it offers a broader risk pool to minimize the volatility and impact of expensive medications and, insofar as it is universal, avoids additional sources of inefficiency such as adverse selection. While I noted earlier that a heavily regulated mixed system could in theory address equity objectives, countries such as Germany that have heavily regulated multi-payer insurance systems have struggled with adverse selection and rising health insurance premiums (Fierlbeck 2012). Moreover, regulations can be costly and evidence suggests that it may be difficult to regulate private payers to pursue public policy objectives (Hurley et al. 2002) or to act in the public interest or in accordance with non-discrimination laws (Lemmens 1999). Further, as Powers and Faden (2006:134) argue, mixed systems in which public coverage consists primarily of public safety nets for the poor often struggle to provide quality coverage if support for public services does not match that of private sector and, moreover, may be at the mercy of political circumstances as they lack a broad political constituency and may thus be 'unequal by design' and resistant to improvement.

Finally, proponents of public pharmacare also argue that such a system would enable joint price negotiations and purchasing to facilitate lower drug prices. Some proponents of mixed pharmacare—notably the insurance industry—have also called for price negotiations and expressed interest in joining the pan-Canadian Pharmaceutical Alliance (pCPA). A single-payer plan would offer the most streamlined mechanism for price negotiation and purchasing, but what is most relevant here is the presence of single *negotiator*. For example, although the UK and New Zealand negotiate drug prices at the national level for the public payer, Germany has a single body that negotiates drug prices on the basis of considerations of comparative effectiveness, the price of other comparator drugs, and prices charged in other European markets, on behalf of all payers (Robinson et al. 2019). As such, the concern for joint price negotiations lends support to the idea of a single negotiator, but not *necessarily* a single-payer. In other words, it lends support to a centralized Drug Agency that would consolidate the efforts of individual agencies such as CADTH, the PMPRB, and the pCPA and also facilitate more efficient information transmission.

Centralized price negotiations would be more efficient in the sense of productive efficiency, or reducing costs for payers, as well as reducing the administrative costs associated with negotiation efforts (e.g., currently the pCPA negotiates on behalf of public payers, but not on behalf of private payers, hospitals, or individuals paying out-of-pocket). However, pricing concerns also raise questions of fairness—or questions about how the benefits and burdens of drug expenditures ought to be distributed between pharmaceutical companies and payers—and echo broader discussions occurring internationally about the 'fair' pharmaceutical pricing (WHO 2017). It is beyond the scope of this analysis to do justice to the question of fairness in pricing for pharmaceuticals, other than to note that insofar as payers have concerns about the cost-effectiveness of medications, as is increasingly the case with respect to highly expensive drugs or 'me-too' drugs, they have reason to demand the cost-effective use of resources and to exercise countervailing power against a monopoly that they see as extracting 'economic rents' and which has been enabled through patents. The pharmaceutical industry and certain patient groups caution that lower prices threaten R&D investment and innovation. However, the extent to which pharmaceutical costs reflect true research and development costs rather than costs that are argued to be economic rents, such as marketing costs or profits distributed to shareholders, is contested in the debate and in literature (Morgan et al. 2011; Jayasundara et al. 2019; Ledley et al. 2020; Wouters 2020; Wouters et al. 2020). Moreover, pharmaceutical R&D investment in Canada has been decreasing and remains below 10% of sales, which was a threshold committed by industry when patent terms were extended in 1987 (PMPRB 2018).

While discussions about 'fair' pricing are ongoing, possible ways forward to address payers' concerns include proposals to introduce value-based pricing or risk-sharing financing approaches in order to incentivize or reward pharmaceutical R&D that is truly innovative in the sense of being markedly more effective or cost-effective (Balderrama et al. 2020). For now, however, I set this aside as both public and private payers have expressed an interest in negotiating lower drug prices, which as I have discussed, lends support to a single national negotiator. Any policy reform in this area is likely to be fraught as has been the case with proposed changes to the

PMPRB pricing guidelines, which have faced fierce opposition and lobbying from the pharmaceutical industry (Martell 2020).[123]

Arguments for price negotiations and information transmission lend support to the notion of a single negotiator or centralized drug agency that could be tasked with negotiating prices as well as more efficiently collecting, disseminating, and assessing information and drug safety, costs, and cost-effectiveness as was called for in the Romanow, HESA, and Advisory Council Reports. Alone, however, these features seem to necessitate a single regulatory, negotiating, and assessment body rather than a single-payer. However, when combined with the superior risk pooling abilities and administrative efficiencies of a single-payer system, as well as the complexities of regulating private industry to meet public health objectives, a single-payer system likely offers the best prospects for implementing an efficient program of universal pharmaceutical insurance.

6.3.4 Individual Choice, Paternalism, and Medical Evidence

If mixed multi-player pharmacare does not, on balance, offer efficiency-based advantages, does it offer liberty-based ones? It is first worth recalling that liberty itself is a contested term in political philosophy, and includes notions of negative liberty (freedom from), positive liberty (freedom to), and republican liberty (freedom from domination or arbitrary interference). Although not as overtly emphasized in arguments for public single-payer pharmacare, egalitarian concerns tied to universal comprehensive coverage often relate to notions of effective freedom, such as self-determination. Some in the debate also explicitly cited the ways in which a single-payer system could contribute to positive liberty, such as by increasing labour market mobility by no longer tying employment to a benefit that is disconnected from the nature of the position itself. A republican concern for freedom from domination also resonates with some form of nondiscretionary entitlements as removing certain interactions from the market can secure individuals against the risk of exploitation of dependencies (Goodin 1988). However, as

[123] The PMPRB assesses prices relative to pricing in comparator countries to determine whether a drug price is excessive for the Canadian market. The PMPRB has proposed to use eleven (rather than seven) comparator countries in its new guidelines as well as exclude Switzerland and the US, which are the only countries with higher drug prices than Canada, as comparators. The Guidelines were set to come into effect on January 1, 2021, have been delayed by six months. Zhang et al. (2017) argue that in the absence of reform, the PMPRB existing, yet ineffective guidelines serve as a ‘regulatory shield’ that is used by industry to protect itself from reforms in the public interest.

discussed in the findings, most concerns related to negative liberties are raised in the context of arguments for mixed multi-payer pharmacare.

6.3.4.1 The Scope of Government

Proponents of mixed multi-payer pharmacare raised two main types of liberty concerns: one that has to do with limiting the scope of government in general, and thus also in the context of insurance, and a second argument, which emphasizes the greater latitude that a multi-payer system offers in choice of coverage and medications. With respect to the first issue, any system of universal insurance will involve an incursion on individual liberty and likely involve cross-subsidization. However, as Buchanan (2009:103) notes, arguments for health care privatization often overlook that any system which seeks to offer just care (in the sense of securing an adequate level of universal coverage that protects against excessive burdens) will require "a good deal of regulation or a good deal of government financing or provision of care, and that for this reason privatization does not necessarily mean less government." Recall, similarly, the earlier discussion of how countries that offer universal coverage through mixed or private insurance rely on both public financing and extensive regulation. Yet, libertarians take issue with universal coverage and instead advocate for voluntary mechanisms of insurance and charitable coverage on the grounds that mandating insurance is an unjust incursion on individual freedom. Moreover, those who also take issue with the inherently redistributive nature of insurance on the grounds that it constitutes illegitimate cross-subsidization and redistribution of resources, tend to advocate for financing mechanisms that limit cross-subsidization altogether, such as individual medical savings accounts (e.g., Ramsay 1998; Gratzer 2002). However, medical savings accounts are neither efficient, as they lack the advantages of risk pooling inherent to insurance, nor provide adequate or equitable financial protection as health care costs are highly uncertain and thus difficult to plan for accurately (Wouters et al. 2016). Thus, unless Canadians are willing to forgo universal coverage to begin with, as well as efficient care, the strictest liberty-based concerns are moot. Moreover, they have not featured prominently as overt arguments in the debate to date.

Meanwhile, liberty-based arguments that accept the objective of universal pharmacare but still argue for a mixed multi-payer system on the basis that it still limits the incursion of government on individuals' freedoms run into a separate challenge. Arguments about limiting the scope of

government activity through a multi-payer system are at odds with calls for increased government involvement in subsidizing high cost drugs, which would involve significant financial resources (and thus tax burden). Yet, as discussed above, certain proponents of mixed multi-payer pharmacare advocate for greater government involvement in this area largely because of the challenges that high cost drugs pose for smaller risk pools to remain solvent or offer competitive coverage. Ultimately, the decision of how to prioritize considerations of liberty against those of equity and efficiency is a normative and political one.

6.3.4.2 Choice

The second liberty-related concern pertains to the observation that private insurance plans tend to offer broader or more 'generous' pharmaceutical coverage, including by reimbursing new drugs earlier than public payers. Proponents of mixed multi-payer pharmacare argue that this offers two main advantages. First, a multi-payer system offers more choice in insurance plans, allowing individuals and employers to select coverage that better suits their preferences or needs and limits concerns about government incursion. Second, broader drug coverage affords patients greater latitude in accessing pharmaceuticals that meet their unique health needs or circumstances, while public coverage is seen as restrictive.

While a public single-payer program would set a floor for coverage (e.g., drugs included on a national formulary), most of the concerns about accessing a broader range of medications or tailoring coverage could be alleviated by using reference-based pricing and allowing for the purchase of supplementary insurance. The use of reference-based pricing, where public reimbursement is limited to the most cost-effective medication in its class above which patients cover the difference out-of-pocket or through supplementary coverage, was cited in the Advisory Council's recommendations (Health Canada 2019:76). It is worth noting that even this presents a trade-off, since reference-based pricing may offer fewer cost-savings and thus be less efficient than more strict purchasing policies that make use of tendering (Kelley et al. 2018). Proponents of mixed pharmacare also raise concerns that strict price negotiations and purchasing policies and a monopsony could restrict the range of medications on the market as well as contribute to drug shortages. In Canada, drug shortages appear to be more likely to occur in pharmaceutical classes in which there is a single generic manufacturer (Zhang et al. 2020). Drug shortages already occur in a multi-payer system, but the risk of shortages can be reduced through contracts

that include financial penalties for suppliers (Law and Kratzer 2013) or through centralized monitoring and stockpiling (Tadrous 2020). These concerns also represent sites where policy makers must balance concerns about choice with considerations of efficiency.

Yet the concern about choice also raises a second consideration about agency in medical decision making. Recall the earlier discussion about the divergent uses of the terms ‘appropriateness’ and ‘medical necessity’ in the debate. The former is cited as necessitating pharmaco-epidemiological and -economic evaluations of safety, effectiveness, and cost-effectiveness, while the latter frames the assessment of medical necessity as occurring primarily at the level of the clinical encounter between the individual patient and prescriber. Proponents of mixed multi-payer pharmacare often claim that individual patient circumstances can limit the extent to which a medication is effective for an individual, and that as such, they are harmed when health care providers do not have latitude in prescribing. While this concern can be mitigated through programs such as prior authorization schemes, which are also used by private insurers (Grootendorst 2013), or through tiered prescribing, it also raises an important question about the nature of decision-making and medical evidence in pharmaceutical insurance. Moreover, concerns that reimbursement is limited for high cost medications have been framed as an imposition of equality of access rather than equity in access, including for expensive, specialized medications, in accordance of needs (Rawson 2020). The question of who determines medical necessity become especially acute in the context of ‘me too’ drugs for which there is little evidence of comparative effectiveness and for expensive drugs for rare diseases for which there is (at least temporarily) limited evidence of safety and effectiveness.

6.3.4.3 Adjudicating Medical Necessity

Despite being a clinical term with certain implications such as distinguishing needs from wants, or treatment from enhancement, medical necessity is also an evaluative and contested term. That medical necessity is evaluative or contested is not an inherent threat to evidence-based medicine, but rather resonates with an understanding of medical facts as being probabilistic, fallible, and value-laden (Upshur and Goldenberg 2020). What this means, however, is that a pharmaceutical insurance system ought not simply rely on a value-free understanding of evidence of effectiveness as an objective arbiter of needs, but rather, demonstrate how it can be cognizant of and conduct fair evaluations of need, including by attending to individual considerations and

circumstances. Not only is this a concern for individual liberty, but also for public health, for as Jennings (2007) notes, ‘publics’ are comprised of people who experience benefits and burdens as individuals.

Proponents of public single-payer pharmacare offer a compelling argument for the efficiency of public and centralized mechanisms for information transmission owing to the informational asymmetries inherent in pharmaceutical use (e.g., the control of clinical trial data by pharmaceutical manufacturers and the filtering of information into assessments of appropriateness and need by physicians and other experts). While a centralized information transmission mechanism can offer efficiency-based advantages, the design of a national formulary must also demonstrate concern for individual patient needs and recognize that assessments of effectiveness are in themselves value-laden. It is not my objective here to argue for one definitive approach to prioritization, but rather to emphasize that any prioritization scheme has distinct normative implications and none are ‘neutral.’ It also suggests that if values are inherent to medical facts, decision-making processes should reflect this, such as by taking patient and public views into account. Determinations of effectiveness, for example, require considering how maximizing and distributive considerations ought to be balanced (e.g., maximizing value for money vs. allocating greater resources to those with rare diseases, or prioritizing many small benefits vs. fewer large benefits), while different theories of justice present distinct accounts of what constitutes fair patterns or process of distribution (Powers and Faden 2006). As such, considerations of fairness, including about equity and individual choice, serve as justice-based deontic constraints on efficiency imperatives.

In addition to substantive considerations of justice, procedural forms of justice or democratic deliberation offer ways to guide fair or legitimate priority-setting (e.g., Bentley et al. 2018; Bentley et al. 2019). Health technology assessment agencies in Canada, for example, include patient and public engagement to inform their decision-making (Abelson et al. 2016), although the use of public engagement in priority-setting decisions appears inconsistent (Regier et al. 2014). As Daniels and Sabin (2001:314) argue by appealing to their account of procedural justice, when people face priority-setting decisions replete with uncertainty or about minimal differences in benefits, it can be expected that reasonable people would still disagree on priorities. Just priority setting, on their account, requires following the principles of accountability for reasonableness (publicity, relevance, revisability, and enforcement). Yet, a

system of fair decision-making that makes room for public and patient involvement will nonetheless not be able to reflect the full range of individual views or circumstances. Moreover, as Powers and Faden (2006) note, procedural justice is no panacea and has its limitations:

> institutional decision makers are still in the end required to make hard decisions, informed if not constrained by the outcomes of the deliberative, or in [Daniels and Sabin's] case accountability for reasonableness, process. At minimum, the process confers a greater likelihood for public acceptance of decisions institutional policy makers ultimately make. At best, such processes help narrow the range of morally permissible options available to policy makers.

Accordingly, as Daniels and Sabin (2001:314) note, "a fair set of coverage rules must allow for a fair set of exceptions," such as reimbursing for more expensive treatments if the first in a class of therapies fails. Moreover, it is worth noting that private insurance plans are increasingly also taking into account considerations of cost-effectiveness to set limits to reimbursement, yet as Daniels and Sabin (1997) argue, they seldom meet standards of procedurally just decision-making.

Ultimately, the decision of how to prioritize considerations of liberty against those of equity and efficiency in the design of a pharmaceutical insurance scheme will be a normative and political one. As insurance is necessarily 'multipolar,' or a mechanism that facilitates cooperation between multiple people, any reimbursement decision and exception affects all others in an insurance pool (Lehtonen and Liukko 2015:158).[124] Accordingly, consideration for individual circumstances will still be subject to limits in any system of insurance. Similarly, just as it is fair to allow for freedom of 'choice,' it is also justified that individuals bear a certain degree of costs associated with their preferences, unless need is demonstrated at a threshold that would qualify for prior authorization or exceptional access. The inevitability of rationing in any system of insurance, however, also has a corollary implication in a liberal society, which is that people should be permitted to purchase approved medications that are not reimbursed. Similarly, the purchase of supplementary pharmaceutical coverage is justified.[125]

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[124] The 'multipolarity' of insurance, which distinguishes it from savings or a simple bilateral relationship between the insured and the insurer, is often overlooked in the context of private insurance, such as when people express concerns about getting their money back (Lehtonen and Liukko 2015:158).

[125] Allowing for the purchase of supplementary coverage that does not overlap with public coverage does not parallel calls for two tier medical insurance in Canada, since a system of public pharmacare would represent a single tier for medications listed on the national formulary, while the purchase of additional medications parallels existing

So far, I have argued that the efficiency of a public single-payer system offers the most compelling justification for why a system of universal, comprehensive, progressively-financed insurance should be financed and administered publicly through a single-payer system. Moreover, I have suggested that insofar as a system of universal comprehensive insurance must set limits on coverage, as it inevitably will for pharmaceuticals, individuals should still be permitted to purchase drugs and/or insurance in excess of the public formulary. Ultimately, however, the extent to which a system will seek to balance considerations of efficiency, equity, and liberty is a normative and political one. A final consideration that I have yet to address, and which I turn to finally, is what the normative status and implications of community-based rationales are for pharmaceutical insurance.

6.3.5 Solidarity and Public Insurance

As noted in the findings, proponents of public pharmacare appeal to community-based rationales, including anti-commodification and solidarity-based arguments, to justify the implementation of a universal public single-payer program. I discuss each in turn and consider their normative implications, including whether they provide compelling support for a public single-payer system. I develop a more in-depth analysis in this section as solidarity is less theorized in the Canadian context, despite being invoked with respect to public single-payer pharmacare, and to explore the relationship between community- and solidarity-based arguments for pharmacare and the 'iconic' status of Medicare.[126]

6.3.5.1 Anti-Commodification

Proponents of public pharmacare sometimes appealed to the notion that drugs are not commodities, but rather are public goods, and thus ought to be provided publicly. At first, this argument echoes communitarian arguments against the commodification of certain goods or services that are not valued appropriately when provided through market exchange, which in the

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opportunities to procure medical care and other health care services that are not publicly covered. Egalitarians might take issue with allowing for supplemental coverage if it were to meaningfully exacerbate inequities in health outcomes or capacities for self-determination, but few do so owing to concerns about 'leveling down.' Moreover, one could argue that a public system which does not cover medications that have the capacity to produce marked differences in health outcomes would have failed to offer comprehensive coverage to begin with.

[126] For a discussion of solidarity in Canadian health care, see *Health Care Analysis* Issue 25: Precarious Solidarity—Preferential Access in Canadian Health Care.

case of medical care and drugs, would be in accordance with medical need (e.g., Walzer 1983). As regulated substances, pharmaceutical are prescribed and used in accordance with an assessment of medical need, rather than according to ‘wants’ as in the case of consumer goods. Even insofar as medical necessity is contested, the range of possible medical needs for a pharmaceutical tends to be defined and regulated. As a result, it is recognized that health care and pharmaceuticals do not behave as simple ‘wants’, in that they are conditioned on needs defined by experts (be it physicians or those determining clinical practice guidelines and drug formularies) who are often not cost-conscious, usually have side effects that dissuade rather than encourage their use, and are also less price sensitive if appropriate (Deber 2008; Grootendorst 2013). Yet these concerns point to the notion the drugs share features with economic public goods insofar as information asymmetries distort their market provision. As was noted during the 1998 Conference on National Approaches to Pharmacare, drugs occupy a complicated space between public goods and commodities that are developed and sold by commercial entities. As such, concerns about the commodification of the provision of pharmaceuticals may be better understood in terms of efficiency, rather than on a ‘thicker’ conception of anti-commodification for goods that pertains to goods that are defiled (e.g., contravening dignity) or not valued in a morally appropriate way if they are bought and sold (e.g., Sandel 2012). Moreover, it is not the selling of medications per se that seems to be morally odious—for pharmacare does not propose to socialize pharmaceutical development and manufacturing[127]—but rather the failure of markets to ensure the effective provision of pharmaceutical insurance so that all can procure necessary medications.

6.3.5.2 Does Public Insurance Express a Sense of Solidarity?

More frequently, however, proponents of public pharmacare appealed to the notions of solidarity or mutual responsibility in calling for a public single-payer system, and more often, when characterizing the existing Medicare system and framing it as a model for pharmacare to emulate. The argument takes on two forms: a public single-payer system embodies a sense of solidarity, relational equality, and national identity or values (and is thus presumably valuable);

[127] Of interest, California recently promulgated legislation that allows the state’s health agency to enter into partnerships with pharmaceutical manufacturers to manufacture or distribute generic drugs in an effort to increase the affordability of medications such as insulin (Stephenson 2020).

and a public single-payer system is justified on the grounds of mutual responsibility or as a 'right of citizenship' (i.e., mutual responsibility and relations of equality necessitate a public single-payer system). Thus, determining whether solidarity necessitates a public single-payer system in particular requires considering whether insurance does, as a matter of fact, shape responsibilities and expectations of mutual responsibility for health, and relatedly, whether *only* public provision generates the desired effect. Moreover, it also requires considering whether pharmaceutical insurance, in particular, is an institution in which we ought to value or seek to foster relations of mutual interdependence.[128]

Solidarity is a relational concept that considers individuals and communities to be mutually interdependent and entails a degree of collective responsibility. Accounts of solidarity can be distinguished by the extent to which solidarity is considered an instrumental or intrinsic value (Komparic et al. 2019). On an intrinsic account, solidarity is understood as being motivated by other-regarding moral considerations rather than just reciprocity (Prainsack and Buyx 2017). For example, as Goodin (1988:77-78) describes:

> Talk of "mutuality" and "reciprocity" rather suggests […] that the reason that one person helps others is to secure assistance from them tomorrow. Communitarians see no role of any such cynical "insurance" or "investment" logic in their mutual-aid arrangements. What motivates members of a true community to render assistance to a neighbor in distress, they would say, is not any expectation of future return on their investment but rather a genuine, empathetic concern for their plight of the needy neighbor. (Goodin 1988:77-78)

I agree with Goodin's (1988) assertion that welfare rights, including public health insurance, do not *logically* imply a sense of solidarity beyond that of an instrumental, institutionalized chance, risk, and income solidarity; in other words, being enrolled in such a program is not by definition sufficient for an individual to be motivated by and act out of concern for others or to feel a sense of community membership. Whether insurance does, as a matter of empirical fact, shape

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[128] For example, Goodin (1988:81) discusses how the relationships between community and welfare entitlements can be ones of logical implication (e.g., "having welfare rights is just what it is to be a member of the community") or empirical observation (e.g., "welfare entitlements are empirically conducive to the feelings of community attachment"). He (1988:70-118) argues that communitarian justifications fail both to demonstrate that the welfare state is either necessary or sufficient for achieving the communitarian ideal or that communitarianism uniquely justifies the welfare state. I have already considered whether equity *necessitates* public, single-payer coverage and concluded that it likely does not.

relationships and expectations concerning responsibilities for health and a sense of social solidarity remains an open question. I suggest that public insurance may engender a deeper sense of solidarity, but it is not clear that it is either sufficient or necessary to do so. Thus, if social solidarity is a desired policy objective, public provision may help, but it does not seem to provide a conclusive justification for a single-payer system.

While my analysis is not suited to decisively address this empirical question, I am sympathetic to the claim that public insurance, as an institution, can in some respect shape relations and expectations between citizens and co-insureds, in part because this seems to be borne to some extent in the history of Canadian Medicare. Earlier, I cited Tuohy's (2018) argument that the introduction of Canadian Medicare preceded and contributed to the widely touted and held beliefs about Medicare's status as a national symbol that embodies 'Canadian values' such as equity. While the history of Canadian Medicare suggests that egalitarian and communitarian considerations motivated interest in universal coverage at the level of policy elites (e.g., Tommy Douglas's concerns for justice and a robust sense of democracy and community membership and Justice Emmet Hall's concern for human rights), efficiency considerations were also significant in tipping the favour towards a single-payer public system in particular (especially on the part of the federal government and in the Hall Report) (Marchildon 2016; 2020; Tuohy 2018). Yet, beliefs about the connection between commitments to equality and solidarity and public, single-payer coverage in particular were not widespread among the electorate until after its implementation. Indeed, Canada and the US appeared to be on a similar trajectory for health insurance policy prior to the establishment of Canadian Medicare, after which Canadians' expectations and self-perceptions as a 'sharing community' shifted and "universal single-payer coverage became politically iconic in Canada and taboo in the US" (Tuohy 2018; 2019:5).

One way in which institutions such as insurance can be understood as shaping relations of solidarity is through expressing a sense of relational equality, or the relational egalitarian idea that justice requires that social or economic arrangements allow members of society to relate to each other as equals.[129] This builds on the notion that social institutions have an 'expressive'

[129] Accordingly, redistribution is not an aim but a means to achieving the objective of relational equality (Landes and Néron 2015).

function, in that they "carry meanings and send various messages," in addition to, for example, their efficiency-promoting or redistributive ones (Sunstein 1996; Landes and Néron 2015:149). Relational egalitarians and communitarians prefer social and institutional arrangements that promote an ethos of equal respect or a "single-status moral community" by uniting benefactors and beneficiaries (Walzer 1983; Goodin 1988:74; Landes and Néron 2015). On such an account, "public insurance furnishes a *social grammar* that allows citizens to make equality claims" as entitlements are contingent on solely one's community membership rather than depending on other considerations such as income or others' benevolence (Landes and Néron 2015:150). Yet, the very fact that the characteristic feature of the welfare state is "not that it consists of *moral* ideas or duties to support the needy, but that this support is legally institutionalized by the state" and thus demoralized as it is "transferred to a bureaucratic apparatus and carried out anonymously," calls into question whether the welfare state is necessarily an expression of solidarity (Goodin 1988; Bayertz 1999:22-25).

Canada's public health care system is cited as embodying or expressing principles of equity and solidarity, which are in turn cited as being 'Canadian values' or as emblematic of national identity (and which are often cited as distinguishing Canada from the United States). For example, the final report from the Advisory Council on the Implementation of National Pharmacare invokes notions of mutuality and fairness early on to frame its approach:

> But most of all, [Canadians] reminded us to heed those uniquely Canadian values: looking out for one another, supporting neighbours and communities through tough times and treating each other with fairness. (Health Canada 2019: 8)

Similarly, and nearly twenty years earlier, The Romanow Report (Commission on the Future of Health Care in Canada 2002:xvi), for example, stated with respect to Medicare that:

> In their discussions with me, Canadians have been clear that they still strongly support the core values on which our health care system is premised – equity, fairness and solidarity. These values are tied to their understanding of citizenship. Canadians consider equal and timely access to medically necessary health care services on the basis of need as a right of citizenship, not a privilege of status or wealth. Building from these values, Canadians have come to view their health care system as a national program, delivered locally but structured on intergovernmental collaboration and a mutual understanding of values.

Given the enduring nature of this narrative in Canadian health policy, it seems reasonable that institutions such as public health insurance can, at least to some extent, express and shape certain expectations about social relations and community identity. Insofar as solidarity "presupposes some kind of identification with the community one belongs to as well as a sense of mutuality between the members of the community," the elevation of Medicare to the status of an identifying feature of Canadian identity lends support to its expressive force (Maarse and Paulus 2003:588).

Yet at the same time, and as was noted two decades earlier by the National Forum on Health (1997), commitments to equality and solidarity invoked in the context of health care do not translate as clearly to other areas of social policy. Indeed, while Canada displays a 'social democratic' public health insurance system that is universal and offers comprehensive care on uniform terms and conditions, other social programs such as for pensions or social assistance do not display the same solidary relations or distributive patterns; the former is a 'quasi-Beveridge' system that is universal and contribution-based, while the latter is residual and mean-tested and has become more residual over time (Tuohy 1994). Accordingly, it is unclear to what extent an expression of solidarity through one institution such as Medicare is sufficient to engender solidarity more broadly in a community. Indeed, the pharmacare debate itself (let alone other areas of care that are not publicly financed, such as long-term care or dental care) calls this into question; on the one hand, pharmacare is framed as the 'unfinished business of Medicare,' while on the other, it has yet to be implemented despite the long-time invocation of solidarity as a guiding value in health insurance. Moreover, in the context of the Canadian federation, it is also worth asking what constitutes the relevant political community. Indeed, defining the scope of the relevant 'sharing community'—whether at the regional or pan-Canadian level—has been an ongoing source of tension in Canadian health policy (Banting and Boadway 2005; Tuohy 2018). Despite being administered by provinces and territories, Medicare has taken on a central role in the national 'sharing community' and is supported through federal health transfers and equalization payments. More broadly, Canada can be understood as a dual sharing community in which residents demonstrate attachment at multiple levels of community (Banting and Boadway 2005).

Yet, even if we grant that institutions can express certain normative ideals and shape moral attitudes and relations between their members, the question remains as to whether universal

insurance must be provided through a public single-payer system in particular in order to achieve these objectives. Relational equality supports creating a system of universal entitlements to coverage. While a mixed system could still in theory meet redistributive egalitarian aims such as redistributing financial burdens associated with medical care (i.e., exhibiting some form of risk and income solidarity), the relational egalitarian may argue that a mixed system would not express or exhibit the same sense of relational equality or solidarity unless every member is seen as a contributor, rather than being divided into beneficiaries and benefactors. Similar concerns are raised about the potential stigma associated with residual public programs (Powers and Faden 2006), which may undermine a sense of community membership and equal-respect. At the same time, solidarity is most often invoked and recognized as a justification for universal health coverage in continental Europe—being cited as one of four values in European healthcare—including in countries that have mixed multi-payer insurance systems (van Leeuwen 2008; Prainsack and Buyx 2016). In these contexts, universality, or the broad scope of entitlements and membership, seems to be a key feature of expressions of solidarity, as do measures to facilitate risk and income solidarity (including through public funding). Yet, solidarity is recognized as a guiding principle even in countries where insurance is not offered through a single system of financing and on strictly uniform terms and conditions (e.g., in Belgium, Germany, the Netherlands, and Switzerland) (Maarse and Paulus 2003). It is not clear, then, that a single-payer system is uniquely necessary or sufficient for engendering solidarity or a sense of shared identity within a community, but ultimately, this remains an empirical question. At most, we can say that a public, single-payer system—if it is compellingly expressive—may be more likely to foster a sense of social solidarity.

6.3.5.3 Does Solidarity Justify Public Pharmacare?

Yet, whether or not public single-payer pharmacare is the only way to foster a sense of solidarity, we can also ask whether pharmaceutical (or health) insurance, in particular, is an institution in which we ought to value and seek to foster relations of solidarity and mutual interdependence. Or, relatedly, does solidarity logically justify, and moreover necessitate, a system of public single-payer insurance? I have already noted that, empirically, it is possible but not certain that a public, single-payer system may be more likely to foster a sense of solidarity than a mixed, multi-payer one. Here, however, I would like to explore whether solidarity, if taken as desired value, logically implies a public, single-payer pharmacare program in particular.

Solidarity-based arguments for public pharmacare can proceed in two related ways: solidarity and relations of equality are required to attain full membership with a community, so public provision for health insurance is required because it the only way to deliver insurance on terms that foster equal standing and reflect its status as 'right of citizenship'; and relatedly, that health is relational and thus requires a solidary insurance system, including one that embodies risk and income solidarity, to assume collective responsibility for health risks.

Walzer (1983:64-65) provides an example of an account that promotes the first line of argument, where all goods that are socially recognized as necessary to common life—including health care—constitute needs that ought to be provided communally, universally, and distributed according to need. Communal provision is taken to promote equality of membership within a community: "mutual provision breeds mutuality. So the common life is simultaneously the prerequisite of provision and one of its products" (Walzer 1983:65). In other words, the public provision of basic needs or entitlements is seen as necessary so as to sustain relations of equality and contribute to a single-status community, and to prevent domination. This line of argument also reflects relational egalitarian arguments that assert that public insurance "aims to create a community of individuals who stand as equals" (Landes and Néron 2015:150).

A program of public, single-payer pharmacare could on such an account be justified on the grounds that the delivery of universal coverage through a single-payer system on uniform terms and conditions—or a 'stronger' form of universality (Marchildon 2014)—and which embodies chance *and* risk and income solidarity, institutionalizes relations of equality between co-insureds (citizens); all members are at once both beneficiaries as well as benefactors with obligations to pay taxes and support others in need. Quebec's existing system of universal multi-payer insurance, for example, was cited as 'dismantling' social solidarity because it created silos between contributors and beneficiaries as well as between public and private insurance pools (Standing Committee on Health 2016). Appeals to solidarity or notions of social citizenship are also used to justify claims to regional equity (Maioni 2010).The normative implication is that a system of health insurance ought to be one in which relations of solidarity, mutual interdependence, and equal standing are engendered and produced.

Yet, it is not clear to what extent a public *single-payer* system, rather than a universal system of some sort or another institution, is required to attain this objective. For even if we can facilitate

relations of solidarity or equality through health insurance, as Goodin argues (1988:63), community membership does not logically imply welfare rights, since the:

> the communitarian ideal is merely to provide *a* sense of community—of solidarity and significance—among a group of people. *Which* sense of community is evoked, from the bare communitarian perspective, a matter of utter indifference. The goal is to produce a community, not a community organized around any particular principle rather than any other.

In this vein, arguments for public single-payer pharmacare grounded in solidarity would need to demonstrate that without a single-payer system, there would be a morally significant reduction in the desired sense of solidarity, be it one of national unity, equal standing, or otherwise.

Moreover, it is ultimately a normative and political question the extent to which societies *ought* to foster community ties or relations of moral interdependence, including fostering altruistic and other-regarding motivations, and moreover, at which level of community they wish to do so. Similarly, the extent to which insurance *ought* to embody and institutionalize a 'thin' sense of the common good, which relies on a liberal understanding of the public as an aggregate of individuals with no intrinsic significance as a collective and that engages in instrumental forms of cooperation, or a 'thicker' sense of the common good, such as on a republican conception of civic political imagination in which the common good represents a shared (rather than overlapping) purpose or concern (Jennings 2007), remains a normative and political question that proponents of this view will need to defend.

Some argue that solidarity is a precondition for justice or functions as a 'shaping sensibility' that informs an understanding of other normative principles and obligations, including obligations of justice (Jennings and Dawson 2015:32; ter Meulen 2015). Krishnamurthy (2013:138), for example, argues that a political conception of solidarity "plays an integral role in both the development of and the motivation to act on a commitment to justice." Political solidarity is understood as a relational concept through which citizens "have attitudes of collective identification, mutual respect, mutual trust, loyalty and mutual support toward one another," rather than one that requires a shared conception of the good life or agreement over fundamental values (138). Since social and political institutions and practices can engender political solidarity, justice requires that states promote the bases for realizing relations of political solidarity. Insofar as a public single-payer system facilitates relations of solidarity or equal

standing, and for example facilitates the acceptability and interest in a system of financing that embodies elements of risk and income solidarity even if they may not be in every individual's self-interest, it is to be preferred on this account.

Yet some, for example, argue that the community ought to be engendered at more proximate or local levels and, moreover, that public welfare programs have dislocated community ties (e.g., Beito 2000; Deneen 2018). The welfare state, for example, can be seen as legally institutionalizing relations of solidarity, but in so doing, it 'demoralizes' them, depersonalizes them, and relies on coercive means rather than on motivations of moral duty or mutuality (Bayertz 1999). On the one hand, the invocation and institutionalization of solidarity through welfare states is at odds with liberal notions of individualism. At the same time, it is perhaps unsurprising that liberal states that are characterized by pluralism also elevate institutions such as Medicare to the status of national icons, as in Canada, as they provide a source of common interests even among people who may disagree on more fundamental questions of value.

This might have practical worth in a liberal, pluralist society by building a sense of common purpose or common good insofar as political communities require a certain degree of identifying features or shared interests to function as effective political communities; this common good is likely both 'thin,' representing an instrumental form of cooperation, but also a bit more 'thick,' insofar as citizens begin to identify their wellbeing or 'fates' as being tied to those of others in their community. As discussed earlier, in the context of the pharmacare debate, Medicare is often invoked as a national symbol and public provision is tied to understandings of social citizenship (Maioni 2010; Tuohy 2018). The Chair of the National Advisory Council on the Implementation of Pharmacare introduced the Council's final report with a similar allusion to a national project:

> Our council has heard the stories of thousands of Canadians and listened to a wide range of perspectives. The time for universal, single-payer, public pharmacare has come. This is our generation's national project: better access to the medicines we need, improved health outcomes and a fairer and more sustainable prescription medicine system. Let's complete the unfinished business of universal health care. That can be our promise, and our legacy, to each other and to all future generations. (Heath Canada 2019:1)

It is worth noting, for example, that the interest in identifying national 'values' in Canadian public policy in the early 1990s coincided with a period of great national discord with the threat of Quebec's secession. Indeed, federal governments have also sought to "reinforce the sense of a

direct linkage between citizenship and health care provision" (Maioni 2010:30). Moreover, Medicare's resistance to reform—for better or for worse—has in part been attributed to the perceived political ramifications of reforming an institution of such iconic status which appears to enjoy broad public report (Bhatia and Coleman 2003; Tuohy 2018). A commitment to solidarity in insurance has been cited as a factor in limiting or shaping the course of health insurance reforms elsewhere as well (Bhatia and Coleman 2003). Insofar as residual public health insurance programs can fail to secure adequate political support to sustain them, a system that is recognized as being a shared objective may be practically significant as well (Powers and Faden 2006).

As Buchanan argues (2009), any account that seeks to determine the just division between public and private sectors in health care will need to go beyond demonstrating that privatization is in principle compatible with just care, but that it is also compatible with the political motivations and behaviours of the electorate. Yet, the more entrenched the private sector is, "the less likely that influential citizens are to give their wholehearted support to public programs designed to fill the access gap and to achieve a fair distribution of costs" (102). The historical absence of strong electoral motivations for pharmacare reform resonates with this observation (Boothe 2015). Accordingly, it is possible that a public single-payer system may motivate a sense of solidarity that makes it more resistant to dismantling or underfunding, whereas an incremental approach to reform in a mixed multi-payer system may leave further reforms without adequate support and possibly result in a 'second best' situation in which partial implementation is worse (e.g., in terms of equity or efficiency) than if none had been instituted. This may be a risk with the introduction of a publicly-financed strategy for rare diseases in the absence of expanding universal care for routine medications for those with lower incomes, since it would not only increase costs and create a potential barrier for further expansion, but also possibly exacerbate inequities.

In the next section, I consider why one might seek to promote relations of solidarity in health insurance in particular.

6.3.5.4 Solidarity and the Relational Nature of Health

As discussed above, some argue for the public provision of pharmacare on the grounds that public provision is necessary to engender relations of equality. It is worth considering why

health insurance in particular is an institution through which we may wish to do so. Some might argue that solidarity is the right aspiration for a public health response because it appropriately reflects and highlights the relational nature of health (Jennings and Dawson 2015). For example, various factors beyond an individual's genetics and life style affect their health; these social determinants of health include income and income distribution, education, employment, gender, and race among others. Moreover, socio-economic status (or relative advantage and disadvantage among individuals and groups) is correlated with health status in what constitutes a social health gradient. (Marmot 2004; Mikkonen and Raphael 2010). The social determinants of health can thus be considered 'social risks' as "the exposure of a given individual depends as much on her own behaviour as on others'" (Landes 2013:12).

A liberal conception of political responsibility, meanwhile, would hold individuals responsible for financing their own health needs, either individually such as through a medical savings account on a libertarian account, or by paying actuarially fair premiums that reflect (as accurately as possible) the health risks that they bring to an insurance pool.[130] Yet, insofar as it becomes difficult to locate 'responsibility' in or for health, either because of the recognition of the impact of the social determinants of health on an individual's health status or because of the technical limitations associated with information asymmetries in accurately assessing an individual's health risks, a system of universal public insurance can become a necessary institutional response insofar as it has the feature of collectivizing material responsibility. Landes (2013) describes how traditional liberal accounts connect three levels of responsibility: causal (pertaining to the origin of the loss or harm), moral (pertaining to the judgement or responsibility), and material (the outcome associated with bearing the costs of the loss or harm). Insurance, meanwhile, 'transforms' responsibility insofar as it collectivizes material responsibility and disconnects it from causal and moral responsibility. Material responsibility is collectivized as the resources used to reimburse a claim do not stem directly from one's own contributions, but rather come from the insurance pool as a whole (Lehtonen and Liukko 2015).

[130] Even a luck egalitarian account that might reach this conclusion based on the distinction between brute and option luck appeals to a principle of solidarity in justifying why health care ought to be subsidized for those facing undue health care costs, since failing to do so could result in disproportionate burdens for some as a result of their circumstances rather than their choices (Segall 2007).

The collectivization of material responsibility contributes to and can be motivated by efficiency when it is difficult to adjudicate moral and causal responsibility and thus ascribing individual material responsibility is costly.[131] It also, however, can send a message (again, insofar as institutions are expressive) that, rather than being at fault for one's own ill-health, and thus responsible for incurring the costs associated with it, one's health is not only conditioned by individual behaviours or genetic circumstances, but also one's social location and the decisions and practices of others; thus, one's health becomes a matter of collective responsibility, while other's health becomes a matter of individuals' responsibility. This resonates with an understanding of health insurance that focuses "on the power to heal instead of on who is to blame" (van Leeuwen 2008: 599). The 'demoralization' of health responsibility in insurance can also offer advantages to the worse off by avoiding intrusive or stigmatizing practices for adjudicating eligibility for coverage or care (Powers and Faden 2006; Landes and Néron 2015).

The argument about the efficiency of collectivizing material risks also resonates with an argument for a 'market failures' account of public health ethics that justifies the scope of state activity in public health not only in the case of 'pure' public goods (as per the strict economic definition), but also in any case where private provision fails to efficiently 'internalize' the costs of activities that impact health (Horne 2019).[132] The major advantage claimed for such an approach is that it avoids being paternalistic. Social determinants of health, the argument goes, are themselves forms of 'externalities' that have not been adequately internalized and thus require public intervention.

Public health insurance, then, can be one way of not only efficiently pooling risks but also collectivizing responsibility and avoiding the potentially stigmatizing, costly, and unfair task of

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[131] As Landes discusses, this has been recognized as a motivating force in the creation of early social insurance mechanisms such as in response to the rise of workplace accidents during industrialization (e.g., Ewald 1986, Moss 2002; Goodin 1988). On the other hand, the institution of the first social insurance schemes for health and pensions by Bismarck is considered to have been motivated by political prudence, in an effort to quell a growing labour movement, rather than a calculation of efficiency or a sense of solidarity or moral duty (Bayertz 1999).

[132] Horne (2019) writes in response to Anomaly's (2011) assertion that public health activities ought to be limited to securing health-related public goods (in the strict sense) both in order to respect individual liberty as well as deliver certain types of goods that markets fail to deliver efficiently. This concerns a debate over the legitimate scope and justification for public health activities, where Anomaly builds on Epstein's (2003; 2004) argues for the return to an 'old' public health, which is limited to activities such as communicable disease control and certain activities that generate health-impacting externalities.

adjudicating causal and moral responsibility on an individual level. Moreover, insofar as it may be expressive and recognized as bounding those who are insured together, public insurance may also express an acknowledgement of the social nature of health through the institutionalization of solidarity in health.[133] However, whether this is broadly compelling and can contribute to motivating interest in addressing the social determinants of health as well or contributes to relinquishing further responsibility is unclear. As the impact of the social determinants is itself a site of political disagreement (recall the debate over the legitimate scope of public health), appeals to solidarity may be compelling for those who already feel a sense of connection with or responsibility for others in the community. Meanwhile, appeals to efficiency may be more compelling for those who see health more as an individual responsibility. The shift towards an increasing or parallel emphasis on the efficiency in addition to the equity or solidarity of single-payer pharmacare may in part be a reflection of this.

6.3.6 Conclusion

The pharmacare debate is a political debate that will necessitate making certain trade-offs between normative principles and competing accounts about the legitimate scope of state and collective responsibility. In this section, I have analyzed the pharmacare policy debate and in so doing, have sought to highlight areas in which normative tensions will need to be addressed. Moreover, I have suggested that insofar as Canada seeks to have a system of universal pharmaceutical coverage, the efficiency of a single-payer system offers the most compelling justification for why a system of universal, comprehensive, progressively-financed insurance should be financed and administered publicly. To achieve similar equity and efficiency objectives, a system of mixed multi-payer insurance would require greater public regulation than has been advocated for. Moreover, insofar as any system of universal comprehensive insurance must set limits on coverage, as it inevitably will with respect to pharmaceuticals, individuals should be permitted to purchase drugs or insurance in excess of the public formulary.

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[133] Some might also argue that many other needed goods are conditioned by a variety of factors beyond one's individual control and responsibility and thus, on such an account, would warrant collective responsibility and provision (e.g., many of the social determinants of health, including food, shelter, etc.), so the relational nature of a good is not sufficient to justify public provision.

While Canadian Medicare has been recognized as expressing a sense of solidarity or being tied to notions of social citizenship and as justifying risk and income solidarity, it is unclear whether solidarity necessitates or is sufficient for justifying a single-payer system of pharmacare in particular. Solidarity bridges both deeper considerations of relational or distributive justice—such as they pertain to a common good in which citizens share a commitment to universal coverage and to risk and income solidarity—and more instrumental ones in the form of efficiency, where the chance solidarity inherent to insurance makes it a productive mechanism for collectivizing responsibility in cases where responsibility is difficult to or ought not be adjudicated.

6.4 Chapter Conclusion

In this chapter, I have analyzed the findings described in the previous chapter in light of policy and theoretical literature from Chapters 2 and 4. In so doing, I have addressed the analytic and normative aims of my inquiry, which are guided by my second research question. I argued that the distinct conceptualizations and uses of medical necessity by different stakeholders in the pharmacare debate are indicative of two competing normative accounts of the purpose(s) of pharmacare and the legitimate scope of state and collective responsibility vis-à-vis health and health insurance. Moreover, I discussed the implications of framing the debate in normative terms. For example, recognizing that costs can serve as proxies for normative positions renders their underlying normative rationales open to critique. I contend that the dispute at the centre of the contemporary pharmacare debate is not simply one of values versus costs, or equity versus efficiency, but rather a dispute over which costs are justified and on what grounds. In other words, cost-related concerns in the debate are indicative of tensions between competing accounts of justice.

Finally, I critically analyzed the normative rationales underlying the main policy arguments in the debate. I asserted that insofar as Canada seeks to have a system of universal pharmaceutical coverage, the efficiency of a single-payer system offers the most compelling justification for why a system of universal, comprehensive, progressively-financed insurance should be financed and administered publicly. To achieve similar equity and efficiency objectives, a system of mixed multi-payer insurance would require greater public regulation than has been advocated for. Nonetheless, adjudicating medical necessity to set reimbursement priorities raises normative and

political questions of how to prioritize considerations of liberty against those of equity and efficiency in the design of pharmaceutical insurance. Finally, while Canadian Medicare has been recognized as expressing a sense of solidarity, it is unclear whether solidarity necessitates or is sufficient for justifying a single-payer system in particular.

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Chapter 7
Conclusion

7 Conclusion

In this concluding chapter, I describe how my study has addressed the research objective and questions and I discuss the substantive and methodological contributions of my inquiry. I conclude with a reflection on the limitations of my research as well as outstanding questions and possible avenues for further research.

7.1 Study Overview

Canada's pharmaceutical insurance landscape, and the absence of universal pharmacare in particular, has been characterized as a "policy puzzle" owing to its anomalous status among similarly situated countries with public health insurance systems (Daw et al. 2014). Those who have sought to explain the genesis and evolution of Canadian health and pharmaceutical insurance identify several causal factors that have shaped the contemporary insurance landscape and have hindered pharmacare policy reform. Against the backdrop of revived public debate and growing interest in pharmacare on the part of key political actors, this inquiry set out to understand what bioethics, as a practically-oriented normative mode of inquiry, could contribute to understanding the Canadian pharmacare public policy debate. In chapters 2 and 3, I described the reasons I chose to conduct an empirical bioethics case study in order to address the descriptive, analytic, and normative aims of my analysis of the pharmacare policy debate.

In Chapter 4, I described four theoretical orientations in political philosophy that constitute a theoretical framework that aids in identifying explicit and implicit normative rationales concerning the legitimate role of public and private institutions and actors in the financing and provision of health insurance. In Chapter 5, I drew on this theoretical framework to analyze the discursive landscape of the pharmacare debate by characterizing the main arguments in the debate in terms of their underlying normative rationales. Insofar as my findings are descriptive, they primarily address my first research question, which asks what normative rationales are invoked in arguments in the debate; however, insofar as I drew on my theoretical framework to identify normative rationales invoked in pharmacare arguments, my findings are also necessarily

analytic and interpretive, and thus also begin to address my second research question, which asks how normative and political philosophy contribute to understanding and informing the debate.

7.1.1 Major Findings

My analysis yielded two main findings. First, the main areas of tension in the debate are normative, not solely technical or evidentiary. In particular, I show how different pharmacare proposals were motivated by distinct understandings of three central policy problems—access, costs, and appropriateness—which were underpinned by different normative justifications, or appeals to distinct sets or conceptualizations of normative concepts and ideas about political responsibility vis-à-vis health. My second main finding concerns the evolution of arguments in the debate during the case study period from 1997 until 2019. The contemporary debate is characterized by convergence around the goal of expanding and universalizing pharmaceutical coverage as well as disagreement about the form that universal coverage ought to take. While public single-payer pharmacare has long been touted as a policy ideal for pharmacare, it was often regarded as infeasible. My findings suggest that there has been a discursive shift in the contemporary debate as proponents of a public system have more explicitly argued in favour of its efficiency-promoting, rather than its equity and community-promoting features.

In Chapter 6, I discuss how my findings suggest that tensions in the pharmacare debate are characterized largely by disputes over normative (political) objectives and that a key issue which remains unresolved and leaves pharmacare policy at a discursive impasse is what the purpose of pharmaceutical insurance *ought* to be. I also explore whether a notion of solidarity can help move the debate forward toward resolution about the ends of pharmacare. I contend that solidarity underdetermines whether pharmacare ought to be administered through a single-payer system. Nonetheless, solidarity may help address this impasse as it bridges both deeper considerations of relational or distributive justice—such as those pertaining to a common good in which citizens share a commitment to universal coverage and to risk and income solidarity—and more instrumental ones in the form of efficiency, where the chance solidarity inherent to insurance makes it a productive mechanism for collectivizing responsibility in cases where responsibility is difficult to or ought not be adjudicated.

7.2 Substantive Contributions

7.2.1 The Pharmacare Debate

My study has contributed to understanding the normative dimensions of the Canadian pharmacare policy debate. My findings suggest that the pharmacare policy debate is characterized by a dispute over what the purpose of pharmacare ought to be, which can be understood as a subset of broader political debates concerning the purpose of health insurance and the role and political responsibility of public and private institutions in health care financing, organization, and delivery.

First, my analysis contributes to recognizing that the pharmacare debate is a fundamentally normative, political debate as it concerns questions about desired and legitimate policy ends within a political community. My findings contribute to understanding how public policy is inherently normative as they illustrate how the framing of policy problems and solutions is underpinned by normative principles and rationales. Even where seemingly technical issues arise, such as those concerning efficiency or medical necessity when considering which institutional arrangements can best deliver on a policy objective, what appear to be empirical questions are nonetheless underpinned by normative considerations. For example, different conceptions of and emphases on medical necessity or appropriateness are used to justify distinct pharmacare policies but are underpinned by differing emphases on individual versus population-level health and relations of responsibility between citizens. Thus my analysis contributes to identifying and characterizing the major normative tensions between different policy positions in the debate as well as characterizing how the main positions frame policy problems and solutions in distinct ways. It also offers insight as to where pharmacare policy arguments are contradictory (e.g., around inconsistent appeals to liberty) or are underdetermined (e.g., appeals to equality or solidarity in connection with single-payer insurance).

My findings also contribute to understanding how the dichotomization of values- and costs-related issues does not simply reduce to a trade-off between equity and efficiency, or ethics and economics, but rather that cost-related issues are themselves normative. Thus, while costs have long been cited as a barrier to pharmacare policy reform—and have operated as seemingly neutral trumps over other policy considerations—surfacing the normative positions that underlie cost-related concerns helps understand that assessments related to costs are not neutral or

inevitable, but rather represent normative decisions about policy priorities. My analysis helps reveal that cost-related issues represent not only considerations related to efficiency, but also considerations related to differing conceptions of justice: one that emphasizes equity and another that prioritizes liberty.

Accordingly, my analysis demonstrates the difficulties of 'removing' politics from health policy debates in a quest for 'the holy grail' of objectivity, as has been called for by some stakeholders, since public policy is inherently political in the sense that it concerns questions about legitimate policy ends and means. Nonetheless, my analysis suggests that public policy debate need not be blindly ideological and can be open to reasoned critique and debate concerning normative issues and ends. Recognizing the normativity of public policy invites a reflection on what justified health policy goals are, and relatedly, what constitutes a policy benefit and how benefits and burdens ought to be distributed.

7.3 Theoretical Contributions

My analysis also contributes to, albeit modestly, to the developing philosophical literature concerning welfare states and public insurance (Landes and Holtug 2015). My study did not focus explicitly on articulating and expanding on a philosophical theory of public insurance, nor did I argue for a superior 'normative model' of the welfare state, or a reconstructive and explanatory account of what states ought to be doing that takes into account what and why states currently do what they do (e.g., for such an analysis, see Heath 2011). Rather, my analysis provides an in-depth case study that serves as an example of how philosophical theories can be used in the systematic empirical analysis of public policy debates concerning health insurance and welfare states.

By characterizing the normative rationales that are invoked in pharmacare policy arguments, my findings provide an indication of the sorts of normative objectives and reasons that are invoked by various stakeholders when addressing the question of 'what makes health public?' or a matter of shared (and state) concern (Coggon 2012). While in and of itself this analysis does not have direct normative implications for theory, in the sense that appealing to a normative rationale does not in and of itself imply that the rationale is sound or politically legitimate, an understanding of the normative rationales that are invoked in public policy debates can offer insight into which rationales resonate with stakeholders in policy making processes and in particular institutional

contexts. This contributes to understanding how the normative purpose(s) of public insurance are understood or framed by various stakeholders, which can be pertinent for informing non-ideal theory. For example, my findings suggest that proponents of public insurance appeal both to egalitarian or communitarian considerations as well as ones of efficiency. Accordingly, my findings resonate with assertions that state involvement in the financing on health insurance is justified on the grounds of the state's ability to facilitate cooperation rather than (or in addition to) its redistributive function or role in fostering community or upholding the common good. As I expand on below, my analysis can form the basis for further research into the implications of taking efficiency seriously as a normative principle when theorizing public and private responsibilities in the context of health policy.

Similarly, while my analysis does not explicitly advance the theorization of solidarity in bioethics, my study offers an in-depth case that facilitates studying whether and how solidarity discourses in a public policy debate resonate with conceptions of solidarity in the literature. Solidarity has garnered increased interest in bioethics over the past several years, which has prompted questions concerning its nature as a descriptive and normative concept and the extent to which it is of instrumental or intrinsic value. As solidarity is often invoked in the context of health insurance and public insurance more broadly, including in Canada (e.g., Reid 2017), my analysis offers a detailed discussion of the ways in which different conceptions of solidarity are invoked in or resonate with normative discourses in health reform debates. Insofar as philosophical theories developed in applied contexts, such as in public health ethics, aim or ought to be grounded in an understanding of real-world contexts, an understanding of dominant policy discourses is one factor that can inform a contextualized understanding of a policy problem and its attendant solutions (and their various framings).

7.4 Methodological Contributions

This study has also made several methodological contributions. The methodology and methods that I drew on to guide my study bridge normative policy analysis with the growing field of empirical bioethics, which draws on both qualitative research methods and moral reasoning. While interest in empirical bioethics has grown significantly over the past two decades with the recognition that empirical methods contribute to meeting bioethics' pragmatic aims, there are limited examples of empirical bioethics approaches for studying public policy debates in

particular. My first methodological contribution is to outline the synergy between normative policy analyses (discussed in the Background Chapter) and bioethics, which is understood as a practically-oriented, normative inquiry that benefits from both philosophical theory as well as qualitative research methods (discussed in the Methodology and Methods Chapter).

The second and more concrete methodological contribution was to develop and describe an empirical bioethics approach for the systematic study of normative discourse within a public policy debate. Moreover, my detailed account of the study design and data analysis can facilitate future use of this approach. In particular, I adapted a case study method and approach to thematic analysis in order to address the descriptive, analytic, and normative aims of an analysis that sought to characterize and critically analyze the normative discourse within a public policy debate. An advantage of my approach to analyzing policy arguments is that it allows for an in-depth analysis of not only explicit, but also implicit normative concepts and claims in order to comprehensively characterize the normative rationales that underpin policy arguments. For example, many other normative policy analyses (including my first analytic attempt[134]) adopt a principles-focused approach to analysis in that they aim to identify and enumerate individual policy principles that are explicitly invoked in policy frameworks or documents. Such analyses have often yielded conclusions that policy principles lack definitional clarity and appear disconnected from their practical contexts (MacPherson and Kenny 2009). My analysis corroborates the observation that principles are seldom *explicitly* defined in policy documents or discourse and may not be clearly tied to their policy contexts. However, rather than identifying a list of decontextualized principles, the method of thematic analysis that I have adapted facilitates an interpretive analysis of normative rationales or accounts that describe both the relationship between normative concepts within an argument and the relationships between normative concepts and the features of the proposed policy. By adapting a thematic analysis to capture dominant policy arguments and their underlying normative rationales, I was able to capture how principles are invoked in relation to one another and are embedded within broader arguments,

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[134] Recall the discussion in §3.2.4 Data Analysis in Chapter 3 (Methodology and Methods) where I discuss how I first approached my analysis by identifying and enumerating individual normative concepts and principles, which were decontextualized from their indigenous discursive contexts, prior to adapting Braun and Clarke's method of thematic analysis to analyze the normative rationales that underpin pharmacare policy arguments.

which provided insight into how they are conceptualized in distinct ways and used to justify the framing of policy problems and solutions.

My analysis also demonstrates how philosophical theory can be employed to inform a thematic analysis of public policy arguments in order to surface the implicit normative and political assumptions that pervade public policy discourse; this can form the basis for "hold[ing] them up to the light of critical reflection, and to make up our minds on whether or not they should be maintained" (Pettit 2006). For example, the adapted thematic analysis enabled me to identify how the same principles are conceptualized in different ways by different stakeholders and used to justify distinct policy solutions that contribute to an impasse in pharmacare reform.

7.5 Limitations

Qualitative research can be understood as being necessarily interpretive, in that the analytic lenses and methods that a researcher employs shape the analysis and interpretation of data; accordingly, each data set can yield a plurality of interpretations (Kvale 1996; Frost et al. 2010). Although it is not a flaw, I recognize that my analysis is limited insofar as it represents *an* interpretation of normative discourses in policy arguments that are presented in public fora where authors or witnesses are engaged in discursive and rhetorical exercises of attempting to convince stakeholders and policymakers of the merit of their positions. My analysis, however, does not attempt to discern people's 'true' normative commitments, nor do I hypothesize about stakeholders' interests or moral or political psychologies. Rather, I have aimed to characterize normative positions as they are presented in the public debate by 'anchoring' my analytic interpretations to the original data sources as well as the theoretical framework that I draw on in order to develop an analysis that is credible and open to critical examination by others (Stenvoll and Svensson 2011:574).

A related limitation is that I focused my analysis on discourse with the *public* policy debate, so I did not conduct interviews with key informants or members of affected and underrepresented communities in the debate, such as patients or low income workers without insurance. Interviews may have allowed me to ask more direct questions to probe participants' normative convictions and commitments with respect to pharmaceutical insurance in greater depth. Similarly, as my study sample consisted of data sources that were publicly available and consisted of arguments made in public fora, my findings do not capture the views or commitments of stakeholders who

have *not* been vocal in the debate (e.g., individual patients or members of the public not contributing via patient or public interest groups, individuals who silently oppose reform, etc.). Thus, my description of the normative discourse within the public debate does not necessarily reflect the diversity of opinions of individual Canadians.

Another limitation of my study is that it is a single case study of a health reform debate in Canada. Accordingly, the findings and analysis highlight certain idiosyncrasies of Canadian public policy discourse, such as the seemingly unique national symbolism ascribed to Medicare, which may not translate directly to other contexts.

Another limitation of my study is that I offer an internalist rather than an externalist critique. That is, my critical normative analysis operates within the parameters of the existing political and economic systems present in Canada (and indeed, a defining feature of welfare states is that they operate within the context of capitalist economies). While I chose to conduct an internalist critique given my focus on a contemporary public policy debate that operates within and assumes these parameters, a critique that more explicitly questions the very foundations of the existing political, social and economic order could very well yield distinct normative conclusions. Similarly, an analysis that questions the centrality of pharmaceuticals in achieving health for individuals and populations could have also drawn very different conclusions.

7.5.1 Explaining Prospects for Reform

My study is also limited in that it cannot explain the prospects for pharmacare policy reform. My analysis did not aim to be explanatory, since it focused on identifying and characterizing the normative content of policy arguments (the ‘what’ of pharmacare policy) rather than the role of institutions, interests, and policy timing (the ‘why’ and ‘how’) in shaping the processes and prospects for policy reform. Moreover, while my findings provide insight into ideational aspects of the policy debate, I neither explain *why* certain rationales are appealed to by certain stakeholders or have become dominant nor *how* they shape prospects for policy reform.

The normative rationales in the debate constitute only one factor that intersects with interests, institutions, policy legacies, and other social, political and economic considerations in the debate (Morgan and Boothe 2016). For example, as I noted but did not engage with explicitly and as has been discussed elsewhere (Morgan and Boothe 2016; Brandt et al. 2018), different interest

groups support distinct policy proposals in the pharmacare policy debate: academics, certain health care professional organizations and patient groups, unions, health charities, and progressive think-tanks tend to call for public pharmacare; some stakeholders support universal coverage while remaining agnostic on its administration; and the pharmaceutical and insurance industries, some patient groups, and conservative think-tanks advocate for a mixed model. Moreover, public opinion polls from the past several years (e.g., Angus Reid 2015; Abacus Data 2015; Ipsos 2019; Angus Reid 2020) suggest that there is broad public support for a pharmacare program that offers universal access to prescription drugs, including across different party affiliations, and similarly, broad agreement in response to statements such as: "Every Canadian – regardless of income – should have access to necessary prescription medicine" or "It's simply not right that some Canadians have to struggle to pay for medicine they need" (Angus Reid 2020:14). Responses to questions about the organization and financing of such a program, including whether it should be administered through a public single-payer plan or build on the existing insurance landscape indicate support for a public plan, but vary more markedly (especially across party lines). For example, respondents affiliated with the Conservative Party of Canada and/or living in Alberta, Saskatchewan, and Quebec (which already has a system of universal multi-payer pharmaceutical coverage) indicate lower levels of support for government intervention (Angus Reid 2020).

Wherever Canadians' interests lie, Boothe (2017) is correct in emphasizing the need to inform the electorate of the benefits and burdens—including those pertaining to costs—of pharmacare, for if the government is to act in the public interest, the public ought to be informed of the potential impact of various policies. For example, public consultation—similar to what was conducted by the Advisory Council on the Implementation of National Pharmacare—is required to discern the range of interests that public health insurance should serve, and at what costs, including relative to other public policy priorities. A normative analysis of the debate, such as the one I have conducted can contribute to clarifying how different policy objectives and justifications align with shared or distinct normative commitments and interests. So, although my study does *not* analyze the interests of stakeholders in the debate nor seek to explain prospects for policy reform, interests-based analyses could build on my analysis to examine how various stakeholder interests intersect with, shape, and are shaped by normative ideas. In all likelihood,

prospects for pharmacare policy reform will be shaped by a multitude of factors beyond (normative) policy ideas:

> …the adoption of [public single-payer pharmacare] would require, if not a macropolitical sea-change at the level necessary to bring about a broader single-payer model in the US, then at least a rare confluence of factors in which political leaders at federal and provincial levels would have both the institutional and electoral resources and the partisan incentives to undertake a major change in health policy. Even then, if history is a guide, the scale and pace of change adopted would depend on strategic calculations about the coherence of the coalition that could be built and the political urgency of action. (Tuohy 2019:20)

7.6 Further Research

In many ways, my analysis raises more questions than it offers answers. As I have already alluded to, there are several topics that I did not address, but which warrant further consideration. First, as I discussed in the preceding section, this study focused on characterizing a specific subset of policy ideas—normative ideas—within the pharmacare policy debate but did not aim to explain the prospects for pharmacare policy reform. Further research could thus examine the intersection between the normative ideas that I have identified and other factors that shape policy, including interests and institutions. While I have argued that many cost-related issues should be understood as raising normative concerns rather than simply as technical questions, it is worth considering how different ideas about fairness or justice that underpin concerns about costs intersect with and shape or are shaped by public and private interests.

A related question that would benefit from further consideration is how ethicists or policy advocates ought to frame policy issues and arguments in policy debates. As Brock (1987) suggests, philosophers engaged in policy-making processes ought to be concerned not solely with truthful argumentation but also with the consequences of framing arguments in particular ways given the pragmatic and consensus-oriented nature of policy-making. Accordingly, how normative concepts are understood by the public has practical consequences for their use in policy discourse. For example, I have discussed how efficiency can be understood as a political principle, but that it is not often recognized as such in public discourse. On the one hand, invoking efficiency to highlight the state's function as a mechanism for facilitating cooperation can be advantageous for policy insofar as it may be less contentious than a justification based on an understanding of the state as a redistributive mechanism. Yet, efficiency is often associated

with private institutions such as markets, so the extent to which appeals to efficiency are seen as compelling justifications for state intervention by the public is unclear.

This raises several questions for ethicists: should ethicists reclaim the language of efficiency from the (seemingly) exclusive purview of defenders of free markets and 'small' government? Or, if efficiency is burdened by the 'catallactic bias' such that it evokes the primacy of markets, would it benefit from alternate normative language? For example, drawing on Charles Taylor's assertion that language is constitutive, Malone (1999) argues that the use of market metaphors and language in medicine constrains ideas about health policy ends as policy language shapes ideas about moral agency and relationships. Does the language of solidarity, then, better address the normative motivations for health insurance, and if so, what are its normative requirements? Notably, while solidarity has been used to characterize Canadian Medicare, it is less frequently invoked explicitly than equity. A related question worth asking is to what extent framing health insurance as a symbol of equity (or solidarity) advances these normative aims or potentially obscures that they demand significant action beyond the relatively narrow scope of health care?

Finally, it is worth noting that my inquiry has focused primarily on examining how the legitimate or appropriate scope of public (or state) activity is conceived of and justified in the context of health policy. Public health ethics scholarship has also largely focused on considering how states rather than non-state actors are morally implicated in and may contribute to public health (Dawson and Verweij 2015; Verweij and Dawson 2019). However, health care has long had a strong private sector presence, including in pharmaceutical development. Accordingly, future research could build on this project by drawing on ethics and political philosophy, as well as bridging the public health ethics literature with that of business ethics, to analyze public policy discourses concerning the ethical responsibilities of private entities in health care and public health. For example, contemporary debates over 'fair' pharmaceutical pricing or the obligations of private entities in the provision of goods such as vaccines in a public health emergency such as COVID-19 could serve as case studies to explore the responsibilities of non-state actors in health. As the presence of the private sector in health increases with the growing involvement of data analytics companies and interest in machine learning and artificial intelligence, questions about the division of public and private responsibilities in and for health—and the obligations of non-state actors in particular—are bound to arise.

7.7 Final Reflections

I set out to study the Canadian pharmacare policy debate at the time when it began resurfacing as a topic of interest in Canadian health policy. Pharmacare has since made it onto the Canadian health policy agenda. Three years have already passed since the Standing Committee on Health (HESA) recommended the implementation of a national public pharmacare program in April 2018. HESA noted that there was broad agreement among stakeholders about the need to universalize pharmaceutical coverage in Canada, which is also one of the findings of my analysis. The federal government has since repeatedly indicated its interest in implementing a national pharmacare program, and has emphasized the need to develop a national drug agency, formulary, and strategy for financing expensive drugs for rare diseases.

Notably, however, the case study that forms the basis for my analysis predates the COVID-19 pandemic. On the one hand, the pandemic has intensified the need for national pharmacare as it highlights the cracks in the existing pharmaceutical insurance landscape: a significant percentage of Canadians have their pharmaceutical coverage tied to employment and many lower-income essential workers are without employer-sponsored benefits and are ineligible for public coverage. Moreover, the pandemic response has exacerbated existing inequities in health and broader socio-economic status. On the other hand, the government's response to the pandemic has also contributed to increased public deficits, which threaten to deepen enduring concerns about the affordability of a national pharmacare program. Furthermore, pharmaceutical policy has been contested as pharmaceutical companies argue that policies such as the proposed changes to the PMPRB guidelines threaten to worsen pharmaceutical research and development infrastructure in Canada, including in vaccine production. All in all, the landscape in which the public policy discourse that I analyzed took place has been irrevocably marked by the COVID-19 pandemic.

If history is any indicator, the pharmacare debate is likely to persist as issues related to inadequate coverage and rising drug costs in a disjointed insurance landscape will remain and continue to hamper other areas of the health care system. Most recently, the government has begun consultations in preparation for developing a national strategy for expensive drugs for rare diseases (Health Canada 2021). What remains to be seen is whether Canada will proceed with incremental or broad pharmaceutical insurance and pricing reforms. While my analysis is limited in its explanatory force, it has highlighted that the decisions facing policy-makers are inherently

normative and will inevitably require prioritizing between competing political principles and visions, including competing ideas about justice and the division between public and private responsibility for health and health care. While COVID-19 has in many ways impacted the policy-making context, it has also heightened existing tensions in the debate. In a policy landscape where costs have long dominated public discourse and that of policy elites and where they are likely to remain top-of-mind, it will be all the more necessary to ask which normative considerations underpin and justify concerns about costs associated with pharmacare policy reform or lack thereof. Moreover, who will define and incur the benefits or costs associated with the reforms?

Concerns about costs are likely to continue to drive interest in policies aimed at addressing financing for expensive drugs or containing rising drug prices for public (and private) payers, but it will also be important to heed calls for universal coverage and the justice-based concerns raised in the COVID-19 pandemic to address the basic gaps and inequities in access to pharmaceuticals that persist in the existing insurance landscape.

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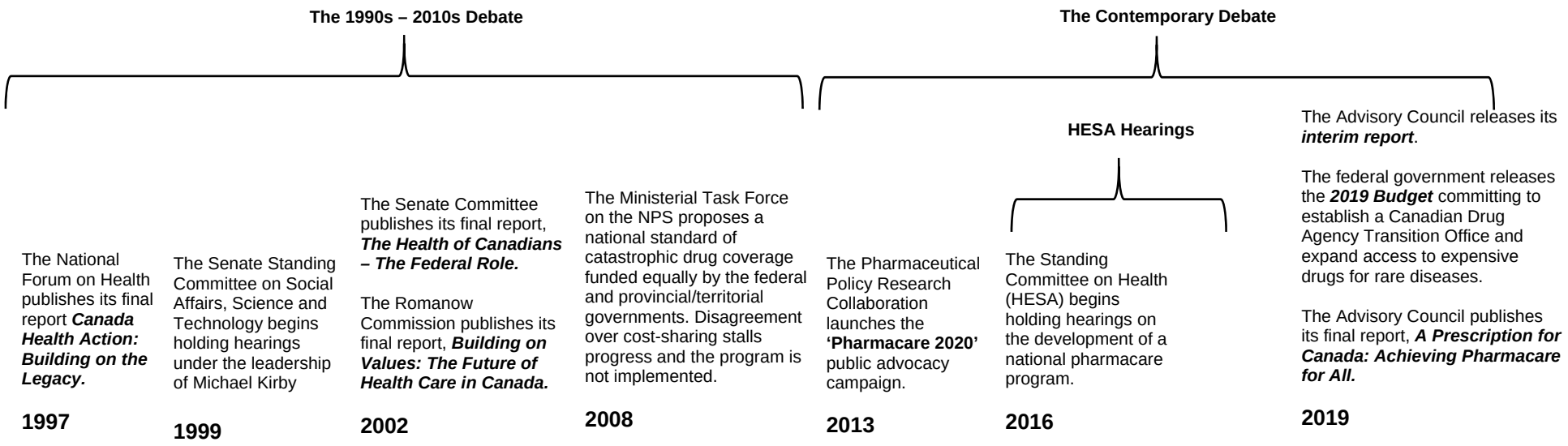
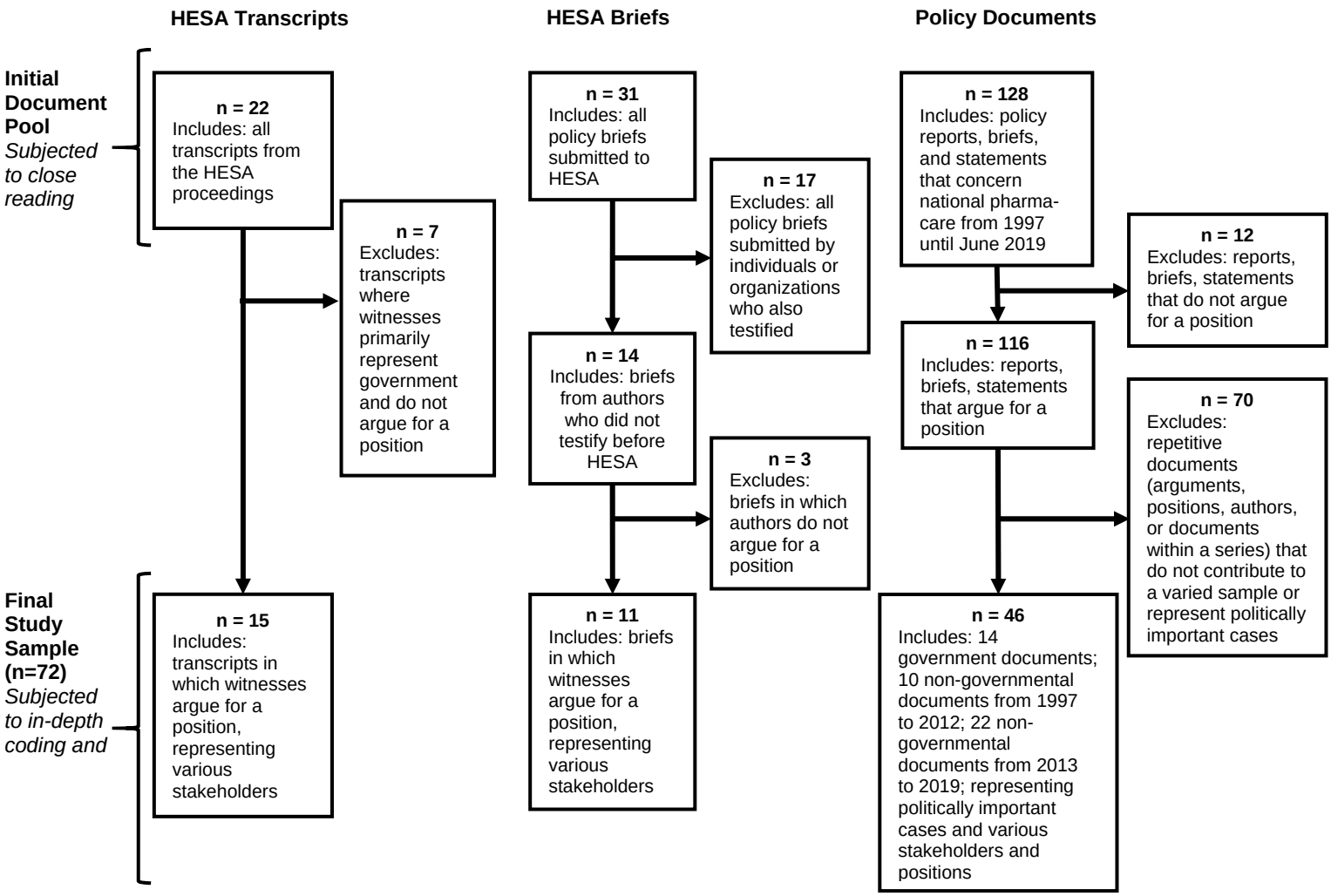
Appendix A: Case Timeline



Appendix B: Sampling Decisions



Appendix C: HESA Transcripts Included in the Final Study Sample (n = 15)

	Date	Witness (Name and Affiliation)	Stakeholder Group
HESA EV07	April 18, 2016	Marc-André Gagnon, Associate Professor, School of Public Policy and Administration, Carleton University	Participation as an individual
		Marie-Claude Prémont, Professor, École nationale d'administration publique	Participation as an individual
		Steven Morgan, Professor, School of Population and Public Health, University of British Columbia	Participation as an individual
		Danielle Martin, Vice-President, Medical Affairs & Health System Solutions, Women's College Hospital	Health Professions
HESA EV08	April 20, 2016	Anne Holbrook, Physician/Clinical Pharmacologist, Professor and Director, Division of Clinical Pharmacology & Toxicology, McMaster University	Participation as an individual
		David Henry, Professor, Dalla Lana School of Public Health, University of Toronto	Participation as an individual
		Katherine Boothe, Assistant Professor, Department of Political Science, McMaster University	Participation as an individual
		Irfan Dhalla, Vice President, Evidence and Development Standards, Health Quality Ontario	Government
HESA EV09	May 2, 2016	William Dempster, Chief Executive Officer 3Sixty Public Affairs	Industry
		Graham Sher, Chief Executive Officer, Canadian Blood Services	Government
		N. Dylan Lamb-Palmer, Manager, Health Economics and Analytics, PDCI Market Access	Industry
		W. Palmer, President and Principal Consultant, PDCI Market Access	Industry
HESA EV10	May 9, 2016	Frank Swedlove, President and Chief Executive Officer, Canadian Life and Health Insurance Association	Industry
		Stephen Frank, Vice-President, Policy Development and Health, Canadian Life and Health Insurance Association	Industry
		Anita Huberman, Chief Executive Officer, ,Surrey Board of Trade	Business
HESA EV11	May 16, 2016	Julie White, Board Member, Canadian Health Coalition	Health Charity
		Lisa Ashley, Senior Nurse Advisor, Policy, Advocacy and Strategy, Canadian Nurses Association	Health Professions
		Perry Eisenschmid, Chief Executive Officer, Canadian Pharmacists Association	Health Professions
		Philip Emberley, Director, Professional Affairs , Canadian Pharmacists Association	Health Professions
		Connie Côté, Executive Director, Health Charities Coalition of Canada	Health Charity
		Debra Lynkowski, Governing Council Member, Health Charities Coalition of Canada	Health Charity

HESA EV 12	May 30, 2016	Christopher McCabe, Capital Health Research Chair, Faculty of Medicine and Dentistry, University of Alberta	Participation as an individual
		Matthew Herder, Associate Professor, Faculties of Medicine and Law, Health Law Institute, Dalhousie University	Participation as an individual
		Robyn Tamblyn, Professor, Department of Medicine, and Department of Epidemiology, Biostatistics and Occupational Health, McGill University	Participation as an individual
		Durhane Wong-Rieger, President and Chief Executive Officer, Canadian Organization for Rare Disorders	Patient Group
		Maureen Smith, Board Secretary, Canadian Organization for Rare Disorders	Patient Group
HESA EV 13	June 1, 2016	Cindy Forbes, President, Canadian Medical Association	Health Professions
		Owen Adams, Chief Policy Advisor, Canadian Medical Association	Health Professions
		Natasha Mistry, Director, Stakeholder Relations and Community Development, CARP Canadian Association of Retired Persons	Patient Group
		Gerry Harrington, Vice President, Policy and Regulatory Affairs, Consumer Health Products Canada	Industry
		Kristin Willemsen, Director, Scientific and Regulatory Affairs, Consumer Health Products Canada	Industry
HESA EV 14	June 6, 2016	Gregory Marchildon, Professor and Ontario Research Chair in Health Policy and System Design, Institute of Health Policy, Management and Evaluation, University of Toronto	Participation as an individual
		Roy Romanow, Commissioner and former Premier of Saskatchewan, Commission on the Future of Health Care in Canada	Participation as an individual
		Shachi Kurl, Executive Director, Angus Reid Institute	Polling Organization
		Monika Dutt, Chair, Canadian Doctors for Medicare	Health Professional Organization
		Brett Skinner, Executive Director, Health and Economic Policy, Innovative Medicines Canada	Industry
		Glenn Monteith, Vice President, Innovation and Health Sustainability, Innovative Medicines Canada	Industry
HESA EV 19	Sept 22, 2016	Andrew Casey, President and Chief Executive Officer, BIOTECanada	Industry
		Jan Hux, Chief Science Officer, Canadian Diabetes Association	Health Charity
		Jessica Harris, Vice President, Government Affairs, Canadian Federation of Medical Students	Health Professions
		Jim Keon, President, Canadian Generic Pharmaceutical Association	Industry
HESA EV 20	Sept 27, 2016	Colleen Flood, Professor and University Research Chair, Director of the Centre for Health Law, Policy and Ethics, University of Ottawa	Participation as an individual

		Mélanie Bourassa Forcier, Professor and Director, Health Law and Policy Programs, Université de Sherbrooke-CIRANO	Participation as an individual
		Ake Blomqvist, Health Policy Scholar, C.D. Howe Institute	Think Tank
		Chandra Pasma, Senior Research Officer, Canadian Union of Public Employees	Union / Labour Organization
		Victor Elkins, Regional Vice President for British Columbia, Canadian Union of Public Employees	Union / Labour Organization
HESA EV 33	Nov 29, 2016	Doug Coyle, Professor and Interim Director, University of Ottawa, School of Epidemiology, Public Health and Preventive Medicine	Participation as an individual
		Janet Yale, President and Chief Executive Officer, Arthritis Society	Health Charity
		Anil Naidoo, Government Relations Officer, Canadian Federation of Nurses Unions	Health Professions
		Linda Silas, President University of British Columbia Therapeutics Initiative, Canadian Federation of Nurses Unions	Health Professions
		Thomas Perry, Chair, Education Working Group, Canadian Federation of Nurses Unions	Health Professions
HESA EV 35	Dec 6, 2016	Larry Lynd, Professor, Pharmaceutical Sciences, University of British Columbia	Participation as an individual
		Jean-Pierre St-Onge, Member, Citizens' Reference Panel on Pharmacare	Patient Group
		Peter MacLeod, Chair, Citizens' Reference Panel on Pharmacare	Patient Group
		Lesley James, Senior Manager, Health Policy, Heart and Stroke Foundation of Canada	Health Charity
HESA EV 39	Feb 2, 2017	Dianne Balon, Vice President, Government, Alberta Blue Cross	Industry
		Margaret Wurzer, Senior Manager, Benefit and Product Development, Alberta Blue Cross	Industry
		Cdr Sylvain Grenier, Senior Staff Officer, Pharmacy Services, Department of National Defence	Government
HESA EV 43	Feb 23, 2017	Amir Attaran, Professor, Faculty of Law, University of Ottawa	Participation as an individual
		Bruce Ryder, Associate Professor, Osgoode Hall Law School, York University	Participation as an individual
HESA EV 74	Oct 19, 2017	Marc-André Gagnon, Associate Professor, School of Public Policy and Administration, Carleton University	Participation as an individual
		Steven Morgan, Professor, School of Population and Public Health, University of British Columbia	Participation as an individual
		Dr. Danyaal Raza, Chair, Canadian Doctors for Medicare	Health Professions
		Karen Voin, Vice-President, Group Benefits and Anti-Fraud, Canadian Life and Health Insurance Association	Industry
		Stephen Frank, President and Chief Executive Officer, Canadian Life and Health Insurance Association	Industry

Appendix D: HESA Briefings Included in the Final Study Sample (n = 11)

Date Published	**Author (Association/Individual)**	**Stakeholder Group**
May 19, 2016	Union des consommateurs	Public / Consumer Interest Group
June 13, 2016	Mood Disorders Society of Canada	Patient Group
September 2, 2016	Canadian Cancer Survivor Network	Patient Group
September 2, 2016	Registered Nurses' Association of Ontario	Health Professions
October 14, 2016	Independent Patient Voices Network of Canada	Patient Group
October 27, 2016	West, David	Participation as an individual
November 17, 2016	Canadian Labour Congress	Union / Labour Organization
November 29, 2016	Robertson, Mary Lou	Participation as an individual
October 12, 2017	Moore, John and Walters, Gary	Participation as an individual
October 20, 2017	Best Medicines Coalition	Alliance of patient groups
December 8, 2017	Bonnett, Chris	Participation as an individual

Appendix E: Policy Documents Included in the Final Study Sample (n = 46)

Date	Document Title	Author(s) and Affiliations	Publisher
Government publications (n = 14)			
1997	Canada Health Action: Building on the Legacy – Volume I - The Final Report of the National Forum on Health; Canada Health Action: Building on the Legacy - Volume II – Synthesis Reports and Issues Papers	National Forum on Health	Health Canada
1998	Conference on National Approaches to Pharmacare – Proceedings	Prepared by Karen Graham, Panacea Consulting Inc.; conference organized by Health Canada and Saskatchewan Health	Health Canada
2001	Pharmacare in Canada: Issues and Options	Åke Blomqvist, University of Western Ontario & Jing Xu, Department of Finance Canada	Health Canada
2002	The Health of Canadians – The Federal Role: Final Report on the state of the health care system in Canada, Volume Six: Recommendations for Reform	Standing Senate Committee on Social Affairs, Science and Technology, Michael J. L. Kirby (Chair)	The Senate of Canada
2002	Building on Values: The Future of Health Care in Canada – Final Report	The Royal Commission on the Future of Health Care in Canada, Roy J. Romanow (Commissioner)	The Royal Commission on the Future of Health Care in Canada
2004	First Minister's Meeting on the Future of Health Care 2004	Federal, Provincial, Territorial Ministers of Health	Health Canada
2006	National Pharmaceuticals Strategy Progress Report	Federal/Provincial /Territorial Ministerial Task Force on the National Pharmaceuticals Strategy, Hon. Tony Clement & George Abbott (Co-chairs)	Health Canada
2008	Annual Conference of Provincial-Territorial Ministers of Health Backgrounder: National Pharmaceutical Strategy Decision Points - Executive Summary	Provincial and Territorial Ministers of Health, Canadian Intergovernmental Conference Secretariat	Canadian Intergovernmental Conference Secretariat
2012	Time for Transformative Change A Review of the 2004 Health Accord	Standing Senate Committee on Social Affairs, Science and Technology, Kelvin K. Ogilvie (Chair)	The Senate of Canada
2015	Joint Statement by Ministerial Participants of Pharmacare Roundtable	Provincial and Territorial Ministers of Health	Ontario Ministry of Health and Long-Term Care
2018	Pharmacare Now: Prescription Medicine Coverage for All Canadians	Standing on Committee on Health, Bill Casey (Chair)	House of Commons of Canada
2018	Towards Implementation of National Pharmacare: Discussion Paper	Health Canada	Health Canada
2019	Interim Report of the Advisory Council on the Implementation of National Pharmacare	Advisory Council on the Implementation of National Pharmacare, Dr. Eric Hoskins (Chair)	Health Canada

2019	A Prescription for Canada: Achieving Pharmacare for All – Final Report of the Advisory Council on the Implementation of National Pharmacare	Advisory Council on the Implementation of National Pharmacare, Dr. Eric Hoskins (Chair)	Health Canada
Non-governmental reports (n = 32)			
2001	A National Pharmacare Plan: Combining Efficiency and Equity	Dr. Joel Lexchin, York University	Canadian Centre for Policy Alternatives (CCPA), progressive/ social-justice-oriented think tank
2005	Canadian Pharmacare: Performance, Incentives, and Insurance	John R. Graham and Tanya Tabler	Fraser Institute, conservative/ libertarian think tank
2005	Pour une politique du medicament qui fair passer la santé de la population avant l'intérêt des compagnies pharmaceutiques	La Coalition Solidarité Santé	La Coalition Solidarité Santé, a Quebec-based public advocacy group advocating for public health care
2006	Framework for a Canadian Pharmaceutical Strategy: Statement of the Coalition for a Canadian Pharmaceutical Strategy	The Coalition for a Canadian Pharmaceutical Strategy	The Coalition for a Canadian Pharmaceutical Strategy (Best Medicines Coalition, Canadian Medical Association, Canadian Nurses Association, Canadian Pharmacists Association and Canadian Healthcare Association), a coalition patient groups and health profession organizations
2006	National Pharmaceuticals Strategy: Issue Paper	Best Medicines Coalition (BMC)	Best Medicines Coalition, national alliance of patient groups
2007	More for Less: Pharmacare – A National Drug Plan	Canadian Health Coalition (CHC)	CHC, Lobby group advocating for the preservation and improvement of public Medicare; supported by 12 trade unions and anti-poverty groups
2008	Life Before Pharmacare: Report on the Canadian Health Coalition's Hearings into a Universal Public Drug Plan	Canadian Centre for Policy Alternatives (CCPA) and the Canadian Health Coalition (CHC)	CCPA, Progressive/ Social-Justice-oriented Think Tank; CHC, Lobby group advocating for the preservation and improvement of public Medicare
2009	A commentary on The National Pharmaceuticals Strategy: A Prescription Unfilled	Health Council of Canada	Health Council of Canada, established in the 2003 First Ministers' Accord on Health Care Renewal. Includes government and non-governmental representatives.
2010	IRPP Study No. 2: Providing Pharmacare for an Aging Population: Is Prefunding the Solution?	Mark Stabile, University of Toronto and Jacqueline Greenblatt, Government of Canada, with a commentary by Michel Grignon, McMaster University	Institute for Research on Public Policy (IRPP), centrist think tank

2010	The Economic Case for Universal Pharmacare: Costs and Benefits of Publicly Funded Drug Coverage for all Canadians	Marc-André Gagnon, Carleton University and Guillaume Hébert, Institut de recherché et d'informations (IRIS)	Canadian Centre for Policy Alternatives (CCPA) and IRIS, progressive/ social-justice-oriented think tanks; Commissioned by the Canadian Health Coalition, a lobby group advocating for the preservation and improvement of public Medicare
2013	C.D. Howe Institute Commentary 384 - Rethinking Pharmacare in Canada	Steven G. Morgan, Jamie R. Daw and Michael R. Law, University of British Columbia	C.D. Howe Institute, centrist think tank
2014	CLHIA Report on Prescription Drug Policy: Ensuring the Accessibility and Sustainability of Prescription Drugs in Canada	Canadian Life and Health Insurance Association (CLHIA)	CLHIA, Organization representing Canadian life and health insurance businesses
2014	A Roadmap to a Rational Pharmacare Policy in Canada	Marc-André Gagnon, Carleton University	Canadian Federation of Nurses Unions (CFNU), health professional trade union
2014	C.D. Howe Commentary No. 417: Should Public Drug Plans be Based on Age or Income	Colin Busby, C.D. Howe Institute and Jonathan Pedde, graduate student at University of Oxford	C.D. Howe Institute, centrist think tank
2015	Do We Need a Public Drug Insurance Monopoly in Canada?	Yanick Labrie, Montreal Economic Institute (MEI)	MEI, Think Tank advocating for economic liberalism
2015	Drug Coverage for Low-Income Families: The Canadian Reality and Lessons from Switzerland and the Netherlands	Nadeem Esmail and Bacchus Barua, Fraser Institute	Fraser Institute, conservative/ libertarian think tank
2015	Pharmacare 2020: The Future of Drug Coverage in Canada	Steven G. Morgan, University of British Columbia; Dr. Danielle Martin, University of Toronto; Marc-André Gagnon, Carleton University; Barbara Mintzes, University of Sydney; Jamie R. Daw, Harvard University; & Dr. Joel Lexchin, York University	The Pharmaceutical Policy Research Collaboration, University of British Columbia, academic research group
2015	Low Earnings, Unfilled Prescriptions: Employer-Provided Health Benefit Coverage in Canada	Steve Barnes and Laura Anderson,	The Wellesley Institute, a progressive/ social-justice-oriented think tank focused on health
2016	A Prescription for Better Medicine: Why Canadians Need a National Pharmacare Program	Michael Butler, Health Care Campaigner, Council of Canadians	Council of Canadians, public advocacy group that advocates for public health care (among other issues)
2016	Necessary Medicines: Recommendations of the Citizens' Reference Panel on Pharmacare in Canada	Citizens' Reference Panel on Pharmacare in Canada	Pharmaceutical Policy Research Collaboration, University of British Columbia, academic research group
2016	Pharmacare Costing In Canada: Estimated Costs of Proposed National Pharmacare Programs	W. Neil Palmer, Courtney A. Nelson, and N. Dylan Lamb-Palmer, PDCI Market Access Inc.	PDCI Market Access Inc., a pharmaceutical pricing and reimbursement consultancy firm; Commissioned by the Canadian Pharmacists Association

2017	A Prescription For A Healthier Canada - Rx: PharmAccord	Canadian Pharmacists Association (CPhA)	CPhA, health professional association
2018	Equitable & Comprehensive Pharmacare for All – Patient Perspectives on National Pharmacare: Current Challenges, Goals and Implementation Issues	Best Medicines Coalitoin (BMC)	Best Medicines Coalition, National alliance of patient groups
2018	Body Count: The Human Cost of Financial Barriers to Prescription Medications	Ruth Lopert, University of Strasbourg, Elizabeth Docteur, Independent Consultant, and Steve Morgan, University of British Columbia	Canadian Federation of Nurses Unions (CFNU), health professional trade union
2018	Understanding the Gap: A Pan-Canadian Analysis of Prescription Drug Insurance Coverage	Greg Sutherland and Thy Dinh, Conference Board of Canada	Conference Board of Canada, think tank; funded by Innovative Medicines Canada (industry), the Canadian Life and Health Insurance Association (industry), the Neighbourhood Pharmacy Association of Canada (industry), and the Canadian Alliance for Sustainable Health Care
2018	IRPP Study No. 68 - Universal Pharmacare and Federalism: Policy Options for Canada	Colleen M. Flood, University of Ottawa, Bryan Thomas, University of Ottawa, Asad Ali Moten, independent legal researcher, Osand Patrick Fafard. University of Ottawa	Institute for Research on Public Policy (IRPP), centrist think tank
2018	The Unintended Consequences of National Pharmacare Programs The Experiences of Australia, New Zealand, and the UK	Kristina M. L. Acri, Colorado College	The Fraser Institute, conservative/ libertarian think tank
2018	Pathways to Sustainable Access to Innovative Medicines for Canadians: Balancing Innovation, Affordability and Outcomes	Public Policy Forum	Public Policy Forum, think tank; funded by Innovative Medicines Canada (industry) and McCarthy Tétrault LLP (law firm)
2018	National Pharmacare: Getting it Right	Sun Life Financial	Sun Life Financial, life insurance company
2018	A Prescription for Savings: Federal Revenue Options for Pharmacare and their Distributional Impacts on Households, Businesses and Governments	David Macdonald, Canadian Centre for Policy Alternatives and Toby Sanger, Canadians for Tax Fairness	Canadian Centre for Policy Alternatives, progressive/ social-justice-oriented think tank; Canadians for Tax Fairness, public interest group advocating for progressive tax policies and reducing inequalities
2019	Charting the Path to National Pharmacare in Canada	Greg Marchildon, University of Toronto and Andrew Jackson, Broadbent Institute	Broadbent Institute, Progressive / social-democratic think tank
2019	C.D. Howe Institute Commentary No. 544 - Filling the Gaps: A Prescription for Universal Pharmacare Gaps	Rosalie Wyonch, CD Howe Institute	C.D. Howe Institute, centrist think tank

Appendix F: Examples from the Original Analysis

List of Primary, Secondary, and Tertiary Codes (Original Analysis)

Primary Codes ***In vivo, descriptive codes***	**Secondary Codes** ***Pattern codes***	**Tertiary Codes** ***Analytic themes***	
Appeal mechanism	Responsiveness	Procedural	Justice (procedural justice/fairness), efficiency
Flexibility			
Responsive, responsiveness			
Diverse, key stakeholders	Stakeholder participation		
Stakeholder participation			
Consultation process			
Solicit the views of Canadians and experts			
Public, health care providers, public and private payers, pharmaceutical manufacturers, health care professionals (e.g., physicians) and patient groups			
Dialogue — with researchers, policy-makers, patients, health charities, health professionals, and industry stakeholder			
Transparent, transparency	Transparency		
Open			
Medical need	Medical need	Substantive	Justice, efficiency
Medically necessary			
Essential			
Unnecessary			
Appropriateness	Medical need: appropriateness		Justice, efficiency
Appropriate prescribing practices			
Medication management			
Underuse			
Overuse			
Misuse			
Off-label use			
Fairness	Fairness		Justice
Tax on sick			
Generosity			
Punitive			
Penalize			
Distributive Justice			
Distribution			
Redistribution			
Vulnerability			
Equity	Equity		Justice
Equality			
Consistency			
Disparity			

Normative Concepts in the Pharmacare Policy Debate (Original Analysis)

PROCEDURAL ***Means and process***	**SUBSTANTIVE** ***Criteria for justifying decision and actions***	**TERMINAL** ***Goals or objectives***
Evidence-based *e.g. evidence-based decision making, informed, real-world drug safety and effectiveness, post-marketing surveillance, (or barriers: imperfect information, lack of information, information gap, uncertainty)*	**Medical need** *e.g. medical need, medically necessary, clinical need, essential, individual need, most in need*	**Access** ***Access to medicines*** *e.g. affordable access, timely access, access to new drugs, drugs for rare diseases, unmet health needs and orphan drugs (barriers: cost-related non adherence, un- or under-insurance)* ***Access to pharmacist services***
Impartiality *e.g. impartiality, objectivity, independence, unbiased, conflict of interest*	**Fairness** *e.g. fairness, punitive, penalize, tax on sick, distribution, redistribution, vulnerability, most in need*	**Healthcare** *e.g. healthcare system, quality of care, best standard of care*
Rationality *e.g. soundness, rationality, reasonableness, coherence, clarity*	**Equity** *e.g. equity, equality, consistency, disparity (across age, disease type, care setting, employment status, region/place of residence, income, generations, and private or public plans)*	**Health** *e.g. physical and mental health, health status, health outcomes, safety, security, wellness*
Accountability *e.g. accountability, publicly accountable*	**Efficiency** ***Collective action*** *e.g. efficiency, collective action, collaboration, integration, cost-sharing, system efficiency*	**Wellbeing** *e.g. wellbeing, satisfaction (barriers: pain, suffering)*
Responsiveness *e.g. responsiveness, appeal mechanism, flexibility*	***Financial, markets*** *e.g. costs, cost-containment, economic, markets, market mechanism, competition, monopsony, economies of scale*	**Life** *e.g. life, life-sustaining, life-saving, longevity, preventing death*
Stakeholder participation *e.g. stakeholder participation, consultation, inclusive, dialogue*	***Cost-effectiveness*** *e.g. cost-effectiveness, value for money*	**Quality of life** *e.g. quality of life, economic wellbeing*
Transparency *e.g. transparency, openness, provision of information*	***Risk pooling*** *e.g. risk pooling, insurance, good risk, bad risk, reduce individual uncertainty (barriers: adverse selection, moral hazard, cream skimming)*	**Avoiding, minimizing and preventing harm** ***Physical*** *e.g. errors, adverse events, invasive care* ***Financial*** *e.g. undue financial hardship, financial burden, financial disadvantage, cost-related nonadherence*
	Information Transmission	**Individual health or wellbeing** *e.g. individual health, patient-centred care, patient-focused, patients' interests at the centre*
	Appropriateness *e.g. appropriate use, appropriate prescribing practices, medication management, off-label use, (vs. underuse, overuse, misuse)*	**Population health**
	Effectiveness *e.g. effectiveness, efficacy, therapeutic value, therapeutic benefits, clinical value*	**Public good** *e.g. public good, common goals, common goals of a community, social impact*
	Comparative effectiveness	**Productivity**

	e.g. comparative effectiveness, comparative advantage, therapeutic advantage **Sustainability** *e.g. sustainable, future* **National Identity** *e.g. citizenship, Canadian, Canadian way, symbolic attachment, national symbol* **Rights, liberties** ***Positive Rights*** *e.g. health as a fundamental human right, a right of citizenship* ***Negative Liberties*** *e.g. individual liberty, choice, freedom, economically liberal, liberalization, opt out, patient autonomy, prescriber autonomy, patient-prescriber relationship (barrier: restrictive, red tape, tax burden)* **Solidarity** *e.g. solidarity*	*e.g. productivity, productive workforce, jobs, industry* **Innovation** *e.g. new drugs, drugs for rare diseases, orphan drugs, research and development, me too, evergreening* **Other policy priorities** *e.g.* Other government spending priorities, already insured health services, more disposable income