Fixing an Accident of History:
Assessing a Social Insurance Model
to Achieve Adequate Universal Drug Insurance

by
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AUTHOR'S DECLARATION

“I hereby declare that I am the sole author of this thesis. This is a true copy of the thesis, including any required final revisions, as accepted by my examiners. I understand that my thesis may be made electronically available to the public.”

ABSTRACT

Canada's drug insurance system remains fragmented and expensive. The plethora of private and public plans still do not adequately cover all Canadians. Demographic changes, disease profiles and the introduction of many new very high cost drugs mean Canadians will be increasingly unable to afford access to medically necessary drug therapy.

The lack of adequate universal drug insurance, a policy known in Canada as national pharmacare (NPh), is an important problem. A solution must address patient needs for access and equity at a cost that is sustainable to payers. Most academic literature has identified a public single payer model as the optimal approach but despite many studies and reports, this has yet to be implemented. This suggests the need for an alternative.

The Canadian alternative to a single payer plan is popularly called "fill the gaps." This approach argues that the federal government should target its funding to expand provincial coverage to cover the uninsured. A social drug insurance model, used in many European countries, retains private insurance but improves on it by regulating, structuring and aligning it with medicare. As such it is the logical proxy for those who favour "fill the gap."

Social insurance may achieve adequate universal drug insurance at a much lower per capita cost. Social insurance financing relies primarily on employers and workers, which is very similar to our very large private drug insurance market. However, private drug plans are mostly tied to employment, are voluntary and face similar threats to sustainability and affordability as provincial plans. An organized mixed-financing model like social drug insurance would spread risk and is a more feasible approach than a single payer plan to achieve adequate universal drug insurance. If a comprehensive single payer NPh plan is not implemented, adopting key social insurance features and regulations would significantly improve access and quality.

An extensive literature review is presented, followed by a qualitative thematic analysis of drug insurance opinion leader interviews and a comparative analysis of health and drug systems in three jurisdictions. The theoretical perspective of how a government may

recognize and prioritize certain problems over others draws on John Kingdon's *Agendas, Alternatives, and Public Policies* (2011).

Major findings are found in four chapters. Chapter 4 examines our current shared-funding model for prescription drugs and establishes that social drug insurance could work in the context of our institutionalized model.

Chapter 5 provides a comparative review of social health insurance (SHI) models in Germany, the Netherlands and Quebec to help identify the form and features useful in a pan-Canadian system. Certain features warrant serious consideration in Canada. The Netherlands has created an aggressive drug price and cost control architecture. Germany's Federal Joint Committee is a participatory multi-stakeholder governance model that could improve transparency and better address system complexity and sustainability. Quebec provides 20 years of guidance on key drug system features and risks in a Canadian context.

Chapters 6 and 7 present the most important findings from 26 interviews with drug plan experts and influencers in different sectors from across Canada. Thematic analysis identified five roles for the federal government: funder, coordinator/secretariat, leader, relationship manager and nation-builder. These can be operationalized as funding that ensures adequate universal access, the creation of national standards for a list of covered drugs (formulary) and for patient cost-sharing to limit personal financial risk. Most participants wanted private insurance to continue as a significant funder but private payers remain marginalized, "outside the tent" in this policy debate. Employers are important funders and have not been extensively consulted. Relationships and trust among key stakeholders are limited or weak. These are crucial constraints to progress.

Kingdon's model, explored in Chapter 8, indicates the problem, policy and political streams are no longer aligned, so a window of opportunity for universal drug insurance has become far less likely. However, the window could re-open with less ideological stances by advocates supporting either model. This requires a standing forum for constructive and time-bounded dialogue to produce a strategy, funding structure, a realistic implementation plan and a modern governance model. Participants recommended the federal government play this leadership role. An influential NPh policy entrepreneur would energize this work.

Related structural changes have recently been proposed to reduce drug prices and costs, such as reform of the Patented Medicine Prices Review Board, the creation of a new Canadian Drug Agency and a strategy for drugs for rare diseases. These financial changes are very important, but are not a comprehensive reform and will not in themselves assure adequate universal drug insurance. NPh is still needed and must proceed in parallel given its complexity and long gestation period.

A carefully designed social drug insurance model that includes a regulated role for private drug plans would spread risk among payers, reflect our social values, provide choice in coverage and enable access to sophisticated consumer- and patient-focused insurer technology that complements public plan expertise in health technology assessment. Mitigating financial and political risk is important to governments, and moving to implementation is important to patients.

Social drug insurance is still a very complex, multi-year change, meaning careful, consultative planning for implementation and transition is crucial. This model could serve as a template to achieve universal funding for other core health services, such as long-term care and community care.

Kingdon notes policy change is more likely if complexity, confounding information and financial and reputational risk for governments can be reduced. Rather than a polarized, dichotomous and perpetual debate typical of decades of NPh failure, a classic Canadian compromise may be possible that allows adequate universal drug insurance to be more quickly implemented through a hybrid model.

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Dr. Roy Cameron, now Distinguished Professor Emeritus, agreed to be my Supervisor as I entered the Work and Health program. Although the match to his expertise was less than perfect, he generously accepted my Comprehensive Exam. I am sure that experience was *not* totally responsible for his retirement shortly afterward.

Dr. Sue Horton has been my Supervisor since 2012. She has been more patient than I deserve awaiting completion of this work. I know I tested her but appreciate her good judgement, her candid and thoughtful remarks, her insightful questions, and her ability to hold my feet to the fire on occasion. Dr. Horton has an impressive ability to respond quickly regardless of her many personal and professional responsibilities. Yes, even on weekends.

My Committee of Mike Law, Gerry Boychuk and John Garcia have been equally patient and provided support and advice as needed. Despite often long delays between hitting my milestones, I am grateful that they agreed to remain on my committee.

I am very pleased that Carolyn Hughes Tuohy has agreed to serve as an External Member of my Committee.

I am thankful I chose an important topic and apologize to all for not doing it justice. National pharmacare remains an essential and long overdue part of Canada's health system, especially for those without any or enough drug insurance.

DEDICATION

While my two adult children have not hung on every word I wrote (and rewrote) they have accepted an unusual avocation for a man the age of their father. I hope to provide some positive example of persistency or perhaps just stubbornness in (eventually) achieving this life goal.

More directly, my long-suffering partner Helen has regularly admonished me to “get it done.” I have always been slower than I’d like at many things, but I am very pleased that I may have finally achieved at least one of her goals…and one of mine.

Of course, so much of the content would not have been possible without the experiences and wisdom of 26 experts in drug insurance who participated willingly in my interviews and without any apparent reward. To each of them I am indebted for their time and participation. To the one who generously promised to buy me a beer at the end of the road, perhaps convinced I might never reach the terminus, I now graciously accept. I hope many others may be similarly inspired.

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LIST OF ABBREVIATIONS

Advisory Council	Advisory Council on the Implementation of National Pharmacare
BC	British Columbia
CADTH	Canadian Agency for Drugs and Technologies in Health
CIHI	Canadian Institute for Health Information
CLHIA	Canadian Life and Health Insurance Association, Inc.
CPI	Consumer Price Index (Statistics Canada)
GDP	Gross Domestic Product
HESA	House of Commons Standing Committee on Health
HTA	health technology assessment
INESSS	Institut national d'excellence en santé et services sociaux
NPh	national pharmacare
OECD	Organization for Economic Cooperation and Development
OPDP	Ontario Public Drug Programs
PBM	pharmacy benefit manager
PBO	Parliamentary Budget Officer
pCPA	pan-Canadian Pharmaceutical Alliance
PHI	private health insurance
RAMQ	Régie de l'assurance maladie du Québec
SHI	social health insurance
WHO	World Health Organization

Chapter 1

Background

"Perhaps the most striking aspect of private insurance in Canada has been the virtual policy neglect of the sector…" (Hurley & Guindon, 2008, p. 33)

Chapter Overview

A brief history of private drug insurance and the industry that provides it is presented. Each of seven third-party payers has different mandates, eligibility, plan designs and cost-sharing. Patients also provide out-of-pocket payments. This fragmented approach creates increasingly insufficient access and financial protection even for a large majority who are covered by public or private plans.

Most government reports and academic papers propose a public single payer plan to achieve universal drug insurance, known in Canada as national pharmacare (NPh). This is similar to existing hospital and physician insurance. After many recommendations and for various reasons over several decades, this model has failed to launch. This chapter introduces social drug insurance as an alternative means to achieve adequate universal coverage.

1.1 History and positioning

Unlike many other OECD countries, Canada has only limited federal government involvement in managing health care services, and then only for specific populations such as aboriginals, RCMP officers, veterans and active members of the Armed Forces, inmates of federal penitentiaries and some refugees. Direct federal health expenditures were forecast to be $7.9 billion in 2018, about 3.1% of all health spending (Canadian Institute for Health Information (CIHI), 2018a. Table A.2.1). The Government of Canada funds provincial health plans primarily through the Canada Health Transfer (CHT), expected to be $38.6 billion in 2018-19. In addition, the federal government provides nearly $19 billion of equalization payments to certain provinces which may also be used to pay for health care. It funds other non-care programs, such as the Public Health Agency of Canada, the Canadian Institutes of Health Research, and the protection and regulation of food and drug products.

The British North America Act (1867) and its successor, the Constitution Act (1982), delegated most health services outside marine hospitals and quarantine authority to the provinces. The first national form of social insurance was the Employment and Social Insurance Act, passed by the federal government in 1935. The first national health insurance plan was proposed in 1944 and rejected later the following year because the federal and provincial governments could not agree on how to finance it. Certain provinces then initiated universal or limited forms of hospital insurance, beginning with Saskatchewan in 1947 (Shah, 1998).

The federal government passed four important insurance-related Acts over the next thirty years to essentially match provincial health funding and spur legislation in all provinces (Shah, 1998).

1. The *Hospital Insurance and Diagnostic Services Act* was enacted in 1958. Since significant (about 50%) funding then flowed to any province with a universal hospital insurance plan, five provinces immediately signed on and the rest were in place by 1961.

2. Insurance for physician services (as well as some dentistry and chiropractor services) followed with the *Medical Care Act* (1966) which was enacted in 1968. Three years later, all provinces had plans in place that were eligible for matching federal funds.

3. The *Established Programs Financing Act* (1977) eliminated the federal government's obligation to provide a completely cash contribution to the provinces for health services. The Act replaced part of the former block health funding with a roughly equivalent transfer of 13.5 personal and 1.0 corporate federal tax 'points' to the provinces. The Act's Extended Health Care Services Program also added block funding "on a virtually unconditional basis" (p. 15) for nursing home, adult residential care, home health care and ambulatory (out-patient) care.

4. The *Canada Health Act* (1984) replaced the hospital and medical care legislation and linked funding to provincial support for five principles: public administration, comprehensiveness, universality, portability and accessibility. Sanctions against provinces that allowed extra-billing were added. It did not change funding or expand coverage and the Act has not been substantially amended since. Federal funding within the Canada Health Transfer is conditional and must be used to support the requirements of the Canada Health Act.

Universal drug insurance, now commonly called national pharmacare (NPh), had been regularly rejected by the federal government for cost reasons, beginning as early as 1949 (Boothe, 2013, p. 420) but were to be considered in a future expansion of Medicare (Hall, 1964). Politicians fear increasing the public's liability for this high-cost, rapidly growing therapy (Boothe, 2013; Macpherson & Kenny, 2009). Absent broad government involvement, we have seen the development of many public plans in each province, and the growth of a private insurance market largely delivered through employer-funded benefits plans.

1.2 Impetus for Change: Achieving a universal health care system

The World Health Organization has defined universal health coverage to mean that:

"…all people and communities can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.

By this definition Canada may not have universal health coverage unless or until it adds comprehensive coverage for prescription drugs and enables better access to other types of care such as home care, long-term care and dental services. No country offers full coverage for all health expenses for all its citizens.

Our single payer model provides first-dollar coverage for hospitals and physicians which now comprise only 42% of total system spending, much less than the almost 57% in 1984 when the Canada Health Act become effective (CIHI, 2018a). The data are dated, incomplete and sometimes use a proxy (e.g., cost-related non-adherence) but about 10% of Canadians do not have any or enough drug insurance (ten studies are described in Sec 4.12). Law et al. (2018) estimated that 8.2% of those who filled a prescription reported some form of cost-related non-adherence to drug therapy, and 4.7% could not afford basic necessities of life like food and heat because of their drug costs. About 2.5% (731,000) of Canadians said they had to borrow money to buy their medicines in the previous year (Kolhatkar et al., 2018). Most provinces provide inadequate protection from catastrophic drug costs (Table 4.1). At 21% of total prescription drug spending, out-of-pocket spending is higher in Canada than in most countries, including the United States at 14%.

1.3 Private Health Insurance

1.3.1 History

Group health coverage has been available since at least 1948 and was described in the 1964 Hall Royal Commission report. In 1960, about two million Canadians had private extended health benefits, but not all included drug coverage. Many included a $50 annual deductible (Hall, 1964, p. 357), equivalent to $430 in 2018. The Commission reported that in 1961, total prescription drug costs were estimated at $154 to $164 million (p. 345) across a population of about 18.25 million. that works out to almost $9 per capita, equivalent to $74 in 2018. The Commission stated:

> In view of the high costs of many of the new life-saving, life-sustaining and disease-preventing drugs, of the unequal incidence of the burden of paying for these drugs, of the integrated character of health services, and of the fact that market forces do not operate effectively to regulate the drug industry…the Commission has concluded that prescribed drugs should be included as a benefit of a comprehensive health care programme for Canada. (p. 349)

Controlling drug cost was already an issue, along with other challenges still relevant today (Hall, 1964, pp. 344-47). Prescription drugs are covered under medicare only in hospitals ("drugs, biologicals and related preparations when administered in the hospital") without direct patient cost under the 1984 Canada Health Act.

1.3.2 Funding and Access

Traditionally, private drug plans have been sponsored (i.e., heavily or even fully subsidized) by employers. In the 1970s private drug and extended health plans were increasingly offered to workers to fill the coverage void left when the provinces introduced drug insurance only to seniors and those on social assistance. Since 1948 (Hurley & Guindon, 2008, p. 24), the Income Tax Act has encouraged growth because employer spending on health insurance benefits have been non-taxable for employees and premiums are deductible business expenses. This remains true today in all provinces except Quebec, and is contentious because it provides a large tax subsidy to employees and is a deductible business expense to employers.

Employer plans are voluntary: not all employers offer them. Only about half (47%) of employers with between two and 100 employees offer a health plan (Manulife, 2013). However, they become more prevalent as employer size increases: over 93% of workplaces with 100 or more employees offered health benefits in 2005 (Statistics Canada, 2008). In addition to employer-sponsored plans, drug insurance can also be purchased through: (i) Individual plans that require initial proof of good health and provide much more limited coverage, and (ii) Association plans such as those offered to university alumni or through business associations such as the Chamber of Commerce. Most employer plans provide larger formularies than public plans (CLHIA, 2018) and require coinsurance: 20% is most common (63%) (Telus, 2019, p. 24).

Telus Health (2019) reports that private plan designs are slowly implementing cost controls. In 2018, 66% of drug plan beneficiaries received less than 100% reimbursement (p. 25). Over one-quarter (27%) are covered by a managed formulary (p. 26). One in six (16%) had an annual reimbursement limit, half of which were $5,000 or less. (p. 29). The number of private plan members with no limit on out-of-pocket costs is not reported, but it is likely a large majority.

Employers can eliminate drug plan coverage or change the formulary, eligibility and cost-sharing provisions at will unless they are specifically prohibited by collective bargaining agreements from doing so. Coverage will terminate upon corporate bankruptcy. Part-time and casual workers may not be covered even when full-time employees have generous protection.

A lack of coordination with provincial drug plans means there are gaps in coverage. Though seniors and those on social assistance generally have good coverage, the provincial

safety net for the general public is available only once drug costs are deemed catastrophic relative to income (see Section 4.2). Excepting Quebec, there are no legal standards for private or provincial coverage, eligibility or cost-sharing. Private health insurance is generally supplemental to public coverage, meaning it reimburses eligible products and services not provided by a public plan. There is no direct competition between public and private health insurance providers.

1.3.3 Insurance Industry

The largest life insurance companies are domestically controlled and owned by shareholders. This thesis focuses on life and health insurers.

Twenty-four private health insurers, including all five Blue Cross organizations in Canada, are members of the Canadian Life and Health Insurance Association (CLHIA). Together, they administer about 110,000 private drug plans (CLHIA, 2013) covering 25 million Canadians (CLHIA, 2018). Insurers were forecast to pay $12.3 billion in prescription drug costs, with individuals paying $7.0 billion more (CIHI, 2018a). Drugs that don't require a prescription ($3.6B forecast, 2018) are rarely eligible under benefit plans and so are also paid out-of-pocket.

Although these numbers are not broken out by line of business, in total the industry reports it employs 156,000 Canadians and has $780 billion invested in Canadian long-term assets (CLHIA, 2019). This is a massive source of employment and investment in Canadian infrastructure, creating a potentially powerful influence on matters important to its success.

Health insurance is provided by both for-profit and not-for-profit companies ("carriers"). Most are for-profit companies, some publicly traded (Including the three largest: Sun Life, Canada Life and Manulife). Others remain mutual companies owned by their policyholders (Equitable) or cooperatives (Desjardins). Blue Cross organizations and Green Shield Canada are not-for-profit. While aggregate drug plan revenues are clear, drug insurance profitability is not. It is this latter metric that may determine how strenuously the industry fights to retain its market in the face of calls for a single payer national pharmacare plan.

More extensive information on private health insurance is in Chapter 4.

1.4 Drug insurance today – Cost and value

Like most hospital and physician services, prescription drugs are a medical necessity. In 1946, the World Health Organization Constitution declares health to be "one of the fundamental rights of every human" (p.1) and its Leadership Priorities call for equitable and universal access to health care and pharmaceuticals.

Kesselheim et al. (2015) examined 23 American studies in their systematic review of the effect of drug insurance on health outcomes. They described the studies as high quality but

there were no randomized trials so several quality assessments could not be done. They found generally positive health effects from access to prescription drugs, reductions in out-of-pocket health costs, and better patient quality of life. They also noted the importance of sustained access to insurance as key to avoiding cost-related treatment non-adherence and achieving and sustaining health outcomes. Studies reported that additional costs for drugs were offset by lower costs for hospital care and overall health system spending.

Drug insurance is presently funded through a combination of public and private payers in Canada, as is social insurance in Quebec and other countries. Since the 1970s, each province has offered a public drug plan with different eligibility criteria, different formularies (lists of covered drugs), and different out-of-pocket costs. In all provinces, seniors and social assistance recipients are covered – also to varying standards – and most provinces offer coverage for those under age 65 with drug costs that are significant relative to family income (Table 5.1). There is no national drug coverage standard in Canada to address access (other than as a hospital inpatient), quality or cost (i.e., personal affordability, system sustainability). The result has been significant and persistent variation in provincial drug plan design and coverage, and continuing variation in time-to-listing for new drugs (Applied Management 2001; Coombes et al., 2004; Demers et al., 2008; Gamble et al., 2011; Daw & Morgan, 2012; Handren 2015; Milliken et al., 2015). Private drug plans also have a wide variety of designs, eligibility and funding arrangements (CLHIA, 2018; Telus, 2019).

In the 1990s, better drugs began to displace spending for certain common conditions that would have previously required surgery (ulcers) or hospitalization (depression, heart attack, cancer). An explosion of blockbuster medicines, defined as each having global annual sales exceeding US$1 billion, began to enter the market at that time. In 2005, blockbuster drugs accounted for 36% of global pharmaceutical sales, and 94 products qualified for this label (Cutler, 2007). Total drug costs exceeded the cost of physicians by 1997 and remain second only to hospital costs (CIHI, 2018). Despite opinions to the contrary, blockbuster drugs remain important. There were 121 drugs with global sales exceeding US$1 billion in 2014 (Special tabulation, IMS Brogan (now IQVIA), 2014).

In addition to traditional chemical drugs, specialty and personalized medicines have emerged that can cost a patient hundreds of thousands of dollars every year. The cost of medicines is highly concentrated among relatively few citizens, and out-of-pocket costs can be high relative to income. For example, CIHI (2018b) reported that 2% of patients had annual drug costs exceeding $10,000 and they accounted for 37% of drug spending. In general, the risk of inadequate or unattainable coverage is low for Canadians but the potential impact is very significant.

1.4.1 Payer Types

Currently, there are nine payer types in Canada for prescription drugs:

1. The federal government for First Nations and Inuit Health Benefits and other specified segments as noted earlier.

2. Provinces for seniors (sometimes only those with low incomes) and welfare recipients, and certain other population segments which vary by province. Most now include coverage for catastrophic expenses.

3. Hospitals when drugs are prescribed for in-patients.

4. Employers for employees and families, but often only for employees designated permanent and full-time, and much more frequently in large and unionized workplaces than small ones (Statistics Canada, 2008). Note that all levels of government and the broader public sector (schools, post-secondary institutions and health care organizations) are all employers and provide private insurance benefits to their employees.

5. Unions, either independently (e.g., asrTrust operated by Unifor, see Sec 7.3.2) or jointly managed with employers (e.g., the federal government's Public Service Health Care Plan.)

6. Workers' Compensation Boards for drugs following workplace injuries or disabilities.

7. Pharmaceutical companies through patient support programs, generally for otherwise uninsured patients when drug costs are high relative to personal income.

8. Patients who are without any insurance, or through co-pays and premiums (either employer, association or individual policies, or certain provincial governments, e.g., Ontario), or when their insurance provides inadequate coverage (e.g., annual or lifetime caps on coverage, restricted formularies).

9. Individual health insurance policies may be purchased conditional on evidence of good health as determined by insurance companies.

Such a patchwork approach is fraught with inefficiencies, leading to higher costs and inequitable coverage depending on many factors beyond citizenship. As Oberlander (2003) stated: "Consensus that a problem exists implies no agreement whatsoever on solutions" (p. W3-402).

1.4.2 Introduction to social insurance

If the goal of implementing single payer drug insurance cannot quickly be achieved, an alternative is timely and important. Kutzin (2001) states that countries ought to use their own experience and culture to shape their health insurance. Other research notes that many nations have gradually evolved their Bismarckian or Beveridge systems to hybrid models of coverage (Sekhri & Savedoff, 2006; Tuohy 2012; Schoen et al, 2010). "Although private and public insurance are often discussed in terms of extremes, the most common arrangements are actually found in the centre" (Sekhri & Savedoff, 2006, p. 360).

Social health insurance achieves universal coverage in many other countries at lower cost than in Canada. Some have proposed social drug insurance as an alternative. Unfortunately, this model has not had much traction in recent years even though these works are rigourous and practical (Flood, Stabile & Tuohy, 2008; Allin, Stabile & Tuohy, 2010; Blomqvist & Busby, 2015). Other studies have used social insurance pension models (i.e., CPP/QPP) to propose pre-funding post-65 drug benefits but these are more narrow in scope (Stabile & Greenblatt, 2010; Busby & Robson, 2011).

However, social insurance is not a well-understood term among the industry, patient and professional groups that want to retain private insurance. Instead, "fill the gaps" is presented as an alternative to a single payer plan. Their argument is that because only 1.8% of Canadians are uninsured (Sutherland & Dinh, 2017, p. 8). the federal government should limit and target its funding to expand provincial coverage to just the uninsured. However, "fill the gaps" is not a plan, only a narrow advocacy argument against a single payer model. It does not propose standards or address the wide variation in public and private coverage. A social drug insurance model retains private insurance in a structured and regulated role that is deliberately integrated with public insurance. As such it is the logical proxy term and will be used throughout this thesis.

Bodenheimer and Grumbach (1992) describe four characteristics that make social insurance affordable:

1. Broad risk spread, ensured through mandatory coverage. Only those who pay premiums or are officially exempted receive coverage. This is the "contributory principle".

2. Employer subsidy of health system costs;

3. Administration through non-profit, low-cost public or quasi-public institutions;

4. Income redistribution towards lower income individuals and families. Like social assistance schemes, social insurance provides social security.

Taxes and premiums are not discrete choices but have seven features operating along a continuum (Bodenheimer & Grumbach, 1992). In most social insurance systems, primary

funding comes from payroll taxes paid by employers and workers to governments, with much smaller contributions from general tax revenues to pay for children, the unemployed and those not in the workforce (e.g., retirees). The payroll tax used elsewhere is similar to premiums now paid by Canadian employers (usually with employee contributions) to private insurers.

There are other reasons for considering an alternative to a single payer approach.

1. While employer-sponsored drug plans are not ideal in terms of equity or efficiency they have reduced the risk and liability to public plans. They are well-established and popular with plan members.

2. Most Canadians already experience two or three payers for their health services because medicare leaves so much care uncovered or partially covered, including drugs, dental and vision care, and services of many health professionals such as physiotherapists and psychologists. The source of payment is not as important as the need for payment or at least a cost subsidy.

3. Even though health spending usually grows faster than GDP per capita, governments have been very reluctant to raise income or corporate tax rates despite regular deficits and growing debt burdens. A single payer plan would likely require a tax increase to fund the transfer of up to $19 billion in prescription drugs now paid by private insurers and individuals. A social insurance model likely reduces this necessity, though some redistribution of costs and benefits is both inevitable and welcome for social solidarity. General tax revenues will still be necessary, but at much lower levels (Allin, Stabile & Tuohy, 2010).

4. Continuing technological and demographic changes in health services are likely to place additional strain on provincial government resources. One way to manage these risks is to reorganize financing in a planned and deliberate (integrated) manner: “Accordingly it is important to integrate the various current sources of finance for healthcare – public revenues, private out-of-pocket payments and private insurance – in a way that preserves and enhances the quality and accessibility of health care” (Flood, Stabile & Tuohy, 2008, p. 11).

5. We can learn from other countries even though their health systems in whole are “not readily transportable to the Canadian context” (Allin, Stabile & Tuohy, 2010, p. 23).

Developing a social insurance model requires private payers be included in policy development (PMPRB, 2015a; Advisory Panel on Healthcare Innovation, 2015. See Chapter 7).

1.5 Defining Terms

1.5.1 Universal Coverage

As noted earlier (Sec 1.2), the World Health Organization has defined universal health coverage to mean that:

> …all people and communities can use the promotive, preventive, curative, rehabilitative and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.

Private insurance is forecast to pay more for prescription drugs in 2017 and 2018 than provincial governments (CIHI, 2018a). Universal coverage can be achieved by either a single payer or a social insurance system. Savedoff et al. (2012) note the evidence supports universality as a means to a better health system and to underpin social solidarity.

1.5.2 Social Insurance

Bodenheimer and Grumbach (1992) credit Lubove (1968) in defining social insurance as "a compulsory program of payments to insure against (i.e., to provide financial assistance for) interruption or loss of earning power due to retirement, unemployment, disability or other causes" (p. 447). They note health issues can cause interruptions in wages and have therefore always been insurable.

A more specific and operational definition is credited to Norman and Busse (2002), cited in Jost (2008): "Social health insurance funding occurs when it is legally mandatory to obtain health insurance with a designated (statutory) third-party payer through contributions or premiums not related to risk that are kept separate from other legally mandated taxes or contributions (p. 170). The underlining (added) highlights important characteristics: coverage is mandatory, coverage is provided regardless of individual risk, and contributions are held in a separate fund, not comingled with general government revenues.

1.5.3 Public coverage

It is important to define "public" health insurance when looking at funding. Consistent with other national and international organizations (Sekhri & Savedoff, 2006), CIHI counts premiums for Quebec's social drug insurance as public funding because they are mandated by government even though the funds are paid by private citizens. Public funding also comes from general and dedicated taxes (Bodenheimer & Grumbach, 1992). Private insurance requires beneficiaries to pay premiums directly to insurers, either directly (individual policies) or indirectly (group or association plans).

But there are few absolutes in health care and insurance. “It should also be borne in mind that compulsory social insurance contributions paid by employers in other countries are counted as public expenditure, while premiums paid voluntarily by employers for health insurance coverage in the United States [and Canada] are classified as private spending” (Docteur, Suppanz & Woo, 2003. p. 20). This commonality is often blurred when reading about the unusually high amounts of private spending in Canada and the US.

1.5.4 Adequate, universal coverage

This phrase is repeated throughout this thesis. Coverage will be adequate when it provides access to a broad formulary of medicines at an affordable level of out-of-pocket cost according to medical need. Coverage is universal when all Canadians have access to necessary medicines. Adequate and universal coverage can be achieved by both single payer and social insurance systems.

Principles are described in Sec 2.2 and are equally important for the good governance and management of the drug and health systems. However, similar principles are likely to apply regardless of the model used (single payer, social insurance or hybrid).

1.6 Chapter Summary

Canada is a wealthy and advanced industrial nation, but does not include prescription drugs in its public single payer medicare plans. This makes it unique among OECD members and at odds with the World Health Organization’s definition of universal health coverage and its declaration that health is a fundamental human right. Our claim to universal health care becomes tenuous without comprehensive coverage for prescription drugs, among other services.

Since the 1970s, the absence of public coverage led to the growth of a complementary private drug insurance alternative that now covers a majority of Canadians. Other payer types each fill part of the gap. Still, a significant number of Canadians are financially vulnerable to high-cost drug claims, even those with provincial or private insurance. Drug costs vary according to where we live or work based on arbitrary policy and independent of need.

Adding prescription drugs to medicare has been recommended over several decades, but it has yet to occur mostly due to government concern about large and rapidly growing costs. As the market changes and health deteriorates, the need for better coverage grows. This thesis argues that a social drug insurance model is a feasible alternative. It improves on private insurance and may allow adequate universal drug insurance to be introduced more quickly because it reduces the cost burden on governments.

Chapter 2

Theory Base and Key Principles

Chapter Overview

This chapter presents foundational elements for this thesis and for supporting a social drug insurance model as an alternative to a single public payer approach. Theories can be used to explain what has happened and may help predict future developments. They are used to interpret relationships and processes among people, organizations and institutions.

John Kingdon's three streams theory is used to better understand – explain, interpret and perhaps predict – drug insurance problems, policy and politics as we consider how to implement universal coverage. A set of principles is proposed to provide governance and accountability for social drug insurance. Introducing and sustaining change has proven to be extremely difficult in drug policy and programs so a brief review of how to encourage more robust assessment (and potentially adoption) of social insurance is presented.

2.1 Theory Base

My research paradigm is pragmatism, focusing on practical solutions to real-world problems. This approach is "value-based [and] action-oriented" (Creswell, 2009, p. 66).

Theory provides a way to assess and act on real-world events and issues. Theories can explain and may help predict the current and potential future states of drug insurance policy and programs in Canada. Private health insurance spending is an important and understudied channel of access to prescription drug therapy. As points of distributive (equitable sharing) and procedural (fair process) justice, including the perception of fairness, one would expect governments to directly involve important stakeholders in deliberations that concern them. An important question is whether private payers have missed an important opportunity to influence how Canada may achieve adequate universal drug insurance.

2.1.1 Kingdon's Three Streams Theory

John Kingdon's "three streams" theory (2011) of problems, policy and politics focuses on assessing the conditions within government politics and bureaucracy that precede a window of opportunity for change. Since funding has been described as an important barrier to implementing adequate universal drug insurance (Hall 1964; Boothe 2015), Kingdon's focus on the "special problem" (p. 105) of budgets may help explain why progress towards universal coverage has been slow. Kingdon also describes regulation of private insurers as a low cost and feasible alternative to eliminating them. Social health insurance regulates private health insurers to protect the public interest.

Kingdon sought to describe and even predict how issues rise and fall in favour among various parties within or connected to the American federal government. Much of his work on agenda setting appears applicable to both senior levels of Canadian governments and may shed light on why NPh has not gained traction with political and bureaucratic leaders. Kingdon's theory may also help suggest a way forward by assessing and overcoming those objections.

Kingdon's work rests on three processes that can either advance or constrain policy:

1. Problem recognition: Among the plethora of issues facing government, a select few are elevated to become problems that attract the attention of bureaucrats and politicians.

2. Policy proposal development: In addition to pressure and influence tactics, Kingdon focuses on ideas, shaped by knowledge, perspectives and values, that may either spring to prominence, or be developed and diffused gradually. Feasibility, budget room and political support are crucial for ideas to flourish.

3. Politics: Problems and potential solutions are affected by elections, ideology, public opinion, advocacy and bureaucratic change. Kingdon portrayed politicians as generalists who combine information from several sources: "…the substantive and the political, the academic and the pressure group information, the bureaucracy and the constituency" (p. 37). They have the greatest influence on agenda-setting. Bureaucrats use their career longevity, expertise and relationships to influence politicians, generate policy alternatives and implement decisions.

Each process can develop on its own but may converge at "critical junctures" to allow change to occur. These three "streams" may or may not be independent of each other.

While agendas may change quickly, Kingdon found that alternative approaches conceived mostly by the bureaucracy tend to occur in smaller steps. "As policymakers consider the alternatives from which they will choose, they repair to ideas and approaches with which they are already familiar" (p. 82). Boothe (2015) points out that incremental change is more likely to frustrate major change and perhaps enable stalling (p. 83).

As noted, Kingdon recognizes the special problem of budget headroom, a key issue that has stalled progress on a universal pharmacare program for decades (Boothe, 2013). Budgets may constrain or promote changes, but in health care may be more likely to frustrate change because the amounts are so high ($33.7 billion in prescribed drugs: CIHI, 2018a) and they have historically increased at rates well above the Consumer Price Index, population growth and aging.[1] Governments perceive regulation as an inexpensive

[1] Average annual rates of increase in prescription drugs were 9.2% (1990-99), 9.3% (2000-09) and 3.5% between 2010 and 2018 (forecast) (Author's calculation based on CIHI, 2018). By comparison, Statistics Canada (op cit.) reported average annual increases in the Consumer Price Index of 1.9% (1990-99), 2.0% (2000-09) and 1.6% from 2011 through 2018. Aging

administrative program, and even more attractive if it aims to control cost when budget constraint is severe.

While noted occasionally in this thesis, application of Kingdon to the implementation of universal drug insurance is considered in Chapter 8.

2.2 Key Principles

Theories are important to help explain what has happened or why, but they do not fully identify the principles or values that should underlie change, or how to implement changes.

For example, inequity is one principle that helps justify the need for adequate universal drug insurance. In the 2003 First Ministers Health Accord, federal and provincial first ministers declared that: "No Canadian should suffer undue financial hardship for needed drug therapy"[2, 3] This statement was essentially repeated in the 2004 First Ministers' 10-Year Plan to Strengthen Health Care: "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."[4]

2.2.1 The Kutzin Contribution

Joseph Kutzin (2001) provides a framework to examine and compare reform efforts in national health insurance systems. He proposes that health care reform in any country should aim to enhance the insurance function, which he defines as "access to care with financial risk protection" (p. 172). Relevant to reforming Canada's drug insurance patchwork, he suggests two principles:

1. Reforms should aim to achieve specific policy objectives.

   It is not at all clear what Canadians should expect in terms of outcomes (e.g., quality, equity, timeliness, comprehensive care, transparency, cost effectiveness) relative to inputs, such as taxes, premiums, and opportunity costs at both personal and system levels. How will those outputs be evaluated and prioritized? Put another way, what problem(s) are we trying to solve? Policy objectives for drug insurance must be clear.

2. Reform should respect a nation's existing structure.

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accounts for an annual increase of about 1% (CIHI) in health costs and the Canadian population has grown steadily throughout this period.

[2] See: http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2003accord/pharma-eng.php.

[3] Section 5.9 includes a list of recent commissions and similar reports calling for comprehensive reform.

[4] The 10-Year Plan is available at: http://healthycanadians.gc.ca/health-system-systeme-sante/cards-cartes/collaboration/2004-meeting-racontre-eng.php. The first sentence is almost identical to the one used in the 2003 Accord.

> Given Canada's historic multi-payer model (sec 1.4), a principled approach may include private funding of drug insurance: "…the starting point for change in any country is the existing organizational and institutional arrangements of its health care system. Hence, an adaptable framework rather than a 'blueprint' is needed…" (p. 172).

Later, he elaborates:

> "In countries in which multiple (often private) insurance funds exist, the appropriate and realistic role for government is to improve its regulatory framework and ability, rather than to try and dismantle the insurance industry. …given the existing market structure, what is the appropriate direction for policy changes that will facilitate active purchasing that is publicly accountable, or at least accountable to the population covered by each purchaser?" (p. 186)

These statements are not meant to prefer social or private insurance but neither should be dismissed out-of-hand. Some parts of our health system are nearly 100% publicly funded, but other essential spending is from mixed sources, including medicines, dentistry, long-term care and community care. After decades, a multi-funder approach has become institutionalized but not optimized. Since other advanced countries have used social insurance to create their health systems, and social insurance is the foundation of our pension and Workers' Compensation systems, it is reasonable to examine as a principled means to adequate universal drug insurance.

2.2.1.1 System Functions

Kutzin describes four system functions for all types of health systems – revenue collection, pooling of funds, services purchase, and service provision. Hussey and Anderson (2003) also use the first three but substitute social solidarity as the fourth function. Focusing on these universal functions can broaden the debate about which institutions and organizations should fund services. The goal of reform then becomes organizing an effective insurance system that can deliver its particular strategy. This is an obvious challenge in Canada and elsewhere.

The payment mechanism offers incentives to product and service providers, so system performance is significantly affected by whether payers are "passive" intermediaries or use their monopsony purchasing power to create or incent quality in service or outcomes, efficiency or value. Competition may enable insurers in multi-payer systems to innovate with provider incentives or control mechanisms that mitigate over-treatment (fee for service) or under-treatment (capitation, especially when not risk-adjusted). Better performance requires management skills and information technology to monitor and adjust the financial incentives that can influence provider costs, quality and outcomes. This is effectively illustrated in both Germany and the Netherlands (see Chapter 5).

Neither provincial nor large private drug insurers in Canada use the full array of interventions noted to manage spending and patient outcomes, although public plans are far more invested in health technology assessment. The tools in use are rarely evaluated against such goals.

Under service provision, Kutzin explains how countries need to choose whether their health systems: (i) ought to be structured as monopolies or encourage competition, (ii) should provide certain degrees of autonomy to institutional providers and health professionals, (iii) and how providers and equipment resources are distributed to meet patient needs for timely access. On the first point, Kutzin states: "[Reform] should not be an ideological question but rather one based on an assessment of the specific mix of approaches that is most likely to yield improvements in efficiency, quality, and equity." (p. 188)

Kutzin notes competition between multiple (private or social) insurers may improve the fit between consumer preferences, purchasing and scope of coverage, and incent innovation but this is not guaranteed. Government systems in general can be bureaucratic, unresponsive to citizen needs, and fail to take advantage of their advantages of scale to ensure high quality, reasonable access and the lowest possible costs. This need not be the case. Ideological arguments, each with evidence for and against, are often used to justify 'public vs. private.' While the policy choice of single or multiple payers provides different processes and outcomes across nations, the number of payers is likely not the pivotal consideration in system design.

In summary, Kutzin provides a rational and practical set of principles that could be used by Canadian policymakers to improve the existing drug insurance system. Very likely, either a single payer or a social insurance system can successfully achieve policy goals once they are articulated, but neither should be considered superior without appropriate evidence. Neither provincial nor private insurers are taking advantage of their present scale and capacity to incent material improvement in system performance. "The challenge for governments is to create the conditions for schemes to contribute to system objectives" (p. 200).

Policymaking should be deliberate, use evidence and not privilege theoretical arguments over practical issues such as our ability to actually implement them (Pomey et al., 2007).

2.2.2 Proposed Principles

A reform strategy must have principles (Macpherson & Kenny, 2009). A principle can be defined as: "A fundamental truth or proposition that serves as the foundation for a system of belief or behaviour or for a chain of reasoning" (Oxford Dictionaries).[5] Principles provide

[5] Available at: http://www.oxforddictionaries.com/definition/english/principle.

guidance to program development and decisions and help ensure consistent and effective governance, management and communication.

Beyond the five principles noted in the Canada Health Act, principles have been proposed by several authors to frame and direct our drug insurance debate. They apply to both social insurance and single payer models.

Macpherson and Kenny (2009) discovered just four common principles – equity, accessibility, safety and effectiveness – after reviewing six independent policy papers focusing on the National Pharmaceutical Strategy.

Morgan et al. (2016) advanced arguments for universal access, appropriate prescribing and use, value for money and patient safety.

Figure 2.1 – Possible Principles for National Pharmacare

Principles in the Literature	
1. Access (universal)	6. Equity, fairness
2. Affordability	7. Patient safety
3. Appropriate prescribing and use	8. Sustainability
4. Awareness, education	9. Value for money
5. Effectiveness	

Sources: As described in Sec 2.2.2.

The CLHIA (2013) produced a drug policy document which includes five principles: accessibility, affordability, sustainability, patient safety and education and fairness (p. 3).

There are two common themes, expressed slightly differently. The third common and consistently linked health tenet – quality – is not mentioned by any party

- The first is Access and related principles of Affordability (CLHIA) and Equity (MacPherson & Kenny) or Fairness (CLHIA). This is a person-centred principle.

- The second is lower drug costs related to Affordability and Sustainability (CLHIA), and to Value (Morgan et al.). This principle is focused on financing.

Unique to the CLHIA is a market perspective that values diversity in approaches and decisions, which allows competition and choice across private health plans. Its fairness principle is more narrow than traditional definitions of equity. By fairness, the CLHIA wants drugs available at the often-lower government price to private drug plan members and to non-insured individuals. While noting that “patient safety is paramount”, it defines Education as enabling “Canadians to make informed decisions” (p. 3).

Provinces and private insurers routinely speak about the need for a sustainable health system and specifically note pharmaceuticals. Cost-related concerns are the most cited reason why governments have not implemented national drug insurance. A principle of Integration is not explicitly mentioned elsewhere, though it is implied by the CLHIA under Fairness ("All Canadians should have access…" (p. 3).

Lower prices have been achieved by leveraging the buying power of government plans and their willingness to delay or deny access to certain drugs usually on the basis of price and poor cost-effectiveness. Similarly, Morgan et al. (2016) in focusing on a single payer plan, do not consider private insurers or plan members. The CLHIA policy anticipates both public and private plans, likely recognizing the primacy of government policy and its power to control targeted parties like brand and generic drug manufacturers, the pharmacy industry, and health professionals.

Principles can be one point of agreement among those promoting different universal drug insurance models. None of the principles suggested are in opposition; none create a divide between provincial and private payers (e.g., improving access and lowering costs). The art of policy and program development will be in assessing priorities and providing appropriate balance, e.g., between bureaucratic rigour and market responsiveness.

Beyond the Canada Health Act and specifically for universal drug insurance, the following six principles are proposed:

1. *Affordable*: Personal drug costs must be capped at a reasonable percentage of household income, defined here as 3%.[6]

2. *Effective*: Administration must provide timely insurance protection and access to drugs that meet the medical need.

3. *Efficient*: New investments in information technology (IT) are needed to enable better prescribing and dispensing, and less redundancy and duplication in procedures. Any new model should be minimally disruptive to stakeholders especially at implementation and through a transition period.

4. *Equitable*: Progressive, income- and needs-based approach to funding insurance, shared among governments, employers and citizens.

5. *Integrated*: A national medicines strategy, policy planning and system-level tactics cover all beneficiaries, allowing a whole-market view. This includes upstream (e.g., social determinants of health and prescribing) and downstream (e.g., collection of

[6] In some provinces the threshold is far higher, e.g., MB, NL, NS, PEI and it may be in QC since its flat deductible ($1,087) is 3% or less for those earning over $36,200. Note there are federal personal income tax rebates when qualifying medical expenses (such as prescription drugs) combine to exceed the lesser of $2,302 (2018) or 3% of net annual income. The 3% cap is meant to be consistent with and replace the existing tax credits which may be fulfilled in whole or in part by prescription drug expenses.

post-launch data and real-world evidence), as well as lateral (rest of the health care system) factors.

6. *Sustainable*: At a system level, drug insurance must be financially managed so that costs do not increase faster than the country's ability and willingness to pay. An acceptable rate of increase should be defined.[7]

Careful consideration will also be given to the place of competition and the need for much improved governance through the balance of this thesis.

2.3 Chapter Summary

John Kingdon's *Agendas, Alternatives and Public Policies* (2011) provides the theory base to consider the likelihood of change to the current mixed funding of drug insurance. Joseph Kutzin's work is valuable as a complementary set of inputs, in part because he frames health systems as insurance, and because he takes a more global perspective. He also sets up work to explore relevant, modern principles applicable to prescription drugs within a broader health system. Six new principles are proposed to reflect the need for a new structural framework and set of decision filters.

Universal drug insurance in Canada exists only in Quebec. A policy entrepreneur (described similarly by Rogers as "informed intermediaries" – see ***Appendix 1***) is needed to bridge differences and forge a made in Canada approach. Social insurance is familiar to Canadians and it is compatible with well-established health system values. Kingdon also notes the importance of value acceptability, which in the case of social insurance should transcend left-right ideological boundaries and easily pass through filters for equity and affordability. Its main weakness is likely economic efficiency – multiple private insurers, even well regulated, are likely to cost somewhat more to administer than a single payer system with a one-size-fits-all approach. However, administrative cost is just one consideration.

The next chapter introduces the research questions and methods that will guide this thesis.

[7] For example, the PBO may define this as drug costs that increase no more than increases in per capita Gross Domestic Product.

Chapter 3

Research Questions and Methodology

Chapter Overview

This chapter presents two research questions and the methodology that reflects the three major information sources for this thesis: a literature search, exploration of comparative models and opinion leader interviews. The qualitative sections use inductive reasoning to identify and assess themes arising from the interviews. Participant questions are listed. Finally, potential biases in the qualitative methodology and approach to mitigating them are identified.

3.1 Research Questions

A better fit between problem – lack of adequate universal drug insurance – and potential principled solutions could lead to wider acceptability of the need to change and therefore a greater likelihood of moving change ideas to implementation. The following two questions explore new empirical information and expert opinion from those with deep, senior-level experience in planning and administering public and private drug insurance plans.

Research Question 1

Could a social insurance model that includes employer-sponsored private insurance be a more feasible way to achieve adequate universal prescription drug insurance?[8] Feasible means probable, with faster and less disruptive implementation.

a. Social insurance: What are the experiences, characteristics and advantages and disadvantages of drug insurance in Germany, the Netherlands and Quebec and could those jurisdictions provide guidance for a similar universal model across Canada?

b. Private insurance: What are the advantages and disadvantages of employer-sponsored drug plans as a complementary channel to fund prescription drug coverage?

Research Question 2

What advantages and disadvantages of our current shared-funding model are recognized by private and public drug plan opinion leaders?

a. What are optimal roles for the federal government to play in achieving adequate universal drug coverage?

[8] Adequate, universal coverage is defined in Sec 1.5.4: Coverage will be adequate when it provides access to a broad formulary of medicines at an affordable level of out-of-pocket cost according to medical need. Coverage is universal when all Canadians have access to necessary medicines.

b. Is private drug insurance acceptable and should it be included in national pharmacare policy?[9]

Kingdon's theory, assessed in Chapter 8, will be used to consider whether current or near-future conditions create a "critical juncture" – convergence of the problem, policy and politics streams – that could lead to adequate universal drug insurance.

3.2 Methodology

3.2.1 Literature search for Research Question 1

The search goal was to identify high quality studies that were current and relevant to my general topic and the research questions. In July 2015, a scoping search was conducted in English using PubMed and MeSH terms "drug costs" and "insurance, pharmaceutical services". Publication dates from January 1, 1990 through June 30, 2015 were input, as were the following article types: Case Reports, Comparative Study, Editorial, Government Document, Journal Article, Historical, Meta-Analysis, Review and Systematic Reviews.

The following MeSH sub-fields were included: "drug costs", "insurance, pharmaceutical services" [MeSH Terms] OR ("insurance"[All Fields] AND "pharmaceutical"[All Fields] AND "services"[All Fields]) OR "pharmaceutical services insurance"[All Fields] OR ("drug"[All Fields] AND "insurance"[All Fields]) OR "drug insurance"[All Fields]) AND ("1990/01/01"[PDAT] : "2015/06/30"[PDAT].

There were 13,852 entries. The entries were manually reviewed until the displayed studies became too distant from the search goals and too dated to be relevant. After reviewing titles, 31 of the first 300 abstracts were selected for reading.

A more focused search was then undertaken using "drug costs" and "social insurance". Titles of 664 entries were reviewed. All relevant articles were saved on PubMed after reading the abstract. Of those, I selected 27 articles for full reading because they pertained to the research questions.

That search returned a number of articles that were not solely focused on social insurance but are relevant for context, including some that were useful for international experiences (Germany, Netherlands, UK, USA). These were supplemented by other references drawn from this thesis proposal (July 2015) and from the focused search described above.

[9] Drawing from the literature, government opinion leaders, primarily senior bureaucrats responsible for provincial drug plan administration, have the tenure, organizational knowledge, network, and subject matter expertise to identify a suitable model(s) and exert significant influence on implementation. Similarly, private payer opinion leaders included also have the tenure, expertise, authority and network to effectively advocate for change and influence implementation.

Some literature examined social insurance using economic theory, sometimes with a specific focus on the efficiency of private insurance. These publications are highly technical and require a strong grounding in economics. They are outside the primary focus of this thesis.

A review of the search strategy and advice to improve search effectiveness were provided by a University of Waterloo librarian in August 2015.

Many articles and studies were located from reference lists in the studies located through the original search (a snowball strategy). Ad hoc searching occurred, e.g., using "Canada" as a search term. Ongoing reading has discovered many newer and specialized articles in both peer-reviewed and grey literature. In particular, two recent federal reports (HESA, 2018; Advisory Council 2019b, see Sec 4.3.2) are central to current deliberations on national pharmacare.

3.2.2 Comparative Country Analyses

A description and comparative analysis was undertaken of health and drug insurance systems in Germany, the Netherlands and Quebec. The goal was to compare and contrast other social health insurance systems and the Canadian drug insurance model.

Relevant and comprehensive reports were found from the Organization for Economic Cooperation and Development (OECD), the Commonwealth Fund and the World Health Organization. These included relatively current reviews of the German and Dutch health systems. Both the German and Dutch governments also publish significant information in English, although often less frequently and in less detail than in their national languages.

Table 5.5 compares features of the German and Canadian drug insurance systems. It was reviewed by Neil Grubert[10] for accuracy and completeness in April 2019.

3.2.3 Qualitative Interviewing[11]

My theory base suggests that health policymaking is an art, with considerable emotion, politics, logic, chaos and an important ethical dimension. Research, evaluation and implementation of policy do not often follow a linear (or logical) path and may be highly politicized. Personalities intervene and influence. For these reasons it is crucial to consider the opinions of leaders in several segments with a vested interest in health services

[10] Neil Grubert is a multilingual pharmaceutical market access specialist with 29 years of experience based in London, England. He has written more than 150 reports covering 20 mature and emerging markets, multiple therapeutic areas and many industry issues. He has chaired international events and spoken at conferences, seminars and training workshops, including bespoke programs commissioned by senior pharmaceutical company executives. More information is available at: https://www.linkedin.com/in/neil-grubert-1658381b/?originalSubdomain=uk.

[11] I presented myself to potential participants as a PhD candidate in SPHHS at the University of Waterloo, not as a consultant.

generally and drug insurance in particular. No previously published research was found that used a formal qualitative methodology to approach this community. Interviews reflected a pragmatic paradigm.

A distinguishing feature of qualitative research is context, and the ability to provide perspective, history, and detail on people and processes. Researchers may evolve their questioning to reflect emerging ideas from the interviews. Research Question 2 uses thematic analysis and inductive logic to understand what participants think about the need for universal drug insurance and whether social insurance could provide a feasible approach to achieving it. The aim is to contribute a better understanding of the policy, processes and relationships that may influence whether and when universal drug insurance may be introduced.

3.2.3.1 Procedures

Twenty-six semi-structured telephone interviews were conducted with opinion leaders including provincial drug plan directors and senior policy experts, leading private drug plan experts, and others (Sec. 3.2.3.3) to identify their views on drug plan sustainability, interest in shared provincial-private drug policy development, and their major challenges to ensure access and control cost. **Tables 3.2** and **3.3** show how many were interviewed from each category. Interviews were scheduled from February to August 2017. Each was at least one hour's duration. This phase was to identify context and process dimensions that need to be considered in order to adopt a feasible solution. (Sec 3.1, research question 1.)

Interviews recorded perspectives on the sustainability of drug plans and the need for change, the conditions necessary for change to occur, willingness to change, and perceptions of other payers. They were asked about key features of social insurance, the value and type of regulation and how minimum coverage standards may be negotiated. These topics were derived from the literature review and are key to relationship building, establishing common ground, and introducing the idea of more integrated strategy, policy and programs.

Interview procedures and questions were reviewed by my committee and revisions were made. The questions were then tested with one private insurer and one provincial government leader for relevance, feasibility, clarity and the ability of these interviews to answer my research questions (Sec 3.1).

Some elements of participatory action research (Minkler, 2000) are used to strengthen my understanding of participants' responsibilities, authority, influencers, boundaries and constraints.

The following steps occurred. Outcomes are described in section 3.3.3.

1. Drug insurance opinion leaders in the federal and provincial governments, private payer community, and selected other groups were identified and contact information obtained. The “other groups” include unions and health professional and industry associations and were selected for their ability to influence payers.

2. Opinion leaders were telephoned with an invitation to participate in a 60-minute interview. There was at least one telephone or email follow-up for any prospect who had not responded after one week.

3. A description of the project and the approved consent letter was provided to each person who expressed interest. Interview questions were provided in advance. Prospective participants were advised the study had received ethics clearance through a University of Waterloo Research Ethics Committee (ORE #21908). They were asked to carefully read, sign and return a consent form and interview times were then arranged.

4. All interviews were conducted by telephone. Email reminders were sent one day prior. It was noted again that the discussion would be recorded but that no attribution would occur without the participant’s express written consent. Interviews occurred as quickly as possible and continued until thematic saturation was achieved.

5. Participants were thanked for their time and invited to provide additional comments. As noted in the consent letter, follow-up contact could be made to confirm previous discussion points or to ask follow-up questions. This is consistent with typical qualitative methodology.

6. A synopsis of major aggregate findings from all participants will be provided to each participant following the thesis defense.

Interview questions are listed in section 3.2.3.4. The following sub-sections cover sensitizing concepts, participant selection, interview questions, personal influences and data protection.

3.2.3.2 Sensitizing Concepts

Bowen (2006) describes sensitizing concepts as “interpretive devices and as a starting point for a qualitative study (p. 14).” He cautions that naming some concepts presents a risk that others not initially identified will remain hidden. These concepts may also be useful again in identifying themes during the constant comparison of data and once interviews have been completed.

Seven concepts from the literature review established a foundation for participant questions.

1. **Ideology:** often "political", e.g., public vs. private funding; the role and degree of regulation.

2. **Principles and Standards:** universal access; fairness; adequacy; inclusive policymaking; program integration; accountable governance.

3. **Sustainability:** of funding pharmaceuticals and cost control at a system level.
4. **Affordability:** of a drug or financial accessibility by a patient.

5. **Goals tension:** making "tough choices"; balancing cost, value and health impacts of drugs.

6. **Pace of change:** dramatic and large-scale or cautious, defensible action; delay tactics; choosing not to act.

7. **Problems, policy and politics (Kingdon):** identifying the key problems, decision agendas, policy entrepreneurs and potential windows of opportunity.

Table 3.1 joins the research and interview questions with these concepts and Kingdon's theory.

Table 3.1 – Links between Sensitizing Concepts and Participant Questions

Research Question 2: What advantages and disadvantages of our current shared-funding model are recognized by private and public drug plan opinion leaders? a. What are optimal roles for the federal government to play in achieving adequate universal drug coverage? b. Is private drug insurance acceptable and should it be included in national pharmacare policy?	
Sensitizing Concept	**Supporting Interview Questions**
1. **Ideology:** often "political", e.g., public vs. private funding; the role and degree of regulation.	Q5, Q6, Q7, Q10, Q11, Q12, Q15
2. **Principles and Standards:** universal access; fairness; adequacy; inclusive policymaking; program integration; accountable governance.	Q3, Q4, Q5, Q6, Q7, Q8, Q10, Q11, Q12
3. **Sustainability:** of funding pharmaceuticals and cost control at a system level.	Q4, Q5, Q11, Q12, Q13
4. **Affordability:** financial access at a patient level.	Q8, Q11, Q12, Q13

5. **Goals tension:** making "tough choices"; balancing cost, value and health impacts of drugs.	Q4, Q9, Q13, Q15
6. **Pace of change:** dramatic and large-scale or cautious, defensible action; delay tactics; choosing not to act.	Q4, Q5, Q6, Q9, Q11, Q13, Q14, Q15
7. **Problems, policy and politics (Kingdon):** identifying the key problems, decision agendas, policy entrepreneurs and potential windows of opportunity.	Q1, Q2, Q2b (for gov't only), Q7, Q8, Q9, Q10, Q11, Q12, Q13, Q14, Q15

3.2.3.3 Participant Selection

The key respondents are senior-level payers (**Table 3.2)** with many years of experience who govern and direct public and private drug plans. Those payer roles are significantly influenced by other groups so smaller samples of benefit and policy advisors, business leaders, academics, unions, the insurance and pharmaceutical industries and pharmacy were included and asked a subset of the questions posed to payers (**Table 3.3**).

A purposive sampling technique was used since the number of potential respondents with suitable knowledge and experience is limited. Those contacted were initially derived from the researcher's personal network and others known to him, and were asked to refer others who may also be interested in participating. One name was proposed (and eventually interviewed) who had not been previously considered by the researcher, indicating the prospective participants were likely representative of those known to have insight on private payer perspectives. Time, research scope and the need to effectively balance the range of data collected put limits on the ability to follow up on all leads provided. After 26 interviews, sufficient thematic scope and depth was achieved. I believe participants are generally representative of the sectors they represented, based on my assessment of the professional reputations each had inside and external to their communities.

Initially, 43 prospective participants were identified and 26 were interviewed (**Tables 3.2** and **3.3)**. Seven did not respond after follow-up and one declined. Nine others on the contact list were not approached because their roles were well-covered by other participants. The refusal was from an insurer. The seven non-responses were an MP, an HR consultant, a provincial manager, a provincial Minister's office, an insurer, an academic and a business organization. Not all were expected to participate, in particular, provincial health ministers.

The researcher had no special influence over anyone contacted. Twenty percent didn't even respond. None has ever been a client. While three could be called regular professional contacts, and two more occasional, the researcher had never spoken to nine participants and had only distant or extremely limited episodic contact with 12 others who agreed to

participate. For example, one was a temporary supervisor of mine almost 20 years ago. They were selected to provide regional representation and to cover a wide range of past and current professions.

Table 3.2 – Payers

Category	Identified Opinion Leaders	Interviews
Provincial health ministers	3	0
Provincial drug plan managers	5	7
Insurers and benefit advisors	14	7
Business leaders	3	1

While only five provincial managers were originally identified, two were substituted (same province) and two were added to increase the scope of experience and insights collected.

Six influencer groups were generally asked questions 3-8 and 12-16 (Section 4.2.5):

Table 3.3 – Influencers

Category	Identified Opinion Leaders	Interviews
Academics	6	1
Labour representatives	2	3
Pharmaceutical industry association	2	1
Federal government[12]	1	4
Health professional association	2	1
Others	2	1

The views of all six academics who had published on this broad topic are well known. One was recruited and a second was contacted three times with no response.

3.2.3.4 Participant Questions

The following questions arose from the literature review that responded to Research Question 1 and the sensitizing concepts (Section 3.2.3.2, **Table 3.1**) derived from it. These questions were deemed relevant to the participant groups and key to relationship building, establishing common ground, and introducing the idea of more integrated strategy, policy and programs. The qualitative methodology and semi-structured approach allowed

[12] I had not originally considered asking federal politicians but one expert policy participant suggested I do so. Members of two different parties were willing to participate. One MP stopped responding after his duties were re-assigned by his party.

significant latitude to adjust, add or delete questions or return to participants if needed. The questions were revised as interviews proceeded to reflect accumulating knowledge. Not all participants answered all the questions, most often due to time constraints but also following the researcher's judgement of their suitability. Questions also evolved as more interviews were conducted.

1. What major problems are you and others in the health ministry [insurance industry] most concerned about these days? Why?

2. Of these major problems, which have the highest priority now and for the next three to five years? Why?

For government participants only. 2 b) Do the priorities vary between political leaders and senior civil servants? Is one group more likely to support or frustrate universal drug insurance?

3. Do you have any (personal or institutional) preference for how prescription drug coverage is structured, administered and funded? (If needed, probe single payer, shared funding, or something else) Why do you think that?

4. How important is the general concern about the sustainability of provincial and/or private drug programs? Does progress towards universal coverage mostly depend on budget, politics, or what else?

5. Why do you think Canada does not have prescription drug insurance like it has for hospitals and physician services? (scale of changes needed; probe incremental vs. large-scale)

6. Some believe private drug insurance should be eliminated, others find it acceptable but not optimal, and others think it is necessary and beneficial. How do you see private drug insurance?

7. Do you think private drug insurance is effectively regulated by federal and provincial governments? [*Note* this question was eventually dropped because no participant admitted to any expertise in this area.]

8. Do you have a sense Canadians have important unmet needs for drug insurance? Which Canadians? How big is the need for that group(s)?

9. Use your experience to consider a major recent change to a provincial drug insurance program [private drug plan design (formularies, cost control, contracts)]. How did this major policy and program change get navigated through government [insurance company/industry]? How long did this process take? Would this process and timing apply to the introduction of a social insurance model? [*Note* this question was asked only in the pilot and then dropped due to a lack of relevance.]

10. How would you describe the current connections between provincial drug plans and private workplace drug insurance? (probe independent / inter-dependent) Between drug insurance leaders in both sectors?

11. Is there an immediate or near-term opportunity for substantive collaboration between provincial governments and private insurers and employers to improve the quality and scope of drug insurance? Specifically, could common coverage standards be developed, or out-of-pocket cost be harmonized?

12. Can we learn anything from Quebec's drug insurance model? Are you familiar with other national drug insurance systems that could inform us? [*Note* this question was asked but only one participant had significant knowledge of the Quebec model.]

13. Two potential scenarios follow. Can you suggest how governments, insurers and employers might respond to:
    a. The transfer of all private drug insurance in Canada to provincial governments with a commensurate tax increase, or
    b. Heavier regulation of private drug plans, minimum coverage standards that apply to all drug plans, and an employer mandate to provide drug insurance?

14. Are there organizations or people – inside or outside government and the insurance industry – who might be willing and able (credible, powerful, connected) to champion this issue?

15. Are there critical, looming issues on the horizon that could open a window of opportunity – inside or outside government and the insurance industry – to achieve universal drug insurance?

16. Is there anything else we haven't discussed that is relevant to achieving universal drug insurance? Is there anyone else I should contact about this issue?

3.2.4 General Information

3.2.4.1 Personal Influences

My work background includes 18 years in underwriting, reinsurance, sales, sales management and business development in the insurance industry and 20 more years as a self-employed health consultant focusing on workplace health strategy and drug insurance. As such, I have a broad background and an extensive network within the broader private payer community (insurers, benefit advisors, pharmacy benefit managers, employers) as well as a smaller number of contacts in government, government relations and the pharmacy and pharmaceutical industries. Several participants had prior work relationships

with me, none subordinate. My experience presents certain biases in my perspective: the need for change, my views of “what works” and how change occurs in private insurance.

An important bias is my view that governments have not played a proactive or innovative fiduciary role in providing universal drug insurance. I also believe private insurance is too narrow in its self-interest to adequately consider the needs of all citizens. Its mandate in offering health insurance has always been to supplement public coverage. I contend there is a mutual dependency between these two payers, but outside Quebec, this has not yet resulted in drug policy or programs that are deliberately co-managed or integrated.

My personal experience influences how I frame, investigate, apply and discuss my research. I believe this experience is also an asset to provide better real-world insight on how problems may be identified and policy may be changed within each payer community, and the interaction effects between the two payer groups. I have no direct experience with those in the political stream and limited experience with those who can lead or build coalitions among important actors. I acknowledge that social desirability bias may be a factor to the extent any participant does not accurately or completely state his or her views during the interview.

3.2.4.2 Data Analyses and Quality Assurance

Each interview was digitally recorded and later transcribed using Dragon Professional Individual Version 15 (Nuance Communications Inc.). Notes were taken as interviews were recorded as a back-up and to record ideas outside the specific conversation. The information collected was first read and manually coded with notes, categorized and assessed for themes and for similar and conflicting perspectives. Next, all 26 interviews were uploaded to NVivo 12 (QSR International Pty. Ltd.). Interviews were re-read and salient passages were organized in 26 Nodes, a number eventually reduced to 23 as comments were reviewed and consolidated. All interviews were iteratively searched for certain key words during writing, such as “fund” and “facilitate.”

Data validity started with clear research questions and careful selection of participants. Questions were revised in late stages of writing to better reflect interview content. Quality was reinforced by generally comprehensive descriptions of the process and the participants, line-by-line coding, constant comparison, negative/dissenting case analysis and personal notetaking (particularly about changes in procedures or questioning). Emerging themes were compared to Kingdon (2011). Reliability was reinforced through consistent use of NVivo categories across all interviews. Credibility was reinforced by establishing clear linkage between data, categories, thematic findings, interpretations and conclusions.

Nodes with the greatest number of comments and the researcher’s judgement of their relevance were used to select three topics. Consideration was given to the current deliberations of the federal government.

The following three topics have among the largest number of relevant quotes (NVivo) and where the participants have provided thoughtful input.

1. The federal role
2. The role of private insurance
3. Relevancy of the social insurance models in Quebec, Germany and the Netherlands to current deliberations on national pharmacare.

Participants may help disseminate the research findings. (An insurance industry executive has made this offer.) Their participation can help create a sense of ownership and potentially extend the researcher's ability to influence policy.

The interviews complement the narrative review and quantitative data and the comparative country analyses, and have provided new insight and context on the goals and process of improving access to prescription drugs.

3.2.4.3 Confidentiality, Privacy and Protection of Data

I promised confidentiality and anonymity to all participants. By confidential, I mean I had written authorization to use and quote (anonymously) the content of my interviews. If a participant chose to be identified (none did.), the participant would no longer be anonymous, but the contents of our interview would have remained confidential.

No personal identifying information appears in the transcripts or the thesis. No remarks were directly attributed to a participant in any public document. Quotations were used in the research report or a presentation but were attributed only to a cohort, such as "Insurance executive", or "Provincial drug plan manager", or "Labour policy expert."

Chapter 4

Literature Review: Drug Insurance for Canadians

Research Question 1

Could a social insurance model that includes employer-sponsored private insurance be a more feasible way to achieve adequate universal prescription drug insurance?[13] Feasible means probable, with faster and less disruptive implementation.

b. Private insurance: What are the advantages and disadvantages of employer-sponsored drug plans as a complementary channel to fund prescription drug coverage?

Chapter Overview

This chapter provides findings from the original literature review and has been updated with relevant information through September 2019. New information is added about private drug benefit plans and current levels of protection from catastrophic drug insurance costs that are provided by provinces to their general population. The very significant and inequitable differences in protection suggest the need for national standards that provinces alone have been unable or unwilling to implement. Eight possible reasons for drug policy inertia are identified and explained. Regulation is briefly described because it is commonly used in social health insurance systems to ensure private insurers operate in the public interest. The potential costs of different insurance models are discussed based on a review of 16 recent studies. Out-of-pocket costs from eight different sources are described.

This chapter identifies the serious and long-term limitations of Canada's historically fragmented "patchwork" approach to providing drug insurance. Generally, public drug plan designs and patient eligibility and cost-sharing have become institutionalized. Private drug benefit plans remain essentially unchanged since the 1970s. Important changes will be very difficult to make even though inequitable and inadequate coverage persists and the pace of technological change is accelerating. The federal government and regulated private insurers could play a larger, complementary and more integrated role with provincial drug plans. This idea will be explored in Chapter 5.

[13] Adequate, universal coverage is defined in Sec 1.5.4: Coverage will be adequate when it provides access to a broad formulary of medicines at an affordable level of out-of-pocket cost according to medical need. Coverage is universal when all Canadians have access to necessary medicines.

4.1 Current Issues

4.1.1 Private Drug Insurance Plans

Private health insurance is contractually provided by an insurer to a covered "person", usually either an employer (group) or an individual.[14] In Canada, associations (professional, alumni and business), unions or labour-management trustees also offer group plans.[15] Eligible expenses are based on the Income Tax Act and conditions of coverage are specified in the contract, as are limits and exclusions. All private extended health care (EHC) plans include coverage for prescription drugs which account for about 65% of all EHC costs (CLHIA, 2018).[16]

The cost is reviewed annually and set according to either the claim patterns of the insured person (experience-rated or self-insured contracts[17]) or the cost may reflect the aggregate claims of many persons (pooled or fully insured). Insurers require employers to pay at least 50% of the premium cost and sometimes the full cost of the benefit plan. Plan members often pay a small (10% or 20%) share of their claims but some pay zero.

Health insurance premiums are usually set using single and family rates (and sometimes a couple rate) that are unrelated to income. That makes private health insurance premiums regressive since low- and high-income earners pay the same premium and the same share (deductible or coinsurance) of each claim. However, much of that inequity is corrected in the broader context of a progressive income tax system.

Enrolment is usually compulsory for all eligible employees except in specified situations such as a spouse with coverage elsewhere. This rule provides adequate risk spread between healthy and less healthy plan members. Some classes of employees are typically excluded, such as part-time, contract and casual workers.

Public and private drug plans have several key features and differences (**Table 4.1**).

[14] Individual policies provide limited coverage for those young and healthy enough to pass medical underwriting and who can pay monthly premiums without subsidy.

[15] A description of private insurance types and a high-level outline of insurance in various countries is available at: http://www.oecd.org/els/health-systems/Table-of-Content-Metadata-OECD-Health-Statistics-2018.pdf. See page 6, Social Protection, Private Health Insurance.

[16] Dental coverage is a separate line of private benefit plans, excluded from Extended Health Care.

[17] Self-insured contracts mean the employer accepts the full risk of claim costs and an insurer provides Administrative Services Only (ASO). A Third Party Administrator (TPA) may provide certain administrative functions, usually for multi-employer trusts.

Table 4.1 – Description of Public and Private Drug Insurance Criteria

Criterion	Public Drug Plans	Private Drug Plans
Sponsor	Government	Employer, union, trust, individual
Funding source	General taxation, patient	Employer, employee / personal
Legal structure	Legislation, regulation – entitlement program	Voluntary contract encouraged by tax policy and labour market expectations
Typical considerations	Budget-based cost control, formulary access based on clinical and economic review, political oversight	Employee satisfaction, cost control, contribution to productivity and corporate reputation
Covered population	Defined and/or voluntary populations within each jurisdiction	Defined employee segments and their family members; local or national

Source: Author.

Some Canadians are eligible for both provincial and private plans, including some retirees. Provincial drug plans integrate with private plans in different ways. Some provinces are first payer[18] (e.g., ON non-Trillium) and some are second payer (e.g., Atlantic Canada). Some allow private insurance to pay for the public plan deductible and coinsurance (BC, MB) and some do not (ON Trillium). Quebec requires private insurance to pay first if a patient has private coverage but if a business does not offer a health plan, the province insures that employer's employees and family members.

4.1.2 Private Plan Advantages

Employees are very satisfied with their private plans. Sixty percent of 1,505 private plan members included in a 2019 national survey said their health benefit plan met their needs extremely or very well and 54% rated the quality of their plan as excellent or very good (Sanofi 2019, p. 10).

Private drug plans typically have much larger formularies and list new drugs faster than provincial plans (CLHIA, 2018). Patients may support private insurance because they are concerned about losing coverage or paying more out-of-pocket (Pollara 2018).[19] The CLHIA

[18] Sometimes a plan member is eligible for coverage under more than one plan, typically an employer plan, a spousal plan and sometimes the provincial drug plan. The order of private claim payment is defined by the CLHIA. Each province determines when their plan will pay if a beneficiary also has private drug plan.

[19] For example, the PBO cut $3.9 billion from its single payer pharmacare model by delisting drugs that would no longer be reimbursed according to the Quebec formulary. With over 8,000 drugs, QC has the largest provincial formulary in Canada however it covers fewer drugs than most private drug plans (10-12,000 DINs – CLHIA 2018). The drugs no longer reimbursed in the PBO model were eligible under private plans. A smaller formulary would lead to greater out-of-pocket

(2018b) estimated that 7.7 million Canadians are taking brand and generic drugs not currently covered by their provincial plans, with an estimated value in 2020 of $1.1 billion. Patients would then either have to pay out-of-pocket for these drugs, or they would have to switch to a different drug of hopefully similar efficacy in order to be reimbursed. Even using a comprehensive public coverage model (under which private plan eligibility would be reduced), "…this may leave 60% of Canadians with private coverage [today] worse off for access to some medicines" (Law, Clement and Dinh, 2018, p. 15). It is not clear if union members support bringing drug insurance under the Canada Health Act[20] or prefer to retain the added coverage available in private drug plans. The Sanofi survey (2019, unpublished data) indicates union members are more likely than non-union employees to rate the quality of their private health benefit plan as excellent or very good (58% union, vs. 51% non-union).

Even in provinces which are notionally first payer (BC, AB, SK, MB, ON non-Trillium), private plans reimburse eligible claims up to the provincial deductible. Private insurance also limits the liability of provincial drug plans and may reduce pressure on public plans to reimburse thousands of drugs not on their formularies.

4.1.3 Contentious Issues

Academics have focused on three drawbacks of Canada's approach to private insurance. First, most insurers operate in the interest of their shareholders or policyholders and not necessarily for the good of society. Insurers (and all businesses) are primarily responsible to shareholders unless otherwise directed by legislation or regulation.

Second, premiums are tax-deductible by the employer and benefits received by plan members are not taxed except in Quebec. The federal Department of Finance (2018) estimates the value of "Non-taxation of benefits from private health and dental plans" at $2.84 billion for 2019, of which about $909 million (32%) is accounted for by drug plans (Author's calculations using CLHIA, 2019).[21] According to Finance, the tax-favoured status of employee benefit plans has three stated purposes: (1) To achieve a social objective, (2) To encourage employment, and (3) To improve access to supplementary health and dental benefits.[22] This is regressive because a larger benefit is provided to higher income Canadians for a given eligible medical cost.

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cost in the absence of private insurance, e.g., ON has just 4,400 "drug products" that include nutrition products and diabetic testing agents.

[20] The Canadian Labour Congress launched their campaign supporting public single payer national pharmacare in late 2017.

[21] Department of Finance, Canada. See: https://www.fin.gc.ca/taxexp-depfisc/2018/taxexp1806-eng.asp#Non-taxation-of-benefits-from-private-health-and-dental-plans. This amount covers $34.7 billion paid for extended health, dental and disability claims in 2018 (CLHIA, 2019). Of that amount, 32% ($11.7 bn) was for drug insurance, so about $909 million of the foregone federal tax could be eliminated if private drug insurance converted to a public single payer plan.

[22] Department of Finance, Canada. See: https://www.fin.gc.ca/taxexp-depfisc/2018/taxexp1805-eng.asp#Employee-benefit-plans.

Third, private insurance has higher costs for drugs, administration and pays higher amounts to pharmacies than do provincial plans. In part, multiple for-profit insurers provide perhaps hundreds of different plan designs. Choice costs more to plan and administer which has led to claims of inefficiency and wasted resources (Gagnon & Hébert, 2010; Law et al., 2014). Morgan, Daw and Law (2013) estimated excess administrative costs for private health insurance at $1 billion (p. 16), but did not show a calculation. In that report, "health insurance" covers several benefits, some of which have highly automated administration (drugs) and some with more manual and personalized processes (long term disability). The authors did not identify premium, sales, income or other taxes paid to governments[23] as part of the higher cost of private health insurance administration, nor the different services provided to clients and beneficiaries by each payer group.

Law et al. (2014) examined the insurance industry's (CLHIA) own health claim reports between 1991 and 2011 and concluded that medical insurance margins (including coverage for hospital and drugs) had significantly increased between 1991 and 2011. "Margin" was defined as premiums less claims. Margins vary by type of insurance, claim experience, and size of employer. For example, Law et al. calculated that insured plans, generally purchased by smaller employers, generated a margin of 26% of medical premiums after paying all claims. In contrast, Law et al. noted that insurers retained just 5% of non-insured medical premiums purchased by larger employers. In 2018 the industry retained 13% of total EHC and dental premiums for administration (7%), taxes (3%) and profit (3%) (CLHIA, 2019, p. 17).[24]

Plan cost is just one of several considerations in determining value. Private insurers offer many plans with different coverage levels and costs, and they usually provide access to leading-edge consumer technology that is not offered by provincial health plans. Various media platforms, i.e., web, smart phone, telephonic and call-centre, are available 24-7 to serve plan members. Services include education on adherence to therapy, health promotion, pharmacy locators and internet-based cognitive behavioural therapy.

Insurers have not always closely adhered to their fiduciary role in spending their clients' funds. Pharmaceutical manufacturers and pharmacies very often take advantage of fewer and less stringent cost controls in most private drug plans by charging higher prices to private plan members. In part, the drug and pharmacy industries support private insurance to minimize threats to their revenue and profits. Many private plans still lack the cost controls used by provincial plans.

Single payer national pharmacare creates potentially important quality, access and cost uncertainties for patients because it could eliminate private drug benefits or make them

[23] CIHI (NHEX, 2018. Methodological Notes, p. 17) calculates private administration cost as the difference between premiums and claims. This cost includes collection of premium, capital, sales and other taxes paid by insurers. The CLHIA (2018a, p. 18) reports $4.1 billion in taxes paid by its members, plus $3.6 billion in sales and payroll taxes paid to governments on behalf of employers and employees.

[24] The CLHIA does not identify drug administration costs separately.

uneconomic.[25] It also creates costs or lost revenue and perhaps profitability for employers, insurers, pharmacy benefit managers and benefit consulting firms. It may also affect governments by not only increasing their share of all prescription drug spending, but also reducing their tax revenue as premium and sales taxes would no longer be paid on private drug plans. The CLHIA has estimated these lost revenues to provincial treasuries at $1.1 billion.[26]

4.1.4 Other Considerations

Chronic disease now accounts for about two-thirds of all drug claim costs (Express Scripts Canada (ESC), 2014). Here too, new drug products are entering the market for common conditions at multiples of current product pricing. For example, Repatha® is a newer drug for certain cases of high cholesterol that costs between $8,000 and $10,000 annually, versus less than $400 for traditional statin therapy.[27]

Specialty drugs, generally biologic in nature rather than chemical, are now common in lists of top ten sales. Annual costs for those products often average tens of thousands of dollars per patient, but account for only about 2% of the number of privately-paid scripts (ESC, 2019). For specialty products in 2013, ESC reported average cost per claim was $1,270 versus $45 for traditional drugs (2014, p. 16). Drugs for rare diseases commonly cost US$240,000 to US$400,000 annually in the American market.[28] With increasing utilization, specialty products[29] now account for 33% of employer drug plan costs in Canada, up from 15% in 2008 (ESC, 2019).

Personalized medicine is emerging, where the patient's own genetic profile guides diagnosis and treatment. Prices per patient will consequently be very high because development costs must be recaptured over small populations or sub-populations. Over 100 drugs in the United States already have labels that include information on genomic biomarkers.[30] Evans (2007) predicted that new drugs based on an individual's genetic profile will be extremely disruptive to the traditional financing model. The new drugs for rare

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[25] Insurers require an adequate spread of risk to price their products. Employers generally reimburse high-cost specialty drugs and DRDs because most plan members make much smaller and predictable claims, or do not claim at all. For example, just 2% of claimants generated 33% of total plan costs from specialty drugs (ESC, 2019).

[26] Personal communication, CLHIA, July 22, 2019.

[27] Source: Aon Hewitt Information Bulletin, October 20, 2015. Available at: http://www.aon.com/canada/attachments/thought-leadership/infobulletin/pub_aon_InfoBulletin-Repatha-102115.pdf. Repatha has restricted access under virtually all drug plans.

[28] Elsevier Business Intelligence, 2013. *Hyperion pricing on Ravicti will test premium for convenience on orphan market*. February 8. Available at: http://www.reimbursementintelligence.com/wp-content/uploads/2013/02/Hyperion_Pricing_On_Ravicti_Will_Test_Premium_For_Convenience_In_Orphan_Market.pdf.

[29] Specialty drugs can be defined as "Medications used to treat chronic, complex conditions such as severe rheumatoid arthritis, multiple sclerosis and cancer. Specialty medications include injectable and non-injectable drugs and have one or more of the following qualities: frequent dosing adjustments and intensive clinical monitoring; intensive patient training and compliance assistance; limited distribution; and/or specialized handling or administration (ESC, 2019 p. 7)."

[30] United States Food and Drug Administration, 2014. See: http://www.fda.gov/scienceresearch/specialtopics/personalizedmedicine/default.htm.

diseases and even some for common conditions (e.g., Hepatitis C) have extraordinarily high treatment costs, most of which are annually recurrent. Genetic testing will undoubtedly reveal that we all have genetic flaws, and in insurance language, "pre-existing conditions" (Evans, 2007, p.2671). With such a huge and expensive risk pool, the only solution will be to spread that risk across national populations (Evans, 2007). Though patients will benefit, governments and private health insurers all face a serious funding threat, one mitigated though progressive policy that includes aggressive and coordinated negotiations on price, cost and outcomes. This is possible in either single payer or social insurance models.

To manage recurrent high-cost claims in some private drug plans, the Canadian Drug Insurance Pooling Corporation (CDIPC) was established in 2012 by the CLHIA. Participation is mandatory for all fully-insured employee drug plans issued by all CLHIA members operating in Canada.[31] CDIPC members paid recurrent prescription drug claims for over 22,200 "certificates" (employee and all family members) that cost more than $10,000 in 2017.[32] Several claims exceeded $500,000 and the highest claim was for $1.2 million.[33] Private drug plans have assumed significant risk which reinforces their important role. Claims of this scale also weaken arguments of "cream skimming" by private insurers, as asserted by Gagnon (2010).

In addition to reports from the House of Commons Standing Committee on Health (HESA, 2018) and the Advisory Council (2019b), discussion papers from various policy forums rarely include a solid understanding of either social or private drug insurance, if these models are assessed at all.[34] The financial implications of changing to a single payer plan are very significant for employers, insurers, pharmacy benefit managers and benefit consulting firms. Not surprisingly, insurers, the pharmacy and pharmaceutical industries and patient coalitions advocate retaining the more generous coverage of private drug plans. Provincial drug plans have smaller formulary lists than most private drug plans and take much longer to review and list new drugs.

Allin, Stabile and Tuohy (2010) caution that: "Social insurance as a method of financing health care will not guarantee financial sustainability" (p. 23). Every health system – public, private and international; single payer and social insurance – has cost control challenges that will require multi-faceted strategies.

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[31] The CDIPC industry-level pool does not include drug plans that are experience-rated or those operated under Administrative Services Only contracts, so most employer drug plans covering more than about 50 employees are excluded. The pool also excludes single, large amount drug claims. Each insurer sells pooling protection against large claims.

[32] News release, December 17, 2018. *More Canadians benefitting from private insurance drug pooling system*. Available at: http://cdipc-scmam.ca/cdipc-information/.

[33] Presentation by Shirley Leong, Executive Director, CDIPC at Connex event, Burlington. October 2, 2014.

[34] Other recent examples: (**1**) Hartmann E, A Davidson, K Alwani, 2018. *Prescribing Federalism*. Mowat Centre (September). Available at: https://mowatcentre.ca/prescribing-federalism/. (**2**) Institute of Fiscal Studies and Democracy, 2018. *National Pharmacare in Canada, Choosing a Path Forward*. Available at: http://www.ifsd.ca/en/rapports-reports. (**3**) Flood CM, B Thomas, AA Moten, P Fafard, 2018. *Universal pharmacare and federalism: Policy options for Canada*. IRPP Study 68. Available at: http://irpp.org/wp-content/uploads/2018/09/Universal-Pharmacare-and-Federalism-Policy-Options-for-Canada.pdf.

4.2 Defining Catastrophic

There does not appear to be a standard definition of catastrophic. Globally, WHO has proposed that catastrophic health expenditure occurs when costs exceed 40% of a household's "non-subsistence income, i.e. income available after basic needs have been met" (p. 2).[35] The (Romanow) Commission on the Future of Health Care in Canada (2002a) proposed the federal government cover 50 per cent of the cost of drug claims exceeding $1,500 per person per year. The Senate of Canada report (2002) recommended the federal government cover 90% of annual drug costs in excess of $5,000 for qualifying drug plans.[36] Public plans would cap personal drug costs at 3% of family income while private plans would limit personal drug costs to $1,500.

Today, most provincial drug plans have implemented varying levels of catastrophic protection, although there is no cap on public drug costs in Alberta and New Brunswick and NL residents with personal or family incomes over $150,000 have no limit on out-of-pocket expenses under the province's Assurance Plan (**Table 4.2**). In its focus on a future single payer system, the Advisory Council (2019b) had no advice on creating protection from catastrophic drug claim costs for the interim period until a comprehensive plan is introduced in 2027.

[35] World Health Organization, 2005. Designing health financing systems to reduce catastrophic health expenditure. *Technical Briefs for Policy-Makers* (2). Available at: https://www.who.int/health_financing/documents/pb_e_05_2-cata_sys.pdf.

[36] Either the provincial or private plan would pick up the costs under the $5,000 threshold and the remaining 10% over $5,000.

Table 4.2 – Provincial Drug Plan Maximum Out-of-Pocket Cost for the General Population

Province	Drug costs exceeding a percent of family income and/or a dollar threshold
British Columbia	$100 (0.7%) > $13,750 up to 4.23%. $10,000 cap > $250,000 net income
Alberta	30% up to $25 per drug. No limit on personal drug costs
Saskatchewan	3.4% of gross income
Manitoba	3.17% to 7.15% of gross income
Ontario	4% of net income plus $2 per prescription
Quebec	$1,187 (2018-19; adjusted annually)
New Brunswick	30% up to between $5 and $30 per drug based on gross family income. No limit on personal drug costs
Nova Scotia	After a 20% coinsurance, 80% satisfies a deductible based on gross family income. Full coverage above the threshold of 5% to 35% of income.
Prince Edward Island	3%, 5%, 8% or 12% of net income
Newfoundland and Labrador	5%, 7.5% or 10% of net income. No limit when income > $150,000

Sources: Provincial websites, current at May 2019. **Notes**: (1) Most provinces adjust thresholds for family size. (2) For citizens with private drug insurance, the province is the second payer in all provinces east of Ontario. In ON, the Trillium program is second payer. (3) Gross means before tax. Net means after tax. (4) The lack of an overall cap in NB and AB could be material for those with low incomes and multiple prescriptions. ESC (2019) reported the top 20% of its private plan claimants had on average 8.6 unique medications.

4.3 Considering social insurance in Canada

While social insurance has been explored by Canadian academics (Sec 1.4.2), it has yet to be widely discussed and was not recognised in important government studies such as those issued by HESA or the Advisory Council. A brief review of three key studies is provided below to frame the detailed descriptions of social insurance systems in Germany, the Netherlands and Quebec.

4.3.1 Flood, Stabile and Tuohy (2008)

These three Canadian academics served as editors of the only comprehensive, multi-author volume found on financing social health insurance. After considering the international

perspectives of ten authors, some cited elsewhere in this thesis, their final chapter presents their prescription for "moving forward" (p. 266). They conclude that combining public and private sources of finance is optimal but that theory and evidence indicates than in Canada, mixed financing is best suited to out-of-hospital drugs because private insurance is well established and there is no universal coverage. A new universal social drug insurance plan with improved benefits is proposed to gradually replace existing public programs. It would require out-of-pocket contributions and exist as a complement to a newly-regulated private insurance system. Five principles are proposed:

1. Private insurers would become partners in achieving universal coverage. They would be regulated and required to offer a minimum standard formulary using community rating. Supplementary plans would be allowed. Risk selection would be carefully monitored.

2. Individual and employer coverage mandates would be introduced to ensure universal coverage, avoid adverse selection and ensure wide risk pooling.

3. A progressive funding mechanism would be introduced. They suggested a refundable tax credit and a risk-sharing pool, presumably national in scope. The tax deductibility of private drug insurance would probably be eliminated.

4. A separate administrative body would be created, isolated from the general tax system, with funding from both employers and employees. This body could undertake formulary design and drug price negotiations.

5. A new retirement benefit would integrate and finance generally predictable costs from pension, drug insurance and long-term care coverage.

Flood, Stabile and Tuohy did not pass judgement on competition, transition, or whether there ought to be patient cost-sharing.

4.3.2 Allin, Stabile and Tuohy (2010)

Financing new social insurance systems for drugs and long-term care could address access, equity and sustainability concerns, and complement Canadian medicare. This paper reviewed the design and funding characteristics of social drug insurance in Quebec, a broader universal state insurance system for working-age adults in Massachusetts, and drugs inside the broader health systems in Germany and the Netherlands. The importance of regulation, scope of coverage, cost-sharing and risk adjustment pools was noted.

Acknowledging the different historical and institutional contexts in each jurisdiction, the authors recommended that Canada have a broad tax base for employer and employee contributions (beyond just payroll taxes) and introduce a robust approach to risk pooling. Like Flood, Stabile and Tuohy (2008), they state that diverse sources of financing (not just public or just private) may increase the public's willingness to pay in part because they can

more easily connect contributions with services provided. The financing flexibility of social insurance means a carefully designed model could align with existing Medicare hospital and physician services and satisfy conditions in the Canada Health Act. Once launched, it would be important to effectively integrate the two systems to ensure continuity of care, manage incentives and ensure financial sustainability.

4.3.3 Blomqvist and Busby (2015)

While the authors did not propose a social drug insurance plan by name, they included tactics that are consistent with one. They proposed the federal government provide funding to the provinces to achieve universal coverage by: (i) Limiting out-of-pocket spending to 3% of net family income, (ii) Establishing a minimum national formulary, (iii) Extending negotiated drug prices to private insurers, (iv) Financing drugs for rare and high-cost diseases, and (v) Incenting better prescribing. Federal government costs were estimated at $2.8 billion annually.

They recommended provincial administration continue in exchange for meeting these five conditions. As in Quebec, each provincial drug plan would cover anyone without private drug insurance. The tax credit for private drug insurance would be eliminated. They noted that continued private insurance funding reduces the amount of new public funding required, and favoured “some degree of competition between public and private plans” (p. 10).

4.3.4 Summary: Social drug insurance for Canada

These reports come to similar conclusions about the viability and feasibility of introducing a social drug insurance model to improve on the patchwork of existing public and private coverage. As a minimum, social insurance provides superior equity, access, and cost control relative to private insurance. Goals and tactics are consistent with needs identified earlier.

Several observations can be made. Social insurance is not a singular panacea for concerns about system sustainability because the public must be willing to adequately fund any model that would achieve national goals (Allin, Stabile & Tuohy, 2010). Neither social insurance nor single payer models will automatically fix important shortfalls in standards of coverage and responsive governance. Similarly, competitive markets alone will not contain costs without purchasing reforms that include price, volume and quality (van Ginneken & Swartz, 2012). Historical, political, social and institutional contexts are very important and not easily transferred from one country to another (Boothe, 2015; Allin, Stabile & Tuohy, 2010).

All these works provide helpful and practical insights, as part of the much greater depth and scope of investigation in this thesis.

4.4 Recent Developments

4.4.1 1997 through 2009

National pharmacare in different forms has been proposed and studied many times in the last several decades. In more recent times, the National Forum on Health[37] in 1997 called for universal, first-dollar drug coverage. Five years later, the Commission on the Future of Health Care in Canada (2002a) and the Senate's Standing Committee on Social Affairs, Science and Technology (Senate of Canada, 2002. Vol 6, Chap. 7) called for protection from catastrophic drug expenses.

These federal reports were followed by the 2003 Health Accord which stated:

> First Ministers agree that no Canadian should suffer undue financial hardship for needed drug therapy. Accordingly, as an integral component of these reforms, First Ministers will take measures, by the end of 2005/06, to ensure that Canadians, wherever they live, have reasonable access to catastrophic drug coverage.[38]

The Premiers, following their 2004 annual meeting, wanted the federal government to "assume full responsibility for these programs across the country."[39] A National Pharmaceutical Strategy was announced in the 2004 First Ministers' 10-year, $41 billion plan to strengthen health care.[40] That plan was to 'buy change, not time,' and the new money came with reporting strings monitored by the Health Council of Canada. Following an update in 2006 by the Health Council, no further progress was reported.

4.4.2 2010 to Present

The pan-Canadian Pharmaceutical Alliance (pCPA) was created by nine Premiers in 2010 under the Council of the Federation to negotiate lower prices for new patented drugs on behalf of provincial formularies. The federal government joined the pCPA in 2016,[41] following Quebec's entrance in October 2015.

Starting when the Canada Health Transfer (CHT) was established in 2004, the federal government provided six percent annual funding increases to the provinces until 2016-17. The 10-year plan was replaced with a series of bilateral deals between the federal

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[37] Government of Canada, 1998. *Canada Health Action: Building the Legacy*. The text of Volumes 1 and 2 is available at: http://www.hc-sc.gc.ca/hcs-sss/com/fed/nfh-fns-eng.php. In Volume 2, Directions for a Pharmaceutical Policy in Canada is at: http://www.hc-sc.gc.ca/hcs-sss/pubs/renewal-renouv/1997-nfoh-fnss-v2/index-eng.php#a7.

[38] Government of Canada, 2003. *First Ministers' Accord on Health Care Renewal*. Available at: http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2003accord/index-eng.php. Viewed June 18, 2014.

[39] News release, July 30, 2004. *Premiers' action plan for better health care: Resolving issues in the spirit of true federalism*. Available at: http://www.canadaspremiers.ca/wp-content/uploads/2017/09/healtheng.pdf. Viewed May 11, 2019.

[40] Government of Canada, 2004. News release, September 16. Available at: http://www.hc-sc.gc.ca/hcs-sss/delivery-prestation/fptcollab/2004-fmm-rpm/index-eng.php. Viewed June 16, 2014.

[41] Additional discussion of the pan-Canadian Pharmaceutical Alliance follows in later pages.

government and each province in early 2017.[42] Since 2017-18, the CHT has been increasing using a three-year moving average of nominal Gross Domestic Product, with a minimum annual increase of 3 percent.[43] Nationally, prescription drug prices have had average annual increases of 4.0%, 5.0%, 2.4%, 1.7% and 5.0% over the most recent five years (CIHI, 2018).

4.4.3 House of Commons Standing Committee on Health (HESA)

Unexpectedly, national pharmacare (NPh) was elevated in federal policy following the 2015 federal election. The House of Commons Standing Committee on Health (HESA) decided to study national pharmacare *as an insured service under the Canada Health Act.*[44] These last nine words are a crucial frame for its work. HESA commissioned a costing study from the Parliamentary Budget Officer (PBO, 2017), which estimated savings of $4.2 billion from a federally-administered national pharmacare plan under the Act. However, the report had some crucial cost-saving assumptions that are most unlikely in the real-world, among other limitations (Bonnett, 2017). HESA (2018) issued its 140-page report in April 2018, recommending NPh as an insured service under the Canada Health Act.

Although HESA was to examine an alternative (reforming the existing system with a collaborative public-private approach aimed at filling the gaps) its report took one page (pp 69-70) on this issue to make statements for which there was no evidence of any broader investigation. The only recommendation that included private payers was to: "undertake consultations with employers, unions, private plans and Canadians at large to identify possible approaches towards financing the expansion of the *Canada Health Act* to include prescription drugs" (p. 56). There was no mention of consultation on design, principles, transition or implementation. The Minister of Health responded in August 2018 while the House was in summer recess, stating the government will "…consider the full range of options,"[45] which were not more fully explained.

4.4.4 Advisory Council on the Implementation of National Pharmacare

The Minister's agnostic statement underscores the importance of the Advisory Council on the Implementation of National Pharmacare (Advisory Council), headed by Eric Hoskins. In February 2018, HESA was overtaken by the federal Budget announcement creating the Advisory Council which was to lead "a national dialogue on how to implement affordable national pharmacare for Canadians and their families, employers and governments." The focus on implementation indicated the Liberal government had become more serious.

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[42] Marchildon G, 2017. *Health funding: Why 12 federal-provincial deals are better than none*. April 12. Available at: https://healthydebate.ca/opinions/health-care-funding-2. Manitoba held out until August.
[43] Department of Finance Canada. See: https://www.fin.gc.ca/fedprov/cht-eng.asp.
[44] A full record of HESA's national pharmacare meetings, briefs and a list of witnesses is here: http://www.ourcommons.ca/Committees/en/HESA/StudyActivity?studyActivityId=8837577.
[45] Petitpas Taylor G, 2018. Letter (undated) to the Chair of HESA responding to the "*Pharmacare Now*" report tabled in April 2018. Response presented to the House of Commons, August 22, 2018.

Its mandate was to:

- "conduct an economic and social assessment of domestic and international models
- work closely with provincial, territorial and Indigenous leaders
- consult with Canadians, as well as experts and stakeholders from relevant fields."[46]

The Council reported to both the federal Minister of Health and the Minister of Finance, indicating that program cost was very important. The Advisory Council had very limited time in the public eye. After the Budget announcement, not much happened until Council members were named on June 20, 2018. Public consultations closed just three months later at the end of September. The Council did not summarize and post findings from 15,000 questionnaire responses and did not post any of over 150 written submissions it received (Advisory Council, 2019a). These decisions may have dampened public interest and awareness of the Council's work and the views of important stakeholders. It may also be true that the federal government did not want to promote the Advisory Council unless or until its recommendations were certain to support government policy. (In contrast, HESA is an all-party standing committee and both the NDP and Conservative parties issued their own pharmacare opinions.[47])

A very short interim report released in March 2019 (Advisory Council, 2019a) provided six core principles and recommended only modest changes: (1) Creation of a national drug agency (2) Development a comprehensive, evidence-based national formulary that considered drugs for rare diseases, and (3) Investment in drug data and information technology systems.

The 2019 federal Budget then announced that the Canadian Drug Agency (CDA) would be immediately established with funding of $35 million over four years. A national strategy for drugs for rare diseases would be developed, but new federal funding of $500 million annually would be delayed four years until 2022-23, the end of the next government's mandate.[48] There was no support for the investment in information technology recommended by the Advisory Council.

The Council's final report (171 pages) was released on June 12, 2019, four months before the next federal election (Advisory Council, 2019b). Similar to HESA, the Advisory Council recommended a single payer universal drug plan under the Canada Health Act be implemented in steps beginning in 2022. CDA would consolidate work now done in other federal and provincial agencies (likely excepting Quebec's INESSS) and develop a national formulary by 2022. A strategy for drugs for rare diseases is also due by 2022. However, the first iteration would be a relatively small list of essential medicines. A comprehensive

[46] See: https://www.canada.ca/en/health-canada/corporate/about-health-canada/public-engagement/external-advisory-bodies/implementation-national-pharmacare.html.
[47] Ibid. Canada, 2018. The main report includes appendices with the dissenting (Conservative Party) and supplementary (New Democratic Party) positions.
[48] See *Moving Forward on Implementing National Pharmacare*, available at: https://www.budget.gc.ca/2019/docs/themes/pharmacare-assurance-medicaments-en.html.

formulary would follow by 2027. The provinces and territories could opt in if they agreed to national standards and funding mechanism. The new drug plan would have very small patient cost-sharing requirements with exemptions for those with very low income or who receive government disability benefits. New federal costs were estimated at $3.5 billion by 2022, rising to $15.3 billion five years later following full implementation.

Similar to HESA, the Advisory Council (2019b, Annex 7) said it studied catastrophic coverage model and a "statutory multi-payer model" similar to systems used in Germany, the Netherlands and Quebec. Both models were briefly described over just 3½ pages but there was no analysis provided. The Council decided these alternatives "were outweighed by the longer-term efficiency and sustainability of a single-payer model" (p. 167).

The government has yet to make a policy commitment to a comprehensive NPh program similar to the models recommended by HESA and the Advisory Council.

4.4.5 Provincial responses

There is no indication the Premiers are willing to support national pharmacare except under specific conditions which include: (1) retaining provincial control over design and delivery, (2) "long-term, adequate, secure, flexible" funding that considers cost drivers, and (3) "the right to opt out unconditionally, with full financial compensation (Canada's Premiers, 2018 Final Communiqué)."[49] This positioning makes the development of national standards (e.g., formulary or out-of-pocket spending caps) very difficult. There was no significant, new and immediate federal funding for medicines announced in the 2019 Budget.

Following their 2019 meeting, the Premiers proposed four principles including improved access and careful assessment of potential benefits, risks, costs, and supply reliability for NPh. They would retain responsibility for public drug plan design and delivery, and repeated their demand for an adequate and secure funding envelope (Canada's Premiers, 2019 Final Communiqué).[50]

4.4.6 Private payer concerns

National pharmacare is of direct concern to health insurers, benefit advisors and pharmacy benefit managers that all derive significant revenue (and unknown profits) from employer-sponsored extended health plans under which prescription drug coverage is provided. However, there is little evidence that this segment, collectively known as 'private payers', is prepared for significant changes.

[49] July 20, 2018. Available at: http://www.canadaspremiers.ca/wp-content/uploads/2018/07/Final_communique_July_20-1.pdf.
[50] July 11, 2019. Available at: http://www.canadaspremiers.ca/wp-content/uploads/2019/07/Health_Sustainability_and_Mental_Health_July11_FINAL.pdf.

The CLHIA has produced one drug policy paper on behalf of life insurers (CLHIA, 2013). In essence, an update to this appeared in its submission to the Advisory Council (CLHIA, 2018). The CLHIA also supports a public advocacy site that calls for universal drug coverage, the protection of employee health benefit plans, and affordability for taxpayers.[51]

There is no advocacy group for group health benefit advisors or for pharmacy benefit managers (PBMs) such as Telus Health and Express Scripts Canada that operate national electronic drug claim payment networks on behalf of private health insurers.

There are two business associations, the Canadian Chamber of Commerce (200,000 employers in 450 local chapters), and the Canadian Federation of Independent Business (CFIB) which represents 110,000 small employers, 96% with fewer than 50 employees. Neither the Chambers nor the CFIB appear to have a sustained interest in health care or drug insurance in order to advocate a position with nearly as much vigour as the CLHIA.[52] Neither organization is listed as a Witness or as contributing a Brief on the HESA website. There are just two relevant communications:

- The Chamber called for an update to the Canada Health Act in 2017, and noted OECD estimates of significant waste (OECD, 2010b) in Canada's health spending relative to the best-performing members. They wanted F/P/T governments to "Collaborate on purchasing and regulation to reduce prescription drug costs."[53] The Chamber has no public documents on NPh other than its submission to the Advisory Council.[54]
- The CFIB notes the creation of the Advisory Council in a media release[55] but has not made public any advocacy document on national pharmacare on its website.

Health professional groups such as the Neighbourhood Pharmacy Association of Canada (NPAC, the industry association for retail pharmacy companies), the Canadian Pharmacists Association (CPhA), the Canadian Medical Association (CMA), the Canadian Nurses Association (CNA) and the Canadian Federation of Nurses Unions (CFNU) have publicly advocated their positions on national pharmacare. All but NPAC appeared as Witnesses before HESA and the CMA, CNA and CFNU provided Briefs to this Committee.[56] The CPhA produced pharmacare-related reports in 2015, 2016 and 2017, and collaborated with

[51] See: https://www.betterhealthbenefits.ca/.
[52] The Canadian Chamber of Commerce made a 4-page submission to the Advisory Council, available at: http://www.chamber.ca/advocacy/submissions/archives-2018/.
[53] Canadian Chamber of Commerce, 2017. *Revisit the 30-year old health act to address looming crisis*. Available at: http://www.chamber.ca/advocacy/policy-resolutions/special-issues/.
[54] Available at: http://www.pdci.ca/wp-content/uploads/2018/09/Canadian-Chamber-of-Commerce-Submission-to-the-Advisory-Council-on-the-Implementation-of-National-Pharmacare-FINAL.pdf.
[55] Canadian Federation of Independent Business, 2018. *The good and bad about what is missing in Budget 2018*. Available at: https://www.cfib-fcei.ca/en/media/good-and-bad-about-what-missing-budget-2018.
[56] Available at: https://www.ourcommons.ca/Committees/en/HESA/StudyActivity?studyActivityId=8837577.

patient groups on a joint paper in 2018.[57] NPAC and CPhA would be expected to support private insurance given their revenue and likely higher margins from private drug plans.

Somewhat paradoxically, the Canadian Labour Congress fully and publicly[58] supports a single payer drug plan despite a belief that its members may receive less generous benefits under that regime.

Allied with the prime antagonists to a fully public NPh are brand drug manufacturers which charge more to private payers than public plans allow. Patient groups are also very concerned since provincial plans provide much smaller formularies and much more limited and slower access to new drugs (Pharmacare Working Group, 2018; BMC, 2018).

4.4.7 Public Interest

Public support for NPh, however it may be defined, has been and remains high (84% to 91%) in large national polls (Angus Reid Institute, 2015; Abacus Data, 2018; Pollara, 2018).[59] This is despite the estimate that 90% or more of Canadians are likely to have adequate drug insurance. This high level of support indicates most Canadians see the lack of universal drug coverage as a problem. Perhaps they perceive NPh as a values question on national identity, beyond their personal situation. As Dr. Hoskins put it in his opening Message, NPh could be a 'great national project', "…one that we can feel in our hearts" (Advisory Council, 2019b, p.3)

There are caveats. One poll (Pollara, 2018)[60] reported that NPh ranked lower in priority (79%) than seven other health system challenges, such as wait times for surgery (95%) and diagnostics including MRIs (93%), and access to mental health services (93%). More than half said pharmacare was less deserving of funding than six other national priorities, including clean water on First Nations' reservations (70%), ending hallway medicine (68%) and tax cuts for the middle class (67%). The survey also reported that "universality" meant that "a service is available to all and that the quality of health care is consistent." Only 25% interpreted this word to mean that the government pays. Almost nine in 10 (87%) of respondents were somewhat or very concerned about governments' ability to administer such a plan efficiently and effectively. Almost three-quarters (72%) were somewhat or very concerned a

[57] These papers are available at: https://www.pharmacists.ca/advocacy/pharmacare-20/.
[58] See: http://canadianlabour.ca/news/news-archive/canadas-unions-step-pharmacare-campaign-labour-day. Follow link to http://www.aplanforeveryone.ca/.
[59] (1) Angus Reid Institute: Ninety-one percent agreed with "the *concept* of having "pharmacare" in Canada, providing universal access to prescription drugs" and 87% supported "adding prescription drugs to the universal health coverage of 'medicare' so all Canadians have access to prescribed medicines without having to pay out of their own pocket (p.12)." Available at: http://angusreid.org/prescription-drugs-canada/. (2) Abacus: Ninety-one percent of 2,000 Canadian adults surveyed said that ensuring everyone can afford the medicine they need should be a high (55%) or medium (36%) priority for the federal government. (3) Pollara: National pharmacare support is high (84% in favour) and intense (52% strongly support it).
[60] The Pollara polling sample of 4,173 adult Canadians was very large. A probability sample of this size has a very small margin of error (+/- 1.5%). Results were adjusted for age, sex and region.

government plan would have fewer choices than their private plan. The poll was funded by Neighbourhood Pharmacy Association of Canada. The finding that support for NPh weakens considerably when alternatives are proposed is not new. Tuohy (2020, p. 2) notes: "Public support for such proposals [universal drug insurance in Canada], however, has historically been broad but shallow."

There are many other issues inside and outside the health domain clamouring for attention and universal drug insurance could easily be sidelined.

4.5 Cost Control

Both provincial and private payers have strategies and tactics to control claim costs driven by higher utilization, the higher prices of new drugs, and escalating pharmacy fees. But while provincial plans are backed by legislation and regulation, employers have been much less inclined to control health and dental plan designs fearing a human resource backlash (Stevenson, 2011). Private insurer administration costs are usually calculated as a percentage of claims and so increase in lockstep with drug costs. Health claims have for decades been escalating at rates exceeding the Consumer Price Index (CPI). That dampens any incentive by the insurer to control drug or administration costs. Over the last decade, provincial drug plans have had lower average annual cost increases than private drug plans, 3.0% (provincial) and 3.8% (private) (CIHI, 2018).

Volume growth for generic drugs outpaced brand medicines between 2010 and 2016, drawing even in 2017 (IQVIA, 2018).[61] Cost reductions for generics are allowing higher spending in specialty drugs without driving total plan costs appreciably higher. In 2018, the growth rate in per claimant drug spending was 0.9%, versus 2.5% in 2017 and 2.9% in 2016 (ESC, 2019, p. 5). By comparison, the Consumer Price Index (CPI) increased 1.4% in 2016, 1.6% in 2017 and 2.3% in 2018.[62]

Average per capita drug costs have escalated at multiples of the CPI, from $9 in 1961 (about $77 in 2018 dollars[63]) to $909 (forecast) in 2018 (CIHI, 2018).[64] Those averages hide a broad range of costs.

Use of drugs is relatively concentrated in both the privately and provincially insured populations. In one private payer portfolio, the top 5% of claimants accounted for 52% of total plan costs and incurred on average $8,982 in annual drug costs (ESC, 2018, p. 17). Similarly, about 8% of Ontario Public Drug Program (OPDP) beneficiaries accounted for half

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[61] See: https://www.iqvia.com/-/media/iqvia/pdfs/canada-location-site/totalprescriptionvolume-growth_en_17.pdf?la=en&hash=F76240C8F04756C3396889720533946401 57B7E4.

[62] Statistics Canada. *Consumer Price Index, annual average, not seasonally adjusted*. Available at: https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1810000501.

[63] Ibid. Timeframe adjusted to 1961 (15.7) through 2018 (133.4).

[64] With a reference year of 2002=100, the Consumer Price Index (CPI) was 15.7 in 1961 and 122.8 in 2013, 7.8 times greater (Statistics Canada, Summary Table). For comparison, per capita drug costs increased by a factor of 88 ($9 to $795).

(49.6%) of the program's total cost.[65] CIHI reported that 2.3% of public drug program beneficiaries incurred at least $10,000 in drug costs in 2017. This small cohort accounted for almost 37% of spending (CIHI, 2018b, p. 22). In 2017, all provincial drug plans and the First Nations and Inuit Health Branch plan paid drug costs of at least $1,500 for almost 23% of their beneficiaries (p. 21). This equates to roughly 2.5% of the median after-tax income of $59,800 that year.[66] Those 23% accounted for 81% of all drug program expenditures.

The Atlantic provinces, Quebec and Ontario's Trillium plan have made their drug plans second payer for any resident with private insurance. In return, insurers have more aggressively pushed claims back to provincial plans.[67] This maneuvering is not helpful to patients.

Implementing change is not a trivial undertaking. In 2018, an estimated $33.7 billion (bn) was spent on prescription drugs, the third largest spending item after hospitals ($71.6 bn) and physicians ($38.2 bn) (CIHI, 2018a).[68] Prescription drug spending consumes 13 cents of each dollar of health spending, versus about six percent in 1985 (CIHI, 2018b). This spending is split between governments ($14.4 bn) and the private sector ($19.3 bn). The private side can be defined as private insurance ($12.3 bn) and out-of-pocket or household spending ($7.0 bn) (CIHI, 2018a). Private insurers are forecast to pay more than provincial governments for prescription drugs in 2017 and 2018. There were about 673 million Canadian prescriptions dispensed in 2017.[69] Policy changes also affect the pharmacy industry. The OPDP reported that $1.53 bn, 25.1% of total program costs of $6.08 billion, was paid to Ontario pharmacies in 2016-17 for wholesale and retail mark-ups and compounding fees.[70]

Health insurance is big business, and it is concentrated. The ten largest health insurers had employer-sponsored health product revenues of $38.6 bn in 2018. The top ten accounted for 95% of health insurance revenues and the three largest insurers alone had $26.5 bn and 65% of total industry health premium revenue (Benefits Canada, 2019). Drug benefits accounted for 32% of all health-related workplace benefits (extended health care, dental, disability and accident) (CLHIA, 2019, p. 16)

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[65] Ontario Public Drug Programs, 2017. *2015/16 Report Card for the Ontario Drug Benefit Program*. Slide 21. Available at: http://www.health.gov.on.ca/en/pro/programs/drugs/pub_drugs.aspx.

[66] Statistics Canada, 2019. *Income of Canadians, 2017*. Available at: https://www150.statcan.gc.ca/n1/pub/11-627-m/11-627-m2019013-eng.htm

[67] Sun Life announced changes typical of other insurers in Focus Update #256 (December 9, 2010), available at: http://www.sunlife.ca/Canada/sponsor/Group+benefits/Plan+sponsor+communications/Focus+Update/Enhancing+integration+with+provincial+drug+programs?vgnLocale=en_CA. The insurer also announced expanded integration with provincial cancer drug programs in Focus Update #282 (May 19, 2011), available at: http://www.sunlife.ca/Canada/sponsor/Group+benefits/Plan+sponsor+communications/Focus+Update/Focus+Update+2011/Expanding+integration+with+provincial+cancer+drug+programs?vgnLocale=en_CA.

[68] In 2018, CIHI forecast an additional $3.6 billion was spent on non-prescription (over-the-counter) drugs. The combined total drug spending of $37.3 billion still trails physician spending.

[69] IQVIA, 2018. See: https://www.iqvia.com/-/media/iqvia/pdfs/canada-location-site/yir_2017_infographic-final.pdf?la=en&hash=D13B58D8E8AB98993F3AEFCD60E623B9CC4BFF43.

[70] Ontario Public Drug Programs, 2018. Ontario Public Drug Programs, OPDP at a Glance. Available at: http://health.gov.on.ca/en/pro/programs/drugs/publications/opdpataglance/.

4.6 Policy and Planning

Provincial and private drug plans co-exist largely in ignorance of each other, and as an "accident of history that no sensible planner would design…" (Morgan & Daw, 2012, p. 16). The status quo and usual debate about public versus private in health care is ideologically framed, dichotomous, and usually not considered in a rational or practical way. A potentially more fruitful discussion would organize an integrated and proactive system that supports a healthy population as well as better economic and financial management (Morgan et al., 2016).

Public, universal, first-dollar coverage for drugs remains the dominant idea (Advisory Council, 2019b; HESA, 2018; Gagnon, 2010; Morgan, 2012; Gagnon, 2014) but history suggests it may be unattainable at least in the short and medium term (Boothe, 2013). That noted, even some proponents of a single payer plan acknowledge important outcomes are also possible through social insurance (Morgan, 2008; Gagnon 2017). A social insurance may be "politically easier to implement" than a single payer plan if it was developed as a replacement for private insurance (Gagnon, 2017, p. 205).

Widespread provincial debt and deficits will discourage any major change to drug programs unless there is adequate and permanent federal funding. Both provincial and private drug plans have become entrenched and institutionalized: both are embedded in our health system. Since the Romanow and Kirby reports of 2002, protection from catastrophic ("last dollar") drug costs has been improved although the level of protection varies widely across provinces and incomes (**Table 4.2**).

Indeed, in April 2014 New Brunswick had proposed mandatory employer funding for a Drug Plan (NBDP) that would cover the 20% of its population who were uninsured.[71] At least partly as a result of strident lobbying by the Canadian Federation of Independent Business, the mandatory coverage provision was set aside for further study. Alberta has a similar issue with estimates of between 20% and 27% (Alberta, 2006) of its population without drug insurance. The provincial government announced "comprehensive drug…benefit coverage for all Albertans" in its 2013-14 Budget[72] and then quietly withdrew its plan. Fortunately, residents of both provinces can immediately get drug plan coverage, at their own cost, through the NBDP and Alberta's Non-Group plan.[73]

[71] The Government of New Brunswick withdrew this plan for further study. See news release, dated December 9, 2014 at: http://www2.gnb.ca/content/gnb/en/news/news_release.2014.12.1381.html.
[72] Government of Alberta, News release dated March 7, 2013. Available at: http://www.alberta.ca/release.cfm?xID=3377946A8CD70-C069-7894-1D9786D5EBBD7C8E. Accessed February 28, 2016.
[73] The New Brunswick Drug Plan is a government plan. Alberta's Non-Group Plan is administered by Alberta Blue Cross on behalf of Alberta Health (see: http://www.health.alberta.ca/services/drugs-non-group.html). Both plans are open to all residents under age 65.

4.6.1 Case Description – The Rise and Retreat of OHIP+

As some opinion leaders noted in their interviews for this thesis, politics can overwhelm good policy. The result can be program lurches in one direction followed by a retreat, with considerable frustration for patients caught in the middle.

This happened in Ontario when the Liberal government in its 2017 Budget announced OHIP+, a new drug plan to provide provincial formulary coverage to all residents under age 25. This moved quickly to implementation on January 1 2018, just a few months before the next provincial election. While the policy was sound – universal public drug coverage for all residents in this age cohort – execution of the new plan was rushed and inequitable. Physicians were sometimes confused and some patients were disadvantaged. First, the public plan formulary was less generous than most private plans, even though private plans required higher cost-sharing. Second, younger residents would have OHIP+ at no cost, while seniors still had to pay small deductibles for their drugs. Third, it was noted OHIP+ was not originally written into the Budget document, suggesting it was added very late in the process, and stakeholder consultation was therefore minimal or non-existent (personal communication, various). The CFIB termed it "one big surprise."[74]

The Liberals at the time were approaching an election they were not expected to win. OHIP+ was conveniently budgeted at exactly $10 million less than the NDP's proposal for an essential medicines formulary projected to cost $375 million. (No funding detail or assumptions were released.) Since many patients were already covered by private insurance significant investigation was required to coordinate transfers ideally without loss of coverage. While this worked well for those with traditional medications, those with drugs paid by their private insurance that were ineligible under the OPDP general formulary had to be individually reviewed for inclusion in the province's Exceptional Access Program. Not all were accepted, sending patients back to their private insurance. CLHIA member insurers had to offer an additional six months of coverage when the government was not ready on its launch date[75] or settle whether OHIP+ would grandfather coverage for private plan drugs.

Telus Health (2019, p. 16) reported that average monthly drug claims in Ontario for those aged 24 and younger were reduced 54% in 2018 versus 2017. Shortly after the 2018 election, the new Conservative government then largely reversed the new plan and another transition period was required.[76] The OPDP would become second payer to those eligible for private insurance as of April 1, 2019. Those without

[74] The Canadian Federation of Independent Business represents 110,000 small business owners across Canada. See: https://www.cfib-fcei.ca/en/advocacy/ontarios-budget-what-does-it-mean-your-small-business.
[75] Ministry of Health and Long-Term Care, undated. See p. 1, 2: http://www.ocpinfo.com/library/practice-related/download/OHIP+Tip-Sheet-Pharmacists.pdf.
[76] See: https://clhia.ca/web/clhia_lp4w_lnd_webstation.nsf/page/9229F048964BB45E852582BB0064A31B.

private coverage would remain part of OHIP+ but those with inadequate private coverage would not return to OHIP+. They would have to apply to the Trillium catastrophic drug program after drug costs exceeded 4% of their family's income. The majority of patients were swept back to private plans and some lost coverage completely,[77] just 15 months after becoming provincial program beneficiaries. Telus Health (2019, p. 16) expected drug claims after April 1 2019 would return to 2017 levels, although no confirming data are yet available.

While the principles of free and universal coverage were honoured, the practical planning and implementation was seriously flawed for many Ontario residents. A rush to install the plan in less than one year for political advantage largely prevented appropriate consultation and coordination with patients and their families, prescribers, dispensers, employers, benefit advisors and health insurers. Importantly, EAP reviews were very slow and some patients were left less well covered. This experience is instructive for planning and implementing national pharmacare.

4.7 Why has nothing changed?

Brownson et al. (2006) outline eight challenges that keep evidence from becoming good public policy, including differences between academic and political culture, the time needed to conduct good research, ambiguous findings (such as the cost of a universal pharmacare program, see Section 4.10), and effective communication of complexity (e.g., systems, research design attributes, and costing). "There is often little correlation between the quality of research and the policy derived from it" (p.164).

There are several possible reasons why a universal pharmacare plan has not been adopted in the 55 years since the Hall Commission report. Based on the researcher's summary of the literature, the most salient are:

1. Cost,
2. Limited policy ideas,
3. Resistance to change,
4. Impractical principles,
5. Indifference of policy elites,
6. Political interpretations of the Canada Health Act,
7. Patients feel protected, and
8. Insurer strategy.

[77] Levy D, J Purvis, H Averns, 2019. Changes to OHIP+ mean some kids will go without life-saving medicine. *Healthy Debate*, April 17. Available at: https://healthydebate.ca/opinions/changes-to-ohip-plus.

These will be described in the following paragraphs.

4.7.1 Cost

One apparent barrier to implementation has been cost. Hall (1964) had already recognized that "many of these drugs [introduced in the last decade] are relatively expensive…" (p.347). The Hall Commission found those costs worried the public because the incidence of high drug costs is "unequal and generally unpredictable" (p.355) among the population. Note that prescription drugs were 12% of total health expenditures in the 1950s (p.344), and as noted above, are only slightly more now (13%; CIHI, 2018a). Citing national programs in New Zealand, Australia, Great Britain and Norway, the Commission assumed utilization (and therefore costs) would be driven higher by a national insurance program – the principle of moral hazard. Despite public concern and even after concluding that prescription drugs should be part of a new comprehensive health care program, the Commission recommended that inclusion be deferred. Cost escalation and predictability (i.e., sustainability) were important factors. This mindset appears to be very durable among governments. Boothe (2013, p. 433) has argued the singular government focus on prices and cost succeeds because it does not involve jurisdictional dispute and its regulatory solutions are relatively inexpensive. As commonly proposed, NPh means governments would not only take on a new $19 billion funding obligation (CIHI, 2018a), but provinces would forego $1.1 billion in lost sales and premium taxes from private insurance.[78]

4.7.2 Limited policy ideas

Boothe (2013) recognizes financial and institutional barriers (e.g., provincial jurisdiction, the interests of private insurers, etc.), but argues "ideational barriers might be even more daunting" (p. 447). When ideas are limited, Boothe argues that that goals, choices and actions are also constrained. Lack of consensus on big ideas may have conditioned both policy makers and the public to seek nothing more ambitious. This narrow perspective may in turn tend to encourage only incremental progress (Kingdon, 2011), if any at all. After decades of national coverage for only hospitals and physicians, and no obvious progress on a national approach to pharmacare, perhaps Canadians have limited their expectations and learned to cope with a fragmented and sometimes inadequate system of drug insurance. While too many citizens remain in great need, this has been reduced since most provinces provide varying standards of protection from catastrophic drug costs (**Table 4.1**).

Successive federal governments over 70 years (1949-2019) have been fixated on better management of drug prices and costs instead of a bigger strategy: insurance which could *also* manage costs in addition to ensuring full access to all Canadians (Boothe, 2013).

[78] Personal communication, N. Simon, CLHIA, July 25, 2019.

Tactical examples of government actions are readily found:

1. Compulsory licensing of brand drugs to generic companies (1969-93).

2. Establishing the Patented Medicine Prices Review Board (PMPRB) in 1987 to review and set new drug prices that are "not excessive" relative to seven comparator countries. Almost 30 years after PMPRB's establishment, reforms were proposed in 2016. Final changes to PMPRB regulations were announced in the Canada Gazette in August 2019 and are to be implemented on July 1, 2020.

3. All provinces except Quebec established the Common Drug Review (CDR) in 2002 to make coverage recommendations for most new drugs. CDR resides in the Canadian Agency for Drugs and Technology in Health (CADTH).

4. The interim Joint Oncology Drug Review (2007-11) was established by all provinces except Quebec to make coverage recommendations for new cancer drugs. It was renamed the pan-Canadian Oncology Drug Review (pCODR) and transferred to CADTH in 2014.

5. The pan-Canadian Pharmaceutical (formerly Pricing) Alliance (pCPA) was established in 2010 by the Council of the Federation. It now includes all provinces, the First Nations health plan and the federal government. The pCPA has significantly cut prices for 67 leading generic drugs and negotiated 257 secret Product Listing Agreements (PLAs) for new brand-name drugs.[79] A PLA reflects the confidential product-specific terms negotiated between a (brand) pharmaceutical manufacturer and a payer. The outcome is usually achieved through a rebate that may be linked to total costs for that drug, to utilization patterns, or (rarely) to health outcomes (Morgan et al., 2013a).

While each of the five actions has been important, all are limited in scope. None has changed the underlying and unequal model of drug access and reimbursement in Canada. No province has ceded any jurisdictional autonomy. No private payer has been included. Each initiative was initiated and is governed by just one level of government.[80] National standards still do not exist, although standards for a national formulary and out-of-pocket limit were proposed by the Senate (2002, p. 142).

We are left to wonder who would want to expand the universal pie if it is already "unsustainable" even without NPh. The "alternative institutional arrangements" (Boothe, 2013, p.447) of private and provincial drug plans cover almost everyone and so any remaining access problem is at the economic margin.[81] However, Boothe (2013) concludes

[79] As at June 30, 2019: 49 more drugs are under negotiation, 40 negotiations have been closed and 66 negotiations have been declined by the pCPA. Updates available at: http://www.canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/.
[80] The PMPRB's National Prescription Drug Utilization Information System has an Advisory Board with nine provincial representatives. The role of the federal government in joint governance of the pCPA is not yet clear.
[81] There are no precise estimates of the number of uninsured and underinsured Canadians – see Section 4.12.

such arrangements: "…may obscure but do not negate real gaps in pharmaceutical coverage" (p. 447).

A more comprehensive policy alternative has not emerged because of limited policymaker ambitions and risk tolerance, and a population that appears to accept coverage on a patchwork basis. Though pharmacare is frequently supported in opinion polls, it is sufficiently complex that awareness of "trade-offs and costs are not made explicit" (Mendelsohn, cited in Boothe, p. 441).

4.7.3 Resistance to Change

Tuohy (2012) draws attention to hybridization, a process where some national health systems are evolving beyond their original (i.e., single payer or social insurance) structures to absorb elements of other systems. She describes major health system changes in the UK and the Netherlands and then points to Canada as a control case. Though most countries have faced swings between periods of runaway costs and periods of retrenchment, neither extreme can persist forever. Ultimately the system must stabilize in some balance of equity, cost control and quality. Tuohy argues this in turn creates opportunities for institutional entrepreneurs who engage their networks of public and private leaders to reorganize system resources using "the politics of redesign" (p. 613). She cites Ostrom (2005) in defining entrepreneurship as "a particular form of leadership focused primarily on problem solving and putting heterogeneous processes together in complementary and effective ways" (p. 615). Tuohy includes state authority and governance as key resources, alongside financial and human capital.

She notes the British and Dutch health systems began as classic examples of general taxation and social insurance models, respectively. Britain has quickly absorbed major changes and moved closer to a single payer model. The Dutch have implemented important changes in slow, deliberate phases towards nation-wide regulated competition that has now placed formerly separate state and private insurers under common corporate ownership. In contrast, Canada has held onto its limited-scope single-payer model with no integrated role for private insurers. Tuohy attributes this to a "bilateral monopoly" (p. 625) between governments and the medical profession which leaves little room for entrepreneurial innovation.

There are few examples of even attempting entrepreneurial innovation in Canadian health care. Tuohy (2018, p. 499) recounts the story of Canadian Radiation Oncology Services, a short-lived experiment (2001-03) with privately-contracted after-hours radiation therapy at Sunnybrook Health Sciences Centre in Toronto. With mixed results,[82] the contract was terminated by the Conservatives after considerable (and predictable) political

[82] Results explained in Tuohy (2018) are complemented by news coverage (https://www.theglobeandmail.com/news/national/private-cancer-treatment-clinic-to-stay/article25444515/) and critique by Mehra (2007), available at: http://www.ontariohealthcoalition.ca/wp-content/uploads/FULL-REPORT-October-1-2007.pdf.

controversy about privatizing health care. However, political ideology cuts both ways and appears undiminished over time. After gaining power in June 2018, a new Ontario Conservative government announced two months later that it would terminate the Basic Income Pilot Project. The three-year poverty-reduction study was launched in 2017 by a Liberal government and was to be carefully evaluated for effects on health, housing, education and employment.[83]

The "third-rail" (***Appendix 1***) imagery of Canada's health care system persists: Ideology typically overwhelms pragmatic innovation, even when government-sanctioned. As behavioural economics predicts, the threat of loss prevails over the opportunity for greater gain.

I am unaware of any peer-reviewed academic paper that has examined the scope, complexity or process of transitioning from private insurance to a fully public coverage. The Advisory Council (2019b) devoted just half a page (p. 99-100) to the transition and simply recommended (#54) that F/P/T governments "engage with" insurers, employers and employees with private drug benefits (p. 100).

4.7.4 Impractical principles

MacPherson and Kenny (2009) explored principles as a possible explanation for why there had been so little progress on the proposed National Pharmaceutical Strategy (NPS – First Ministers, 2004). They identified unanimous agreement in six independently-sponsored policy discussion papers on principles of equity, accessibility, safety and effectiveness. However they discovered that each term had significantly different meanings and use, and the relationships between them had not been described in the existing literature. Importantly, principles had not been linked to practical or political concerns. They concluded: "…to date, these principles have done no meaningful work for us, but rather appear to function as we have seen elsewhere (Giacomini et al. 2009) – as conventional, politically correct decorations" (p.34). While principles are important to guide decisions and some have been agreed upon within at least the policy community (see Sec 5.7), this process of identifying and debating principles may have distracted us from more practical and meaningful progress. Further, the OHIP+ experience (Sec 4.6.1) indicates that principles are important but not sufficient to implement practical change.

4.7.5 Indifference of policy elites

Another possibility that could explain why universal insurance coverage for out-patient prescription drugs has not been implemented is that established organizations do not support the idea. Deber and Berger (2004) surveyed 2,522 "policy elites" representing 24

[83] News release, April 24, 2017. Ontario. See: https://www.ontario.ca/page/ontario-basic-income-pilot, and link to termination news release: https://news.ontario.ca/mcys/en/2018/08/ontarios-government-for-the-people-announces-compassionate-wind-down-of-basic-income-research-projec.html.

organizations including medical, nursing, hospital, other health sector associations and three business-oriented groups.[84] The general focus was to determine what health care services should be publicly-funded, which was variously defined as:

a. *Universal* – without cost according to the Canada Health Act.
b. *Partial coverage* – income-tested with coverage declining as income increases.
c. *Subsidized* – universal, but only partially paid by government.
d. *Not included* – privately paid.

The researchers found broad agreement for retaining full public coverage for hospital-based care and some support for cost-sharing physician services. Coverage for out-patient prescription drugs was among several services for which only a minority (25%) of the elites thought there should be universal public coverage. More supported partial coverage (38%) and nearly as many (23%) chose subsidized coverage. Fourteen percent said there should be no public coverage. The survey was undertaken just as expensive specialty medicines were being introduced.

4.7.6 Political interpretation of the Canada Health Act

The 1984 Canada Health Act (CHA) advances five principles that underpin all publicly-funded health services: universality, comprehensiveness, accessibility, portability and public administration. Each province structures and funds its suite of publicly-insured health care services accordingly, and many have created additional rules that appear to expand the reach of the CHA principles.[85] Following the 2005 Chaouilli decision in Quebec, there was heated debate about two health reform proposals in Alberta (Mazankowski in 2001 and Alberta's 2006 Health Policy Framework[86]) and one in Quebec (Castonguay in 2008). Boychuk (2008) examined all three proposals for consistency with the CHA and concluded all provinces could allow increased latitude for private funding of health services. The 'heat' was driven not by the CHA but by political dynamics and feasibility within Alberta and Quebec, and by reasonable extension, all other provinces. Fear of vocal public concern about abandoning rigid enforcement of the Act appears to have led politicians to a cautious interpretation of the CHA.

[84] The three business groups were the Conference Board of Canada, The Canadian Federation of Independent Business and the Ontario Chamber of Commerce. Participation among these groups' members was typically poor. The Canadian Life and Health Insurance Association was not one of the research partners.
[85] Boychuk (2008) states the CHA does not: (1) Ban the private purchase of any health service; (2) Require physicians to operate completely within or outside the provincial system; or (3) Ban private insurance for publicly-insured services. In Chaouilli, the Supreme Court of Canada ruled unconstitutional a Quebec law that bans private health insurance for services covered by the public health care system. The decision applies only in Quebec, but other provinces have similar restrictions.
[86] The Framework is available at: https://open.alberta.ca/publications/077853491x.

Political interference and pressure from advocacy groups are common in tax-funded health systems like Canada's. One of the advantages of a separate and dedicated social drug insurance fund is better protection from political whim (Mintz & Tarasov, 2008, p. 71-72).[87]

It's unclear if this fear continues. If it does, F/P/T politicians may be unlikely to champion a pharmacare program that formalizes or institutionalizes private funding. However, high plan member satisfaction with private health benefit plans (Sanofi, 2019) may mean politicians do not actively resist a role for private drug insurance either.

4.7.7 Patients feel protected

Since the 1970s, the provinces have ensured that their potentially most vulnerable residents have been protected, namely seniors and especially those on social assistance who have the lowest drug co-pays. Some provinces have specific programs for those with serious, high-cost conditions such as cancer, multiple sclerosis, or certain genetic disorders. Rarely do other patients in need generate headlines, so the general population may feel public drug insurance is adequate. Pharmaceutical manufacturers often provide no- or low-cost compassionate access programs when the cost of their drug is high relative to family income.[88] Media coverage of drug policy and programs has been limited (Daw et al., 2013), so pharmacare may not be perceived as an unmet need.

Boothe (2013, p. 438) argues that chronic issues related to existing programs, notably surgical wait times and access to physicians, have taken precedence over the desire for new programs. Other gaps in health services (e.g., home care, long-term care) have been seen as higher priorities by both elites and the general public (Pollara, 2018).

About 90% of the private insurance that covers about 60% (Law, 2018) of the population is provided through employer-sponsored contracts (CLHIA, 2019). The employer determines plan design and cost-sharing among workers, although union negotiations will influence those decisions. Generally, enrolment is a condition of full-time employment. Employees in most mid-sized and large companies expect health plans as part of their total compensation. While plan termination or a significant reduction in workplace coverage would garner attention by plan members, this has rarely happened to date. Cost-sharing between employers and employees is mostly affordable[89] and insurers offer 24-7 access to customer service and health education that public plans do not. Administration generally

[87] In this same volume, Jost points out that politically powerful organizations, such as physicians and drug manufacturers, might prefer to negotiate with social insurers to avoid direct government oversight (p. 177). However, social insurers are usually tasked with selective (conditional) contracting with providers. The pCPA negotiates and recommends drug prices with drug manufacturers but not drug policy. There is no selective contracting with physicians in Canada.

[88] Innovative Medicines Canada, the brand drug industry association, reported 673,000 Canadians benefited from $900 million in spending on these programs. See: http://innovativemedicines.ca/wp-content/uploads/2017/10/20171030_EY-REPORT_IMC_FINAL.pdf. (p. 3).

[89] Those with private drug plans still report cost-related non-adherence, though at half the rates (3.4% vs. 7.1%) of those with provincial coverage (Law, 2018, Table 4).

works as advertised. Employees are very satisfied with their drug benefit plans (Sanofi, 2019).

This helps ensure there is little pressure to change delivery or funding. From the perspective of those who enjoy protection from insurance, "If it ain't broke…". It must also be remembered that the status quo also serves to marginalize those who do not enjoy adequate provincial or private coverage. Those in poor health with the lowest incomes are not as well satisfied with private plans as those in better health with higher incomes (Sanofi, 2019).

Driven by theory and real-world issues (primarily in the United States), some politicians, bureaucrats and academics have been uncertain or even hostile to changing the role of private insurance. A counterbalancing tension exists in that governments do not always generate public confidence to provide adequate or timely health services, and have not yet used proven cost-control levers available to them (Skinner et al., 2015). Sometimes, they act in arbitrary, budget-driven ways, as in Ontario's decision to control access to Avastin, a drug used primarily to treat metastatic colorectal cancer.[90] (The provincial Ombudsman reported there was no medical evidence for an "arbitrary" government limit of 16 cycles of Avastin. Funding was terminated even when the patient was responding to the drug.) Ontario's recent experience with OHIP+ (Section 4.5.1) provides a cautionary tale of the politicization of a well-intentioned new policy.

Among voters, the salience of drug insurance reform remains low. They may also be uncertain what is on offer. Current polling indicates NPh has wide public acceptance however the term has different meanings and the intensity of support appears low (Pollara, 2018). Patient groups fear being left without adequate coverage in a budget-driven public system (BMC, 2018). All this must change before politicians can back what may be seen as "a risky, radical approach to policy development" (Boothe, 2013. p. 430).

4.7.8 Insurer strategy

Historically, the health insurance industry has maintained a low public profile on health care services and insurance. Most of its political capital has been invested in Ottawa to protect its traditional, federally regulated financial services business from incursions by the big banks. Life and health insurers are massive investors and provide secure employment to tens of thousands of Canadians. NPh would cost insurers over $12 billion in revenue and unknown profit. While the industry has thin relationships with provincial governments, it is well-connected to the federal department of finance. If Ottawa is driving the introduction of NPh, this industry may have significant influence over the direction and pace of change.

[90] See: http://www.ombudsman.on.ca/investigations/SORT-investigations/completed/Cancer-Drug-Funding-A-Vast-Injustice.aspx.

The 2005 Chaouilli decision did not encourage a rush of new private health insurance products. It was only in 2009 that the industry publicly released its first policy paper, *The CLHIA Report on Health Care Policy*,[91] followed by its drug policy report (CLHIA, 2013). Quietly, the industry approached all provincial governments to ensure regulatory changes lowering the cost of generic drugs would also apply to those covered under private drug plans.[92] Various health insurers have introduced some product and adjudication changes to control client costs. However, these recent developments are relatively few and most are tactical. Other than a response by the CLHIA in the CMAJ (Frank, 2014), the industry has not publicly responded to academic research that is generally critical of private drug insurance (Hurley & Guindon, 2008; Stevenson 2011; Kratzer et al., 2013; Law et al., 2014).

As political interest in national pharmacare has increased since the HESA investigation began, the CLHIA appeared twice before HESA and has released its submission to the Advisory Council and related documents, helped fund the Conference Board of Canada's National Pharmacare Initiative, sponsored a paper on the Quebec drug insurance model,[93] and promoted its position to the public.[94]

Contrary to expectations, Boothe (2013) found that insurers were "surprisingly muted" (p. 428) to both Romanow's and Kirby's reports in 2002. Currently, the CLHIA directly supports pharmaceutical initiatives announced in the 2019 federal Budget and of many of the tactics in the Advisory Council's final report.[95] Boothe (2013) points out the inconsistency of business stakeholder (and provincial government) reactions to various federal health care proposals since the Second World War. She concludes these stakeholders cannot fully explain the failure of NPh: "…opposition varied from one policy episode to another, while the policy outcomes did not" (p. 426). Rather, she suggests that historically limited federal policy ideas and consequently lower public expectations were as likely to have prevented NPh as more conventional explanations centred on opposition from provinces, physicians or organized business groups such as pharmacy, pharmaceutical manufacturers or private insurers.

Indeed, the CLHIA has also called for more cooperation. "The Canadian life and health insurance industry stands committed to working with governments to obtain these savings [in pharmacare programs]," notes [Frank] Swedlove. At the same time, we must preserve the

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[91] Available at: http://www.clhia.ca/domino/html/clhia/CLHIA_LP4W_LND_Webstation.nsf/resources/Health+Care/$file/CLHIA_Report_on_Health_Care_Policy_ENG.pdf.

[92] Personal communication, 2012, with Stephen Frank, then VP Policy Development and Health, CLHIA.

[93] These initiatives or links to them are available at: https://clhia.ca/web/clhia_lp4w_lnd_webstation.nsf/page/1B6F3681BFB12B838525831A004D6A14!OpenDocument.

[94] See, for example: https://www.betterhealthbenefits.ca/.

[95] CLHIA, 2019. News release, June 5: https://www.clhia.ca/web/CLHIA_LP4W_LND_Webstation.nsf/page/E7010B7FD78BDC4685258417005D0245!OpenDocument. The CLHIA continues to advocate for a robust private insurance role, contrary to the Advisory Council's recommendation for a single payer model that retains only a minor residual role for private insurance.

benefits from competition and innovation that the private sector provides to the marketplace."[96]

Insurer clients (employers) may feel differently than the insurance industry. Employer views are ambivalent about NPh, and there have been no high quality, current and comprehensive surveys about NPh.[97] While many companies might like to terminate their increasingly complex drug benefit plans, employers are unlikely to see any short- or medium-term cost advantage under NPh since today's insurance premiums are likely to transition to higher corporate or payroll taxes.

4.8 Plan Design Considerations

Building on the principles (Sec 2.2.2), certain plan design attributes are recommended based on the referenced literature and briefly described below. Public and private payers and citizens and patients could help negotiate roles and responsibilities (Savedoff et al., 2012).

1. Governments and all employers are required[98] to provide an adequate minimum standard formulary for cost-effective prescription drugs. Citizens are mandated to have drug insurance from employment or government. Mandated employer coverage will "level the playing field among employers and remove the competitive advantage currently enjoyed by those who provide no health care coverage to employees." (Rasell, 1999, p. 185)

2. Consistent out-of-pocket limits allow people to get drugs without financial hardship.

3. If governments cannot afford to provide adequate coverage, there is provision for citizens to buy additional coverage from private sources.

4. Governments use general tax revenues and dedicated payroll taxes to fund the public share of universal drug insurance (Allin, Stabile & Tuohy, 2010). These funds are directed to the unemployed and other vulnerable population segments who cannot pay for themselves. Employers and employees share responsibility for payroll taxes equally.

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[96] News release, CLHIA, March 26, 2015. Available at: http://www.clhia.ca/domino/html/clhia/clhia_lp4w_lnd_webstation.nsf/page/AA2597E98A11A70085257E140047580C. Mr. Swedlove was President and CEO of the CLHIA at that time.

[97] In addition to Sanofi (2019), HR consulting firm Aon published a poll of 120 employers in 2015, available at https://www.aon.com/canada/insights/RR-PharmacareEmployerPerspective.jsp. The sample is not described. Similarly, the CFIB published some findings from its members but details are scant. See: https://www.cfib-fcei.ca/en/media/national-pharmacare-must-not-impose-new-costs-and-taxes-small-business.

[98] A less rigid approach would be to allow the smallest employers, e.g., those with fewer than 5 or 10 employees, to avoid drug insurance for affordability reasons. Their employees would be covered by the provincial plan, similar to the employees of Quebec employers that do not provide an extended health benefit. Otherwise, an employer would be required to provide coverage to all employees and family members.

5. Patients pay a share of drug cost, and ideally cost-sharing is integrated with the income tax system to mitigate the deterrent effects on access of up-front deductibles and high co-pays. Costs will be reduced or eliminated for low-income patients or those with expenses exceeding 3% of net family income.

6. There are clearly defined boundaries between payers. The government covers anyone without an employer plan (e.g., outside the labour force) and employers cover all employees and their dependents (Kutzin, 2001).

7. Prescribers are aware of drug cost (Blomqvist and Busby, 2015) and respect cost-effectiveness analyses provided by expert panels. Ideally, physician incentives would be introduced to improve prescribing.

8. All plans reimburse drugs using the same negotiated price. Private insurance plans also benefit from product listing agreements negotiated by the pCPA. In exchange, insurers would contribute appropriately to pCPA costs and resources.

9. Efficiency is improved through lower administrative costs. For example, insurer profit and risk charges and premium and sales taxes can be reduced through regulation and an effective risk-sharing mechanism.

10. Drug manufacturers are required to prove the value of their products. Prices and pharmacy fees that reflect value to patients and payers will improve system sustainability.

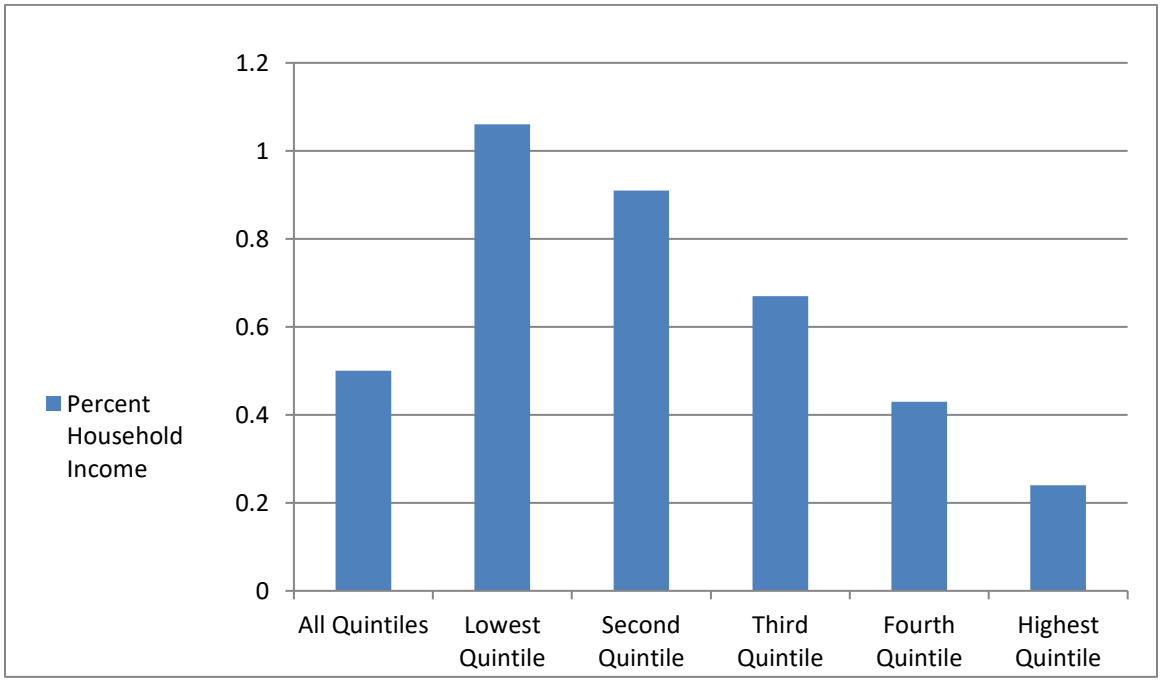
An important consideration in plan design is whether plan designs create regressive effects on lower income patients. Sanmartin et al. (2014) found 37% of those in the lowest income quintile (Q1) spent more than 5% of their total household income on prescription drugs in 2009, versus just 14% of those in the highest income quintile (Q5) (p. 15, Table 2).

Many private drug plans are regressive because all employees pay the same premiums, deductibles or coinsurance regardless of their incomes. Some provincial drug plans fail this test as well (e.g., AB, ON, NB, QC) when there is a flat dollar co-pay. A single percentage of income applied to all beneficiaries is proportional at best. (**Table 4.1**).[99] Provincial plans that increase co-pays with income are not considered regressive. It is important to consider the out-of-pocket cost of public drug plans in the context of the overall burden of taxes and other fees. For example, the income tax system is highly progressive and blunts the effect of drug plans that do not have progressive co-pays or income-based caps on out-of-pocket expenses. The timing of co-pays can be an issue when they must be paid at the point of dispensing. Collecting them through the income tax system (Blomqvist & Busby, 2015) is easier to afford and reduces the effects of cost-related non-adherence to therapy.

[99] The same coinsurance percentage is similar in effect to a flat tax. Although the dollar value rises with income, a flat percentage is likely to consume a larger share of disposable income for those with lower incomes.

As the Senate Committee proposed in 2002, it would seem administratively simple to require private health plans to limit out-of-pocket costs to a certain annual dollar amount. This would improve protection for all beneficiaries, although higher-income plan members would be advantaged because any cap would be a smaller share of their income. Currently private insurers do not have access to income information.

Figure 4.1 – Average Portion of Household Spending for Prescribed Medicines and Pharmaceutical Products, by Before-tax Household Income Quintile, 2015



Source: PBO (2017) p. 23. Analysis of Statistics Canada, Survey of Household Spending (CANSIM 203-0021). Note: Reported spending may not necessarily take into account the Medical Expense Tax Credit.

Using IQVIA and CIHI data, PBO (2017) included estimates on out of pocket spending as a percent of gross (pre-tax) household income (**Figure 4.1**). Average out of pocket prescription drug spending was fairly similar across all quintiles, between about $350 (lowest quintile) and $460 for the second and third quintile (p. 23), however average household health expenses cost lower-income Canadians proportionately more than those with higher incomes (Sanmartin et al, 2014, p. 5). Using averages may disguise affordability issues if the range of expenses is very wide per quintile. Using median drug expenses by quintile and data on the drug cost ranges would help provide targeted solutions.

4.9 The Opportunity for Regulation

Health insurance is funded through a combination of tax-based, social insurance and private pay models. In 2001, 38 nations had private health insurance markets, about half in high-income countries generally with well-developed regulation (Sekhri & Savedoff, 2006). Governments routinely cover certain market segments, such as seniors, low income and chronic disease groups in which private insurers cannot function over the long term (Bodenheimer & Grumbach, 1992; Kutzin, 2001; Savedoff et al., 2012). Private insurers add resources to the system by funding health insurance for employed citizens, but controls are required to ensure the public interest – defined by Sekrhi and Savedoff as equity, affordability and access – is met and is held above the interests of shareholders.

Governments must make decisions about the degree to which they will intervene in the private insurance market. Kutzin (2001) describes five regulatory options each with progressively more intervention than the one before:

1. Information is provided to various external stakeholders.
2. Insurer function and reporting is regulated.
3. Regulation mandates specific actions or terms by insurers or citizens.
4. Health services are financed with public funds but privately delivered.
5. Health services are provided by government employees.

While the financial services industry has very significant federal and provincial oversight, health insurance is only lightly regulated in Canada (Hurley & Guindon, 2008). Regulation may encompass: (i) prohibiting coverage limits or exclusions related to age or health status, (ii) provision of (at least) a defined minimum level of coverage, including formulary and out-of-pocket expenses, (iii) marketing, (iv) a risk sharing mechanism for insurers to stabilize premiums, (v) consumer protection and decision-appeal mechanisms, and (vi) ensuring people can switch their insurers without penalty (Kutzin, 2001).

Social insurance system regulation addresses concerns about private insurance, such as operational efficiency,[100] pricing, quality, formulary breadth, waiting periods, limitations and exclusions, and claim payment accuracy. Policy determines if private insurers can sell supplemental coverage, and under what conditions. Like public utilities, regulation also allows insurers to make reasonable returns for shareholders, which is also in the public interest.

[100] Operational efficiency is likely better in a regulated social insurance system relative to private insurance, however a single payer system will have the lowest administration costs. Insurer administration charges decreased in the Netherlands after the introduction of its social insurance market in 2006 (Sec 5.4.5).

These requirements become feasible when an entire population is required to enrol. Concerns about adverse selection[101] and knowledge asymmetry by patients or countervailing risk selection ("cream-skimming") by insurers are significantly mitigated.[102] Moral hazard, defined as the incentive for excessive service use based on the insurance subsidy of provider cost, can also be managed by ensuring patient cost-sharing is reasonable and progressively geared to income.

The OECD (2010a) found that health inequalities were lower in Germany, the Netherlands and Switzerland – each with private insurance-based systems – than several countries having predominantly public systems including the United Kingdom (UK) and New Zealand: "…indicating that regulation and equalisation schemes can help mitigating cream-skimming and the effects of other market mechanisms which can raise equity concerns" (p. 14).[103]

As a matter of policy, regulation may also allow the reduction or elimination of certain costs now borne by the industry. Private insurers levy risk charges to employer clients for insured health plans, reflecting the risk that the client could cancel the plan while the insurer is in a loss position. Given universal coverage, an appropriate risk-sharing model (described in Chapter 5) and no anti-selection for a standard plan, risk charges are no longer needed. Supplemental private drug coverage that could top-up a basic mandated drug plan would have to be managed through regulation as in the Netherlands. Perhaps health insurers would no longer pay premium taxes to provincial governments, and sales taxes in QC, ON and MB. Under a public mandate, the federal government would have to consider the tax deductibility of employer premiums and the tax-free benefits (claim reimbursements) received by employees. Bringing private insurers or plan sponsors into public policy and operational bodies such as the pCPA and PMPRB would enable all patients to pay lower drug prices. Right now, public drug plan beneficiaries pay lower prices than other taxpayers. With a single national price, public payers may get a smaller discount, but private plans might get a larger one. It should be clear that beneficiaries also benefit from the negotiated discount on their cost-sharing. With a public mandate, pharmacy mark-ups and fees might also be renegotiated.

Government policy also decides the place of competition between insurance providers. Such a principle can be used to improve quality in systems as different as US private

[101] Anti-selection is defined as knowledge asymmetry between insureds and insurers. Insureds are more likely to buy health insurance when they believe their benefits will exceed their premium cost, typically due to a diagnosed or suspected health issue. Insurers balance anti-selection with underwriting rules that require proof of good health, or they may limit their exposure to known risk through coverage limitations, or by packaging different benefits together, or by charging higher premiums for sub-standard risk. The threat of anti-selection is eliminated when insurance coverage is mandatory, giving insurers an optimal spread of risk across 100% of a population. Risk-sharing mechanisms among insurers are also typical.

[102] There is some evidence that some insurers in the Netherlands offer inducements to enrol healthy younger people. However, since enrolment is mandatory and 84% of residents buy private insurance this has limited negative effects.

[103] The OECD's report focuses on policy enabling health systems efficiency. Collectively, social determinants of health will have much greater effect on population (vs. personal) health than the health system itself. That noted, health system design, funding, policy and governance materially impacts equitable access to health services.

insurance plans (see: NCQA.org) or the UK's public National Health Service (Frakt, 2015). The key difference between single-payer and multi-payer systems is that the former can better control costs, but the latter allows more consumer choice (Hussey & Anderson, 2003; Oliver, 2009). The latter approach allows employers to customize their plans to align with their human resource strategy. They may improve coverage for drugs that enable better health (e.g., nicotine replacement therapy) or that impact disability (income replacement) costs not borne by governments. Competition can enable more innovation, customized policy designs and better plan member services. Without adequate regulation, poorly capitalized and administratively inefficient companies can waste resources and poorly serve both customers and policy interests (Sekhri & Savedoff, 2006) at least for a period.

Regulation allows governments and societies at large to place a value on externalities, defined as the effect of health care decisions (societal, organizational or personal) on others. At the macro level, societies choose to value equity and so ensure that governments pay for health services for individuals who could not otherwise afford them. Regulation of organizational (meso) mandates, such as for public health, can enable financial coverage for mass vaccinations for contagious diseases, or manage workplace health programs (e.g., the US Affordable Care Act). At a micro level through an individual mandate, regulation can ensure that employees are able to work because they have access to health services that can mitigate work absence (Sekhri & Savedoff, 2006).

The amount of consumer protection should increase in proportion to the importance and scope of the role played by private insurers in a social insurance system (Sekhri & Savedoff, 2006). It is crucial to find the right balance in regulatory policy decisions. For example, controls can be so rigid that insurers cannot afford to invest, innovate or provide expected service levels, but they can also be so loose that insurers ignore the public interest. Arguably, if private insurers are to continue, their fiduciary and public interest roles should be clear, compelling and consistent. One way to protect health insurance offered by employers to their employees would be to expand the CLHIA's industry-wide high-cost drug pooling arrangement to benefit all private plans, not just those for small employers. This could be part of a broader industry risk sharing mechanism, an essential part of social insurance systems. Anecdotally from benefit advisors, smaller employers already "protected" by the industry pool continue to face higher pooling charges that trigger at higher claim thresholds. As a result, some small and mid-sized employers may be tempted to reduce or terminate their drug plan financial risk and thereby shift costs to provincial drug plans that offer catastrophic coverage.[104]

There is little discussion of regulation in Canadian drug policy research. One reason may be that a single payer system allows more dramatic contrast to the expensive, multi-payer American private health insurance system, and its stark image of privilege for those with insurance and hardship for tens of millions of its citizens who are un- or under-insured. One study linked medical problems to 62% of all bankruptcies filed in the United

[104] Personal communication, Dave Patriarche, Mainstay Insurance and Canadian Group Insurance Brokers. January 2016.

States in 2007 even though 78% were insured at the onset of illness (Himmelstein et al., 2009, p. 743).

However, regulation is a low-cost approach (Kingdon, 2011, p. 107) to addressing the classic concerns of anti-selection and cream-skimming by ensuring that coverage is provided regardless of health status or age. Insurer concerns about anti-selection can be addressed through risk-pooling mechanisms. For insurers, regulation need not be unduly stringent. Quebec requires annual filing of reports with the government but provides insurers with significant latitude.[105] There's an obvious parallel between insurers and self-regulating health professional Colleges established to oversee their members and protect the public interest. Regulating health insurers can provide a simpler and still effective approach. A fully public drug insurance system is not essential to provide universal coverage.

4.10 Model and Outcomes

OECD nations use different models to provide universal health coverage, and while none is broadly superior to others (Glied, 2009; Oliver, 2009; OECD, 2010b), most provide superior results to those of Canada (Institute for Competitiveness & Prosperity, 2014; Davis et al., 2014; Schneider et al., 2017). Commenting principally on the US health system, Glied (2009) states:

> "The similarities among OECD countries – and the glaring difference between the OECD and the United States – suggest that it is universal coverage and not the mechanics of system design that explain the divergence [in health system performance]" (p. 614).

In comparing the health systems of 29 member states, the OECD (2010b) concluded:

> "Efficiency estimates vary more within country groups sharing similar institutional characteristics than between groups. [See **Table 4.3**] This suggests that no broad type of health care system performs systematically better than another in improving population health status in a cost-effective manner" (p. 14).

Using the OECD (2010b) country categories and comparing them with the 2014 and 2017 Commonwealth Fund rankings, there appears to be minimal linkage between health system category and overall performance ranking (**Table 4.3**). The ranking for several countries changed between reports. The OECD determined six institutions groups. Groups **1 to 3** were: "Reliance on market mechanisms in service provision", and Groups **4 to 6** were: "Mostly public provision and public insurance".

[105] Personal communication, Claude Di Stasio, (former) Vice-présidente, Affaires québécoises, CLHIA. October 20, 2015.

Table 4.3 – Comparing Health System Performance and Structure

Country	Commonwealth Fund Performance Ranking		OECD Institution Group (2010)
	2014	2017	
United Kingdom (UK)	1	1	*6* – Ample provider choice / strict budgets
Switzerland	2	6	**1** – Private insurance for basic coverage
Sweden	3	6	*4* – No gate-keeping / ample provider choice
Australia	4	2	**2** – Public for basic / private beyond
Germany	5	8	**1** – As above
Netherlands	5	3	**1** – As above
New Zealand (NZ)	7	4	*6* – As above
Norway	7	4	*6* – As above
France	9	10	**2** – As above
Canada	10	9	**2** – As above
United States	11	11	Not Included

Sources: (1) Davis et al., 2014. (2) Schneider et al., 2017. (3) OECD, 2010b. Note the Institution Group descriptions are paraphrased from the OECD report descriptors in Figure 0.1 (p. 15). Davis and Schneider reports published by the Commonwealth Fund.

Commonwealth Fund comparative health system performance rankings put Canada in tenth place in 2014 (Davis et al., 2014) and ninth in 2017 (Schneider et al., 2017) among eleven nations reviewed.[106] In 2014 Canada placed no better than fifth in eleven measures, and had seven measures ranked 9th, 10th or 11th. In 2017, Canada's best showing was sixth in two domains and the other three were ranked 9th and 10th. The domain names were somewhat different between reports but the descriptions were very similar. Four of the five 2017 domains include metrics that impact drug prescribing, dispensing or utilization, and reflect the interplay of hospital use, physician and drug access on chronic disease management.

Such dismal international performance does not support greater public stewardship of prescription drugs within our health system. These findings do support the need for better

[106] These reports assess health system performance rather than prescription drugs specifically. These reports rely on data from a variety of sources including Commonwealth Fund international surveys of patients, physicians and the general population (2014 only) plus data from the OECD, WHO, and the European Observatory on Health Systems and Policies (2017 only).

health system governance in Canada in order to improve our actual and relative performance.

4.11 Cost of Universal Access

Cost estimates for universal single-payer (government) coverage of prescription drugs vary significantly according to design, quality/rigour, time period, roles and political agenda. The following 15 cost studies were identified from the literature review and have been updated since. The researcher is not aware of other major costing studies since the late 1990s. Some assume a continuing role for private payers.

1. In February 1997, the *National Forum on Health* recommended universal, publicly-funded, first-dollar drug coverage. It did not provide costs, but said: "Over time, we propose to shift private spending on prescribed pharmaceuticals (estimated at $3.6 billion in 1994) to public funding" (p. 17).

2. In September 1997, the *National Pharmacare Cost Impact Study* (Palmer d'Angelo Consulting, 1997) estimated that a first-dollar, publicly administered drug plan would increase government drug costs by $4.31 billion. Plans with typical patient co-pays would cost governments $2.1 to $2.5 billion more. Using a Quebec public-private model with 25% coinsurance, the government cost would increase only modestly by $82 million. The Quebec plan with no co-pays would cost governments $1.55 billion more. In 1996, prescription drug costs were $6.8 billion (CIHI, 2018a).

3. In 2002, the *Senate* Standing Committee on Social Affairs, Science and Technology recommended catastrophic drug coverage when individual drug costs exceeded $5,000 annually. The federal government would pay 90% of costs thereafter. The province or employer would pay the remaining 10%. Individual out-of-pocket costs would be capped at 3% of family income, or $1,500 for private plans, whichever is less. The plan incorporated both public and private coverage. The federal cost was estimated at $500 million annually. Prescription drug costs in 2002 were $14.8 billion (CIHI, 2018a).

4. Also in 2002, the *Royal Commission on the Future of Health Care in Canada* (2002a) valued a catastrophic model providing citizens with full coverage above $1,500 annually at between $749 million and $1.01 billion.

5. The Competition Bureau (2008) estimated Canada could save $800 million (20%) by changing the way it pays for generic drugs, e.g., through tendering supplies and better monitoring prices. Most of the savings – about $600 million – would accrue to private insurance plans. This analysis was limited to generic drugs but helps illustrate the order of magnitude of savings available. Generic drug spending was $4.1 billion in 2007 (p. 8).

6. The OECD (2010a) estimated Canada could potentially save 2.5% of government health costs if we could "become as efficient as the best performing countries" (p. 6. Those countries were not identified.). If we assume the 2.5% applied equally to prescription drug costs, the potential government saving would have been $360 million using 2018 public expenditures of $14.4 billion.

7. Gagnon and Hébert (2010) estimated that Canada could save between $2.7 billion (11%) and $10.7 billion (43%),[107] in prescription drug costs depending on changes to industrial policies favouring drug manufacturers, if it moved to universal, first-dollar coverage. About $1.5 billion would come from eliminating extra administrative costs and the tax subsidy for private drug plans. The politics, mechanics, timing and overall feasibility of transferring billions in private spending to government plans was not explored.

8. Using a proprietary database, Morgan et al. (2015) estimated that Canada could save $7.3 billion (26%, range $4.2 to $9.4 bn) if it moved to a universal public drug plan. The private sector would save $8.2 bn and government costs would increase about $1 bn. Their model used prices from the UK NHS to arrive at an immediate 23% cost reduction for brand drugs. They used an undisclosed cost reduction for generic drugs "…equal to moderate performing comparators, such as the United Kingdom and Sweden" (Morgan et al., Appendix 1, p. 2). Their model assumed co-pays of $2 bn and that costs would rise by 3% due to additional claims (moral hazard) from the (previously) uninsured. Prescription drug expenditures were $28.3 bn in 2012 (CIHI, 2018a).

9. Skinner et al. (2015) concluded a national single-payer drug plan was not needed and would transfer $13.2 billion in costs to taxpayers. While this cost is not realistic because it ignores changes in plan design and timing that would accompany NPh, it identified some transitional and implementation costs of moving to a fully public system. These were estimated at $4.1 billion, mostly from assumptions about employment and tax revenue losses. Eliminating private drug insurance administration costs would save an estimated $937 million. They suggested considering "mandatory universal private [social] drug insurance systems supported by means-tested public subsidies" (p. 3). Drug expenditures were $30.8 bn in 2015 (CIHI, 2018a).

10. Through the CD Howe Institute, Blomqvist and Busby (2015) published a short paper suggesting a "politically feasible way forward" (p. 1). They recommended a specific role for the federal government to partially fund a cross-Canada cap on catastrophic drug costs, as well as managing drug pricing, developing a model formulary with the provinces, and addressing high-cost drugs for rare diseases. Use of the income tax system for managing individual entitlements would be administratively simple and

[107] Note this study used 2008 Rx drug costs of $25.1 bn. CIHI (2018a) now reports $23.4 bn for 2008. The dollars and percentages used reflect the original values in Gagnon & Hébert (2010).

inexpensive. They estimated costs would increase by $2.8 billion. They also argued against the Morgan et al. (2015) study and suggested the immediate cost transfers to government were so large as to make them completely infeasible. Private funding would continue and prices negotiated by the pCPA would apply to private plan beneficiaries.

11. In 2016, the Canadian Pharmacists Association (CPhA) released two commissioned studies that challenged the assertion that a fully-public national pharmacare plan would save $7.3 billion (Morgan et al., 2015). In the first study, Palmer, Nelson and Lamb-Palmer (2016a) adjusted two major assumptions used by Morgan et al. First, they updated the 2012-13 prices and the UK exchange rate used previously. That added $3.25 billion in costs. The second adjustment applied to Morgan et al.'s assumption that governments would save the full cost of their employee drug plans once that obligation became publicly funded. Palmer et al. assumed public sector unions would bargain most of those drug plan savings into higher compensation. That added $2.4 billion. Using these new assumptions, the $1 billion net government cost reported by Morgan et al. (2015) in their moderate scenario increased to $6.6 billion in added government and taxpayer costs.

    In the second study (Palmer, Nelson & Lamb-Palmer, 2016b) seven different plans of varying designs and funder combinations were modelled. They argued that evolution in inter-governmental cooperation could lead us to universal drug coverage while still respecting provincial autonomy and retaining a role for private insurers. Large and disruptive cost transfers to governments and taxpayers from the elimination of private plans would be avoided, and equity and sustainability would be improved. As for Morgan et al.'s assumption that governments would use their clout to force huge price concessions from global drug companies: "Given that the monopsony buying power that could achieve these lower prices has existed for years though [sic] the pCPA and PMPRB, it is not apparent how this would change as a result of establishing national pharmacare" (Palmer, Nelson & Lamb-Palmer, 2016b, p. 23).

12. As directed by HESA, the Parliamentary Budget Officer (PBO, 2017) released a cost estimate for a single federal payer national pharmacare plan. The PBO was required to use the Quebec formulary, by far the most extensive of provincial plans. That requirement eliminated $4.0 billion in spending reimbursed by private plans. The PBO made other assumptions including an immediate 25% price reduction for all covered drugs (PBO Table 3-6), saving another $4.2 billion. The PBO reported total spending $2.3 billion less than reported by CIHI that year (2015-16), which reduced new federal spending by the same amount. The net effect of these and other assumptions by PBO was to increase federal spending by $19.3 billion and reduce total spending by $4.2 bn (17%) if their NPh model was introduced in 2015-16.

13. Canadian Doctors for Medicare, in association with the Canadian Centre for Policy Alternatives, estimated gross savings from a single payer national pharmacare plan of $31.8 billion using 2016 figures. This is 101% of $31.4 billion in actual

prescription drug expenditures that year. Two requests for clarification went unanswered.[108]

14. Macdonald and Sanger (2018) revised the PBO (2017) model using the Quebec formulary and projected costs to 2020. Their main goal was to explore seven different revenue generating approaches that would cover the $10.4 billion incremental cost to the federal government. Their model indicated new federal costs would be more than offset by $16.6 savings to individuals and employers, netting $6.1 billion in annual savings.

15. Using the Quebec provincial formulary, the Advisory Council (2019b) estimated a comprehensive universal single payer NPh plan would cost governments $15.3 billion more per year when fully implemented in 2027. The interim step of an Essential Medicines List in 2022 would increase cost by $3.5 bn. Even with universal coverage, net savings were estimated at $300 million in 2022 and $4.8 bn in 2027.

[108] Canadian Doctors for Medicare, 2017. News release, September 17 available at: http://www.canadiandoctorsformedicare.ca/Press-Releases/report-shows-canadians-will-save-billions-with-pharmacare.html. The report is no longer available on this website.

Table 4.4 – Summary of NPh Cost Studies

Year	Study (data year)	Plan Design	Net Cost Impact	
			Dollars (bn)	Percent
1997	National Forum on Health (1996)	SP – FD	Not specified	
1997	National Pharmacare Cost Impact Study (1996)	SP – FD	4.3	+ 63%
		SP – CS	2.1 – 2.5	+ 31 – 37
		QC 25% CS	0.08	+ 1
		QC – FD	1.55	+ 23
2002	Senate Standing Committee	Cat	0.5	+ 3
2002	Royal Commission	Cat	0.75 – 1.01	+ 5 – 7
2008	Competition Bureau (2007, generics only)	No Chg	- 0.8	- 20
2010	OECD	No Chg	- 0.7	- 2.5
2010	Gagnon & Hébert (2008)	SP – FD	- 2.7 – 10.7	- 11 – 43
2015	Morgan et al. (2012-13)	SP – FD	- 7.3	- 26
2015	Skinner et al.	SP – FD	Not specified	
2015	Blomqvist & Busby	Custom	2.8	+ 10
2016	CPhA (2015)	SP – FD QC	- 1 0.1	- 4 + 0.4
2017	PBO (2017)	QC Custom	- 4.2	- 15
2017	Doctors for Medicare (2016)	SP – FD	- 31.8 (gross)	- 101
2018	Macdonald & Sanger (2020)	SP	- 6.1	- 17
2019	Advisory Council	SP – FD	- 0.3 (2022) - 4.8 (2027)	- 0.8 - 9

Key: **SP-FD** = Single payer, first dollar; **SP-CS** = Single payer, cost-sharing; **QC** = Quebec; **Cat** = catastrophic; **No Chg** = No change.

Fifteen reports have been summarized (**Table 4.4**), and none propose exactly the same solution. Most recent studies suggest NPh will save money overall, however the amount of inadequate coverage is unclear and the cost of implementing a universal drug insurance plan is based on varying assumptions, data, timing and ideologies. Recent studies, almost all by credible organizations and authors, report a pharmacare plan could save $31.8 billion or cost $2.8 billion by 2027 (Advisory Council, 2019b). This range in costs creates

significant uncertainty and is perhaps the most likely reason why this country has not progressed to any form of universal coverage (Boothe, 2013).

In determining a role for the life insurance industry, its financial and therefore political importance should be considered. The CLHIA (2019) notes its members have $867 billion in investments in Canada, of which $136 billion is invested in government bonds. The industry has 156,400 full-time employees and agents. Member companies pay $4.3 billion in taxes to all levels of government and collect another $3.7 billion in sales and payroll taxes. The association estimated that provincial governments would forego $1.1 billion in annual premium ($380 mm) and sales ($720 mm) taxes currently collected on private drug plans.[109]

Plan design also matters. While there is agreement on developing a "national formulary", the meaning and scope of those words will determine the cost. As Blomqvist and Busby (2015) point out, there is a more pressing need for national standards for out-of-pocket costs as well, since there are very significant differences according to where you live or work.

There are several reasons to believe this will be a slow, step-wise transition that may not deliver transformational change for several years. Time will be needed for F/P/T negotiations about funding, plan design, timing and compensation, and the potential role(s) of private insurance. A transition period is needed and transitional costs need to be accurately calculated based on the final NPh strategy. Provincial governments may not all implement a new NPh program at the same time. Private plans that are collectively bargained may need special attention. The 2019 federal Budget set up a four-year period just to develop the Canadian Drug Agency (including a national formulary) and a strategy for rare diseases. This is not a comprehensive NPh strategy. The Advisory Council recommendations beginning in 2022 and through 2027 assume future governments will implement NPh exactly as planned. All these considerations and the likelihood of unexpected developments mean it will be extremely difficult to calculate changes to overall drug spending as a result of NPh whatever form that finally takes.

4.12 A fiscal opening?

The federal government funding formula changed significantly beginning in fiscal 2017-18. Instead of annual increases of 6%, the Canada Health Transfer now grows according to a three-year moving average of nominal (after inflation) growth in Gross Domestic Product (GDP), with a minimum annual escalator of 3%.

While this change makes federal spending sustainable, it will seriously aggravate deficits of sub-national governments assuming healthcare costs rise faster than inflation (PBO, 2012). Fiscal sustainability, as defined by the PBO, requires that government debt at all levels cannot grow faster than the economy. The most recent projection (PBO, 2018) is that

[109] Personal communication, CLHIA. July 26, 2019.

the federal government has the fiscal room to increase spending or reduce taxes by 1.4 per cent of GDP per year – about $29 billion annually – over the next 75 years. Conversely, sub-national (provincial, territorial and local) governments will on average need to decrease spending or increase revenue by 0.8% of GDP ($18 billion) to keep debt levels at the same percentage of GDP. (The fiscal situation of each province varies markedly.) The provinces fund the most capital-intensive and high-wage obligations – health care and education. The federal government has the financial capacity to fund almost any variation of national pharmacare, while the provinces in aggregate do not. This may open a window of opportunity if the federal government chooses to make pharmacare a priority over other large-cost projects such as oil pipelines and fighter jets.

The provinces may be amenable to a larger role for Ottawa, and Ottawa may be interested and able to facilitate change early in the mandate of the next government (2019-2023). Indeed the Communiqué from the 2004 Premiers Meeting welcomed the federal government to take over responsibility for all provincial drug plans, though that call was never repeated.[110]

4.13 Inadequate Insurance and Out-of-Pocket Costs

A key dimension of quality is the share of personal out-of-pocket costs, even though "how much is too much" is contentious. It is unclear how many Canadians have no drug insurance or inadequate coverage that exposes them to high out-of-pocket costs. Several older estimates exist (Applied Health Management, 2000; Kapur & Basu, 2005; Dewa, Hoch & Steele, 2005) but all these precede the advent of catastrophic plans in several provinces. There are ten newer studies but none capture the combined breadth of the un- and under-insured population nor have the methodological rigour to confidently provide accurate and current estimates.

1. Based on responses to the 2007 Canadian Community Health Survey, Law et al. (2012) reported 9.6% of Canadians (2.8 million) who received a prescription experienced cost-related non-adherence (CRNA) to drug therapy. CRNA was lowest in Quebec and highest in British Columbia. Using 2016 data, Law et al. (2018) reported 5.5% of Canadians were unable to afford at least one drug in the past year. The prevalence of CRNA reported in employer plans was half the level of public plans (3.44 vs. 7.13. Table 1, Part 2). CRNA is a proxy measure for inadequate insurance.

2. Statistics Canada (2010) has estimated the proportion of households spending between zero and 5% of their after-tax incomes on prescription drugs.[111] In 2008, 3% of Canadians spent over 5%, a percentage that is less than in previous years. While 7.6% of all Canadians spent over 3% of after-tax income on prescription drugs in 2008, provincial figures ranged from 4.7% in Ontario to 13.3% in PEI. Equity is an

[110] Council of the Federation, 2004. News release, July 30. *Premiers' Action Plan for Better Health Care: Resolving Issues in the Spirit of True Federalism*. Available at: http://www.canadaspremiers.ca/wp-content/uploads/2017/09/healtheng.pdf.
[111] The figures noted do not include non-prescription drugs or any drugs paid by governments or insurance companies.

issue across provincial plans; a "postal code lottery" exists for a medically necessary expense.

3. McLeod et al. (2011) used 2006 Statistics Canada data to estimate portions of general, social assistance and senior households with median and 95th percentile household spending on prescription drugs. The top 5% within those three household categories spent 2.6%, 5.4% and 7.4% of their household incomes, respectively. There were significant inter-provincial variations.

4. Sanmartin et al. (2014) found 37% of those in the lowest income quintile (Q1) spent more than 5% of their total household income on prescription drugs in 2009, versus 14% of those in the highest income quintile (Q5). Average costs in 2009 were not very different by quintile, at $296 for Q1 and $268 for Q5. The highest costs ($388) were incurred by those in Q2, who may not qualify for public (or private) drug insurance subsidies. The mean household out-of-pocket expenditure for prescription drugs was $321 in 2009.

5. Personal, out-of-pocket health costs for Canadians (15.5% of total health spending in 2011) exceed those of Germany (12.4%), the United States (12.1%), and were twice the level paid in France (7.7%) and the Netherlands (6.0%) (Lorenzoni, Belloni & Sassi, 2014).

6. Skinner et al., (2015) estimated about 100,000 Canadians have no drug insurance, relying on coverage data provided by IMS Brogan and the CLHIA. However, both Alberta (2006) and New Brunswick (2012)[112] have reported that about 20% of their citizens have no drug insurance, equalling about 994,000 (2.75% of) Canadians.

7. The Survey of Household Spending provides average household expenditures on "prescription drugs and pharmaceutical products." Figures in recent years have been between $400 and $450: 2013 ($451); 2014 ($408); 2015 ($417); 2016 ($455); 2017 (452).[113] Again, using median may be a more appropriate statistic assuming the range is very wide among all households.

8. The Angus Reid Institute (2015) published a survey of 1,556 Canadians drawn from a proprietary panel that reported 11% of households paid for all of their drugs, ten percent paid for most and six percent reported a 50-50 cost-sharing. Descriptive statistics of the panel were not published, nor were the amounts paid for drugs, nor were there details of any available insurance so it is not possible to generalize these findings to all Canadians. The survey implies all those without coverage need coverage. Morgan et al. (2016) cite this survey in stating "approximately 10% of

[112] News release, 18 December 2012. Provincial government receives recommendations on drug insurance plan. Available at: https://www2.gnb.ca/content/gnb/en/departments/esic/news/news_release.2012.12.1197.html.
[113] Statistics Canada Table 11-10-0222-01, *Household Spending, Canada*. Available at: https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1110022201.

Canadians [have] no prescription drug coverage at all and a further 11% [have] limited drug coverage, requiring them to pay for most of their prescription drug costs out-of-pocket (p. 7)."[114]

9. Public drug plans tend to provide drug benefits based on net (after-tax) family income. Using 2017 data, the median after-tax family income of $59,800[115] and the average prescription drug expenditure of $452 (#7 above), the typical household spend 0.76% of net income on prescription drugs. However, that percentage varies by province, workplace, family type and other criteria.

10. The Conference Board of Canada (Sutherland & Dinh, 2017) estimated that 1.8% of Canadians had no drug insurance, about 667,000 people, as of January 2018. Based on catastrophic coverage availability, most of these were thought to be residents of Ontario and Newfoundland and Labrador. However, Ontario's Trillium plan notionally covers everyone with prescription drug costs exceeding about 4% of income.

Another indicator of need is that almost one-quarter (23%) of "sicker" Canadians reported not filling a prescription or skipping a dose due to costs in 2011 (Health Council of Canada, 2011).[116]

In addition to a widely studied and quantified general problem about non-adherence to drug therapy, these studies suggest affordability problems based on people in specific circumstances: (i) those in fair or poor health with certain chronic conditions, (ii) residence in BC (Law, 2012), PEI and NL, (iii) lower income working Canadians without access to drug plans, and (iv) Canadians spending over 3% of after-tax income on prescription drugs.[117]

There have been important changes in generic and brand drug spending levels in recent years so data older than five years may not be sufficiently accurate to estimate current out-of-pocket costs.

These studies measure out-of-pocket and inadequate insurance in different ways and provide mean prescription drug spending estimates of as little as $320 per family (Sanmartin et al., 2014) to perhaps $2,100 (Statistics Canada, 2010). There could be 2.5 million spending over 3% of family income on prescription drugs (Statistics Canada, 2010)

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[114] I note the percentages are reversed between the survey and the subsequent article, but there is only one percent difference between those reported with no coverage and those paying the majority out-of-pocket. The greater issue is using a single proprietary survey with unreported generalization to infer 21% of Canadians have no or very limited drug insurance. Dr. Morgan worked with the ARI and "contributed significantly to the research and analysis of this study (ARI survey cover page)."

[115] Statistics Canada Table 11-10-0190-01. *Market income, government transfers, total income, income tax and after-tax income by economic family type*. Available at: https://www150.statcan.gc.ca/t1/tbl1/en/cv.action?pid=1110019001#timeframe.

[116] The Health Council defined "sicker" Canadians as those with fair or poor self-reported health and who had at least one of seven common chronic conditions.

[117] If the 7.6% figure from 2008 remains accurate in 2019, about 2.8 million Canadians spent over 3% of their net income on prescription drugs.

or perhaps four million who pay the full cost of their drugs (Angus Reid Institute, 2015). Average cost data indicate a fairly narrow issue, but personal experiences at the margins of society and the labour force, and in certain jurisdictions, are likely significant and need action. A worst-case estimate might be 10% of Canadians who are under- or uninsured. This conclusion suggests a targeted approach that includes a national standard of coverage would address the problem of Canadians without any or enough drug insurance. It may also be a more feasible and effective solution and less expensive for governments to fund and implement than a single payer plan.

Regardless, a major need in determining the impact and extent of inadequate drug insurance is current, accurate data from a reputable source.

4.14 Chapter Summary

This chapter reviewed private and social drug insurance in Canada. There is a wide range of plan designs, eligibility criteria and cost-sharing. Protection from catastrophic cost varies widely and is often insufficient. Fragmented governance means there are no national standards and the goal of harmonizing and improving coverage across Canada will be very difficult.

Research indicates a well-designed social drug insurance plan could achieve adequate universal coverage and improve equity, quality, financial feasibility and sustainability.

Costs have also been very difficult to predict, in part because of flawed models and implementation marred by politics. For example, the PBO (2017) report used the Quebec drug formulary as a model plan, eliminating $4 billion in previously paid private drug plan claims by without providing alternative coverage. The messy implementation of OHIP+ created concerns about public administrative competency, lost coverage and political interference in essential health care. The Advisory Council did not address the need for lowering and standardizing out-of-pocket costs and improving protection from catastrophic drug costs. Strangely, neither HESA nor the Advisory Council explored social insurance as an alternative to a single payer drug plan.

Problems and solutions are complex, technical and involve different levels of government, as well as important stakeholders such as insurers, employers, health professionals and patients. Health system performance is weak in Canada relative to other OECD nations, but this appears to be independent of the model. Better governance could help improve performance.

The combination of extremely high-cost gene- and cell-based therapies and a lack of current, complete and well-accepted costing studies for alternatives creates significant

political, financial and reputational risks for governments and present important barriers to action.

Chapter 5

Comparative review of drug insurance in Germany, the Netherlands and Quebec

Research Question 1

Could a social insurance model that includes employer-sponsored private insurance be a more feasible way to achieve adequate universal prescription drug insurance?[118] Feasible means probable, with faster and less disruptive implementation.

a. Social insurance: What are the experiences, characteristics and advantages and disadvantages of drug insurance in Germany, the Netherlands and Quebec and could those jurisdictions provide guidance for a similar universal model across Canada?

Chapter Overview

This chapter compares demographics, the pharmaceutical sector and the social health insurance systems of Germany, the Netherlands and Quebec (drugs only). Each provides a customized variation of social insurance, showing this approach is flexible, even to the point of mixing a social insurance drug plan with a single payer hospital and medical model in Quebec. All three jurisdictions have formalized and regulated roles for private insurers that include risk-sharing vehicles. Funding is not mainly through general taxation, but primarily through employers and citizens with a top-up by the government. Each state includes different levels of provider regulation to manage cost, quality and access to health services. The two European systems also feature active legislative and regulatory changes to protect and optimize the performance of their health systems. Each offers various lessons and cautions for Canada.

5.1 Introduction

> "The phrases "National Health Service" (NHS) and "market forces" both carry powerful ideological overtones that make calm and practical discussion of appropriate principles of organization and management very difficult. Any serious proposal for change in Britain's NHS is sure to be attacked as "an attempt to destroy the National Health Service." Perhaps that is why there has been so little such discussion in public…" (Enthoven, 1991, p. 61).

Enthoven was an important influence behind structural reforms to the UK's NHS in the later 1980s, and in the Netherlands through the Dekker Commission's instrumental 1997

[118] Adequate, universal coverage is defined in Sec 1.5.4: Coverage will be adequate when it provides access to a broad formulary of medicines at an affordable level of out-of-pocket cost according to medical need. Coverage is universal when all Canadians have access to necessary medicines.

report. His concerns apply equally to Canada's historical position on health system innovation and evolution. Our current opportunity to achieve universal drug insurance looks increasingly like a limited set of tactical responses without any overarching system goals and with no improvement in transparency or accountability or governance.

This thesis attempts a "calm and practical discussion" of alternatives to existing programs and governance. Enthoven identified nine structural problems within the NHS.[119]

1. Gridlock: Change is "exceedingly difficult;" health system is "extremely politicized. (p. 62)"

2. Inefficiency: "No serious incentive to make change to improve efficiency. (p. 62)"

3. Perverse incentives: Provinces with better drug plans need less federal funding to meet a national standard. They all want more money, including Quebec which has the best plan.

4. Provider [and funder] domination: "Nobody [has] responsibility to measure and prioritize patients' needs and wants. (p. 63)"

5. Inadequate accountability: Prescribing or dispensing quality is not measured or directed.

6. Capital spending / Management information systems: Inadequate funding meant "the necessary management information systems did not exist. (p. 63-64)"

7. Poor customer service: Provinces and employers make drug plan design, funding and administrative decisions with limited or no structured accountability to patients.

These issues surface in Canada today and will be regularly noted as the German, Dutch and Quebec models are assessed in this chapter.

5.1 Country Overview

Germany, the Netherlands and Quebec will be reviewed to draw important lessons that could allow Canada's drug insurance systems to evolve to provide universal coverage.

Germany provides universal, mandatory drug coverage through self-regulating social insurance funds that compete regionally under the overall supervision of the federal Ministry of Health. Its Federal Joint Committee provides a unique and relevant model to improve drug insurance governance. Its approach to new drug assessments improves timeliness and pricing. Private health insurance (PHI) substitutes for Statutory Health

[119] Overcentralization is not included in my list. Two problems have been combined in point 6.

Insurance (SHI) in three select cohorts amounting to 11% of the population. SHI provides an out-of-pocket cost cap of no more than 2% of income (Schoen et al., 2010). The division between SHI and PHI is contentious, with inequity from different risk-sharing, financing, access and services (Busse & Blümel, 2014, p. 2324).

The Netherlands uses a managed competition model and an active approach to system governance and management. Its health system supports privately-owned but heavily regulated insurers that compete nationally to provide universal, mandated social health insurance. The country has implemented an increasingly rigourous risk sharing model for insurers. In addition to basic SHI over 80% buy complementary PHI for additional coverage.

Both Germany and the Netherlands present two important characteristics distinct from Canada. First and most obvious, their social health insurance provides far more integrated governance and comprehensive coverage – including drugs – than our deep but narrow public coverage of hospital and physician services. Second, both European countries have a long history of corporatist involvement in their health systems. Interest-based organizations (firms, industry and professional associations) outside the government have had important influencing and self-governing roles. That noted, Germany and the Netherlands are different. Advocacy bodies still play important roles in Germany, for example as members of the Federal Joint Committee. Industry and professional groups have also been important in the Netherlands although traditional corporatist bodies that "shared political space" (Tuohy, 2018, p. 105) are being replaced by expert regulatory committees (p. 349-50). The Dutch also benefit from a uniquely collaborative approach to health system modernization which allowed changes to ebb and flow but still progress in a stepwise "blueprint" strategy (see: Tuohy, 2018, Chapter 8).

Since 1997, Quebec has achieved universal access with mandated and relatively generous drug coverage and mild regulation of private insurers. It is the only model of its kind in Canada. Provincial per capita costs are second-lowest (after BC) and cost-related non-adherence to medications is the lowest in Canada (Law et al., 2012). However overall per capita spending is the highest in Canada. Private insurers have their own risk-sharing agreement and report annually to the province. Quebec residents are protected from annual drug costs exceeding $1,117 (2019-20).[120]

[120] See: http://www.ramq.gouv.qc.ca/en/citizens/prescription-drug-insurance/Pages/rates_effect.aspx.

Table 5.1 – Demographic Comparison, Canada, Germany and Netherlands

	Canada	Germany	Netherlands
Population (millions)	35.9	80.5	17.2
Population Growth Rate (%)	0.72	– 0.17	0.38
GDP per capita ($US PPP)	$48,400	$50,800	$53,900
Median Age	42.4	47.4	42.7
Percentage Age 65+	19.1	22.4	19.1
Life expectancy at Birth	82	80.9	81.5
Infant Mortality (Deaths per 1,000 Live Births)	4.5	3.4	3.5

Source: *CIA World Factbook*. Viewed May 18, 2019. Available at: https://www.cia.gov/library/publications/resources/the-world-factbook/rankorder/rankorderguide.html. Most recent data used, generally 2017.

Table 5.2 – Pharmaceutical Industry Comparison, Canada, Germany, Netherlands

	Canada		Germany		Netherlands	
	Value	**Rank**	**Value**	**Rank**	**Value**	**Rank**
Population (millions)	35.9	38	80.5	19	17.2	66
Gross Domestic Product (Trillions, $US PPP)	1.77	17	4.2	5	0.92	27
Industry Employment	28,494		115,663	1	17,900	14 (tie)
Production (millions)	$9,600 (2017)		€29,117	3	€6,180	11
Pharmaceutical Trade Balance (millions)	– $5,500		€24,792	2	€7,410	5
Research & Development (millions)	$920		€6,227	2	€642	10

Notes: Average exchange rate in 2018 was €1.00:CAD1.53 (Bank of Canada, available at: http://www.bankofcanada.ca/rates/exchange/annual-average-exchange-rates/.
Sources: (1) **Population and GDP (2017):** Rankings are world. *CIA World Factbook*. Available at: https://www.cia.gov/library/publications/resources/the-world-factbook/. (2) **Canada:** Industry Canada, *Pharmaceutical Industry Profile*, 2016 data, available at: https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html. Canadian values may not be calculated the same as EFPIA. (3) **Germany** and **The Netherlands**: Data and rankings are from 32 European nations, effective 2016: European Federation of Pharmaceutical Industries and Associations: *The Pharmaceutical Industry in Figures, Key Data,2018* available at: https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf.

5.2 Germany

The key features of the underlying Bismarckian model of social protection has been in place since 1883. Germany then implemented industrial accident insurance (1884), old-age and long-term disability insurance (1889), survivors insurance (1911), and unemployment insurance in 1927 (Bodenheimer & Grumbach, 1992). By 1925, about two-thirds of German workers, mostly blue-collar, were covered (Cutler & Johnson, 2004). Canada uses different models, structures and revenue sources to address pensions, workers' compensation and disability, health insurance and drug insurance specifically.

Germany also has a very important pharmaceutical manufacturing industry (**Table 5.2**), fourth largest in the world and is the fourth-ranked country for clinical trials (IGES Institute, 2018). Its population is also one of the largest consumers of prescription medicines and its drug prices (USD, PPP) rank fifth just behind Canada (OECD Health Statistics, 2018). Among European nations, Germany ranks first in pharmaceutical industry employment, second in research and development expenditures and third in sales revenues.[121]

5.2.1 Financing and Spending Overview

Comparative health system costs between Canada and Germany are shown in **Table 5.3**.

Table 5.3 – Canada and Germany: Health Cost Comparison (2016 and 2017, $US PPP)

	Canada	Germany	OECD Average
Health costs Percent of GDP (2017)	10.4	11.3	8.9
Health costs per capita (2017)	4,826	5,728	4,069
Drug costs per capita (2016)	833	777	577

Source: OECD Health Statistics, 2018. PPP = Purchasing Power Parity

Germany's total health spending was €375.6 billion in 2017.[122] **Figure 5.1** shows the distribution of funding sources, excluding statutory pension insurance of €4.7 billion. The total public share is 74%, the sum of the first four categories.

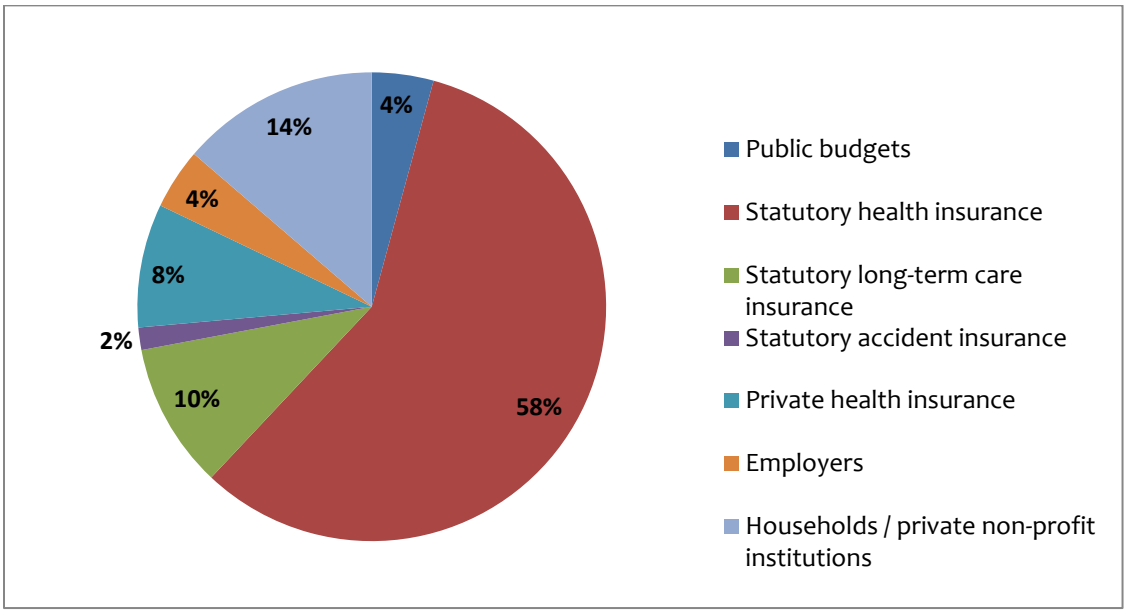
Most social health insurance (SHI, aka sickness funds) revenue is raised through a payroll tax of 14.6% of income (unchanged since January 2015), split equally between employers and employees. Contributions stop once annual income exceeds €54,450 (2019), meaning the effective contribution rate declines as income increases above that threshold. Individual funds are permitted to set a supplementary income-based surcharge for members, which was 0.9% of income on average in 2017.[123] Long-term care coverage is also mandatory at extra cost and employer subsidized. Residents of the employee's home are included in the employee rate. Patients pay coinsurance of 10% for prescription drug costs, with a minimum of €5 and a maximum €10 per script. There is a €10 charge for the first physician or dentist visit each quarter. Hospitals charge €10/day for up to 28 days of in-patient care.

[121] European Federation of Pharmaceutical Industries and Associations, 2018. *The Pharmaceutical Industry in Figures, Key Data 2018*. Available at: https://www.efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf.

[122] Statistisches Bundesamt, 2019. Table 23611-0001, Health expenditure: Germany, years, sources of funding Available at: https://www-genesis.destatis.de/genesis/online/data;sid=0FCA45F48DE7B43755FB80900AE2CC87.GO_2_1.

[123] Association of Private Health Insurers (Verband der Privaten Krankenversicherung, PKV). See: https://www.pkv.de/service/zahlen-und-fakten/rechengroessen-der-pkv-und-der-sozialversicherung/. Google Translate.

Figure 5.1 – Health System Funding, Germany 2017



Source: © Statistisches Bundesamt / Federal Statistical Office, Wiesbaden 2019. Table 23611-0001. April 2019.

While Canada had lower drug costs than Germany until 1997 (**Table 5.4**), our drug costs have been higher ever since, peaking at 21% higher in 2006 and running at 7% higher over the last three years where data is available for both countries (2014-16). Overall private health insurance spending is somewhat larger in Canada at 12.4% (CIHI, 2018) versus 7% for Germany (OECD, 2015). Public funding is also similar, at 73% for Germany (Busse & Blümel, 2015) and 69% for Canada (CIHI, 2018a).

Table 5.4 – Ratio of Canada (CA) to Germany (DE), Drug and Medical Non-durables and Health Costs. 5-Year Bands, Cost per capita, $US PPP.

	1985	1990	1995	2000	2005	2010	2015
CA / DE Drugs	0.62	0.78	0.97	1.05	1.18	1.18	1.07
CA / DE Health	0.88	0.96	0.89	0.89	0.99	0.96	0.87

Source: Author's calculations based on OECD 2018 Health Statistics.

5.2.2 Insurance Market

Since 2009, hospital, medical and dental insurance has been mandatory except for public sector workers and retirees, the self-employed and those with incomes exceeding €60,750 (2019).[124] These three exception groups have private health insurance (PHI). Citizens may be

[124] For reference, the average annual wage in Germany is almost identical to Canada at about $47,600 (2017, USD, PPP). Available at: https://data.oecd.org/earnwage/average-wages.htm.

covered by both SHI and PHI plans and residents use the same hospitals and physicians. Ninety percent of the population is enrolled in a social insurance plan.[125] Also in 2009 the government made SHI funds responsible for negotiating prices, quantities and provider quality assurance (Busse & Blümel, 2014). The 110 (2017[126]) non-profit public health plans (*Krankenkassen*) compete regionally but all charge the same premiums through payroll deduction. All plans are regulated (Schneider, undated)[127] and must meet minimum coverage standards, although some variation is allowed beyond that.[128] Reforms introduced in 2015 were to improve service and care quality.

PHI offers somewhat broader services and pays providers higher rates (OECD, 2017a, p. 7). PHI can provide complementary or substitutive coverage. In 2017, PHI was offered through 41 insurers, and covered 11% (8.75 million) Germans.[129] Private plans cover physicians, private hospital rooms, vision care, homeopathy and other alternative treatments, and provide more dental coverage. They are risk-rated (underwritten) only at the onset of coverage but must accept all applicants regardless of health status. Insurers must set aside reserves to offset the costs that come from aging.

Busse and Blümel (2014) note "substantial problems" (p. 265) from the co-existence of SHI and PHI. Inequity occurs because only citizens in the three exception groups may opt for private insurance, and they tend to be younger, healthier and wealthier than those with SHI. Over time, this would tend to accelerate cost increases in the SHI risk pool. However, this negative effect is somewhat offset by the fact those with higher incomes also pay more income tax, and general tax revenues provide a share of health system funding (**Figure 5.1**).

5.2.2.1 Risk Sharing

Germany uses a model including age, sex and the prevalence of 80 chronic and costly diseases to prospectively set sickness fund compensation. There are two goals for the morbidity-based risk-adjustment scheme. The first is to discourage cream-skimming. The second is to promote competition based on service quality, especially for patients with chronic conditions.

[125] National Association of Statutory Health Insurance Funds (GKV Spitzenverband). Available at: https://www.gkv-spitzenverband.de/english/statutory_health_insurance/statutory_health_insurance.jsp.
[126] National Association of Statutory Health Insurance Funds (GKV Spitzenverband). Annual Report 2017, Annex. Available at: https://www.gkv-spitzenverband.de/media/dokumente/presse/publikationen/geschaeftsberichte/GKV_GB2017_english_barrierefrei_final.pdf.
[127] Regulation is comprehensive and covers: (i) prices, (ii) underwriting, tariff switch and termination, (iii) premium and reserve calculations, (iv) premium adjustment, and (v) use of profits.
[128] Note German public health plans include disability benefits of 70% of wages (before deductions) for up to 78 weeks after the typical employer covers 100% of pay for the first six weeks of disability.
[129] Association of Private Health Insurers (Verband der Privaten Krankenversicherung, PKV). See: https://www.pkv.de/verband/ueber-uns/. Google Translate.

Risk adjustment was first introduced in 1994 and 1995 based on age, sex, disability, income levels and number of dependents, and was specific to each sickness fund. Refinements implemented in 2001 focused on morbidities, the incentives for disease management programs, and prohibiting cream-skimming (risk selection by insurers). Then in 2009, risk adjustment was pooled for all sickness funds across the country (Busse & Blümel, 2014).

5.2.3 Drug Price Regulation

Several legislative levers used to control drug prices are in **Table 5.5** (Busse & Blümel, 2014).

Table 5.5 – Recent Health Legislation in Germany affecting Prescription Drugs

Year	Act / Action
1989	Reference pricing introduced (Henschke, Sundmacher & Busse, 2013).[130]
1993	Health Care Structure Act
1998	Act to Strengthen Solidarity in Statutory Health Insurance [SHI]
2001	Pharmaceutical Budget Redemption Act
2002	Pharmaceutical Expenditure Limitation Act
2004	SHI Modernization Act
2006	Act to Improve Efficiency in Pharmaceutical Care
2007	Act to Strengthen Competition in SHI
2010	SHI Reform Act
2011	Act on the Reform of the Market for Medicinal Products (AMNOG)
2017	Statutory Health Insurance Medicinal Product Supply Improvement Act (AMVSG)

The comparison is dramatic with Canada. Our federal government is armed only with the Canada Health Act (1984) and one section of the Patent Act (Sec. 79-103) under which the PMPRB operates. Established in 1987, the PMPRB was proposing its first new strategy only in 2015 (PMRPB, 2015a). Each province has separate health legislation, some specific to drug plans such as Ontario's Drug Interchangeability and Dispensing Fee Act. It was the provinces that led with the pCPA to force down the prices of new patented and existing generic drugs.

[130] According to Henschke et al., patented medicines were originally included in reference pricing along with their approved generic or therapeutic substitutes. In 1996, patent drugs were excluded to encourage innovation, but then included again in 2004 because so many "me-too" drugs (those without clear additional benefits) had been introduced.

Generic penetration in Germany has increased rapidly to second highest in the world by value – 76% in 2016, versus 74%. Canada was ranked third (PMPRB, 2018b. Fig. 1.4). However, generic drug prices in Germany were much lower, just 74% of those in Canada, on average (PMPRB, 2018b. Fig 2.6). Since 2004, OTC drugs in Germany have been excluded from coverage.

Germany has regulated drug prices and costs in five ways (Busse & Blümel, 2014).

1. *Standard Rebates* must be paid to social insurers. Since April 2014, drug manufacturers have paid rebates of 7% for patented drugs not subject to reference pricing and 6% for off-patent drugs (Busse & Blümel, 2014). Pharmacies also pay a rebate to the insurers of €1.77 per prescription, which amounted to a discount of about 4% overall (Busse & Blümel, 2014). In addition, each insurer can negotiate its own rebates in exchange for exclusive listing on its formulary. Busse and Blümel (2014) reported the legal and mandatory manufacturers' rebates, and those negotiated by individual insurers, were each worth about 8% off the list price in 2012. These rebates are often not reflected in German list prices for drugs and so overstate the price paid for the drug as well as total expenditures when quoted in international comparisons.

2. *Price Freezes* apply to all drugs at 2009 price levels until 2022. Starting in 2018, annual increases for inflation have been allowed.[131]

3. *Reference Prices* have been set by the FJC since at least 1989 and are defined as the upper limit of a drug's price that will be paid by the insurer to the pharmacy. Since 2004, all generic drugs and patented medicines that provide no additional therapeutic benefit over existing products are included in reference price groups. Patients pay any extra cost and flat co-pays when their drug price is less than 30% below the reference price. Few drugs are sold above the reference price due to competition and because physicians are legally bound to inform patients of their out-of-pocket cost. Novel patented drugs with additional therapeutic value are not subject to reference pricing (Gress et al., 2007).

   Additional therapeutic value over existing products is decided by the FJC and defined as "improved health status or quality of life; reduced duration of illness or side effects; extended length of life" (Henschke, Sundmacher & Busse, 2013. p. 266). The degree of additional benefit is considered in the price negotiation between the manufacturer and the Federal Association of Statutory Health Insurance Funds. The Association of Private Health Insurers attends these negotiations as an observer. By the end of 2017, 337 products with additional benefit had been through the FJC evaluation and rebates had

[131] Ministry of Health, Germany. See: https://www.bundesgesundheitsministerium.de/preismoratorium.html. Translated using Google Translate.

been set for 161 of them, mostly through negotiation. [132] Between 2012 and 2016, €2.85 billion was saved through price rebates.[133]

4. *Reimbursement Limits* were first negotiated between 2007 and 2010 for new drugs not subject to reference pricing. To avoid the price ceiling, the manufacturer had to: (i) establish product development costs, (ii) that the drug was cost-effective, and (iii) that it had no alternative treatment. Additionally, SHIs considered "the suitability and reasonableness of having the insured community take on the costs of reimbursement" (Busse & Blümel, 2014, p. 211). After 2011, drug manufacturers set the price for drugs containing new active substances for the first year while it is being reviewed for additional benefit.

5. *Provider Tactics* include (i) limits on physician "no substitution" orders, (ii) periodic spending caps and incentives for physicians to prescribe within a defined budget limit (5%, 10% or 12.5% of target), and (iii) an obligation (between 2002 and 2008) by pharmacists to sell less expensive drugs from other countries if the price difference was at least €15 or 15%.

   Regarding physician interventions, Barnieh et al. (2014) in their review of 34 OECD members reported that Germany and five other countries have introduced compulsory prescribing guidelines for physicians.[134] Ten other nations have non-compulsory guidelines, including the Netherlands. Physician prescribing patterns and volume are monitored in 19 countries, often with peer benchmarking. Four countries have introduced incentive rewards for physicians, and three have penalties directed at physicians who over-prescribe. Canada had no regulation of prescribing. In Canada, the Advisory Council (2019b) proposed a national strategy on appropriate prescribing focusing on "prescribing guidelines, assessment, feedback and tools" (p. 80).

   Busse and Blümel (2014) report a variety of approaches to impose drug spending caps on physicians, starting in 1993. Controls started at the regional level (1993-1997), were abolished in 1998, reintroduced in 1999 with individual targets, abolished again in 2001 but replaced with non-compulsory targets. Since 2000, each physician has been given a cost-focused report showing his or her prescribing behaviour relative to others in their region. Physicians are regularly audited and those shown to prescribe off-label (for unapproved uses) and outside the social insurance formulary are penalized. Each wave of controls succeeded in redirecting prescribing to better and less expensive drugs, including generics.

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[132] As of March 13, 2020, this link is broken. National Association of Statutory Health Insurance Funds (GKV Spitzenverband / GKV-SV). Available at: https://www.gkv-spitzenverband.de/english/statutory_health_insurance/amnog_evaluation_of_new_pharmaceutical/amnog_english.jsp.

[133] GKV-SV. *Focus: AMNOG negotiations*. Google Translate used. Available at: https://www.gkv-spitzenverband.de/gkv_spitzenverband/presse/fokus/amnog_verhandlungen/s_thema_amnog_verhandlungen.jsp.

[134] According to Gress et al. (2007), German insurers could not at that time exclude any prescriber that serves one of their plan members, so insurers had no influence on prescribing quality and costs.

Physicians are assigned an individual medicines budget based on prescribing data for similar patients. When their budget is exceeded by 15% physicians are investigated and told to prescribe less. Physicians may be liable for overspending if their budget is exceeded by 25% or if they prescribe drugs outside FJC guidelines. Physicians may also incur fee penalties or be required to undertake training on selecting more economical drugs if they over-prescribe certain therapeutic classes (IGES Institute, 2018).

Since 2004, the FJC can exclude drugs if clinical effectiveness has not been demonstrated. Otherwise, once approved by the FJC, all drugs must be reimbursed by all insurers (Gress et al., 2007).

Germany has a unique practice of providing reference drug reviews and prices. This transparency policy has broad effects because so many countries, including Canada, use Germany as a reference country for their own pricing reviews.[135]

5.2.4 Opportunities for Canada

Two key features of the German system have potentially high value to Canada:

1. Governance authority, structure and principles
2. New drug assessment, including reference pricing

5.2.4.1 Governance authority, structure and principles

Similar to Canada, Germany is a federation of 16 jurisdictions, including three city-states. Unlike Canada, its health system is controlled by the national government through the federal Ministry of Health.[136] The health system includes an explicit goal of social solidarity and has been defined by its self-governing health institutions (Busse, Blumel, Knieps & Barnighausen, 2017). It has similar challenges to other OECD countries, i.e., how to ensure access and control costs.

The Ministry of Health supervises the Federal Joint Committee (FJC; formally the G-BA – *Gemeinsamer Bundesausschuss*) which was established in 2004, as well as national associations for social insurance funds (GKV-SV), physicians (KBV) and the hospital association (DKG). The Ministry audits resolutions and directives passed by the FJC. To increase transparency and accountability, many must be published in the Federal Gazette before they take effect.

[135] The price list is in German at: https://www.dimdi.de/static/de/amg/festbetraege-zuzahlung/festbetraege/index.htm.
[136] An organization chart showing accountabilities is here: https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/G/Gesundheitssystem/German_Health_System.pdf.

Other members of the FJC are the IQWiG, the Institute for Quality Assurance and Transparency in Health Care (IQTIG), and the national association of statutory health insurance dentists (KZBV). The FJC and institutional associations are all private, not-for-profit and self-governing, an important principle within the German health system.

On behalf of 73 million insured persons, the FJC determines SHI benefits, is responsible for inpatient and outpatient quality, and makes final decisions in the self-governance of physicians, dentists, hospitals and health insurance funds in Germany.[137] This non-arm's length relationship at the highest operating level of the health system must balance the public interest with the proprietary interests of its members.

There are 13 voting (Plenum) members including the Chair and two other salaried impartial members who are proposed by member organizations and approved by Parliament. In addition, there are two members each from the hospital and physician associations, one dentist and five others representing the statutory insurers. Care providers vote only on topics within their area of expertise.

Five non-voting patient representatives participate in all Plenum discussions and submit petitions, and more than 100 other patient representatives are involved in various subcommittees and working groups. The Plenum typically meets twice a month in Berlin and sessions are open to the public.[138] Three committees focus on rules and procedures, finance and innovation. There are nine sub-committees.[139]

Six other groups participate in the Plenum and are involved in at least one of the sub-committees:

1. Two members represent the 16 states in the needs planning sub-committee;
2. One member from each of the professional associations of physicians and nurses and the private health insurer federation sit on the quality assurance sub-committee; and
3. Dental and psychotherapy professional association members are engaged on quality assurance matters that concern these two professions.

The pharmaceuticals sub-committee includes three hospital and physician representatives, plus six from the statutory health insurance funds. Since 2011, the Institute for Quality and Efficiency in Health Care (IQWiG) has assessed the benefits of new medicines on behalf of the FJC.

[137] Source: http://www.english.g-ba.de/.
[138] Source: http://www.english.g-ba.de/downloads/17-98-2804/2018-12-04_G-BA_Flyer_Der_Gemeinsame_Bundesausschuss_EN_bf.pdf.
[139] The nine sub-committees are: pharmaceuticals, quality assurance, disease management programs, highly specialized outpatient care, method evaluation, ordered services, needs planning, psychotherapy and dental treatment.

5.2.4.1.1 Application to Canada

Relative to Canada, the FJC includes a higher level of professional and public participation and transparency in health system planning. Its self-governing institutional structure is completely novel relative to Canada's public structure and oversight. Its explicit principle of solidarity is only implied in the Canada Health Act's equal treatment for Canadians accessing hospital and physician coverage. However, when Canadian patients need additional health and social services, solidarity is violated because such services are fragmented according to where you live or work, your age, whether you are covered by a Workers' Compensation Board, or perhaps by what health condition afflicts you. Medicare here runs deep but is very narrow in its scope of covered services relative to Germany.

The current interest in national pharmacare is an opportunity to experiment and engage citizens in system improvements. The FJC model suggests establishing a multi-stakeholder Plenum to inform and coordinate key stakeholders in ongoing drug policy and programs. A Canadian "Medicines Advisory Council" (MAC) could include physicians, pharmacists and patient representatives, as well as business and labour leaders, health insurers and provincial drug program leaders. The pharmaceutical industry – brand and generic – could have observer roles. If additional participation, transparency and better policy and programs work with drug policy, the idea could be expanded to inform other health areas such as long-term care or community care.

The breadth of stakeholder engagement in a new MAC could counter-balance political interference in drug insurance operational decisions. (This was a concern of three research participants – see Chapter 6) Open meetings would help engage and educate Canadians, especially if they were broadcast online or if Minutes were published. That public-facing posture would help ensure Plenum members actively consider the public interest, which could be included in their Terms of Reference. The Plenum could advise the jurisdictions on such matters as strategic planning including development of national standards, formulary management, system integration, finance and budgets and program delivery and evaluation.

Oversight of the MAC could be provided by the Council of the Federation's Health Care Innovation Working Group which is currently comprised of provincial and territorial Ministers of Health. An alternative mechanism would be through the new Canadian Drug Agency or a new dedicated committee of F/P/T Ministers of Health.

Politicians willing to consider any major change in drug insurance need to ensure adequate public support (Kingdon, 2011, p. 146-49). The MAC should be mandated to improve public awareness and confidence in drug system management. One study of print media indicated public engagement in health services is limited, flaring only when specific initiatives ("focusing events") are underway such as Royal Commissions (Daw, Morgan, Thomson & Law, 2013). Even then, interest can fade rapidly.

Going to the source of prescribing is a bold and important initiative that has not been tried in Canada. It would no doubt be very contentious. Physicians drive costs for drugs,

diagnostics, hospital procedures, access to other professionals and to other services. There is a plethora of prescribing guidelines developed by expert panels but training on new drugs ("detailing") is mostly provided by drug manufacturer sales representatives. The Advisory Council (2019b) noted some jurisdictions use trained health professionals to provide prescribing evidence to physicians (p. 79). No comparative information is provided to Canadian physicians on their prescribing relative to similar peers, and drug prices are not readily available. Patients don't know out-of-pocket costs, an important factor in mitigating cost-related non-adherence. While prescribing and dispensing controls may be intrusive to self-regulating professional associations, national pharmacare presents a rare opportunity to monitor and improve prescribing, dispensing and adherence behaviours.

5.2.4.2 New drug assessment

Germany has a more structured process for evaluating and approving new drugs than Canada. While regular changes have been made to its laws and regulations (**Table 5.5**), some of the most important occurred when the *Arzneimittelmarkt-Neuordnungsgesetz* (translated as the Act on the Reform of the Market for Medicinal Products[140] and abbreviated as AMNOG) was enacted on January 1, 2011. According to the GKV-SV, AMNOG's stated goal is "to limit the cost of pharmaceuticals."[141] Important differences are summarized in the following 13 steps and then compared to Canada in **Table 5.6**. Several points in this list are from Wenzl and Paris (2018). Others are from the GKV-SV.

1. New drug prices are set by the manufacturer for the first year, and are then adjusted by the FJC according to its determination of additional value.

2. Germany automatically excludes certain drug types (e.g., over the counter, lifestyle, herbal remedies, treatments for minor illnesses) in a "negative" formulary.

3. On behalf of the FJC, IQWiG[14] (usually) assesses the additional value of new drugs to patients relative to existing comparators ("early evaluation"). The comparators are determined by the FJC. Drugs with sales less than €1 million (~$1.5 mm) are not evaluated. This work must be completed within three months following market launch. IQWiG has six added-benefit categories (major, considerable, minor, non-quantifiable, added benefit not proven and less benefit) and also assesses the probability of the additional benefit (proof, indication or hint).

4. The FJC then has three months to decide on the added benefit (until month 6). It can also commission reviews of existing therapies already on the market in order to establish the added value of a new drug.

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[140] Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG), 2018. *In a nutshell, Facts and Figures from IQWiG 2018*. Available at: https://www.iqwig.de/en/press/media-centre/flyers-annual-reports-and-brochures.7357.html.
[141] GKV-SV, *AMNOG – evaluation of new pharmaceutical* [sic]. Available at: https://www.gkv-spitzenverband.de/english/statutory_health_insurance/amnog_evaluation_of_new_pharmaceutical/amnog_english.jsp. As of March 13, 2020, this link is broken.

5. If there is no added value, the new drug price is set according to a reference group, if one exists, containing at least three therapeutically similar medicines already on the market. The price of a new drug with no added benefit is capped at the price of the lowest cost alternative. If there is no reference group, the new drug's price will be the same as the alternative drug. The difference between the manufacturer's price and the market price is a negotiated rebate ("refund rate") or a supplement relative to existing comparators.
    - Reference pricing applies to 34% of drugs, 80% of prescriptions and 33% of drug spending, and
    - Most drugs (84%) in a reference group are priced at or below the limit (about the 30th percentile) set by the social insurer association (GKV-SV) and so avoid any patient cost-sharing (Robinson, Panteli & Ex, 2019).
    - Reference drug prices are public and updated bi-weekly by the *Deutsche Institut für Medizinische Dokumentation und Information* (DIMDI).

6. If there is added value, then a price supplement over less effective comparator(s) is negotiated between the GKV-SV and the manufacturer. This process can take no longer than six months (month 12).

7. If there is no agreement between the parties, then the price is set through arbitration no more than three months later (month 15). If the manufacturer does not like the arbitration price they may withdraw their drug. As of December 31, 2017:
    - Historically the price of between 15% and 20% of new drugs is determined by arbitration.[142] Another 13% settled the price after arbitration had been initiated.
    - About 20% of new drugs since 2011 (N=29) were withdrawn from the German market because the manufacturer did not get an acceptable price. Of this group 40% decided immediately following the FJC assessment; 55% were withdrawn once the price had been decided, and one drug was not sold in Germany because its manufacturer went bankrupt.
    - On average, arbitration favours payers. It reduced new drug prices to 20% below the mid-point between the initial manufacturer and social insurer prices (Wenzl and Paris, 2018).

8. The drug price may vary according to the condition it treats, i.e., higher for one indication than another for which the value is deemed less. This is called indication-based pricing.[143]

[142] GKV-SV, 2018. *Self-government for the future, Annual Report 2017*. p. 65. Available at: https://www.gkv-spitzenverband.de/english/statutory_health_insurance/statutory_health_insurance.jsp.

[143] See: Kaltenboeck A, PB Bach, 2018. Value-based pricing for drugs, Theme and Variations. *Journal of the American Medical Association* June 5. 319(21): 2165-66.

9. Drug prices, including rebates or supplements, apply to the entire market – social and private insurance, and out-of-pocket.

10. Drugs dispensed in hospitals are separately negotiated by the hospital, a hospital chain or a group purchasing organization. Hospitals cannot pay more for an outpatient drug than the FJC allows.

11. Orphan drugs (drugs for rare diseases) are automatically listed once the product has been approved by the FJC. If annual sales exceed €50 million (~$75 mm) then IQWiG will formally evaluate the orphan drug in the same way as non-orphan drugs.

12. Manufacturers must provide a 7% discount off the ex-factory price of non-reference drugs to social insurers. Generic drugs not in reference clusters have a 6% discount plus up to 10% more. Most generic drugs are tendered by individual insurers (IGES Institute, 2018). Total drug discounts are about 16% of the pharmacy retail price.

13. Insurers may negotiate the price of a drug lower than the price negotiated by the GKV-SV but this applies almost always to generic drugs.

5.2.4.2.1 Application to Canada

Since 1987, Canada's PMPRB has attempted to control patented drug prices primarily by comparing them to prices in a basket of seven other countries, including Germany. A complicated set of reforms to the PMPRB mandate and operations was proposed in 2016 aimed at lowering drug prices. Changes announced in August 2019 will take effect on July 1, 2020.[144] The new PMPRB11 includes Germany and the Netherlands.[145]

Drug manufacturers argue that these changes will likely slow the introduction of new drugs[146] or deter manufacturers from selling them in Canada.[147] PMPRB reforms do not consider patient perspectives and its new cost-effectiveness review may duplicate health technology assessment (HTA) already done by the Canadian Agency for Drugs and Technology in Health. CADTH procedures include patient input. The new Canadian Drug

[144] Norton Rose Fulbright, August 13, 2019. See: *Pharma in Brief*, available at: https://www.pharmainbrief.com/2019/08/government-releases-final-amendments-to-the-pmprbs-patented-medicines-regulations-to-lower-the-prices-of-patented-medicines/?utm_source=Mondaq&utm_medium=syndication&utm_campaign=View-Original

[145] The PMPRB7 are the seven comparator countries currently used by the Patented Medicine Prices Review Board: US, UK, Germany, Italy, Switzerland, France and Sweden. The PMPRB11 drops the US and Switzerland and adds Australia, Belgium, Japan, the Netherlands, Norway and Spain.

[146] EY, 2019. An assessment of Canada's current and potential future attractiveness as a launch destination for innovative medicines. Innovative Medicines Canada. Available at: http://innovativemedicines.ca/wp-content/uploads/2019/02/2019_01_29_-IMC_PhRMA_LaunchSequencing_vFINAL3.pdf.

[147] Innovative Medicines Canada, 2019. *Annual Report 2018*. Available at: http://innovativemedicines.ca/wp-content/uploads/2019/01/2018_IMC_Annual_Report_EN_PublicWeb_Final.pdf.

Agency proposed in the 2019 federal Budget and by the Advisory Council (2019b) may create a single HTA process.

External price referencing was innovative in 1987 but is far less useful now because many countries negotiate the prices of new drugs and those outcomes are confidential. That makes it very difficult to accurately estimate net, currency-adjusted prices for the same drug in foreign markets. Drug manufacturers may inflate their "asking" prices for new drugs knowing price negotiations will follow (Henschke, Sundmacher & Busse, 2013). The pCPA's price negotiation does not benefit taxpayers who are private plan beneficiaries or patients who must pay out-of-pocket. In fact, it may harm many taxpayers by encouraging drug manufacturers and pharmacies to resist discounting and maintain higher product and service prices for private payers, including patients with no insurance, to offset the discounts given to governments.

Germany's approach may, but not always, provide potential advantages to Canada. Its national system is simpler, more consistent and more efficient to manage than our "patchwork" of public and private drug plans. Both Canada and Germany allow a higher price for a new drug only if it provides a clinical improvement over existing therapy.[148] However, the PMPRB still allows new patented drugs with minimal or no improvement over existing products to be priced at the top of the therapeutic class (PMPRB, 2015a).

While drug prices in Germany are high, OECD drug cost comparisons include Value Added Tax which is 19% in Germany. (GST does not apply to prescription drug sales in Canada.) The PMPRB excludes VAT from its comparisons.[149] In 2016, drug costs were almost 22% lower in Germany (PPP US$653 net of VAT, versus US$833) than in Canada, equivalent to a difference of $7.5 billion in that year.[150] Germany's GDP per capita is 11% higher than Canada's (**Table 5.1**), suggesting greater overall affordability in Germany. Germany's lower drug costs occur alongside a much more significant drug manufacturing industry, the fourth largest in the world. Perhaps Germany does a better job balancing cost controls on drug spending with investments in innovation and the biotechnology sector. They have certainly introduced more legislation to actively manage their health and drug spending than Canada (**Table 5.5**).

Germany's health system draws criticism for high prices, over-service in the hospital sector and poor integration of ambulatory and inpatient care, as well as primary and specialized care (OECD, 2017a). Germany and Canada share many concerns related to efficiency and equity. The continued split of sickness funds and private insurance for higher earners argues against solidarity even though most (75%, according to Blümel & Busse, 2016) of those who qualify for private insurance continue under social insurance.

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[148] PMPRB, 2018. *Guidance document on changes to the Guidelines*. Available at: http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1376#a.

[149] Personal communication, Elena Longu, Manager, Policy Development, PMPRB, April 20, 2019.

[150] OECD cost comparisons include prescribed and over-the-counter medicines and other medical non-durables, not just prescription drugs.

Considering the Enthoven quotation that began this section, changing a health care system, or even one part of it, is fraught with challenges including the potential loss of current coverage even if that protection is inadequate. Yet this current opportunity to introduce national pharmacare could encourage a better overall universal health care system. Some characteristics and tactics of the German system bear consideration.

1. Germany controls a **new drug's price** mainly by assessing its added benefit to patients. Efficiency and quality matter more than cost containment (Busse, Blumel, Kneips & Barnighausen, 2017). "Additional benefit" is defined as improvement in health or quality of life, reduced duration of illness or side effects, or longer life (Henschke, Sundmacher & Busse, 2013). Indication-based pricing may also provide a way to ensure better value. This review of comparative effectiveness sidesteps the lack of transparency in international prices and provides an essential patient focus. The drug's price is a second-level and minor consideration (Lauenroth & Stargardt, 2017).

2. **Rebates** were estimated to reduce the price of new drugs in Germany by 20% on average, with greater savings on drugs that offered no additional benefit.[151] As with Canada's pCPA, rebates have been applied only to drugs assessed since the inception of the FJC.

3. **Reference pricing** is far more extensive in Germany, applying to 80% of prescriptions. The FJC establishes a single negotiated or reference price for new drugs that applies to all patients: no German will pay more than another. One insurer-sponsored study estimated reference pricing saved social insurance funds €9.9 billion in 2017, roughly 25% of the €39.9 billion prescription drug bill in that sector.[152] Setting new drug prices based on existing comparator/reference products (internal market pricing) also seems more practical than using retail prices that do not reflect confidential price rebates. Three older Canadian studies noted reference pricing used for certain drug classes in British Columbia had no statistically significant effects on physician visits or hospitalization (Lee et al., 2012, Table 3).[153] In BC, eight drug classes have internal reference pricing.) Reference pricing is effective at controlling cost without a material effect on health (Law (2018, in Sec 5.1.4)

4. Most drug **prices are transparent** in Germany which contrasts to Canada (and virtually all other countries) where a negotiated price is confidential. Canada requires biosimilar and generic drug prices to be public and proposed PMPRB changes will enable it to collect price information on patented drugs net of rebates.

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[151] Grubert N, 2018. German health insurer call for tougher pharmaceutical cost-containment policies. Available at: https://www.linkedin.com/pulse/german-health-insurers-call-tougher-pharmaceutical-policies-grubert/. Grubert references the *Arzneiverordnungs-Report 2018* provided by AOK, the largest statutory insurance fund in Germany. That report is available only in German: https://aok-bv.de/presse/pressemitteilungen/2018/index_21055.html.

[152] Ibid. Grubert, 2018. Savings were somewhat less (25% vs. 33%) than cited by Robinson, Panteli and Ex (2019).

[153] The three Canadian studies were excluded in the latest Cochrane Review (2014) because they did not have two intervention and control sites (p.25). See: https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD005979.pub2/epdf/standard.

5. The explicit **timelines** for each part of the new drug evaluation process are an advantage in Germany. Since most new drugs take a year or more to reach their sales potential, this doesn't give away much to drug manufacturers. Predictability and generally faster access benefits both patients and manufacturers. One industry study noted Canada ranked 15th of 20 countries in the time between market launch of a new drug and public plan reimbursement (T=449 days, or about 15 months). Germany ranked second (about 120 days). The study average was just under one year (353 days).[154]

6. Once a drug for a **rare disorder** is determined to be safe and effective by the European Medicines Agency it is immediately accessible by patients which can help build real world evidence faster than the DRD regulatory void that remains in Canada.[155] A DRD is fully assessed only when sales become a material amount (€50 million).[156] It is not clear which approach is more appropriate: Canada requires HTA which delays access, but Germany provides access without ensuring added health benefit for the patient.

7. **External reference** country comparisons are less prominent in Germany than in Canada. Set discounts to drug and pharmacy prices and the deferral of a cost-benefit analysis until after the arbitration award[157] may tempt drug companies to inflate their asking prices in Germany. Ruggeri and Nolte (2013) reported in their study of 24 EU countries plus Norway that 13 countries in 2012 included Germany as an external reference country which means that prices in Germany have an indirect effect on prices in those other countries. Germany's high per capita drug costs – second in Europe only to Switzerland – tends to increase the composite reference price in those other countries. Put another way, for every €1 of lower prices in Germany, drug prices dropped €0.15 in Austria and €0.36 in Italy (Stargardt & Schreyögg, 2006).

8. The **Federal Joint Committee** could be adapted to improve governance in Canada. The Advisory Board (2019a) spoke of greater participation in governing national pharmacare. The final report (2019b) notes only that the board of the new Canadian Drug Agency should include patients and the public (p. 68). This is a minimalist start and public members will be dwarfed by provincial and federal appointees. Including other stakeholders, especially insurers, employers and patients, becomes more crucial if private drug insurance continues. Supporting sub-committees can represent the important interests of prescribers, pharmacy, labour and drug manufacturers if they are excluded from the main "Medicines Advisory Council." MAC deliberations ought to occur in a similarly open way. The MAC may also help Canadians better understand, sustain and future-proof their drug insurance system.

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[154] *Access to new medicines in public drug plans: Canada and comparable countries*. *2016 annual report.* IMS Health data were used and 4 of five authors were employed by IMS Health. Available at: http://innovativemedicines.ca/wp-content/uploads/2016/05/20160524_Access_to_Medicines_Report_EN_Web.pdf.

[155] The 2019 federal Budget proposed funding DRDs in 2022 and the Advisory Council (2019b) proposed a new national strategy for DRDs.

[156] This is similar to Canada's proposed PMPRB regime where more intense evaluation occurs if a drug is expected to generate sales greater than $20 million. This is one of the Category 1 criteria.

[157] Op cit. GKV-SV. *AMNOG - evaluation of new pharmaceutical* [sic]. As at March 13, 2020, this link is not working.

Table 5.6 – Comparative Drug Access Features, Canada and Germany

	Canada	Germany
Process to access drugs	Federal and each province; separate for each private insurer	Federal with state input. FJC determines added benefit of new drugs or indications, comparators, net price, patient eligibility
Regulatory structure	All regulatory bodies are controlled by governments.	Self-governance overseen by Minister of Health
Initial review of new drugs	Health Canada	European Medicines Agency (EMA)
Time limits on review	No	Yes
Health technology assessment	CADTH recommendation to pCPA. INESSS to RAMQ. Cost-effectiveness research used. Insurers/PBMs: limited economic review on some new drugs.	IQWiG provides recommendation to FJC. Comparative effectiveness research can be used.
Drug price limit and negotiation	PMPRB first determines a "non-excessive" price based on 7 comparator nations, then pCPA negotiates public plan price. Some insurers negotiate prices of selected drugs. Drug prices vary by jurisdiction and payer, including hospitals and WCBs.	Second-level, price review based on 15 countries.[158] GKV-SV negotiates national net prices but individual funds may sometimes negotiate a lower price. New drugs are not evaluated if expected sales are < €1 million.
Assessment of patient value (added benefit)	Implied for public plans. CADTH allows patient input. Not done for private plans except in actively managed formularies.	Key, explicit and patient-centred: Improved health or quality of life, reduced duration of illness or side effects, or longer life.
Arbitration	None. pCPA decision is final.	Yes, with 3-month limit on process

[158] The 15 countries are: Austria, Belgium, the Czech Republic, Denmark, Finland, France, Greece, Ireland, Italy, the Netherlands, Portugal, Slovakia, Spain, Sweden and the United Kingdom. **Source**: https://www.gkv-spitzenverband.de/english/statutory_health_insurance/amnog_evaluation_of_new_pharmaceutical/amnog_english.jsp. As at March 13, 2020, this link is not working.

	Canada	Germany
Reference pricing	BC only since 1995. Applies to eight drug classes	Since 1989, default for all new drugs unless added benefit proved. Reference and generic drugs often tendered.
Pricing transparency	Confidential discounts, rebates. Private payers do not get pCPA discounts.	FJC publishes drug price list and rebate/supplement details. Insurers may have proprietary drug prices.
Access to new medicines	Price set before access. Process typically 1 to 2 years. Private plans usually list within weeks.	After EMA approval, immediate access for one year at the drug manufacturer's price.
Standardized discounts	None for drugs. Pharmacy caps depend on province and insurer.	Overall, 16% of pharmacy price for non-reference. Mandatory rebates 7% (patent), up to 16% (generics).
Price increases	CPI on patented drugs. Older generic prices frozen; pCPA Generics Initiative (April 2018).	Frozen on all drugs since 2009 with annual inflation-based increases in 2018 until 2022.
Prescribing oversight	Multiple guidelines but prescribers have full discretion.	Since 2002, systematic assessment with penalties
Formulary	Positive – all eligible drugs. Vary by province. Most private plans have broader formularies.	Negative – ineligible drugs only.
Drugs for rare disorders (DRDs)	CADTH review and recommendation, then pCPA price negotiation. Private insurers use prior authorization and may negotiate price.	Assumed value upon licensing by the government. No detailed IQWiG review until sales exceed €50 mm.
Drugs dispensed by hospital	Each hospital determines own formulary. Buying groups often negotiates secret price. No reference to community cost. No patient cost.	Each hospital determines own formulary. Most use a buying group. FJC has price cap for outpatient drugs. No patient cost for inpatient drugs.

Source: Author. Table kindly reviewed by Neil Grubert, April 2019.

German Acronyms

FJC (G-BA)	Federal Joint Committee (*Gemeinsamer Bundesausschuss*)
GKV-SV	National Association of Statutory Health Insurance Funds *(GKV Spitzenverband)*
IQWiG	*Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen*

Canadian acronyms: See List of Abbreviations, p. xii.

5.3 Netherlands

The Netherlands has adapted the original social insurance model created in Germany to its own political and cultural philosophy of market orientation, personal choice and social solidarity (Maarse, Jeurissen & Ruwaard, 2016). This began with German occupation during the Second World War when sickness funds were established in 1941 for lower income workers.

This section identifies key features and lessons from the Dutch hybrid social insurance model that can be applied to Canada's implementation of NPh. Key features of the Dutch system, narrowed to drug insurance, will be assessed. A recurring theme is active management and evolving governance.

5.3.1 Health System Reform

Countries choose the most appropriate balance point along the continuum between system archetypes. For the Dutch, this shifted dramatically in 2006.

In 1967, the Netherlands combined health care for the general population with health coverage for industrial accidents and occupational disease. There is no separate Workers' Compensation health care system as there is in North America and most European nations (Government of the Netherlands, 2011).[159] WCB organizations in Canada have separate drug formularies and benefit entitlements for injured workers. Reflecting its German roots, the Dutch market at that time was split into a social insurance (sickness fund) model that covered about two-thirds of citizens and a separate private insurance model for wealthier people (van Ginneken, Shäfer & Kroneman, 2010). Funding was provided through general taxation.

The latest reform cycle began in 1987 with a contentious report from the Dekker Commission (Maarse et al., 2016). Dekker proposed changes to create a hybrid and unified health insurance market that would include elements of both social and private insurance, with the former given priority (Vonk & Schut, 2018). At the time, it was suggested these

[159] The Government of the Netherlands published *Health Insurance in the Netherlands* in 2011. It is still available at: https://www.government.nl/documents/leaflets/2012/09/26/health-insurance-in-the-netherlands.

changes would take about five years to implement (Tuohy, 2012). Reforms began in 1988 that slowly migrated coverage to a compulsory plan.

Interesting and relevant to Canada, prescription drugs were originally covered by sickness funds but in 1992 medicines were transferred to the tax-funded but privately-administered Exceptional Medical Expenses Act (AWBZ) (Götze, 2010). A change in government returned drugs to the sickness funds in 1996 (Götze, p. 21). While Tuohy (2018, p. 351) describes the political reason as "austerity" in transferring drug cost from government to private payers, perhaps the government also hoped drug costs may be better managed by the private sector through regulated competition.

The first serious attempt to implement Dekker in 1992 was strongly opposed by insurers and employers, but important transitional changes still occurred (Vonk and Schut, 2018). As a result, consumer choice grew to include national and regional insurers, community-rating now allowed price competition, capitation payments changed insurer revenue and risk, and selective provider contracting first appeared. Income-based premiums remained. The former legal barriers that distinguished sickness funds and private insurers were removed so the two forms began to merge (Vonk & Schut, 2018).

Over the next few years, changes to Workers' Compensation shifted risk to employers who became concerned about the cost of long health system waiting lists that prevented or delayed employees from returning to work. This problem created a coalition of interests between business, unions and the public. Insurers were then isolated as they resisted change (Vonk & Schut, 2018). Finally, serious consultations and negotiations began after the government issued a new proposal in 2001, still based on the Dekker Report. A precipitating event (ultimately, wait times) opened a window of opportunity that led to government action.

Almost 20 years following Dekker, two Acts were passed in 2006: the Health Insurance Act (Zorgverzekeringswet: Zvw), and the Healthcare Market Regulation Act (Wet marktordening gezondheidszorg: Wmg) which set up the Dutch Healthcare Authority (Nederlandse Zorgautoriteit: NZa). In this legislation, van Ginnekin, Shäfer and Kroneman (2010) state: "The role of the government was envisaged to change from direct control of volumes, prices and productive capacity to safeguarding the process from a distance (p.24)." This has likely not created less work for the government (Kroneman et al., 2016). The Zvw consolidated social and private coverage into universal health insurance and created an individual mandate (everyone must have coverage). A sophisticated risk-adjustment formula deters insurers from 'cream-skimming' to enrol only the healthiest people (van Ginneken, Swartz & Van der Wees, 2013).

The Ministry of Health, Welfare and Sport sets overall policy and controls the national budget that includes health insurers, drugs and providers. A complex array of advisory and/or supervisory bodies as well as self-regulating provider organizations replaced its direct steering role (Kroneman et al., 2016, Table 2.2 p. 47). Based on advice from the

National Healthcare Institute[160] (Zorginstituut Nederland: ZiNL) the government decides the components of the Basic health insurance package. It provides legislative and regulatory structure to allow the independent NZa to regulate providers and insurers, determine services and their maximum prices and generally administer policy, all in the public interest.[161] The NZa has authority to intervene and impose tariffs or other sanctions when market power is abused (van Ginneken, Shäfer & Kroneman, 2010). The Minister rarely intervenes in the NZa's operations.[162] "The result of these reforms is a unique Dutch hybrid in which the public-private boundary is hard to discern" (Tuohy, 2012, p. 624).

As van de Ven (2008) nicely summarizes: "That is, the law describes the nature, content and extent of the care, while the insurance contracts determine who delivers the care, where, and under what conditions" (p. 155).

The Zvw divides coverage into three "compartments." The first is tax-financed and was introduced in 1968. It covers home and long-term care. The second compartment provides standardized mandatory Basic coverage with cost shared primarily by employers and workers. The third type is voluntary coverage, which comes in many forms and price points. Among other services, Basic insurance includes (Government of the Netherlands, 2018):

- Medical care provided by GPs, medical specialists and obstetricians
- Hospital care
- Prescription medicines (formulary-based)
- Dental care for children under age 18
- Mental health services, including related hospital care up to three years
- Nutritional/dietary care
- Medical equipment
- Ambulance
- Various therapists, including speech and occupational therapists

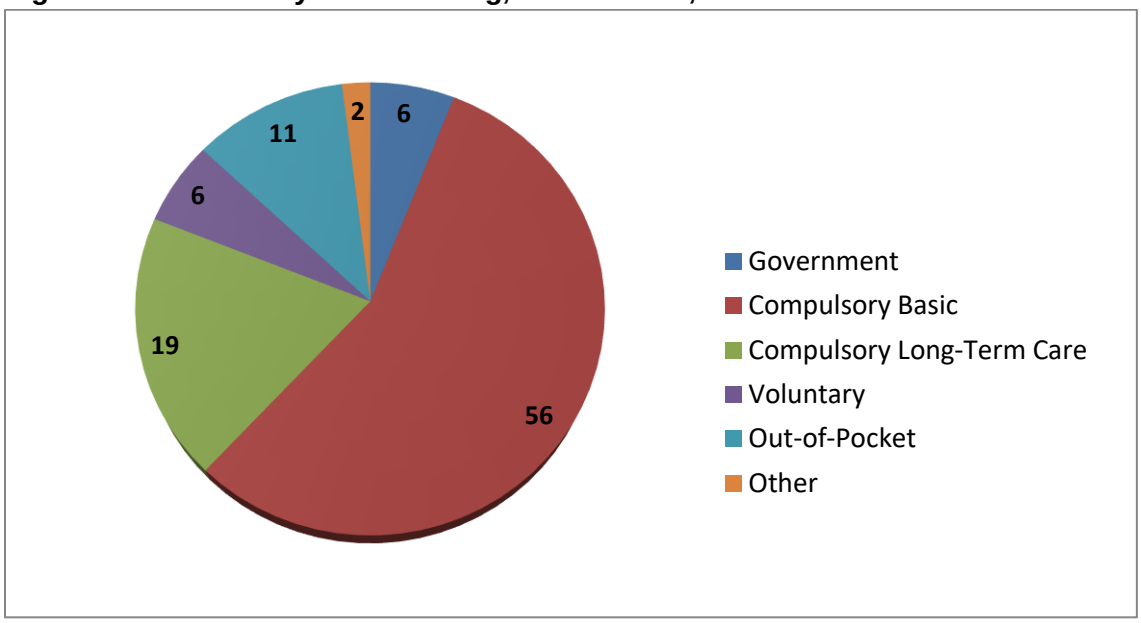
5.3.2 Financing and Spending Overview

At 81%, public funding of the Netherlands health system is well above the OECD average (73%) and that of Canada (70%) (CIHI, 2018a) (**Figure 5.2**). By convention, both compulsory insurance and government funding is defined as "public." The state's contributions cover

[160] ZiNL administers the risk adjustment pool for insurers and performs health technology assessment for new drugs.
[161] See: https://www.nza.nl/english.
[162] Maarse et al. (2016) describe one situation in 2008 where the Minister overruled a decision by the NZa to restrict funding to a hospital that could result in its bankruptcy (p. 174).

costs such as health promotion and care for children under age 18, illegal immigrants and for the disabled.

Figure 5.2 – Health System Funding, Netherlands, 2017[163]



Source: Statistics Netherlands, 2018.

Table 5.7 – Canada and Netherlands: Health Cost Comparison (2017 or 2016, $US PPP)

	Canada	The Netherlands	OECD Average
Gross Domestic Product (GDP, 2016)[164]	44,819	51,340	42,466
Health costs as percent of GDP	10.4	10.1	8.9
Health costs per capita	4,826	5,386	4,069
Drug costs per capita	860	410	577

Source: OECD Health Statistics, 2018. PPP = Purchasing Power Parity controls for buying power in various jurisdictions

Despite higher per capita health spending, drug costs per capita[165] in the Netherlands are about half those of Canada (**Table 5.7**). Costs from the Netherlands include Value Added

[163] Available at: https://opendata.cbs.nl/statline/#/CBS/en/dataset/84043eng/table?ts=1553971778498

[164] OECD Data. Values are from 2016, $US PPP. Higher health costs may reflect that GDP per capita is 14.5% higher in the Netherlands than Canada. Available at: https://data.oecd.org/gdp/gross-domestic-product-gdp.htm.

[165] OECD Health Data combine prescription (Rx) and over-the-counter (OTC) drugs and add medical non-durables.

Tax (now 9%) on prescription drugs;[166] in Canada drugs are exempt from GST. The difference has grown in recent years as the Dutch have mandated steady declines in drug prices and costs through much expanded use of generic drugs and controls on pharmacy fees. Pharmaceutical budget costs have also been supressed because access to certain high-cost specialty drugs (auto-immune and oncology therapies, growth and fertility hormones) was shifted between 2012 and 2014 to the hospital sector (Kroneman et al., 2016). This somewhat distorts direct comparison with Canada. For example, many oncology drugs in Canada are paid from hospital and cancer agency budgets and some of this spending is separate from how CIHI reports prescription drug spending (CIHI, 2018b, p. 26-27).

Drug prices are externally benchmarked to prices in Belgium, Germany, France and the UK. Dutch prices can be no more than the average prices across these four countries. The Beneluxa consortium provides joint health technology assessment and price negotiation with drug manufacturers on behalf of Belgium, The Netherlands, Luxembourg and Austria. Ireland became the most recent partner in June 2018.[167] As an interesting sidebar, as Brexit concerns grew in 2016, the British pound lost value against the Euro. Since the UK is one of four drug price benchmark countries, the Dutch government was able to reduce drug prices by 4% later that year (SFK, 2017, p. 11). In Canada, external price benchmarking is done only at the time a new drug is being reviewed by the PMPRB, although regulatory changes are proposed to allow for periodic therapeutic class reviews.

The decrease in drug cost in the Netherlands is remarkable over the last decade (**Table 5.8**).

Table 5.8 – Annual Cost of Prescription and OTC drugs and Medical Non-durables, per capita, $US PPP

	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	Change
Canada	680	731	781	778	774	788	794	812	833	860	26.5%
Netherlands	450	450	455	462	422	411	403	399	406	411	(8.7%)

Source: OECD 2018 Health Statistics.

Table 5.9 – Ratio of Canada (CA) to Netherlands (NL), Drug and Medical Non-durables and Health Costs. 5-Year Bands. Cost per capita, $US PPP.

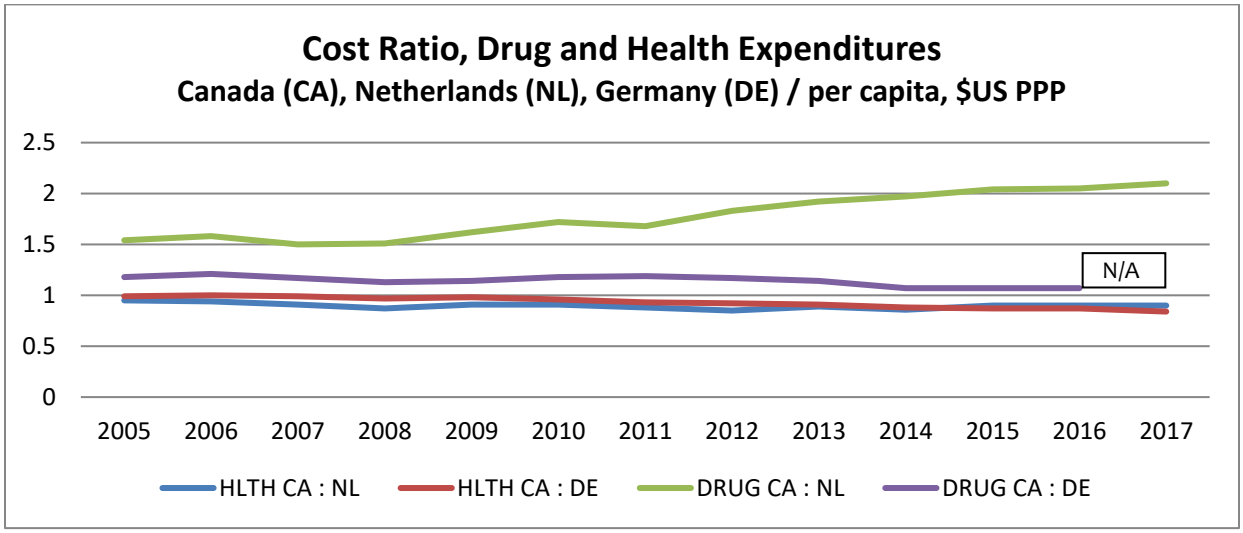
	1985	1990	1995	2000	2005	2010	2015	Latest (2017)
CA / NL Drugs	1.38	1.49	1.45	1.47	1.54	1.74	2.04	2.10
CA / NL Health	1.31	1.27	1.18	1.09	0.95	0.91	0.90	0.90

Source: Author's calculations based on OECD 2018 Health Statistics.

[166] See: https://www.medicijnkosten.nl/servicepagina/engelse-informatie/objectives. On January 1, 2019, the VAT increased from 6% to 9% on Rx drugs. The OECD appropriately uses 6% in historical figures.
[167] See: http://beneluxa.org/news3.

Figure 5.3 also uses ratios, but displays them annually in graphic form over a much shorter period to illustrate similar and divergent cost differences. Data begins in 2005, one year before the Netherlands implemented reform. The CA:NL drug ratio (top/green line) dropped slightly in 2007, 2008 and dipped in 2011 but has otherwise steadily increased from about 50% higher (1.5 on the y-axis) to over twice as high in 2015. (Costs for prescription drugs and public health are the only two segments of health spending that have decreased since 2006.) Germany was added for comparison purposes. Both Canada and Germany have high per capita drug costs.

Figure 5.3 – Canada, Netherlands and Germany: Cost Ratio Health and Drug Expenditures



Source: OECD Health Data 2018. PPP = Purchasing Power Parity.

The line showing overall health system spending in the Netherlands and Germany follows a similar pattern of gradual decline over this 13-year period, meaning lower health systems costs in Canada relative to each comparator.

5.3.3 Health Insurance Overview

The Netherlands is unique among OECD members in its heavily regulated, competitive and universal social insurance market. Regulation is "complex and extensive" (p. 16) and can be segmented into three parts: public health, service quality, and health insurers and providers (Kroneman et al., 2016). Overall health expenditures are high (9th) but are consistent with the country's GDP per capita, also ranked 9th (OECD, 2018). Kroneman et al. (2016) reported very high (91%) citizen satisfaction with health system quality in 2013.

While drug costs are exceptionally low, long term care (LTC) costs are extremely high (National Institute for Public Health and the Environment (RIVM), 2014). Before reform in 2015, the Netherlands spent more (about 4% of GDP) on LTC than any other EU nation

(OECD, 2017b). All in, the Dutch health system consumes less of GDP than does Canada's (**Table 5.7**) so its system appears relatively affordable despite constant concern about costs and prices.

The 2006 Health Insurance Act (Zvw) identifies four system objectives that support public solidarity: accessibility, quality, efficiency and affordability of health care (Netherlands Authority for Consumers & Markets, 2017a). Competition is meant to help achieve the last three objectives (Netherlands Authority for Consumers & Markets, 2017a). These terms were not defined in legislation so meanings had to be developed by stakeholders as the Act was implemented (Maarse et al., 2016). The general rationale is that competition should create conditions for innovation and efficiency that improve the quality of health services and controls cost, while responding to customer preferences (van de Ven, 2008). For several years, competitive advantage focused on volume and prices because sufficient provider quality information was not available (van Ginneken, Shäfer & Kroneman, 2010).

Insurers may be for-profit public companies or not-for profit mutual cooperatives: "virtually all" (Netherlands Ministry of Health, Welfare and Sport, 2018. p. 3) are the latter. Most operate nationally. The number of insurers has declined steadily since the 1960s when it peaked at about 165 (Vonk & Schut, 2018). Maarse (2009) reported there were 57 insurers in 2006, but only 33 remained in 2009. Currently 23 health insurers operate in ten groups, and the four main insurer groups account for 86.5% of industry revenues.[168] (In Canada, there are 24 health insurers, 19 of which are independent. There are five Blue Cross affiliates. The three largest insurers are for-profit: the four largest control 71% of health revenues (Benefits Canada, 2018))

In addition to Basic coverage, almost 70% of citizens had group insurance coverage in 2017 (Netherlands Authority for Consumers and Markets, 2017c), up from 64% in 2010 (van Ginneken, Shäfer & Kroneman, 2010). In the Netherlands, group contracts get a maximum discount of 10%. About two-thirds of Canadians have private drug insurance (CLHIA, 2018, p 3), although surveys indicate a smaller amount (60% according to Law, 2018).

Insurers must accept everyone under the Basic insurance package. However, while insurers set their own prices the cost of the Basic package is community rated – the same for all clients of each insurer which reinforces social solidarity. Additional voluntary health insurance (VHI) is available. Residents can change insurers each January and about 6% do so annually (Netherlands Authority for Consumers & Markets, 2017b). This threat to the incumbent insurer is designed to be a catalyst for quality improvement. Maarse et al. (2016) report it is young, better educated consumers who are more likely to switch, primarily to obtain a lower premium. Age and the amount of health care expenses are inversely related to switching insurers. Higher age creates psychological switching costs, such as fear of getting less coverage with a new insurer (Duijmelinck & van de Ven, 2016).

[168] NZa, 2018. *Monitor Zorgverzekeringen 2018*. Available at: https://puc.overheid.nl/nza/doc/PUC_254666_22/1/. See pp. 5, 6. Translated from Dutch using Google Translate.

The government sets a maximum price for drugs on its approved formulary twice each year but the final cost to the patient is determined by insurer negotiations with drug manufacturers, hospitals, physicians and pharmacists. Insurers list eligible providers on their websites and reimburse others not on their list at lower rates, usually 75%.

Since 1991, health insurers have used reference pricing to identify a preferred drug from among therapeutically equivalent and interchangeable drugs (Habl et al., 2006). Patients pay the difference for higher priced drugs out-of-pocket (Kroneman et al., 2016). Mandatory substitution and competitive bidding (tendering) is used to lower the cost of generic drugs. Tendering contracts run for two years with locked-in prices and no minimum specified volume.[169] Generic substitution rates are high at 74% of all prescription volume and account for less than 17% of prescription sales (SFK, 2017, p. 13), vs. 72% of scripts and 20% of costs in Canada (CGPA, 2018).

5.3.4 Managed Competition among Insurers

5.3.4.1 Defining managed competition

According to Vonk and Schut (2018) managed competition is an attempt: "…to reconcile the tension between a competitive insurance market pressuring for selective underwriting and actuarially fair premiums (the insurance logic) and an upcoming welfare state pressuring for universal access and socially fair premiums (the welfare state logic) (Abstract)." They summarize the two polar positions (Den Exter and Guy, 2014) as follows:

- **Insurance logic:** Voluntary individual responsibility for buying insurance to protect against financial losses. Competition enables product and service innovation. Insurers are protected against moral hazard through medical underwriting, risk-adjusted premiums, waiting periods and coverage limits. Insurance is privately administered. Citizens can apply for extra coverage but they may be rejected or their policy terminated, most often due to age, pre-existing conditions, changing health status or risk behaviours. A pool for high risk insureds is typical, either by one insurer or among several insurers, to dampen premium fluctuations and protect insurer solvency.
    - Archetype: Private insurance.

- **Welfare state logic:** Social solidarity pools risk among a large population and protection is a right of citizenship. This model requires mandatory enrolment, universal entitlement and Vonk and Schut would say public administration. Social insurance also qualifies, administered by governments and private insurers. To

[169] Medicines for Europe, 2016. *Market review – European generic medicines markets: Policy Overview*. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2016/11/Market-Review-2016-Generic-medicines-policies.pdf. See p. 10.

properly function, this model must include six other features: periodic open enrolment, community rating, prescribed/standard benefits, low income subsidies, risk-sharing and limited competition if private insurers are included. Income-based and community-rated premiums often co-exist. Social insurance also requires an insurer pool for high risk insureds to dampen premium fluctuations and protect insurer solvency which is threatened by moral hazard and adverse selection.

- Archetypes: Single payer and social insurance

Vonk and Schut drew three conclusions relevant to both Dutch health insurance and national pharmacare in Canada. First, a well-functioning health insurance market can include private insurers only if they are effectively regulated. Second, changes take considerable time and are ongoing and controversial in the Dutch market. Finally, achieving managed competition in the Netherlands has been complex and requires sustained political, institutional and public support.

5.3.4.2 Key features

Six key features of the Dutch managed competition model will be reviewed and then the model will be assessed for application to drug insurance in Canada.

1. Mandatory Basic insurance: Personal choice and voice
2. Voluntary health insurance
3. Risk sharing
4. Transitional measures
5. Market monitoring and transparency
6. Policy dynamism

Feature 1: Mandatory Basic insurance: Personal Choice and Voice

The mandatory Basic health insurance plan is offered by 23 insurers through 55 policies with a choice of deductible. Insurers must accept all applicants regardless of health, age or sex. Costs are primarily covered by community-rated individual premiums and payroll deductions. Overall cost increases have been moderate, and per capita drug costs have actually declined in many recent years. Out-of-pocket costs are low, and subsidies are provided to those with lower incomes.

- **Annual Premium:** In 2018, the average cost per adult was €1,332 (NZa, 2018. p. 19). There was a €390 (29%) difference between the least (€1,126) and most expensive (€1,506) Basic premium (NZa, 2018. p. 19).[170] Even though nominal average premiums increased about 3% annually (17% overall) between 2014 and 2018 inclusive (NZa,

[170] Coverage was not the same in each insurer's policy but was often similar.

2018. p. 20), the 2018 premium was slightly lower than it was in 2012 (€1,361) (Maarse et al., 2013).

- **Payroll Contribution:** The average worker[171] paid €1,750 in 2018 (NZa, 2018. p. 18).[172] The total payroll deduction of 12.65% (2019) is shared between employers (6.95%) and employees (5.7%) up to maximum annual earnings of €55,927.[173]

- **Annual Deductible:** It has held at €385 per adult since 2016 and applies to all eligible Basic health insurance expenses.[174] It may be voluntarily increased in €100 increments to €885 (total) in order to lower annual premiums. Almost 12% of the population has opted for a higher deductible, most of those (9%) at the €500 limit (NZa, 2018. p. 29). Deductibles can be waived when patients used preferred drugs or participate in certain prevention programs (Kroneman et al., 2016).

- **Tax Credits:** Over one-third (36% according to Kroneman et al., 2016) of low income adults qualified for subsidies in 2015, paid monthly in advance (van Ginneken, Swartz & van der Wees, 2013). In 2019, the maximum monthly allowance is €99 single and €192 for two or more with a household income of €20,500 or less. The allowance diminishes until it disappears at €30,000 for singles and €38,000 for two or more people in a household.[175]

- **Out-of-Pocket Health Costs:** At 11.5% of total health expenditures, these are low relative to Canada at 14.6% and the OECD average of 20.3% (OECD Health Statistics, 2018). This figure does not include social insurance premiums or income-based payroll deductions.

- **Voice:** Though in a less prominent and influential role than Germany's FJC, patient involvement is institutionalized. Health providers must have patient advisory councils and health insurers must involve patients in purchasing decisions (OECD, 2017b).

Consumer ratings of provider and insurer quality have been published and promoted by the government since 2005. Hendriks et al., (2009) examined seven health plan quality variables from among 54 core quality items across the health system. Five of these showed small but statistically significant improvements over the four years, while two were

[171] In comparing annual premium and deductible with payroll contribution, note that all workers are adults but not all adults are workers.
[172] An industry website (https://www.zorgverzekering.org/eng/insurance-companies/) shows monthly costs by insurer according to age and annual deductible, and includes a consumer rating.
[173] E&Y, 2019. *Netherlands payroll tax in 2019 and 2020*. Available at: https://www.ey.com/Publication/vwLUAssets/EY-pas-memorandum-loonheffingen-2019-en/$FILE/EY-pas-memorandum-loonheffingen-2019-en.pdf. See Table 2.2, p. 36.
[174] There is no deductible paid for children under age 18 or for maternity care and family medicine (GP) visits.
[175] Government of the Netherlands Tax Authority. See: https://www.belastingdienst.nl/wps/wcm/connect/bldcontentnl/belastingdienst/prive/toeslagen/zorgtoeslag/voorwaarden/inkomen/bedragen-zorgtoeslag-per-maand.

unchanged. They also found that below-average health plans improved in 2008 more than those providing average or above-average quality in 2005. Den Exter & Guy (2014) determined that competition based on quality (vs. price) is not yet effective.

Feature 2: Voluntary Health Insurance

Voluntary health insurance (VHI) is complementary: it reimburses services excluded or only partially covered under the Basic plan such as dental and physiotherapy for adults, vision care, and costs for drugs above the reference price. VHI creates an outlet for those who are in good health, desire more extensive benefits and have the financial ability to pay. VHI can be risk-rated (medically underwritten) but insurers have not implemented this restriction (Kroneman et al, 2016). VHI does not buy faster access or permit queue jumping (Wammes et al. 2017). Most Dutch buy their Basic and VHI plans from the same insurer (van Ginneken, Swartz & Van der Wees, 2013) since VHI on a stand-alone basis is more expensive than when packaged with Basic (Kroneman et al., 2016).[176] A large majority of Dutch citizens make this choice: despite a good Basic plan, 84% also had VHI in 2018 (NZa, 2018. p. 24). That figure is unchanged from 2015 (OECD, 2017), but lower than in 2012 (88% (Maarse, Jeurissen & Ruwaard, 2013) and 2009 when 91% had VHI (Schäfer et al., 2010).

Feature 3: Risk Sharing

Risk sharing is an essential feature of both private and social health insurance systems. Payroll contributions from Dutch employers and workers are paid into the Health Insurance Fund operated by ZiNL. This allows greater transparency and public support (Allin, Stabile & Tuohy, 2010). The Fund is used to equalize risk among insurers according to market share and seven variables (shown next page). It either charges or credits insurers based on the deviation of their book of business from the "standard" set for overall risk (Schäfer et al., 2010).

The Dutch use a very sophisticated model but even so, it cannot fully anticipate or neutralize all risk. Risk sharing models are designed to support social solidarity without limiting price competition and system sustainability (Fouda, Fiorentini & Paolucci, 2017). Regulation, including risk-sharing, helps protect both insurers and patients from potentially adverse market effects. High-risk and high-cost patients may choose any plan and insurers are compensated for the extra costs these patients incur. All patients have more secure and affordable coverage. Insurers have much reduced incentive to "cream-skim" or otherwise game the market in the pursuit of lower risk patients which leaves them to focus on improving administrative efficiency, reduce costs and product prices and improve quality (Kroneman et al., 2016; van Ginneken, Swartz & van der Wees, 2013).

[176] This is similar to the standard discount applied when Canadians buy home and auto coverage from the same insurer. Two complementary policies provide better risk spread.

Kroneman et al. (2016) report recent changes to risk sharing. While the first five ex-ante factors below are unchanged, two more have been added.

1. Age and sex
2. Income source and socio-economic status
3. Region
4. Prescription drug use for chronic diseases according to 20 therapeutic classes (outpatient)
5. Inpatient chronic disease groups (N=13)
6. Use of medical aids, high health costs from conditions not included in #4 or 5, and previous use of mental health care.
7. Mental health care for single patients living alone.

The ex-post system introduced in 2006 for Basic insurance recognized that risk cannot be perfectly predicted. As more claim experience data were collected, the need for ex post adjustments diminished. It was terminated in December 2014 once information systems and market predictability improved. (Adjustments were to remain in place for mental health care, nursing and personal care until 2017.) Canadian insurers should be interested in the *ex post* adjustment model if they introduce a national drug claim pool. Ex post adjustments originally included:

- Outliers, in which most costs above a threshold were reimbursed by the government.
- "Bandwidth", based on the average cost difference between an insurer and the country.
- Macro developments beyond the control of insurers. An example might be the mid-year market entry of costly new Hepatitis C drugs. However, insurers may also be required to refund costs to the HIF if the company's average claim cost is lower than that incurred by other insurers.

While insurers may still try to unfairly attract lower-cost risk there are financial and reputational costs with insureds and regulators. For example, since VHI costs are not regulated, claim patterns under the Basic plan could be used to sell VHI to low-risk customers (Maarse et al., 2016). However, most people buy VHI from the same insurer due to visible pricing incentives so these selection risks are minimized. Delaying or denying services is likely to drive high-cost patients to other insurers on January 1, but will not help attract preferred risks except through very low rates which then lowers revenues and profit/surplus (van de Ven, van Kleef & van Vliet, 2015).

Feature 4: Transitional Measures

After the Zvw legislation was passed in 2006, reforms to hospital and insurer roles and processes took several years and interim measures buffered these organizations from both anticipated and unforeseen changes to revenues and profits (or surplus for not-for-profit organizations). Insurers were to negotiate prices and services with hospitals but only 7% of hospital revenue was immediately put at risk. The share exposed to market forces increased to 34% by 2010 (van Ginneken, Shäfer & Kroneman, 2010) and to about 70% by 2012. The other 30% was protected due to risks that could not be planned (emergencies) or for which there were too few incidents to predict. Similarly in 2006, insurers were allowed to protect 53% of their earned profits or inversely, were compensated for 47% of their losses (Kroneman et al., 2016).

At least two performance reviews published in 2010 and 2016 made it clear that the transition was incomplete (van Ginneken, Shäfer & Kroneman, 2010; Maarse et al., 2016). Premium competition caused many insurers to merge or to leave the market, and hospitals and physicians had other unexpected experiences as they adjusted to the consolidating power of the insurers and the evolving role of government (Maarse et al., 2016). Following the first three years of system adjustment losses, insurer profitability has remained strong. That "success" has led to public resentment as the appropriate balance is negotiated between retaining surplus to meet capital and solvency standards and the short-term option to invest in new or improved services or reduce premiums. The latter approach provides immediate gratification – and good politics. These experiences could be very relevant to Canada as it works to introduce a comprehensive public single payer NPh plan by 2017.

Subsidies for lower income residents were increased in tandem with the Basic health insurance deductible. Health insurance is compulsory but is obviously less affordable as incomes decrease.

Health costs increased faster than expected for the first two years so the government began to claw back funds from providers that were over-budget. That act penalized efficient organizations. In 2011 (Maarse, Jeurissen & Ruwaard, 2013) and/or 2013 (Wammes et al., 2017) the government negotiated cost growth and quality targets for hospitals, insurers, medical specialists, mental health care and then primary care in a four-year agreement (2014 – 2017).

Coverage entitlements have also been adjusted over time. Mental health coverage was reformed and improved and session costs were eliminated in 2014. Long term care was extensively revised in 2015. But certain drugs have been delisted or removed from the drug budget and physiotherapy is reimbursed only under VHI unless it is for a chronic condition requiring more than 20 visits per year.

Feature 5: Market Monitoring and Transparency

Price and quality transparency is essential in competitive markets. The Netherlands Authority for Consumers & Markets (ACM) is an independent regulator of several sectors including health insurance. It oversees competition and enforces consumer protection laws.[177] The ACM's consumer website (consuwijzer.nl, in Dutch) encourages informed comparison shopping for health insurance.

Five years post-launch, information for patients was described as inadequate and did not reflect their diverse needs (van Ginneken et al., 2010). Insurance packages remain difficult for many consumers to compare, reducing market competition and innovation. Advertising may create confusion as well as clarity among consumers on important coverage differences. A patient who is afraid of not getting equivalent coverage is likely to be reluctant to change health policies.

A 2018 study by the ACM and NZa reported that almost 10 million people – 72% of the 13.6 million covered by Basic policies they had personally selected – could have chosen less expensive policies with similar coverage. (An earlier version of this joint study reported average savings of €100 (8%) were possible in 2016.)

Another study by the ACM and NZa reported very similar health policies were offered at very different prices, and insurers were criticized for placing undue emphasis on minor policy differences and misleading consumers (Netherlands Authority for Consumers and Markets, 2017a). The insurance industry also provides a website where consumers can get comparative information on health insurers, prices, quality and benefits.

The ACM expressed concern that stable market shares of insurers may indicate the market is not sufficiently dynamic and competitive (Netherlands Authority for Consumers and Markets, 2016). This study observed that insurers value stability in market share (and its more predictable revenue) over the risk of acquiring competitors. It noted that no new insurers have entered the market since 2006 and that smaller insurers are not growing.

Another ACM study noted that insurers, mostly not-for-profit, feel public and political pressure to convert surplus into lower insurance premiums rather than increase capital which can in turn support innovation and long-term solvency (Netherlands Authority for Consumers & Markets, 2017a). In 2014 insurers reduced their rates by an average of €115 (Maarse et al., 2016).

All these investigative studies are instructive for Canadian patients and taxpayers, policymakers and politicians. They improve transparency, market functioning and allow monitoring of intended and unintended consequences related to the introduction of NPh.

[177] See: https://www.acm.nl/en/about-acm/our-organization/the-netherlands-authority-for-consumers-and-markets.

Feature 6: Policy Dynamism

Over 25 years, the Dutch government has intervened to make important though often very targeted changes in its laws or practices in order to improve drug affordability and health system sustainability. Aggressive drug policy changes have had generally[178] steady and deliberate effects on drug prices (see Figures 5.4 and 5.5). It's important to note that while Dutch drug policies have been unusually effective, the country still struggles to bring other costs, e.g., long term care, in line with EU comparators.

The following ten policy actions illustrate the scope of changes and the Dutch government's willingness to remain focused on achieving the prescribed outcomes of its system: market orientation, personal choice and social solidarity.

1. Generic drug prices were cut by 40% in January 2004 based on an agreement between the Ministry, insurers and the generic drug industry (SFK, 2010, p. 27). The price of new generic drugs would be 40% below the brand product and the brand industry signed a similar agreement in 2005 to drop their product prices to the same level if generic equivalents were available. In 2008, generic prices fell 10% more due to the Pharmaceutical Care Transition Agreement and new generic drug prices were then set at 50% of the brand price (SFK, 2010, p. 28).

2. Drug preference policies introduced by four large insurers reduced the price of the most frequently prescribed generic drugs by 90% in mid-2008 (SFK, 2010, p. 30). This policy meant only one drug within a therapeutic class has full reimbursement. The cut was delivered through a tendering process that awarded exclusive supply contracts.

3. Generic drug shortages continue[179] mostly due to tendering practices that create sole supplier contracts. Occasional manufacturing quality problems also restrict supply. During the first quarter of 2014, inadequate supply affected a monthly average of 800,000 prescriptions (4.3%) involving nearly 150 different medicines on at least one insurer's preference list (SFK, 2014, p. 26).

4. The large price cuts allowed the Ministry to reduce its drug budget for insurers. In response, one insurer introduced a "concealed price model" in which the drug manufacturer paid the insurer a confidential rebate (SFK, 2014, p. 20). This practice spread among other Dutch insurers and created a further reduction in generic drug prices of about 9%.

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[178] "Generally" does not mean uninterrupted, as shown in Figures 5.4 and 5.5 which cover drug prices during 1996 to 2017. Policy direction has sometimes altered course for political, practical or ideological reasons, e.g., drug coverage did swing between sickness funds to government and back to sickness funds in the 1990s, as noted in Sec 5.3.1.

[179] Medicines for Europe, 2018. *Medicines for Europe: Country specific market access policies*. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2018/05/20180524-Medicines-for-Europe-recommendations_V1.0.pdf.

5. By 2009, drug price cuts had a small (1%) cumulative negative overall effect on pharmacy revenues. However, the NZa allows pharmacies to earn considerably (26%) more in fees if there is a written agreement with an insurer that sets out quality and efficiency targets (SFK, 2010, 67). The number of pharmacies has been steady for several years (SFK, 2017, p. 15) indicating these changes have not led to widespread bankruptcies and reduced patient access.

6. In 1998, the Ministry mandated a discount ("clawback") be paid by pharmacies to insurers and patients. The discount started at 3% of prescription cost and was increased two years later to 6.82% (max €6.80) when pharmacy fees were increased (SFK, 2014, p. 20). In 2008, the Minister agreed that further efficiencies beyond the targeted amounts in the Transition Agreement would be returned to pharmacists, however, as of 2010, this had still not been paid. This delay undermines solidarity and trust.

7. In 2009, 42 quality indicators were reported for the first time to monitor prescribing and dispensing behaviours in 2008. One insurer used two of these indicators to identify and reward exceptional pharmacy practice with higher fees, and a second insurer introduced several more the next year to their pharmacy contracts (SFK, 2010, p. 81-83). One limitation is that pharmacy-level indicators do not follow patients across more than one pharmacy.

8. Deregulated pharmacy prices in 2012 eliminated the government-mandated clawback and allowed pharmacists to set their own prices generally after negotiations with the insurers. Insurers quickly implemented their own clawback of pharmacy fees SFK, 2014, p. 20).

9. Drugs that are not on the government formulary cannot be reimbursed under Basic insurance but they may be paid out-of-pocket or are eligible for VHI policies. In 2013, patients paid for ineligible drugs valued at €185 million and €38 million more for costs above the price cap set by their insurers (SFK, 2014, p. 37). These amounts were 5.5% of total drug expenditures. Some drug manufacturers rebate these out-of-pocket costs back to the patient. A €250 maximum patient contribution for off-formulary drugs was introduced in 2019.[180]

10. Parallel imports of brand drugs into the Netherlands from within the EU are allowed when such drugs are less expensive in other countries. This is a relatively small share of all drugs dispensed due mostly to supply problems, manufacturer resistance, and because Dutch prices on average are lower than any EU member of the OECD except Estonia, Poland and Denmark.

[180] See: https://www.rijksoverheid.nl/onderwerpen/zorgverzekering/vraag-en-antwoord/veranderingen-basispakket-2019. Translated using Google Translator.

The Dutch approach indicates far more can be done. To recap, Canada is currently ranked 4th ($833) in drug costs among 32 OECD countries with 2016 data available, and its average per capita cost is 144% of the OECD average ($577). In comparison, the Netherlands is ranked 27th ($406) and its per capita cost is just 70% of the OECD average (OECD, 2018).

5.3.4.3 Application to Canada

There are four important challenges with negotiating and implementing this model within Canada's single payer, top-down, government-controlled health system.

5.3.4.3.1 Conflicting Philosophy

The fundamental difficulty of the Dutch market-based policy is reconciling the business-oriented motivations of competitive private markets with the legislative goals of improving quality, enabling choice, enhancing affordability and supporting social solidarity (Maarse et al., 2016). Kroneman et al. (2016) state: "Yet, friction seems to be growing between competition as the driver of the healthcare system and reforms that demand cooperation and integration among actors (p. xxvi)."

Canadian Health Ministers and bureaucrats might find it extremely difficult to limit their primary role to oversight instead of direct administration and imposing plan design and funding. Recurring fears of privatizing and "two-tier" health care are real political threats and even the act of confirming or institutionalizing private drug insurance through regulation will be challenged unless the public supports this. As my interviews revealed, the relationships among public and private health stakeholder groups in Canada either do not exist (insurers and health ministries) or are fraught with mistrust (pharma and payers).

5.3.4.3.2 Regulation

The Dutch model includes heavy regulation of insurers. In contrast, the federal Office of the Superintendent of Financial Services does not regulate Canadian health insurance. The provinces regulate insurer marketing but not plan design. Only Quebec makes eligibility mandatory and regulates a minimum formulary and a basic risk-sharing mechanism among insurers.

Regardless of the model to be implemented in Canada, laws and regulations would have to be restructured to bring private drug plans (assuming they continue) under the law to protect the public interest. The degree of regulation would vary according to policy goals selected by the federal government after consultation with the jurisdictions and private insurers.

5.3.4.3.3 Selective contracting

This was introduced in the Netherlands in 1992 and now includes factors such as price, quality, and access (waiting times, opening hours).

Currently in Canada all regulated health professionals and institutions are equally qualified and accessible. Since the 1980s, almost all pharmacists and dentists, and more recently other regulated professionals have been enrolled in electronic networks operated by private-sector pharmacy benefit managers under contract to insurers, or by Green Shield and the Blue Cross organizations. Canadian benefit carriers (i.e., Sun Life and Green Shield) are beginning to collect plan member ratings of health professionals like pharmacists and dentists but this is likely only the first step in differentiating patient-perceived quality and perhaps to linking scores to provider compensation. (Patient ratings will need to be validated to objectively measure provider quality.)

While this broadly supports the public interest, it also creates challenges. First, robust information management systems are needed. Second, prescribers and dispensers may have trouble agreeing to provide quality information or responding to its findings, especially if the outcome is lower compensation. Third, support for such changes is uncertain since patients and governments sometimes value convenient access over higher quality or lower price. Fourth, regulatory colleges may have concerns if insurers start to differentiate among equally qualified regulated professionals unless the public interest is clearly demonstrated.

5.3.4.3.4 Information Technology (IT)

The Advisory Council (2019a) made three initial recommendations, and one was to: “Invest in drug data and information technology systems” that would track prescriptions from the physician to adjudication to post-marketing data collection (p. 7). The 2019 federal budget ignored this recommendation, but the Advisory Council’s final report (2019b) reinforced the need: “The council is keenly aware that data on prescription drugs in Canada is fragmented and incomplete. We at times found it tremendously difficult to get information we needed on how Canadians use prescription drugs, to learn about the impact of prescription drugs on the health of Canadians, or to find out who spends what on prescription medicine” (p. 102). There are at least two opportunities for IT infrastructure to manage drug costs.

The first is risk-adjustment. The Netherlands has a sophisticated system that works well to equalize morbidity across all health insurers, but the model must be continuously refined to monitor new market practices, deliberate or otherwise. It requires robust data to minimize gaming opportunities by insurers. While Canada may be able to learn from the Dutch (and other) countries and start with a more robust model, this would also require data and reporting that does not currently exist. Quebec’s risk sharing model reportedly includes fewer and simpler data – insurers must track the number of employees by contract, report drug claims, and provide market share by revenue for each insurer.

The second opportunity is better performance monitoring. Technology must be sufficiently integrated and robust to measure and forecast system performance in terms of cost, quality and access (Advisory Council, 2019a).[181] Misunderstanding and mistrust are likely to be more evident in the absence of robust drug claims data collection, analysis and reporting. At present, there is no integrated information technology system that includes all of the nearly 700 million prescriptions written each year in Canada.[182]

Whether in system governance or planning a market-oriented managed competition system for drug insurance, Canada's historical behaviour indicates it is not ready to copy the Dutch system in any comprehensive way.

5.3.5 Outcomes: Drug Policy and Spending post-2006 Reform

At a system level, at least some hospital wait time indicators – the catalyst for reform legislation in 2006 – have shown improvement and NZa reported some were better than national standards by 2013 (Maarse et al., 2016).[183] The OECD (2017) stated wait times were at a "historically low level (p. 12)" following an agreement about waiting times signed in 2009 between providers and insurers. All insurers still offer waiting list mediation services.

Administrative costs have also decreased, in part due to market consolidation. Administration costs in 2005 (before reform) were 4.2% for social insurers and 10.7% for private insurers. In 2013, these costs had decreased to a combined figure of 3.5%, including commissions and marketing (Maarse et al., 2016).

While Canada's drug cost increase has been relatively modest (about 2% compounded annually) between 2008 and 2017, the Netherlands is one of only six OECD members to have experienced a *decrease* in per capita drug cost (**Figures 5.4** and **5.5**).[184] Other variables held constant, if Canada had the same per capita costs our total drug costs (Rx + OTC) would be almost CA$21 billion *lower* in 2017, dropping from $39.8 billion to $19.0 billion. A saving of even half this would be compelling, but must be considered in the context of the overall health system.

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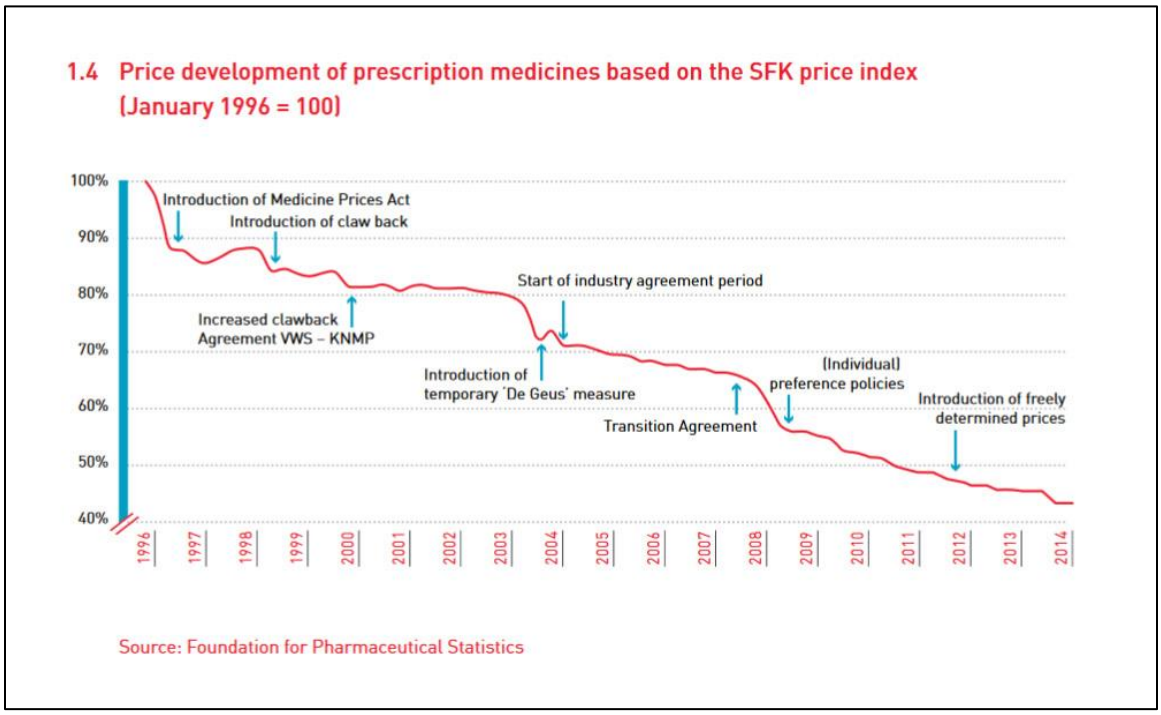
[181] One of the three recommendations was "to invest in drug data and information technology (IT) systems (p.7)."

[182] About 673 million retail prescriptions were dispensed in Canada in 2017 - see: https://www.iqvia.com/-/media/iqvia/pdfs/canada-location-site/yir_2017_infographic-final.pdf?la=en&hash=D13B58D8E8AB98993F3AEFCD60E623B9CC4BFF43. No drug claim system has complete national data. Claim systems installed in retail pharmacies do not send all claims through the provincial system before allocating them to the appropriate private insurer. This prevents a complete provincial record. CIHI relies on the CLHIA to provide health claims but these are not reported by province. Not all private insurance companies provide drug claim data to IQVIA, although this company has most of the available data. The PBO costing report noted IQVIA could not allocate drug claims proportionately to each payer so it attributed funding only to the majority funder. Quebec's drug claims have only recently been included in PMPRB's NPDUIS-based reports. Drug claims for hospital in-patients are separate, as are cancer drug claims when provincial cancer agencies exist.

[183] Kroneman et al. (2016) reported similar results.

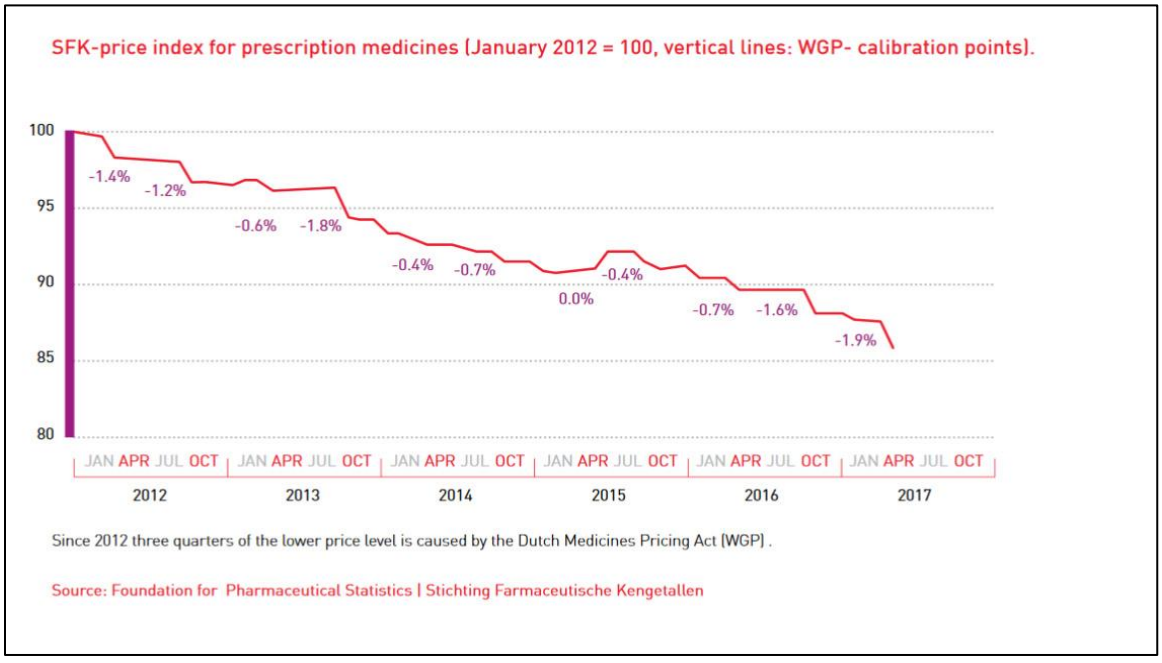
[184] Six of 36 OECD countries had lower per capita drug costs in 2016 than in 2008, based on available data (OECD Health Statistics 2018): Greece (estimate), Iceland, Luxembourg, Mexico, the Netherlands and Portugal.

Figure 5.4 – Netherlands Drug Price History 1996-2014



Source: SFK, 2014 Facts and Figures report, page 21, Figure 1.4. Used with permission.

Figure 5.5 – Netherlands Drug Price History 2012-2017



Source: SFK, 2017 Facts and Figures report, page 11. Used with permission.

The Foundation for Pharmaceutical Statistics (Stichting Farmacuitische Kengetallen: SFK, 2017 and various) collects dispensing data from 95% of Dutch pharmacies covering more than 90% of residents. SFK annual reports are released in English every second year and the following information is derived mostly from those documents, unless otherwise referenced.

The outcome of many policy changes and market forces is very significant. Between 1996 and 2012, the drug price index dropped about 53% (**Figure 5.4**. SFK, 2012; p. 25). After the Index was re-set to 100 in 2012, **Figure 5.5** shows the average price dropped another 14% due to semi-annual price changes mandated under the 1996 Medicines Pricing Act (*Wet Geneesmiddelen Prijzen*: WGP). The WGP alone has contributed to average price decreases of 3% to 4% annually (SFK, 2014, p. 14). However, insurer negotiations and practices have also had important effects, primarily from a preference policy.

One important policy outcome is that generic drug market share increased from 47% of all prescription volume in 2003 (SFK, 2004, p. 9), to 59% in 2009 (SFK, 2010, p. 11) and to 74% in 2016 (SFK, 2017, p. 13). Generics accounted for about 17% of all drug costs in 2016.[185] Generic prices typically stabilize at 15% of the brand drug price after about two years on the Dutch market (SFK, 2017, p. 13). The market share of generic drugs increased 12% between 2009 and 2014, tied with Switzerland as the biggest increase among 20 countries. The Netherlands also had the greatest volume of prescriptions filled with generic products in 2014.[186]

In Canada, Germany and the Netherlands, drug spending follows different patterns than overall health spending in both amount and in rate of annual increase. This may be from accidental or deliberate policy and program decisions, or from other variables. Health system-level and broader cultural and demographic differences are not explored in this investigation.

Canada's health system history over decades has been marked with small, step-wise public policy and program changes rather than large-scale innovation and expansion driven by any burning platform (Boothe, 2015). The Advisory Council's final report (2019b) and the 2019 federal Budget suggest this is not changing. Similarly, most employers make only minor benefit plan changes and continue to accept annual increases in health benefits costs for fear of upsetting employees in an era of low unemployment and skills shortages. Data and documentation from the Netherlands suggest that bolder changes, carefully managed with genuine consultation, can provide exceptional results.

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[185] As noted earlier, Canada has similar though somewhat lower figures: 72% of costs and 20% of volume.

[186] IMS Institute for Health Informatics, 2015. *The role of generic medicines in sustaining healthcare systems: a European perspective*. Available at: https://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS_Health_2015_-_The_Role_of_Generic_Medicines_in_Sustaining_Healthcare_Systems_-_A_European_Perspective.pdf.

5.3.6 Criticisms of the Dutch health system

There have been several criticisms of the Dutch system. While most are broader than drugs alone, they are listed to address potential criticisms of using the Netherlands as a comparator. These system issues affect Canada, and they affect prescription drugs as part of the larger health system. They may be summarized as: misinformation (see 1 below), similar quality and pricing issues (2), data issues (3), periodic cost escalation (4), disparities and inequity (5), and concern (still) about insurer behaviour and the effectiveness of regulation (6). The most drug-specific criticism of the Dutch (and German) approaches is the balance between statutory and voluntary insurance systems.

1. Tunstall (undated) noted "an increasing number of people are not using the system due to user fees, especially visits to family doctors. (p. 5)" However, Westert and Wammes (2013) point out General Physician care is exempt from cost-sharing, as is maternity care and health care for children (p. 85). Tax credits (p. 109) are available to low income residents. Allin, Stabile and Tuohy (2010) report exemptions from the deductible for those with long-term chronic illness (p. 15).

2. The Dutch have struggled to measure health system quality, incent providers and implement improvements (Vanden Ber et al., 2014). The government's periodic Health Care Performance Report (National Institute for Public Health and the Environment (RIVM), 2015) pointed out significant variations in quality and price between providers. Medical practice variations have been a common finding in Canada and many other countries (Corallo et al., 2014). Private plan design parameters are not systematically collected or reported by insurers or by their industry association in Canada. While quality is negotiated between providers and insurers, it is not influencing purchase decisions nearly as much as price and service volume. Part of this is a lack of reliable quality indicators although some exist and others are under development (OECD, 2017b). Hendriks et al. (2009) measured seven quality markers in The Netherlands as determined by large patient samples in 2005 through 2008, and found four markers improved, and three first declined and then rose to pre-2006 levels.

3. Although the Netherlands has been a pioneer in producing comparative health system reports (OECD, 2017b), current and accurate comparative data has taken time to develop and disseminate (Tunstall, undated). The OECD (2015c) reported that spending data can take up to two years to be reported to the government's Finance ministry.

4. Between 2009 and 2012, health system costs increased as a percentage of GDP and increases were higher than OECD averages. Special agreements between the government and various providers (professionals and insurers) in 2012 helped moderate annual increases (OECD, 2017b). The rate of increase has been well below

the OECD average from 2013-14 through 2016-17, including two years of negative growth between 2013 and 2015 (OECD Health Statistics 2018).[187]

5. There was a significant increase in the percentage of Dutch respondents to a Commonwealth Fund (2016) survey who did not access their physician (12% in 2013, vs. 2% in 2011), or undergo medical tests or treatment (16% vs. 3%) due to costs. As in other countries, an inverse relationship between income and use of health services has been reported, and this included buying prescription drugs (National Institute for Public Health and the Environment (RIVM), 2015). About 1.6% (277,000) defaulted on their annual health insurance premium in 2016 (OECD, 2017b).

6. Voluntary private insurance provides extra services only to those willing and able to pay. This issue is somewhat blunted since so many (84%) purchase voluntary insurance and because government subsidies are available to about 30% of the population. However, since most people buy voluntary insurance from their basic plan insurer, insurers can offer low voluntary premiums to preferred-risk people they want to insure for both basic and voluntary plans (van Ginneken, Swartz & Van der Wees, 2013).

5.3.7 System Governance

One of the biggest differences between Canada and both the Netherlands and Germany is in the frequency of meaningful course correction through legislation and regulation. Over the last two decades, the Dutch health care environment has been punctuated with active governance and fundamental change, new laws and heavy regulation, and a familiar back-and-forth debate on how to resolve insurance logic and modern welfare state logic (Vonk & Schut, 2018). Germany has also regularly updated its health and drug legislation over the last 30 years (**Table 5.5**). The NZa and Germany's FJC fulfill similar oversight and control roles and provide an organizational buffer for politicians. There is no similar entity in Canada's confederation.

Power relationships between the major players has proven challenging in the Netherlands (Maarse et al., 2016). As directed by government, insurers have exerted purchasing power over hospitals and volume controls on physician services, and introduced reference drug pricing and generic drug tendering. Although the presumption is that insurers are acting on behalf of their patient-clients, they have not fared well in public opinion. When plans include selective contracting with preferred providers, patients must trust that insurers are as concerned with quality as with unit prices or service volumes.

There is a cultural mismatch between the structure and operation of health care systems in Canada and the Netherlands. The Netherlands has a big advantage based on

[187] Author's calculations from OECD data: *Annual growth rate of government and compulsory health insurance schemes, per capita expenditure, in real terms.* Calculated and Dutch growth rate (bracketed): 2013-14: 4.3 (-1.0); 2014-15: 2.7 (-2.0); 2015-16: 3.9 (1.6); 2016-17: 3.7 (3.3).

drug cost and coverage outcomes and improved collection of quality data. The Dutch social insurance model has been regularly adjusted to fit its culture of market orientation. Social solidarity is reinforced through heavily regulated Insurance and provider services to serve the public interest. The Dutch government has often intervened to lower drug prices following its twice-annual reviews. These qualities are mostly missing in Canada.

Canada can reflect a health culture of policy confusion (OHIP+; regionalization/centralization) and inertia (national pharmacare, PMPRB reform). The provinces have cooperated in drug price negotiations and are very slowly synchronizing their generic formularies, but there are still significant differences in eligibility, cost-sharing and access to specialty, gene and cell therapy. An important question is whether Canada could lower drug prices by following the Dutch approach. Unfortunately, there is little evidence of a determined effort to develop an integrated national prescription medicines policy or intensify price and cost control activities. Public and private payers largely remain in their own silos. Two prime examples:

1. Reform of the PMPRB's 32-year old mandate will be changed effective July 1, 2020, a process that took four years. Public input on its Guidelines (June 2016) and Regulations (June 2017) was requested. Changes were proposed in May 2017[188] originally to be effective on January 1, 2019.[189] This long and uncertain process creates considerable uncertainty for drug manufacturers.

2. Canada announced an Initial Draft Discussion Document for A Canadian Orphan Drug Regulatory Framework[190] in December 2012. By October 2017 all references to the Draft had been removed from the Health Canada website.[191] Then a "national strategy for high-cost drugs for rare diseases" was announced in the 2019 federal Budget and by the Advisory Council (2019b) but funding is deferred until 2022-23…the end of the *next* session of Parliament when a different party may change direction.

More broadly, both the Netherlands and Canada have struggled with long health system wait times. Again, the approach and the success are considerably different between the two countries. Dutch wait time indicators improved after 2006 and many continue to meet standards. In Canada, the $5.5 billion Wait Times Reduction Fund addressed just five clinical areas[192] starting in 2004. After ten years of extra funding, the results were mixed and uncertain. CIHI (2012) reported: "Different time frames, definitions, summary measures

[188] See: https://www.canada.ca/en/health-canada/programs/consultation-regulations-patented-medicine/document.html.
[189] See: http://www.gazette.gc.ca/rp-pr/p1/2017/2017-12-02/html/reg2-eng.html.
[190] See: http://www.orpha.net/national/data/CA-EN/www/uploads/Initial-Draft-Discussion-Document-for-A-Canadian-Orphan-Drug--Regulatory-Framework.doc.
[191] See: https://nationalpost.com/news/politics/health-canada-gives-kiss-of-death-to-planned-policy-for-rare-disease-drugs.
[192] There were five broad areas named, but only specific procedures (in brackets) were targeted: Cardiac care (bypass surgery), Cancer care (radiation therapy), Diagnostic imaging (MRI and CT scans), Joint (knee and hip) replacement and Sight restoration (cataract surgery).

and inclusion criteria [meant] no interprovincial comparisons [were] possible likely because each jurisdiction managed its own strategy" (p. 4). This lesson suggests real challenges for the federal government if it introduces national standards as part of national pharmacare, even with generous funding.

The Canadian group insurance industry – insurers and advisors – operate independently of governments and have even less incentive to aggressively lower drug costs because their administrative charges and commissions are based on a percentage of drug premiums or claims, and not on a per transaction basis. Higher drug prices and pharmacy fees mean higher insurer revenues. Dutch insurers are mandated to negotiate lower prices and better quality. While both public and private payers negotiate drug prices (most new drugs by the pCPA, and far fewer among private payers) through Product Listing Agreements, the terms are confidential. Private insurers and pharmacy benefit managers incur extra cost for this work but get no credit from their customers for lowering drug prices, an oddity in a competitive market.

5.4 Summary of International experience: Germany and The Netherlands

The recurring struggle of introducing national pharmacare in Canada demonstrates Enthoven's complaints of the NHS in the 1980s. As Boothe (2015) makes clear, the Canadian health system seems to prefer small-step and slow-moving change even when something different is required to fix an important problem.

Germany and the Netherlands were selected because they have social insurance systems that are founded on the same principles of social solidarity but have taken different approaches to reflecting their own political, structural, historical and popular needs. They have integrated planning for both social and private insurance systems. The private role has encouraged a competitive market that can adapt to a fluid, steadily evolving drug insurance system. Governments have supported more types of drug price and cost controls than in Canada. The Dutch model of managed competition, in particular, appears to have achieved superior value for money in drug access.

Both EU countries have aggressively managed their legislative and regulatory framework to address drug cost issues. This has happened despite having a much larger domestic pharmaceutical industry (in absolute terms for Germany and in relative terms for the Netherlands) that is a very important driver of employment and research and development investment. Germany's prices and policies are more transparent. While its patented drug prices are significantly higher (PMPRB, 2018a), Germany's per capita drug spending (after removing the 19% VAT) is significantly lower than Canada's according to OECD reports. Unlike Canada, Germany's policy includes some controls and incentives for improved physician prescribing, which Canada may now consider (Advisory Board 2019b). All three countries have achieved very high generic penetration though Germany and the Netherlands have achieved this through tendering rather than negotiation.

In structure, the Dutch approach of a universal Basic plan seems more appropriate for Canada and more equitable. Unlike Germany, we have no legacy of sickness funds aimed at low and middle earners. Access to private health insurance by exempted segments of the population creates equity and financing concerns. The earmarked contributions of SHI models funded by employers, workers and the state tend to generate greater public support because funding can be more easily compared to the benefits received (Allin, Stabile & Tuohy, 2010).

Drug costs per capita in the Netherlands are among the lowest in the OECD. Its overall health expenditure is higher, however, driven by its costly long-term care sector but also reflecting its greater national wealth. Its transition to today's model was long and somewhat painful. Many private insurers left the market but those that remained ultimately took over the public sickness funds. The single, mandatory national health system introduced in in 2006 has reinforced social solidarity and significantly reduced private insurer administration costs (Allin, Stabile & Tuohy, 2010). It is unclear what difference not-for-profit status might make to insurer performance in the Netherlands, relative to the publicly-traded, for-profit status of many of Canada's insurers, including the three largest. Voluntary insurance and group coverage in the Netherlands remain very popular despite the wide coverage and relatively low out-of-pocket cost. While insurers continue to compete on service, price, operational efficiency, Dutch reforms have yet to demonstrate a material effect on quality.

Broader governance participation in both Germany (through the FJC) and the Netherlands (through mandated patient involvement with insurers and providers) is appealing even if confined only to prescription drugs. There is growing but still limited experience with this in Canada.[193] Broader governance participation better reflects the increased complexity of health care and drug insurance and dampens the opportunity to politicize decisions. Governments could rely on more diffused responsibility for policy and program decisions. That is important because improvement will take far longer than a four-year election cycle, as the Netherlands has demonstrated.

Operating a federally-governed health system may be easier than Canada's patchwork of provincial jurisdictions, but lower levels of government may also be better suited for adapting policy to local and regional situations.

While Germany established the social insurance model 136 years ago, the Netherlands has demonstrated its adaptability to introduce an even more market-oriented system. That suggests the Canadian situation can also be transitioned from today's large, though largely autonomous, public and private payer segments into something far more integrated with superior governance.

[193] Examples would be the Ontario Ministry of Health and Long-Term Care's Citizen's Council and CADTH's Patient and Community Engagement Framework. See: https://www.cadth.ca/patient-and-community-engagement.

Both these EU governments have refined its governance role over time to provide appropriate and effective regulations and oversight, facilitate stakeholder discussion, protect public values and reinforce solidarity by developing consensus. Both countries have much more sophisticated risk-sharing controls on health insurers designed to curtail behaviour not in the public interest. Such a framework would have to be developed here. Clear rules and roles ought to improve trust which is a necessary foundation given the otherwise competitive role of these players.

Although this comparative review cannot conclude Canada should adopt either country's model in whole, it is reasonable to assume a more regulated and better governed mixed funding model could work and be no less effective than a single payer. Quebec's experience (Sec 6.7) indicates the model is not as important as the quality of governance and the execution of timely policy changes.

5.5 Quebec

Quebec implemented a social insurance model in January 1997 (Pomey et al., 2007; Busby and Robson, 2011; Institute for Competitiveness & Prosperity, 2014) with a formalized private-public partnership to provide mandatory drug insurance to all residents. Before then, 15% to 21% of the population had no drug coverage and others had only partial coverage.[194] With the introduction of universal coverage, the number of provincial claimants reportedly increased from 1.5 million to 2.1 million (Actegis, 2018). After 1997, private drug plans could no longer discriminate on the basis of age (up to 65), sex (virtually never an issue in practice), or health status (e.g., through the exclusion of pre-existing conditions), and coverage had to be at least as generous as the provincial plan administered by the Régie de l'assurance maladie du Québec (RAMQ). Employers do not have to cover drugs unless they provide any form of health or disability plan, but if they do, coverage is mandatory for all employees and their dependents. Private plans are first payer for those under age 65. Over 8,000 drugs are covered.[195]

5.5.1 Cost sharing[196]

Cost-sharing rules (except for the annual premium) apply to both RAMQ and private plans and change annually on July 1. Most private plans cover more drugs, have lower deductibles and coinsurance but may have higher premiums. For those aged 18-64 during 2019-2020:

[194] There are three sources. 1. Marc Desmarais, President, Conseil du Medicament, Province of Quebec reported 17% in a presentation, "Quebec's "Régime général d'assurance médicaments" (Prescription drug insurance plan), undated. 2. Actegis (2018) states 1.1 million had no coverage, equal to 15% of QC's 1996 population of 7.25 mm. 3. Labrie (2019) reported 1.5 million uninsured in Quebec in 1993, almost 21% of the population of 7.16 mm. These percentages are similar to AB and NB.

[195] Available at: http://www.ramq.gouv.qc.ca/en/citizens/prescription-drug-insurance/Pages/prescription-drugs-covered.aspx.

[196] Available at: http://www.ramq.gouv.qc.ca/en/citizens/prescription-drug-insurance/Pages/rates_effect.aspx.

- Annual premium for RAMQ beneficiaries varies by net family income and is from $0 to $636. For private plans, premium varies and is negotiated by the insurer and the employer.
- Deductible is $21.75 per month ($261.00 annually).
- Coinsurance is 37% of the balance after the deductible.
- Annual out-of-pocket maximum is $93.08 monthly ($1,117 annually).

The combination of premiums, deductible and coinsurance means out-of-pocket cost is very high in Quebec's provincial plan relative to other provinces, up to the out-of-pocket limit.

5.5.2 Coverage

The RAMQ covers three groups: people age 65 or older who choose the RAMQ plan, those on social assistance, and those aged 18-65 (and their dependents) who are not covered by a private drug plan (Adhérants). Currently, about 3.6 million residents (RAMQ, 2018, p. 62) have prescription drug coverage through RAMQ. **Table 6.9** provides comparative information.

Table 5.10 – RAMQ Coverage by Number of Residents and Cost

Group	Number Covered by RAMQ (000s)	RAMQ Drug Cost ($MM)	Personal Drug Cost* ($MM)
Seniors (65+)	1,376	2,323	641
Adhérants	1,833	820	259
Social Assistance	426	761	0
Adjustments		(382)	
Totals	**3,635**	**3,522**	**900**

Source: 2017-18 RAMQ Annual Report, pp. 62, 107, 109. *Personal cost means the payment of deductibles and coinsurance to a maximum annual out-of-pocket payment of $1,066 (2017-18).

In addition to the RAMQ drug cost noted ($3,522 million), $1,225 million in premiums are paid by Adhérants and seniors, and administration costs of $61 million are not included. The total cost of the program was $4.8 billion in 2017-18.

Equity is provided through exemptions and subsidies for certain residents. The cost of the following groups is fully covered by the province (RAMQ 2018, p. 109):

- Families on social assistance. (N=331,000)
- Seniors receiving 94% or more of the federal Guaranteed Income Supplement.[197] (N=69,000)
- Adhérants
    - Children under age 18, and people with disabilities. (N=197,000)
    - Full-time, unmarried students living with their parents between ages 18 and 25. (N=32,000)
    - Low income adults.

In all, 627,595 (22% of) RAMQ beneficiaries who have made at least one claim paid nothing for their provincial drug coverage. The subsidy for those people amounts to $1,054 million (RAMQ 2018, p. 109).

The most recent information is that about 878,000 people (24%) insured by the public plan pay nothing for their drugs and about 500,000 low-income persons pay no premium.[198] Quebec has the lowest estimated rate of cost-related non-adherence in Canada (Law et al., 2012; Law et al., 2018).

RAMQ (2018) reported 4.6 million people were covered by private drug insurance (p. 107).[199] The CLHIA (2018a) reported 5.9 million Quebec residents were covered by private extended health plans in 2017 within which drug coverage is mandatory. The difference is 1.3 million people. The CLHIA attempts, perhaps unsuccessfully, to eliminate duplicate coverage which happens when one person is covered as an employee in one plan and a spouse in another, or when dependent children are covered in each parent's plan.

In addition to a much larger formulary, Labrie (2019) reported that Quebec residents have the advantage of access to more drugs approved by Health Canada than the average of other provinces (33.4% vs. 25.6%). Provincial coverage decisions were also made faster in Quebec than the rest of Canada after a new drug is approval by Health Canada: 477 days on average in Quebec instead of 674 days for other public drug programs.

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[197] The maximum annual income eligible for the GIS for a single person between October 1 and December 31, 2015 is $17,280. Other income caps apply depending on spousal age and income. Source: http://www.servicecanada.gc.ca/eng/services/pensions/oas/pdf/table-of-rates-oct-dec2015.pdf. There is a lower maximum out-of-pocket cost for residents receiving less than 94% of the maximum GIS.

[198] RAMQ news release, June 25, 2019. Available at: http://www.ramq.gouv.qc.ca/en/regie/press-room/news/2019/Pages/public-prescription-drug-insurance-plan-changes-to-the-financial-participation-of-some-insured-persons.aspx.

[199] The population of QC was 8.4 MM on July 1, 2018 (Statistics Canada, Table 17-10-0009-01. Population estimates, quarterly), leaving 0.2 MM unregistered or covered by private insurance.

5.5.3 Does Quebec Cost More?

A major failing of Quebec drug policy has been cost control (Pomey et al., 2007; Smolina & Morgan, 2014; Gagnon, 2015). Smolina and Morgan (2014) calculated that Quebec spent about $1.5 billion more in 2012-13 than other provinces would have spent based on spending differences per capita. They calculated a difference of almost 23%[200] on a $6.6 billion annual drug budget.[201] Most (80%) of this difference was due to more prescriptions[202] and higher prices paid (26%), offset slightly by the use of somewhat less expensive drugs overall (– 5%).

Pomey et al. (2007) cite the Quebec Minister of Economic Development who attributed this extra cost to the 18,600 jobs provided directly by pharmaceutical manufacturers in the province (p. 475).[203] Industry employment is now considerably less. Pharmaceutical and medical manufacturing jobs in Quebec reportedly fell 28 per cent between December 2006 and October 2011, from 10,422 jobs to 7,549 (Silcoff & Marotte, 2012). Still, the Patented Medicine Prices Review Board continues to report that Quebec has disproportionately more research and development (R&D) work by patented medicine manufacturers relative to its population – 34% of Canadian R&D in 2017 (PMPRB, 2018 p. 60) versus its 23% share of Canada's population.[204] However, Quebec's share of R&D is declining: it was 41% in 2012 and 44% in 2007 (PMPRB Annual Reports). Persistently lower employment and research spending may be part of the reason why Quebec has recently made changes to its industrial policy for this sector.

Some of the higher cost is also due to Quebec's reluctance to engage in Product Listing Agreements before it joined the pCPA in 2015. Using data from Ontario's Auditor General 2017 Annual Report that reported Ontario had created savings of 15.2% of its total public drug program costs in 2015-16, Actegis (2018, p. 27) estimated Quebec could have saved $352 million that same year if it had all the same PLAs in force as Ontario. In 2017-18, Quebec received drug price rebates of $222.3 million on 82 products (RAMQ, 2018, p. 110).

Since at least 2002, Quebec's per capita drug costs have been described as the highest in Canada (Pomey et al., 2007; Smolina and Morgan, 2014). Quebec dropped to third highest in

[200] This is higher than CIHI (2013) which showed a 17% difference in 2012. Smolina and Morgan report 5% of the excess is due to age differences in the population of Quebec versus the rest of Canada. See Table A, Canada, per capita ($795), and Table B, Quebec, per capita ($928). Note that CIHI averages all of Canada, while Smolina and Morgan remove Quebec before calculating the average for the rest of Canada which helps explain the larger difference.

[201] This figure is not easily reconcilable with CIHI data that shows 2012 spending in Quebec of $7,532 MM on prescription drugs. Of that total, Quebec provincial spending is $2,457 plus Drug Insurance Funds (premiums) total $886, equalling a sub-total of $3,343 MM. This is about equal to drug spending of $3,315 MM shown in the 2012-13 RAMQ Annual Report (p. 96).

[202] Smolina and Morgan reported the average days' supply dispensed in QC was 20, versus 36 in SK, 39 in MB, 41 in ON, 46 in AB and peaking at 51 in NS.

[203] Many of the major brand drug companies maintain their Canadian head offices in Quebec, such as Merck, Novartis, Pfizer, PharmaScience, Sanofi and Bausch Health, among others.

[204] Statistics Canada, as at Q4 2019. See: https://www150.statcan.gc.ca/t1/tbl1/en/tv.action?pid=1710000901.

in total per capita prescription drug spending in 2013 but is again the highest, 15% above the national average (CIHI, 2018a).

The private per capita share of drug spending in Quebec is equal to the national average (57%) and almost identical to Ontario, Manitoba and Alberta (**Table 6.9**). ESC (2019) reported specialty drug use is higher in Quebec than other provinces (p. 62).

The provincial share of per capita drug spending in Quebec ranks third highest by dollars and second lowest by percentage among Canadian provinces. These figures do not include premiums contributed to the Drug Insurance Fund (DIF) by individuals which are counted as public by convention. Spending differences may be due to many reasons, such as plan design, age, ethnicity, prevalence of private coverage, disease incidence and prevalence, treatment access and protocols, prescriber and pharmacy behaviours, and policy decisions (**Table 5.11**). There is a nearly ten year difference in median age among ten provinces, with Quebec ranked fifth.

Table 5.11 – Prescribed Drug Spending per capita (2018 Forecast)

	Provincial Share, Dollars	Total, Dollars	Percent Provincial of Total	Percent Private of Total	Median Age
NL	274	905	30.3	66	46.5
PEI	243	747	32.5	65	43.6
NS	291	962	30.2	67	45.1
NB	270	1,018	26.5	70	45.9
QC	294	1,046	28.1	57	42.5
ON	393	940	41.8	56	40.6
MB	244	692	35.3	55	37.3
SK	290	784	37.0	52	37.3
AB	379	887	42.7	55	36.9
BC	221	664	33.3	61	42.2
Canada	*330*	*909*	*36.3*	*57*	*40.8*

Sources: (1) CIHI, 2018a. Table G. (2) Statistics Canada: Population Estimates on July 1, by age and sex, Table 17-10-0005-01. Available at:https://www150.statcan.gc.ca/t1/tbl1/en/cv.action?pid=1710000501.

Table 5.12 shows that the overall provincial share of costs in Quebec has escalated somewhat less than in Ontario and considerably less than in Alberta since 1997. However, the Quebec provincial increase is 88% higher than British Columbia has experienced. Each of

these provinces has very different eligibility and cost-sharing criteria. However, over the last 15 years, Quebec social security (Drug Fund) premiums generally increased much more than costs for the Quebec government and other provinces. Costs have shifted to citizens who contribution to the DIF. Increases have been more similar in recent years.

Table 5.12 – Percent increases in provincial per capita drug costs, selected years

	1998	2003	2008	2013	2018F	Cumulative Increase 2018F/1998
Quebec – Province	10.8	6.9	4.4	-3.3	3.1	173
Quebec – Drug Insurance Fund	25.9	29.7	10.5	6.4	-4.3	383
Ontario	8.8	10.1	5.6	0.7	8.1	189
Alberta	6.5	12.5	2.1	-0.06	4.6	295
British Columbia	8.4	-2.8	2.3	-3.3	1.9	92

Source: CIHI 2018a, Table G. **Notes**: (1) "Cumulative" is the percentage increase calculated by dividing the 2018F per capita provincial spending amount (not shown) by the same figure noted for 1998. (2) The QC DIF is considered public spending even though contributions are paid by individuals. (3) The 2018 increase in Ontario reflected new spending from OHIP+. (4) The BC provincial share increased much less than the other four segments, and was the lowest in Canada in 2018F. However, BC's costs were the second-highest among all provinces in 1998, second only to Ontario ($115 vs. $136).

5.5.4 Policy Roadblocks

Under RAMQ's "BAP 15" rule, brand drugs enjoyed 15 years' protection from generic substitutes but also required drug manufacturers to provide the "Best Available Price" in Canada to Quebec (Paris & Docteur, 2006). The 15 year period began when a brand drug was listed on the RAMQ formulary and continued even though generic products may have been (and were frequently) available earlier. In other provinces, 20-year patent protection begins when a drug's product or process patents are filed with the Canadian Intellectual Property Office. The Quebec rule was introduced in 1994 and rescinded in January 2013. At that time a drug price freeze was also implemented (Norton Rose LLP, 2012). One report indicated the net cost to the province of BAP-15 had risen to $193 million annually by 2011-12, making it no longer feasible (Lacoursière 2012, in Actegis 2018, p. 20).

Since January 2013, Quebec's private plan generic fill rate has been increasing faster than other provinces but it still lags the Canadian average. It was 54% QC and 57% nationally in 2013 (Express Scripts Canada (ESC), 2014, p. 35). Across both private and public plans,

generic substitution rates in Quebec (75%) were higher by volume than the Canadian average of 72% (CGPA, 2018). In private plans, Quebec's generic fill rate increased the most of all provinces from 53% in 2014 to 62% in 2018, and is now just slightly below the national average of 63% (Telus, 2019, p. 17-18).

Another unique policy decision is that Quebec pharmacists are not required to provide 100-day supplies of well-tolerated chronic use drugs, as is the general practice across Canada. Instead, 30-day supplies are dispensed, meaning pharmacists earn three dispensing fees when most often a single fee would be paid for the larger quantity elsewhere (Smolina & Morgan, 2014). In 2012, 99.5% of all maintenance drug claims in Quebec were dispensed with 30 days' supply or less. The comparable Canadian private plan figure was 60% (Express Scripts Canada (ESC), 2013, p. 61). On average, Quebec private-pay prescriptions contained 35 units of oral solid drugs, only 55% of the 64 units dispensed in Ontario (PMPRB, 2015b, p. 25). The average quantity supplied per prescription in Quebec is about half (54%) the level in the other nine provinces. Quebec with 23% of the national population accounts for 43% of all prescriptions.[205]

Finally, members of private plans usually pay a share (50% or less) of the market premium negotiated between the employer and the insurer. Although likely rare, it is possible the provincial plan could have lower monthly premiums. This situation has not been evaluated.

Gagnon (2015) called the RAMQ model "inequitable, inefficient and unsustainable." He stated:

- "The public [drug] plan tends to balance its budget by shifting costs onto the shoulders of private plans rather than containing its costs." There is another side:
    - For many years, all provincial plans have shifted costs to private plans by listing products much more slowly or by negotiating lower prices that apply only to the province through confidential Product Listing Agreements.
    - Quebec has typically listed far more new drugs than other provinces, and lists them much faster than all other provinces (Gamble et al, 2011).
    - Until December 2015, Quebec was not part of the pan-Canadian Pharmaceutical Alliance (pCPA) and its legislation did not allow it to negotiate Product Listing Agreements. However, Section 60 of the Medications and Pharmaceutical Services Act Respecting Prescription Drug Insurance[206] was changed in April 2015 (Fasken Martineau, undated), and shortly after the province announced it would join the pCPA. While the prices

[205] Personal communication. IQVIA, Canadian CompuScript. MAT September 2017. November 10, 2017.
[206] See: Section 190, page 61 of http://www2.publicationsduquebec.gouv.qc.ca/dynamicSearch/telecharge.php?type=5&file=2015C8A.PDF.

negotiated remain secret, private insurers and brand drug manufacturers are now negotiating their own PLAs (PDCI Market Access, 2015) and the CLHIA wants to join the pCPA (Personal correspondence, 2015).[207]

- Private plans are inefficient because "drug plans without the capacity to evaluate cost-effectiveness become a major source of waste."

    - Economic analysis is rare but increasing in private drug plans. All three of the largest Canadian insurers now consider CADTH recommendations. Manulife was the first to launch its DrugWatch program in 2015.[208] Telus Health, the largest Pharmacy Benefit Manager, also performs an economic analysis on new drugs.[209]

    - It is also important to remember that employers cover a working population and private drug plans are part of employee compensation. Employers have different motivations, such as productivity, employee satisfaction and good labour relations, and so often choose to pay for drugs that provincial plans do not. That noted, there is wasted spending when generic and therapeutic substitution happen less than in provincial plans, and when pharmacy fees and drug mark-ups are not controlled. Express Scripts Canada had estimated one-third of every dollar spent on chronic use prescription drugs is wasted.[210]

- Gagnon did not specifically address his statement about unsustainability.

    - The sustainability issue is important for both private and provincial drug plan managers in Canada and elsewhere. In Canada, the threat is greater among small employer plans where company finances may be inadequate to cover even one specialty drug claim, and where employees are not often represented by a labour union. Anecdotally – and there are no other data available – some small employers have terminated their "defined benefit" drug plans in favour of "defined contribution" plans where their liability is capped at a set level each year, such as $5,000 or $10,000. Such plans cover routine claims, but will leave thousands of dollars payable by employees – or transferred to provincial drug plans – in the event of a typical specialty drug claim. While provincial drug plans work within annual budgets, governments have theoretically unlimited taxation power to fund such entitlements.

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[207] Personal communication with Stephen Frank, (then) VP Policy Development and Health, Canadian Life and Health Insurance Association. Letter dated September 22, 2015.

[208] See: http://www.benefitsconsultant.ca/wp-content/uploads/2015/09/Manulife-DrugWatch-Brochure.pdf

[209] O'Reilly D, 2019. *Evidence-informed drug reimbursement: The role of health economic evaluation*. Presentation available at: https://plus.telushealth.co/blogs/health-benefits/en/telus-health-2019-conference-toronto/

[210] This statement appeared in its *2012 Drug Trend Report* although ESC no longer supports this statement. Personal communication, J. Herbert, ESC, August 23, 2018.

5.5.5 Risk-sharing through industry pooling[211]

Each year, the insurers operating in Quebec update a mandatory, self-regulating pooling mechanism that applies to all insured and Administration Services Only (administered by an insurer but self-insured by the plan sponsor) group drug plans except those having at least 6,000 employees. The pool is operated by the industry-owned Quebec Drug Insurance Pooling Corporation under the authority of the Quebec government. The corporation's small governing Board has representatives from insurers, employers and/or benefit plan administrators and/or trustees. Claim costs are transferred among the insurers on a break-even basis so that no insurer or employer profits. Like all risk-sharing processes, insurers that better manage claims and keep them below the threshold may be disadvantaged over more laissez-faire claim management by other insurers.

Pooling charges are collected as part of the group premium and pooling thresholds and charges vary by group size. Larger groups pool drug claims at higher levels and also pay lower charges per employee. For 2019, the threshold ranges from $8,000 per certificate (employee and all dependents) for groups with fewer than 25 employees, to $120,000 for groups between 1,000 and 3,999 employees.[212] Once an employer has 4,000 or more employees, a "free market" exists because claims costs are highly predictable, employers are large enough to absorb most claims, and sophisticated enough to obtain pooling protection from their insurer.

The Quebec system is different and more comprehensive than what the CLHIA introduced in the rest of Canada.

5.5.6 Taxation

Quebec charges premium taxes to employers with life and health plans, and this remains at 3.48% of total premium. Quebec requires individuals to pay a 9% sales tax on group life and health insurance premiums. These are general taxes, not specifically levied to provide for health services and help offset the above-average share paid by Quebec for its public drug plan. The Health Services Fund levies a payroll tax on employers of between 1.25% and 4.26% of payroll depending on the employer's industry and revenue.[213] Unlike all other provinces, employer contributions to group medical and dental benefit plans are taxable benefits to employees, meaning there is no tax subsidy in Quebec.

[211] All information is from the Quebec Drug Insurance Pooling Corporation website: https://mutualisation.ca/en/.
[212] The 2019 Terms and Conditions are available at: https://mutualisation.ca/en/2018/10/22/2019-terms-conditions-are-now-available/.
[213] Raymond Chabot Grant Thornton. See: https://www.rcgt.com/en/tax-planning-guide/sections/section-12-social-programs-benefits/health-services-fund-quebec/.

5.5.7 Governance

While the Quebec drug plan is governed and operated by the Province, the role of private insurance is enshrined in the underlying legislation, *An Act respecting prescription drug insurance (The Act),* Section 3.[214]

Section 37 of The Act prohibits group insurers or employers discriminating on the basis of age, sex or health status of the employee or a dependent, or "a person suffering from a functional impairment who is domiciled with the person."

Section 43 of The Act requires insurers and drug plan administrators to pool high-cost drug claims "according to the terms and conditions they determine." Insurers and administrators must report their terms and conditions to the Minister by November 1 each year.

The Act clearly provides a great deal of latitude to insurers and administrators to administer and report in accordance with the letter and spirit of the law.

5.6 Summary: Quebec

The social insurance model in Quebec specifically divides responsibility for universal drug coverage between the government and employers. It has significant premiums, coinsurance (37%, the highest in Canada) and deductibles. It also has generous exemptions and subsidies and caps individual out-of-pocket costs at just over $1,100 annually. The RAMQ limit on out-of-pocket cost is the same for all incomes, meaning it is regressive: it provides greater benefit to wealthier individuals who would find this amount more affordable. (Other provinces typically set personal cost limits as a percent of the prior year's family income – see **Table 4.2**.)

Until 2013, Quebec's industrial policy favouring the pharmaceutical industry has superseded cost pressures from its health spending. Quebec's BAP 15 policy, its decision to shield pharmacies from pricing transparency and its failure to negotiate drug prices with manufacturers have all driven up costs beyond those of other provinces. So did its decision to mandate a place for private insurers that have much higher administration costs and pay higher costs for a wider range of drugs than offered by the provincial plan. However squeezing them out would have alienated the private insurers that remain important corporate citizens, employers, and investors in Quebec (Pomey et al., 2007). In 2018, the life and health insurance industry employed 31,700 Quebecers and had $138 billion invested in Quebec.[215] A fully provincial drug plan would also have cut significant provincial revenues for premium and retail sales taxes.

[214] An English version of the Act is available at: http://legisquebec.gouv.qc.ca/en/ShowDoc/cs/A-29.01.
[215] CLHIA: *2018 Provincial Facts and Figures*, available at: https://clhia.ca/web/CLHIA_LP4W_LND_Webstation.nsf/page/CCC69F7D565FDA75852581FC005BAF8B!OpenDocument.

The model has been criticized (Smolina & Morgan 2014; Gagnon, 2015) but they have not generally separated the model from the underlying policy. For example, although Smolina and Morgan report that 80% of the overspending is caused by more drugs dispensed per capita, and explain the balance by higher drug and pharmacy prices, they state higher overall use "may, in part, be explained by the introduction of Quebec's compulsory drug insurance program…" (p. 24). They believe policy options will be difficult to introduce because of "structural inefficiencies created by the mixed funding model…" (p. 25). Another explanation may be politics and slow-moving policy changes, but the model did not cause those.

Since 2013, the province has dismantled many of the barriers to lower prices and costs it set up in an effort to support brand drug manufacturers with Canadian headquarters in the province. Generic substitution rates are now almost at the Canadian average. While the pharmacy industry has largely escaped demands for greater transparency and accountability, its autonomy could be reined in whenever sufficient political will exists.

While the Quebec model of social insurance is not perfect, it mandated universal coverage 22 years ago and even under questionable policy, its financial performance has not been so far off provincial averages that it has not been able to recover ground quite quickly following recent policy changes. Pomey et al. (2007) wrote:

> Policy-making would be more responsible and have a better chance of success, [Giandomenico Majone (1975)] wrote, if it were founded on the scrupulous consideration of social, political, economic, and other constraints, rather than on theoretical arguments about what was most desirable. Twenty years later…Marmor reframed the issue in terms of the importance of an execution strategy, arguing that "we need to move beyond our preconceptions of plans to realistic forecasts of their implementation" (1994, p. 216)." (p. 486)

Beyond financing, implementation is perhaps the most difficult aspect of any change to drug insurance, whether single payer or social insurance.

5.7 Summary of Health System Features in Three Jurisdictions

Table 5.13 – Key Drug System Comparators – Germany, Netherlands and Quebec

	Germany	Netherlands	Quebec
Health System Rank	8th of 11	3rd of 11	9th of 11 (Canada)
Drug Cost per capita	$777 (5th)	$406 (25th)	$833 (4th) (Canada)
Scope	Universal health coverage regardless of age or health status for all employed citizens earning less than €60,750 (2019) annually. Civil servants, self-employed and higher earners may purchase private coverage. Private health insurance (PHI) is 11% of all system spending.	Basic universal health coverage regardless of age, health status or sex. Voluntary private insurance (VHI) covers 84% of population and is 6% of spending.	Universal drug coverage regardless of age, health status or sex. Private plans must be at least as generous as the Quebec provincial plan. Employers with a health plan must cover drugs for all employees. Province covers all others. Private health insurance covers 65% and is 12% of spending (Canada).
Mandate	Individual and employer.	Employer and individual, except if 'conscientious objector'.	Individual and employer.
Governance	Federal Joint Committee determines all health services and sets provider quality measures. FJC has 13 voting members from social insurers, physicians, hospitals, dentists, 3 unaffiliated. Five	Under the Health Insurance Act (Zvw), the government sets coverage with advice from the National Healthcare Institute (ZiNL).	Régie de l'assurance maladie du Québec (RAMQ). Insurers are self-regulated with annual report to the province.

	Germany	Netherlands	Quebec
	patient reps are observers.		
Funders	124 not-for-profit social insurers, residents and German government	23 mostly not-for-profit social insurers, residents and the Dutch government	Provincial and federal governments, employers, residents. Most insurers are for-profit.
Health Funding	73% public, 27% private. Out-of-pocket: 14%. Health insurance payroll tax: 14.6% split equally between employers and employees. Drugs: 10% coinsurance with min. personal cost €5, max €10 per script. No coinsurance if drug cost is at least 30% below reference price (N=5,000 drugs). Insurers may risk-share with individuals (rare).	88% public; 12% private. Out-of-pocket: 11% Health insurance payroll tax: 12.65% with 6.95% paid by employers. Employees taxed on this. Annual health insurance premiums averaging €1,300 plus €385 deductible per adult. Government funds children, refugees, and certain services for all such as General Physician visits. Insurers may risk-rate under VHI, but none do.	69% public, 31% private. Out-of-pocket: 15% (Canada). General tax revenues. QC Health Services Fund (Employers): 1.25% to 4.26% of payroll depending on revenue. Retail sales tax: 9%. Insurance premium tax: 3.48% RAMQ: Drug premium up to $636; deductible of $261, coinsurance 37%. Private: Premium amount and sharing variable by plan; 20% coinsurance typical.
Out-of-Pocket Drug Cost Limit	2% of family income. 1% for those with specified chronic diseases (all health).	After Basic premium payment, the deductible is the limit (€385 – all health).	$1,117 (drugs only). Private insurance cannot exceed RAMQ limit.
Tax Subsidies	About 9% are exempted due to income cap or chronic disease costs (Blümel and Busse, 2016).	"Health care allowances" graduated for low income singles and families. Eligibility tested by incomes and assets.	Focused on low income singles and families. One in 5 (22%) of those covered by RAMQ paid nothing for their drug insurance. Others get subsidies.

	Germany	Netherlands	Quebec
Formulary	Negative formulary. All patented drugs are included but must have added benefit to get price premium over reference drug(s). Many generics are tendered for lowest price.	Standard national drug list. Many drugs subject to reference pricing. Many generics are tendered for lowest price.	Province sets drug list, minimum level of reimbursement (65.1%). No tendering. Generic price agreement with drug manufacturers. New drug prices negotiated since 2015.
Risk-sharing	Prospective. Age, sex and presence of 80 chronic and costly diseases. Social insurers can negotiate drug rebates. Private insurance: 1.No government subsidy. 2.Personal risk is under-written at policy onset, then does not change. 3.Employer contributes up to maximum social insurance premium but not more than 50% of insured's premium. 4.Separate risk-sharing scheme. Must set aside "aging reserves" which follow the insured.	Community rating. Sophisticated. Prospectively based on age, sex, income source, socio-economic status, region, if one of 20 chronic diseases, if one of 13 in-patient diagnostic groups.	In Quebec, the insurance industry manages a pool for drug claims exceeding a certain value according to the size of the employer. This claim pool is then allocated to each insurer operating in Quebec according to their market share. In the rest of Canada, insurers pool recurrent high-cost drug claims above a set annual threshold only for small employers with fully-insured health plans.
Open enrolment	Twice annually. New applicants any time.	Each January 1. New applicants any time.	Not available. Automatic RAMQ enrolment at age 65.

	Germany	Netherlands	Quebec
Provider Negotiation	Self-regulated through FJC. GKV-SV (insurer association) negotiates drug rebates with manufacturers and pharmacies.	Self-regulated through NZa. Zn (insurer association) negotiates with drug companies and pharmacies.	RAMQ: By regulation up to late 2015. Drug price now as part of pCPA. No pharmacy mgmt. Private: Individual drug price negotiation now allowed. No pharmacy negotiation.
Insurance Regulation	Self-regulation. Prices, underwriting rules, rates, premium and reserve calculations, premium changes, use of profits. PHI rates are set and frozen at enrolment based on age, sex and health status.	Self-regulation.	Self-regulation. Enforces mandatory minimum standards for plan design and eligibility. Government receives annual reports from insurance industry every November.
Overall Comments	Price transparency: Drug prices for reference drugs and those with costs 30% below the reference price are public. The latter group are exempt from coinsurance. Reference pricing ensures better value from new products. Regular legislative changes address emerging issues. Aggressive prescribing controls engage physicians in cost control. German drug prices are still among the highest in the world,	Unique to the three, The Netherlands has achieved much lower drug prices and costs, and has seen drug prices decline in some recent years. The private insurance market has retained significant competitive latitude, even though insurers are almost all not-for-profit. Managed competition / regulation in health insurance appears to be slowly achieving policy goals (e.g., improving quality), although the Dutch health system remains	Canada has not introduced the price and cost controls found in other nations, especially reference pricing. Canada has not reacted to much diminished R&D spending by patent drug manufacturers. Canada has retained a fully private and competitive insurance market with a cost structure much higher than provincial drug plans. QC has an increasingly competitive market, now aligning with other provinces in pricing and policy. In the past,

	Germany	Netherlands	Quebec
	although this is balanced to some degree by a sizable domestic drug manufacturing and R&D complex.	one of the most expensive in the world.	industrial policy has inflated prices and costs. Pharmacy industry not subject to price controls.

Sources: As in text.

Chapter 6

Opinion Leader Interviews: The federal role

Research Question 2

What advantages and disadvantages of our current shared-funding model are recognized by private and public drug plan opinion leaders?

a. What are optimal roles for the federal government to play in achieving adequate universal drug coverage?

Chapter Overview

This chapter will identify and examine the role of the federal government in achieving universal drug insurance, commonly known as national pharmacare. It outlines recent developments undertaken by the federal government, and reactions from provincial governments and private payers.

As a reminder, this chapter relies on 26 semi-structured telephone interviews conducted with opinion leaders in 2017. Participants were drawn from the federal (N=4) and provincial (7) governments, private payers (7), professional associations (2), labour (2), business (1), public policy, (1), the pharmaceutical industry (1) and academia (1).

Opinion leaders clearly and unanimously agreed the federal government's engagement was crucial. Five themes regarding federal leadership were inductively uncovered: facilitation, research, funding, relationship management as well as nation-building.

Opinion leader participants unanimously agree that the status quo must change but they differ in priorities, process and goals. Almost all are focused on lowering drug prices and costs. National pharmacare (NPh) has rapidly ascended to prominence over the last three years, and yet no participant in 2017 suggested it was imminent. Single payer is described as an ideal option by some participants but is described as impractical and unnecessary by other whose employer has a financial stake in the current model, such as insurers, pharmacy and the brand pharmaceutical industry. Those groups promote a 'fill-the-gap' model that retains a role for private insurance. One of the major umbrella patient advocacy groups, the Best Medicines Coalition, is indifferent to the model.[216]

Although one or two leaders blamed the bureaucracy for a lack of progress, positioning in the October 2019 election and this sample suggest the barrier is political. This is consistent with Boothe (2015) who has described NPh as a political deliberation. Responsibility for delay may rest with the Liberal party leadership since the membership at

[216] See Pharmacare Position Points: September 2019, available at: https://bestmedicinescoalition.org/

its 2019 policy conference endorsed "Implementing Universal Access to Necessary Medicines" as their first priority.[217]

6.1 Overview of the federal role

Canada does not have an overarching strategy for its prescription drug programs (Morgan and Boothe, 2016). There are no explicit goals for $34 billion in total annual spending. A strategy and goals are structured to solve problems but the problem(s) may be unclear or contentious. The problems and solutions may be mismatched. One participant spoke for several when he said:

> "*In many ways, pharmacare is a solution in search of a problem, a philosophical debate, as opposed to what is the problem we're trying to solve? If it's drug cost, pharmacare, most would argue, is not the solution. Providing more drugs to everybody is certainly not going to reduce cost. I think our biggest challenge is to identify what truly is the problem, which I don't think anyone has done very well yet.*" (Health professional association executive)

However, the federal government has been clear that there are two problems from their perspective and they must be solved in order. The first is that drug prices are too high, and the best-matched solution is reform of the PMPRB and its potential integration under the Canadian Drug Agency. The second problem is the lack of universal access to a standard national formulary.

That noted, the quote above indicates there is confusion among other stakeholders, and confusion creates resistance to change. Given our fragmented provincial and private systems, one important role for the federal government is to gain consensus on the problems and then mediate solutions with the provinces and possibly private payers to address those problems. Recent F/P/T meetings indicate this process has begun at least between governments, but progress is uncertain, other stakeholders may not have been engaged, and so decisions will be deferred.

By convention, the provinces have authority over most operational aspects of health services, but the federal government provides funding through the Canada Health Transfer (and other means) which in turn provides leverage to pull the jurisdictions into new programs or improve existing ones. The important roles of each level of government are not explicitly set out in the Constitution Act of 1867. The Act and subsequent court decisions have given the provinces authority over hospitals, professional services, health care, public health and the market behaviour of insurance companies (Flood et al., 2018).

[217] See page 3: https://www.liberal.ca/wp-content/uploads/2018/04/2018PolicyResolutions.pdf.

Potential Federal Roles

A recent policy paper (Hartmann, Davidson & Alwani, 2018) identified seven objectives for the federal government (p.31) related to NPh. There was no clear definition of terms or any discussion of relative priority or the trade-offs among them.[1]

1. Access (universal, or for selected population cohorts)
2. Affordability (patient-level cost-sharing, including premiums)
3. Consistency: Formulary
4. Consistency: "Parameters" (variations in provincial program eligibility and out-of-pocket costs)
5. "Cost" efficiency (drug cost; drug price negotiation)
6. Role of private (insurance)[1]
7. Additional federal cost (multiple estimates, half without sources referenced)

This 65-page report devoted less than one page to describing private insurance. Private insurance was not mentioned in the more detailed assessment and discussion of approaches, nor in the concluding chapter. (See Chapter 7)

The scope and impact of the federal role evolves as the Premiers change their positions. This is not predictable given provincial election cycles. It was previously noted (Section 4.3.1)
that the Premiers in power in 2004 wanted to hand drug programs to the federal government. But following their annual meeting in July 2018, the Premiers articulated four expectations of the federal government regarding NPh. In addition to improved access to therapies and better understanding of the administrative 'business case', they wanted to retain autonomy over the design and delivery of public drug coverage, they insisted that federal NPh funding be "long-term, adequate, secure, flexible and take into consideration present and future cost pressures" and they demanded full opt-out privileges and full financial compensation.[218] (At that time, Quebec stated it would opt out.) Insistence on provincial autonomy has created significantly different entitlement programs across Canada, which creates important hurdles for a federal government intent on developing a national formulary and universal access.

Given this background, the general question is whether or how the themes arising from participants may inform or predict federal policy, funding and program design, and how the current and emerging approach to NPh has been predicted by Kingdon.

[218] See: http://www.canadaspremiers.ca/wp-content/uploads/2018/07/Final_communique_July_20-1.pdf.

6.2 Ideas from Experts

The federal government already plays several roles in health, consisting of regulatory, such as drug approvals (safety and efficacy), reviews of new patented drug prices, clinical and economic reviews of new drugs, public health, and funding of research (Canadian Institutes of Health Research), health information (Canadian Institute of Health Information) and health services from five federal health plans (Non-Insured Health Benefits, Military and RCMP personnel, Veterans, Corrections, Refugees) as well as coverage for federal employees and retirees.

Active and retired senior bureaucrats responsible for administering provincial drug plans favoured the continued involvement of private insurance plans to help them manage both their budget and the public's expectations. The Advisory Council (2019b) recently reported its recommendation for a public single payer drug plan to be phased in over eight years. This indicates some daylight between politicians who are largely responsible for the decision agenda and bureaucrats who are most knowledgeable about alternatives and implementation.

The next sections use a range of expert opinion to identify four tangible roles believed to be most appropriate for the federal government. An important intangible role is also revealed.

6.2.1 Findings

When interviewed in 2017, none of 26 opinion leader participants anticipated the federal government's commitment to publicly explore NPh in general, let alone its implementation.

> "*In my lifetime, I don't believe it will ever happen.*" (Former provincial drug plan manager)

An important question is why these leaders, almost all of them senior and many of them very close to the issue, did not mention the federal government's interest in NPh. Policy development does not appear to have included consultation with any of the experts included in this study. This suggests policy can be random, secretive or politically motivated[219] rather than consultative, transparent and rationally constructed. While Kingdon's model would properly position single payer NPh as an 'off-the-shelf' solution, to these experts it did not appear ripe for federal political interest. Cuts to the Canada Health Transfer had just been introduced and plan administrators knew NPh was likely to increase costs. They were certainly aware of previous NPh initiatives given their positions and tenure. The question was not "if" NPh would return to active consideration, but when. It was the timing that surprised them.

[219] Political motivation was frequently brought up when discussion turned to the Ontario government's original OHIP+ drug plan. This Case Study is described in Sec 4.5.1. Policy must appeal to politicians and advance their decision agendas.

Virtually all participants believed that federal government involvement was essential for universal drug insurance to be developed, although a range of goals, processes and intensity was noted. In the absence of national standards or a strategy for access to prescription medicines, provincial responsibility for health care has led to a variety of plan designs and eligibility rules. Former provincial drug plan leaders pointed out that provinces are unlikely to improve eligibility or formularies without federal leadership and funding. Against this variation and interest in developing national standards and a national formulary is the HESA recommendation that drug plan consistency be voluntary for each province. This echoes the National Forum on Health (1997) which concluded: "While a national formulary for Canada might be considered, it is probably not necessary and could take a long time to develop… there would be no reason not to let each province establish its own rules" (p. 15).

Finally, two participants cautioned that while our present discussion focused on drugs, we should understand drug insurance exists in the context of an entire health system.

> *"… any discussion about a pharmacare program hopefully involves the federal actors that are responsible for industry strategy and support and that as well as price, so that we're having an integrated conversation about the whole pipeline and not just the particular valves along the way."* (Labour policy expert)

> *"… too often we talk about drug coverage and particularly outpatient drug coverage and we do not embed it in the context of health care as a whole for the patient."* (Federal senior bureaucrat)

Contrary to these expressed views but consistent with its mandate, the Advisory Council's final report (2019b) did not nest NPh in a broader system context.

Eighteen participants made at least one comment on how the federal government could encourage NPh. No participant opposed an important federal role. The most commonly mentioned roles were financial or funding (N=10), administrative support such as facilitation, formulary development and principles (N=9), explicit leadership (N=8), and relationship management roles that enable policy and program development (N=8). These four have been grouped and labelled tangible. Specifically mentioned twice but perceived as a common thread across many comments is a more general but intangible role of nation-building.

6.2.1.1 Funder

Participants were asked generally about major problems and priorities, their preferences for the structure, administration and funding of prescription drug coverage and about sustainability. All questions are listed in Section 3.2.3.4.

The context of the following statement was about ideas and lost opportunities to act. Participants were asked about the structure of drug plans and how we might transition to a new model. The participant had countered that before that, "we have to agree on what good looks like."

> *"Government has many funding tools. A social insurance model is one. General tax revenue is another. A dedicated tax is another. But I think until we come to ground on what that type of coverage could look like, what do we want it to look like? What does good look like for Canadians? Then you can cost it. And then you can sit and have a reasoned discussion about can we afford this?"* (Federal senior bureaucrat)

This statement echoed comments made by others that problems, options and goals should be defined before we leap to solutions – a rational rather than political approach to policy. The context was more generic than specific to the federal government's role.

Among those with an opinion, there was general agreement the federal government will need to provide adequate and sustained funding. Without that, national pharmacare becomes unattainable.

> *"I think if you're coming to the table with money, then you're at the table with a perspective and the right to be able to control certain things. Without putting federal money on the table, I don't think the provincial governments are going to be even remotely interested in having a conversation that might somehow go to more of a federal [national] solution than a provincial one."* (Private insurance senior executive)

This participant clearly stated that the 'old way' of provinces drifting along with only incidental alignment between them was unlikely to solve the need for universal drug insurance. New federal funding should be conditional on the provinces meeting national standards for eligibility and formulary.

> *"…[*no one*] has [*yet*] suggested we use the same model for pharmaceuticals which would in essence entail re-acknowledging that delivery of a pharmaceutical insurance program would be at the provincial level, a provincial responsibility in the same way that the delivery of hospitals is a provincial responsibility. But that there would be a requirement to meet common standards in terms of who has access to coverage, what kinds of things are covered, etc., and under what conditions, and to have those standards in return for an appropriate measure of federal contribution for financing."* (Former senior federal bureaucrat)

This is the crux of the constitutional allocation of responsibility for health insurance. While the Premiers clearly want to retain control *and* get new federal money, the federal perspective is that they must agree to act in the national interest by meeting new national standards, and new federal monies would now make that possible. The federal government has been very clear that consultation with the provinces is crucial to implementing NPh, and

that each province may opt in on its own schedule. Quebec is usually a special case, and would be very likely to continue its own plan:

> *"I think for me, it's really that possibility to have a national drug insurance plan is more a political issue than a civil servant, I would say, issue, because we have one here in Québec. So I think there is no appetite I would say to try to modify it. In a sense, if the federal government decided to implement one, I think the Québec government would want to receive money and they will manage it like they are doing right now."* (Former provincial drug plan manager)

There is a general consensus when participants spoke of funding that the federal government should come to the table with money in order to have legitimacy, leverage and greater persuasive power. This is consistent with the federal government's greater fiscal capacity to spend. But the national standards discussed are not limited to a formulary design or universal coverage. They are framed very generally.

> *"Personally I think they* [the federal government] *should probably define minimum coverage which should apply to all Canadians, but with that they will have to provide budget to the provincial governments to support that [unclear]. For me if they take the decision to impose a drug plan, a minimum for all Canadians, they will have to provide budget for it."* (Former provincial drug plan manager)

The Premiers have been clear and consistent in their funding demands: "long-term, secure, flexible and fully offset present and future cost pressures" (Canada's Premiers, 2019 Final Communiqué, p. 2).[220] The federal share of direct health spending has decreased significantly since hospital and physician coverage were originally introduced with 50-50 funding and that has been a concern to provincial governments.

> "*On top of all, you know the challenge that we've seen is that over the years the feds have stepped away from funding healthcare, and so they don't have the same influence over the provinces and the provinces haven't got the same, we haven't come up with the consistent goals of where we need to go.*" (Former provincial drug plan manager)

Before a program can be launched, even minimal funding can be useful to facilitate progress. For example, data and research are needed to consider any changes.

> *"I don't think they have to fund everything but I think them funding certain components really gives a lot of traction on moving an issue forward only because then it stops the jurisdictions from saying, oh well we would love to do this but we don't have A, B and C. And then they can come in and say look, we'll take that problem off your table and we'll deal with it."* (Former provincial drug plan manager)

[220] Available at: https://www.canadaspremiers.ca/premiers-committed-to-healthcare-sustainability-call-on-federal-government-to-be-full-partner/.

The major challenge at the moment is that funding roles and commitments are purely speculative. Liberal policy is suggested through the Advisory Council's report, but the government has not yet announced any model or mechanism.

6.2.1.2 Administrative Support (Coordinator / Secretariat / Facilitator)

This role was mostly derived from a question about the opportunity for substantive collaboration between governments and private payers. Some participants framed it more broadly to include both senior levels of government. Despite its periodic funding decisions that have harmed Federal/Provincial/Territorial (F/P/T) relations, in a very practical way, the federal government's bureaucracy has facilitated provincial cooperation in the past and can continue this. They can propose national issues that need jurisdictional engagement. However, bridges between governments and private payers have barely been established.

> *"I think one of the advantages of the federal government, so from a provincial perspective, people will look to them as the money-holders for some of this stuff. I don't know how realistic that is… But I think they should be taking on that role to bring together folks to talk about common issues, to try to find some solutions… So they're able to help mobilize, trying to move it from policy to reality. …In the previous years there used to be something called the Pharmaceutical Issues Committee [PIC]. There was a Secretariat within Health Canada that, they didn't have a huge amount of staff but they were able to develop the white papers, the policy papers, engage folks in conversation, to do a lot of the legwork that's needed to resolve some of these issues. Because in the absence of that, the individual jurisdictions will just say, look we're really busy with our own issues. We just don't have the time to do that.*" (Former provincial drug plan manager)

Previous experience noted above with the PIC and current success with the pCPA suggests a ready-made forum and process for bureaucrats to develop the operational goals, priorities and processes needed to implement national pharmacare. The pCPA also reports to the Premiers through the Council of the Federation, a direct line to real power.

Such a forum might enable well-informed discussion of alternative models, including two provincial approaches that already exist in Canada: Quebec (social insurance) and the 'western Canada' (catastrophic) model established in BC, SK and MB.

> "*Really what we are talking about is how that share between government and private occurs within drug spending. Québec's created a way to share it on populations and BC and Manitoba and Saskatchewan have learned how to share it on spend, economics. Which is better, I don't know. When you look at Europe, one would say that Québec probably is more like Germany. BC and others are more like the NHS. Both seem to work. …I don't know what the answer is, but I think that it's tweaking either the Québec approach to make it applicable across the country or it's tweaking the BC, Saskatchewan,*

Manitoba approach to make it more applicable across the country." (Former provincial drug plan manager)

In other words, there is no need to reinvent the wheel, just adapt one of the two models for use across the country and bring all other plans up to that standard. Quebec's goal was a unified system with universal coverage, while western Canada focuses on income-dependent levels of catastrophic coverage.

Some participants believe the provinces are unlikely to come together on their own to harmonize their plans in terms of eligibility and funding even though they are getting closer with formulary drugs, especially for generics (See ***Case Study – Formulary Consistency***).

"If you get every province coming up with their own formularies, I think that starts to become somewhat counter-productive. So if you could sit down and say let's all come to the table, again, in a facilitator role and say, let's take a look at what your formularies are and let's try to come up with a common formulary which then could result in common pricing and purchasing or pricing models and stuff." (Private drug plan expert)

This suggests an opportunity for the federal government to facilitate an important improvement that the provinces have yet to achieve on their own – standardized formularies. Another participant generally agreed with that assessment and the need for greater alignment in formularies but added a loud note of skepticism that the federal government would play, or be allowed to play, some kind of facilitative role.

"If you leave it up to provinces, there is going to be winners and losers because our programs are all so different…. Our formularies are pretty in sync now…what's different is who we cover and how we cover them in terms of deductibles and that whole structure. It would be very difficult to change, if you left it just up to the provinces, because again of the political cycle and there's going to be winners and losers. …So I think in order for anything substantial to be done, it would have to be national, it would have to be federally led [and] federally funded. In my lifetime, I don't believe it will ever happen." (Former provincial drug plan manager)

There may be several reasons why provincial formularies have not been harmonized and why eligibility criteria and cost-sharing differ by province and even by plan within each province, excepting Quebec. Creating a national standard, beyond just a formulary, could be undertaken by the new Canadian Drug Agency which was announced in the February 2019 federal Budget. The CDA appears likely to merge two provincially controlled agencies (the pCPA and CADTH) potentially with the federal PMPRB and part of Health Canada.

Case Study – Formulary Consistency

> Formularies are not as well coordinated as some participants suggested. The PMPRB (2017) examined a sample of 729 drugs (half of 1,456 drugs listed on at least one of the 11 public formularies included), that accounted for 82% of total prescription drug costs in 2015. Over all 11 plans, the Board found that 79% of drugs representing 95% of all spending, on average, were found to be commonly listed. For generic drugs, the average increased to 86% (97% of costs) but dropped to 67% for single-source drugs (93% of costs).
>
> Pairing each plan with another, there was less consistency for single-source drugs (51% to 80%) than for generic drugs (78% to 92%), and the variation was much greater for the 41 high-cost (annual cost >$10,000) drugs included in the study (37% to 90%). Only 48% (350) of the drugs were listed in all 11 plans and 18% (131) were listed in less than half the plans. This study supports part of the concern expressed by patient groups about the "quality" of public plans.
>
> This PMPRB study indicates that there remain significant differences in provincial formularies. Even though common drugs account for a very high share of spending overall, there are much bigger differences for high-cost drugs…which are likely the hardest to afford for patients and unlikely to be part of the essential medicines list proposed by the Advisory Council (2019b).

The federal government could also play one or more important niche roles, perhaps in coordinating policy to ensure access to very expensive drugs for rare diseases (DRDs, also known as orphan drugs). A DRD strategy was announced in the 2019 federal budget and recommended by the Advisory Board (2019b), but funding would not begin until 2022, very near the end of the current government's full mandate.

> *"You know, I think the orphan drug thing is one that naturally we look to them for. I think that's where conversations are happening and whether they need to step in and coordinate that across geographic boundaries and stuff."… I think it's fair to say that the spirit of Canada would suggest that we shouldn't have people in one part of the country with a clearly inferior formulary and access to the drugs that others have."* (Insurance executive)
>
> *"And then the federal government, if their mandate, as they say, is to provide access to drugs, then there is a role I think for them to play… Why don't they take on all of the rare disease drugs and let us handle what [is] outside of that?"* (Former provincial drug plan manager)

In summary, administrative support can be in one or more specialized areas, but participants believed the federal government must again play a role to facilitate and incent coordination among the jurisdictions. While some of this may be intended in this year's

Budget and Advisory Council report, it will also require spending significant political capital to plan and launch a new drug program.

6.2.1.3 Leader / Policy Leader

Over decades pharmacare as a policy initiative has started in Ottawa, though clearly made no further progress. Federal leadership has been in word but not in deed or dollars. This potential role emerged as participants responded to questions identifying major problems, to addressing sustainability and unmet needs for drug insurance, asking why there was no universal drug plan in Canada and about the opportunity for collaboration. Participants from various sectors said the federal government had to lead change, but it was most commonly stated among labour experts.

> *"I think the federal government should provide leadership."* (Labour policy expert 1)

> *"No, I see it as the federal government needs to take the bull by the horns. It has to be there, one, because everyone agrees there has to be one formulary, one bulk buying. …They* [the federal government] *will have to work with the provinces. There's no doubt about it but they need to lead it. And if they don't lead it then we will continue to having a piecemeal."* (National labour executive)

> *"I think it is probably fair to frame that question, why hasn't the current federal government been a leader on the issue of pharmacare? We have in Ontario had fairly strong statements from Ministers if not the Premier around pharmacare. Maybe the question is then why are we not hearing similar comments and very affirmative statements from others in other provinces?"* (Labour policy expert 2)

> *"I think my view is that probably federal leadership is necessary. Not that we need a federal plan but there probably has to be federal money and a certain amount of political will and political capital expended on that."* (Academic)

> [Researcher] What prevents Canada from having universal drug insurance as we do for hospitals and physicians? What's behind all that?
>
> *"I think it is a, it's the lack of leadership from the federal government."* (Former provincial drug plan manager)

> *"It's just time for national leadership on this one. I really do think it's time for national leadership."* (Federal politician)

> *"I think that means that we've got to crack open, or at least it's high time to crack open the Canada Health Act [to include drugs]. And that's going to take leadership at a federal level, and whether the current Liberal government has that appetite, I'm not really sure."* (Insurance executive)

Related to the need for federal leadership, two participants suggested provinces might fear accountability, and resist supporting NPh in exchange for federal funding.

> *"I think people are always wary that if they get money, there's going to be strings attached to it all the time, and I think that's happened in the past, right? So there's a lot of historical biases as well."* (Former provincial drug plan manager)

> *"But historically as soon as the provinces are told what to do with the money they fight back and go "that's not your jurisdiction, that's ours." So is it [conditional funding] reasonable? It may be intelligent but I don't know whether it would be deemed reasonable or not."* (Private drug plan expert)

The F/P/T relationship is a crucial dimension that must be solved before NPh can be introduced. Provinces have reservations with the adequacy and permanency of federal funding based on past experience. Equity among the jurisdictions is also a concern, as illustrated in the following exchange with a provincial drug plan manager.

> [Researcher] Now if I challenged you the same way you challenged me at the onset, what do you mean by national pharmacare?
>
> *I mean the federal government pays for the drug plan for every Canadian whatever level that is. It is not provincially or territorially funded.*
>
> [Researcher] I guess some people would define national pharmacare as a more coherent or coordinated or consistent level of coverage where jurisdiction remains with the provinces, but there may be some national standards or some targets around access, formulary breadth, out-of-pocket costs, things like that. Do you see that coming?
>
> *It's not going to happen unless the feds pay.*
>
> [Researcher] Okay, so the only way universal coverage, if I can bring that term back, the only way universal coverage could happen is if the feds come up with the money to either fill the gaps or completely change the existing model.
>
> *No, filling the gaps won't do it.*
>
> [Researcher] Okay, why? Because…
>
> *Because every province gets a different amount.*
>
> [Researcher] Yes, okay, so the equity between provinces is a problem.
>
> *Correct.*

HESA directed the Parliamentary Budget Officer to model NPh on Quebec's formulary presumably because Quebec has the most drugs on its formulary. If provinces with better plans get less federal compensation to meet a new national standard formulary, then Quebec would likely see itself as disadvantaged. (The alternative that every province gets the same per capita 'bonus' would dramatically increase program cost.) However, if federal

funding accounts for differences in patient cost-sharing, Quebec would get more federal money because its out-of-pocket costs are relatively high.

It's important to note the federal government has never been the sole payer for a major ongoing health program. Even in the 1950s and 1960s, its limit was 50% and that applied only to the two medicare programs. It's not clear why a national drug program needs full federal funding, other than the trust issue between politicians and the negotiating tactic of asking for more than you think the other party will give in order to get a minimally acceptable deal. Fortunately, participants report there are successful bureaucratic channels and precedents to work out administration and implementation. However, which level of government funds, administers and/or leads a new NPh program will be determined through political negotiation.

In order to sell NPh implementation as an issue of national importance, the federal government must sustain a collaborative relationship with the 13 jurisdictions at both the political and bureaucratic level. The jurisdictions must reciprocate. These roles set up the final tangible role, described below.

6.2.1.4 Relationship manager

Trust is a common and essential thread in a democracy. Citizens need to trust their governments to act in the collective best interest of the country rather than in parochial or political interest. Businesses have to know that their interests are being heard and considered in policy and programs. Within government, politicians have to trust the information and recommendations provided by their bureaucratic deputies. As two senior bureaucrats noted, stakeholders that lose ground following any major policy announcement have to be considered as well, since they can be the most difficult to manage post-decision.

At the meso level, trust is the foundation of relationships which were assessed at three levels: (i) Between senior levels of government (the jurisdictions), (ii) Between bureaucrats and their political masters, and (iii) Between government and business players.

6.2.1.4.1 Jurisdictional relationships (F/P/T)

Participants reported good trust and close working relationships between bureaucrats representing the federal government and the jurisdictions, borne of several years of working together.

> *"I think things are in pretty good shape in terms of the provincial drug plans and federal drug plan leaders. There's a long history of working collaboratively together since the inception of CDR[221] and numerous collaborative work since then. So there's lots of respect.*

[221] The Common Drug Review was established in 2003 through the Canadian Agency for Drugs and Technologies in Health. CDR includes six federal drug plans and all jurisdictions except Quebec.

There is a proven track record despite our many challenges because of our political cycles and priorities, different budgets and different drug plan structures that can work together." (Former provincial drug plan manager)

However, that trust is not absolute. Adequate and sustained federal funding is also crucial for provincial bureaucrats to support federal initiatives. That trust must operate at professional and personal levels.

"Yeah, and I think that's [sustained federal funding] a real concern for folks. What am I buying myself into? I'm going to say yeah, we need to do this. I'm going to lose control over individual decisions. I'm going to be left holding the bag at the end of the day. If somebody has to say no to coverage of a particular drug, people aren't going to go running to the federal government. …they're going to start attacking the provincial folks. …I think people are uncomfortable, as much as we want to support each other, you end up taking the flak for decisions that are often made outside of your jurisdiction. And people don't want to know the history or understand why. As much as they say they do, and you try to explain it to them, it's yeah, yeah, but I just need my drug. That's just human nature." (Former provincial drug plan manager)

Determining the roles and responsibilities of each level of government is a recurring problem in health care. There are legitimate reasons for wanting the federal government to negotiate and enforce national standards, and why provincial governments would be better equipped to operate NPh with adequate and permanent federal funding. The public then has to consider how to pay for it.

"*So if the idea is that we just ramp up pharmacare underneath something like the Canada Health Act, within there or separately, then there's still that, once again it's still up to the individual province to determine what's medically necessary so we can get different coverage.*

…. So it could mean in the end that individuals have less choice than what we have today, right? That we are covering a broader population, therefore we are taking up more of the expenses and all the math I've seen behind the scenes saying that we can see savings in there, but that comes at an increased cost to government. Then the next question is how do we fund that? What's my revenue flows? Premiums or increased taxes, right?"
(Provincial drug plan manager)

6.2.1.4.2 Bureaucrats and Ministers

Politicians have far higher visibility than bureaucrats but have no direct responsibility for program operations. They are, however, specifically accountable to voters and taxpayers. Bureaucrats have operational skills and responsibility coupled with political and budget accountability. It is assumed NPh would be professionally administered by the civil service with politicians providing oversight (governance) and Finance or Treasury Board people

focusing on spending. Government participants were asked whether the priorities vary between political leaders and senior civil servants. Their comments focused on their own experience and revealed a sense of vulnerability.

> *"So as a bureaucrat, you're accountable for the management of your program, the expenditures, so I had to follow the drug line and look at growth. You're reporting to Treasury Board folks around if you've underspent or overspent and why, and why didn't you get your forecast right? You've got a lot of financial folks in government that are sitting there watching you very closely."* (Former provincial drug plan manager)

Clearly governments must live within their budgetary limits. A good example would be the home care program in Ontario. Its budget now exceeds $3 billion annually but it is not an entitlement program like drugs, hospital and physician coverage. Once those earmarked funds are spent, no additional money is available until the next fiscal year. This approach requires rationing (limiting hours and types of services) in order to ensure the funds last 12 months.

> *"I think all of these pieces fit together in the sense that where you have a publicly funded system to one degree or the other, you're always going to be faced with financial constraints and more demand than you can meet. So you know ultimately the Ministers or whoever is responsible has to ultimately make a tough decision."* (Federal senior bureaucrat)

Kingdon positions bureaucrats as knowledge brokers and process leaders who are chiefly responsible for developing alternatives. (Politicians generally control the policy agenda.) Career-oriented bureaucrats believe they provide politicians with professional advice and options. Others see them anchoring the status quo, resisting change and focusing only on budget control. Both political and bureaucratic roles are important and typically complementary as reflected in this lengthy quote:

> *"Political folks don't want to get into the minutia of implementation. They want to understand what are the risks? Who's going to get hurt or harmed through this process? What's the benefit to them and their government? They are there to, as soon as a party is in power, what they're focusing on is how do they stay in power, not working on the logistics of how do you move the current drug program to a pharmacare type program.*
>
> *"I think sometimes the staff within the Minister's office don't fully appreciate that the bureaucrats have been talking about stuff like this for probably five or 10 years and so whenever you try to, try to engage in some of those discussions, unfortunately it sometimes comes across as, okay fine, you're just being obstructive and they don't pay as close attention. Whereas I think really the intent of the bureaucrat is to say look, we've gone down this path. There's* [sic] *a lot of lessons learned. You need to understand the context of some of this stuff. So that's where I think there is sometimes that adversarial approach. …But any senior bureaucrat is going to try to at least take what the end-state*

is that the Minister wants and will try to figure out what is the right path to get to that end-state." (Former provincial drug plan manager)

However, if the introduction of NPh becomes imminent, politicians may need to become better informed so they can explain, defend or advocate their party positions to their constituents. Ideally, we would want them to make astute, fair and timely decisions and understand the costs and benefits of adequate universal drug insurance on patients' lives.

6.2.1.4.3 Business and governments

Since a single payer model is very likely to require employers to continue to pay for drug insurance through some form of taxation, it is important that employers (and private plan members) trust governments to understand and respond to their workplace needs.

One insurer executive candidly admitted that the insurance industry is frequently left out of health ministry deliberations and that governments seem to go to the same stakeholder groups – an "echo chamber" – where the same ideas bounce back and forth between familiar players in a closed system.

"Health policy is very challenging. First of all, as I'm sure you know [laughs]. ... I find it to be a bit of an echo chamber. There's [sic] stakeholders that are not recognized as being inside the tent and I think we're probably one of them. The doctors, the nurses, the hospitals, to a large extent the drug companies, they're all at the table, and employers and insurers and consumers of health services are not often inside the tent. (Insurance executive)

Decades ago, insurers and physicians were positioned against a public health care system for hospitals and medical services. Physicians went on strike in Saskatchewan to retain professional independence before medical insurance was implemented there in 1962 (Shah, 1998, p. 289). Physicians in Ontario went on strike as recently as 1986 over the right to 'extra-bill' patients beyond negotiated rates (Bliss, 2010, p. 11-12). In the 1940s, Boothe (2013, p. 427-28) reports insurers supported public health insurance although they joined physicians in opposing public hospital and medical coverage during the 1950s and 1960s.

The participant idea that insurers are not "inside the tent" on health policy is in some ways complementary to Boothe (2013). If insurer views on health are not valued by government, let alone sought, they will have minimal if any influence on policy and program decisions. When insurers do express views, they do not appear to influence decisions either…although it may be a relief for public officials to know they will not face direct opposition from this otherwise powerful lobby. This lack of influence helps explain why private insurance has been minimized and barely considered in NPh-focused documents. This is despite decades of presence, massive spending and high public support for private drug insurance.

Insurers do have power in financial circles though. Relationships between insurers and financial services regulators and federal Department of Finance officials are long-standing, deep, broad and reciprocal.

> *"…we will get calls from Finance because they know we will be impacted by something, or because they want our opinion on something. Before they do, if they're even thinking of doing something, sometimes we'll get calls and they say, hey, we're thinking of doing this. What do you guys think, or would that work? They will consult with us. That doesn't happen in the health policy field to any significant extent. Because we don't have those relationships, we don't, we're not seen by the health policy folks as an important stakeholder. We tend to be later to the table and because you're late to the game you are dealing with sometimes decisions that have already been made, and therefore you have to go in at a higher level… That's also happened where we'll have to go in at a high level just because we don't know where in the bureaucracy an issue is being dealt with."* (Insurance executive)

This is important because of the central role Finance plays in all new spending decisions, especially a program potentially as costly as NPh. It's also worth noting that before he entered government, the current Finance Minister led the largest pension and benefits consulting firm in Canada. He is closely tied to private insurance. Insurer power and influence with the federal government in financial services does not extend to health decision-making in provincial domains. The insurance industry association (CLHIA) has made only limited progress in establishing itself as a partner of provincial governments and there has been no public collaboration on drug issues.

> *"I think that there is a relationship, particularly with CLHIA now and the drug plans, but struggling I guess to figure out how the two can work together."* (Former provincial drug plan manager)

We may question why insurers have not invested in better health-focused relationships with provincial governments considering over $17 billion (CLHIA, 2018) in revenue from extended health benefits that supplement medicare services is at stake. Employers and benefit advisor firms have achieved even less. Since relationships are weak between public and private payers, there is a struggle to understand and anticipate what the other side may do, or what priorities exist.

From an arms-length vantage, insurers are concerned that health ministry bureaucrats limit their concerns and consideration to their own purview and their own budget accountabilities. They aren't trusted to see the bigger picture, the need for more integrated strategy, or the national interest.

> *"I think the politicians get a better understanding of this. You have to almost go outside the Ministry of Health to other folks to start making this case because then folks at the Ministry of Health are not always focused on the overall health of Canadians. They're focused on managing the health care system. So if it's going to cost them something and*

it doesn't help the health care system but it helps the health outcomes of Canadians, or it might not even be cost, it might just be time and resources, not a dollar cost. But it's hard to get their attention on things that are outside the health care system, the publicly-run health care system. I'm not sure that they look at the broader health care, like non-publicly funded health system, as anything that they have any responsibility for." (Insurance executive)

But it can cut both ways. One provincial drug plan manager believed that insurers and employers can be fickle in the scope and quality of benefits they provide, and shift costs to government plans almost at will.

"Private drug coverage, they de-list drugs. They don't add new drugs. They have co-pays, percentage co-pays with no annual max, and they just keep ratcheting that up to reduce either the employee's or the employer's [unclear] contribution. So if we're looking at filling the gaps, they're just going to keep taking and taking and taking and dumping and dumping. To me that's a losing battle. I wouldn't fill that gap."

[Researcher] If I can paraphrase, the more the provinces pay or expand, the more private insurance will back off and reduce the level of coverage that they provide.

"Yes, and they're doing that. In [province], there aren't that many gaps except in the private insurance world that there's a bit of a growing gap in that many employers are moving to maximum benefits or health spending accounts and people don't understand enough what they're choosing to make sure they have enough coverage." (Provincial drug plan manager)

If this comment is representative of provincial drug plan managers, it suggests a level of frustration and mistrust or misunderstanding between the two key payers borne either of experience or ignorance. It means that discussing or negotiating a place for private drug insurance under national pharmacare will be even more challenging.

6.2.1.5 Nation building

The final federal role arose from statements asking why Canada does not have universal prescription drug insurance and whether there are important unmet needs for drug coverage. Responses indicated that national pharmacare, especially when framed within the Canada Health Act, may have high iconic and intrinsic meaning in terms of the Canadian identity, nation-building or citizenship. Just as the five principles of the Canada Health Act are inseparable, so too might be the addition of pharmacare to existing hospital and medical services. On a rational level, NPh is just another health program. However, NPh may also have a "higher calling," well suited to the federal government.

"*I think my view is that probably federal leadership is necessary. Not that we need a federal plan but there probably has to be federal money and a certain amount of political will and political capital expended on that. And I don't see that in the federal government*

right now, right? They've got other priorities related to health, which is fine. There's lots of important work going on there, but I think that's an important piece of the puzzle that is missing right now in terms of pharmacare." …Partly I think there are both practical and symbolic reasons why federal involvement is important." (Policy expert)

One participant clearly framed national pharmacare as nation-building, as something that affirms Canadian values.

"I think there is this acknowledgement that this will be a major project. This would be an historic moment. If people understood it for its significance, it would be, it would be that second stage of Medicare that Douglas had talked about but we've largely forgotten about. It would be another generation's contribution to our social architecture. As much as we think of the CPP and the hospital insurance or the physician services insurance act as historic documents and certainly historic moments, we haven't been animated by that process of nation-building in a sense, defining ourselves in some very tangible way in terms of what we will be in the future as a country." (Labour policy expert)

6.3 Discussion: The Federal Role

The role of the federal government was not anticipated. Originally, there was no question or sensitizing concept that directly asked about this. However, question 5 (*Why do you think Canada does not have prescription drug insurance like it has for hospitals and physician services?*) often elicited a response that included the federal government or the topic simply became part of the discussion. As the interviews proceeded, the topic repeatedly appeared and its importance became clear. This was amplified as I became aware of the HESA investigation which was happening concurrently…although I was not following HESA at that time.

Four tangible roles were inductively identified through participant interviews – funder, administrative support, leader and relationship manager. Participants also positioned NPh as a rare opportunity for nation-building, a theme picked up by Dr. Hoskins (Advisory Council, 2019b): "The time for universal, single payer, public pharmacare has come. This is our generation's national project…" (p. 3). The roles are both rational and emotional.

All these roles require trust and done well, can even create trust. "Trust is an axiomatic element of successful leadership" (Hasel & Grover, 2017, p. 849). At a personal level, leaders demonstrate several key qualities such as integrity and trustworthiness, communication skills, and providing clear goals and direction (Giles, 2016). Leadership includes what decisions are made and how they are made which captures the need for transparency. While a detailed review of leadership is outside the scope of this thesis, we can conclude that trust in leaders is needed to allow policy to be supported and successfully implemented.

Participants have described sectoral coalitions in government and industry but weak or uncertain levels of trust between them. Periodic withdrawals and restructuring of federal

health funding, the latest in 2017-18, leave provinces unwilling to trust the federal government as a funder of change. For their part, provincial 'avoidance behaviour' during 10-Year Plan requires the federal government to ensure accountability for any new funding. Both levels of government must see themselves becoming willing agents of nation-building. Against these challenges, participants from many sectors recognized the federal government as the natural leader notwithstanding its need to act accordingly.

Along with the "special problem" of funding, implementation must now be considered. These two problems are the left and right Achilles heel for NPh, especially for academics proposing a single payer model.

> *"I think the political leaders are often targets of some of the papers that keep flying around from [Pharmacare] 2020 so obviously when it's presented in a certain way, it looks attractive. When you look at potential cost implications or the potential impact on service delivery there are some questions that are raised. Probably you're talking about incremental cost [versus savings]. Probably you're looking at getting into that cost discussion too, which taints the whole thing."* (Provincial drug plan manager)

> *"Often these cases say if we implemented [NPh], this will be your savings. There is often, they are often silent on the actual reality of the cost of implementation and when you can actually, tangibly realize these savings. And there's not a lot of honesty about how do we get from here to there. And I think that's actually, I would suggest to the detriment. It's always: 'if you put in place it's going to be fine.' Well that's fine and dandy, but really the, I would say the real test of a good strategy is the feasibility of implementation. And they're often silent on that. They're often silent on shared jurisdiction and silent on many things that really are key…*" (Federal senior bureaucrat)

> *"It is such a complex system, and I do think some of these researchers do have some good points but I think that this… call for a national pharmacare program and these numbers like [Dr. Steve Morgan is] throwing out that save the system $15 billion or whatever he said, and then when you read all of the limitations which nobody reads, the fine print, you know he has lost a lot of credibility. So I do think they do bring up some good points about the gaps in our system and that kind of thing, but I think they've gone a little too far.*" (Former provincial drug plan manager)

Others clearly trusted and could accurately cite the key findings of some academic studies:

> "*When you think that if they would establish a national pharmacare program, and CMAJ, what in 2015 came out with that report [Morgan et al.], it would cost, it would cost you around $1 billion. You could save $7 to $9 billion. … Right now the evidence is showing us if it's single-payer, one administrator, one bulk buying, one formulary that's how will you will save more money and protect Canadians better.*" (Labour executive)

"*Every piece of information we heard from people who are knowledgeable about the subject have convinced me that by bringing in universal healthcare system that the initial cost of it, and my best numbers that I can quote are somewhere between maybe three and $5 billion a year would end up, once it's running and all the efficiencies of universal pharmacare are realized, would end up saving Canadians and Canadian society as a whole somewhere between nine and $14 billion. So I think actually as a society, we can actually achieve 100% coverage and save money through a well-designed universal pharmacare system.*" (Federal politician 1)

"*Nobody knows yet what that cost equation looks like. I think the Pharma 2020 group would argue that there is significant savings available across Canada and those savings, if properly deployed should be sufficient to make this a universal program without additional cost to anybody.*" (Federal politician 2)

It was noted earlier that none of the experts interviewed for this study recognized any significant or imminent action on this file. Perhaps none of them were consulted, or perhaps they had been but it was confidential and they were unable to speak of it. It's also possible that bureaucrats were looking for a more compelling argument that included robust, real-world cost estimates.[222] Though it had been persistently presented, perhaps bureaucrats did not consider national pharmacare, in any model, to be an appropriate solution to the problem of high and rising drug prices and cost. They may have assessed that expanded coverage would immediately add cost but savings from "bulk buying" would only gradually lower unit prices for new drugs. Private insurance would no longer be a budgetary safety valve. The influence of variable prescribing, dispensing, health literacy and other practical factors are not integrated into published NPh studies.

Within government, the potential or preferred role of private insurance varies. Politicians speak publicly about minimizing or even eliminating a role for private insurance but the bureaucrats interviewed who are operationally responsible for provincial drug plans universally support the role played by private drug plans in reducing public risk and cost.[223] The two politician participants were unable to articulate a case for private insurance. One policy expert participant repeatedly noted that the private coverage given to politicians is an important reason why they have not yet implemented a single payer public drug plan: their current access to medicines would also be reduced with a smaller public formulary and sometimes higher cost sharing.[224]

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[222] At the time of the interviews, HESA had not yet issued a report and the Advisory Council had not yet been established.
[223] This is different in that total cost is likely higher with private insurance. However, bureaucrats are only accountable for their own budget envelopes.
[224] Politicians did not address the gap between their coverage as members of a private plan and the coverage provided to their constituents through provincial plans. The private drug plan for Members of Parliament has lower cost-sharing (20%), a broader formulary and a lower annual cap on out-of-pocket costs ($3,000, p.19). In 2019, an MP's salary is $178,900, plus non-taxable expense allowances. In Ontario, the Trillium plan would require an MP to spend 4% of salary ($7,156) before receiving any benefit, and then only on the smaller formulary of the Ontario Public Drug Plan. The Public Service Health Care Plan document is available at: http://www.pshcp.ca/media/38813/pshcp-member-booklet-web-en.pdf.

A comprehensive counter-proposal that includes private insurance could still appear. (As noted earlier simply adhering to "fill the gaps" is not a strategy.) More commonly, specific tactics and positions that may together create a strategy have been proposed. Papers by the pharmacy professional association and recent submissions to the Advisory Council by the CLHIA and others are confronting limited and dated research on transition, implementation, costs, models and how to fund this new policy. Within the crucial realm of funding are the sensitive issues of taxation, fairness and patient choice. The emphasis on fidelity to the single payer model has been challenged by practical concerns about feasibility by vested interests in private insurance. While those interests will (should) be challenged, feasibility and practicality are important filters if important changes are to occur. All solutions, traditional and alternative, ought to be rigorously assessed for their fit with cost, access and equity problems.

> *"So I think the biggest challenge we have is that the drug file is exceedingly complex and simple solutions don't work necessarily for complex problems. I think that right now because of the budget issues, the bureaucrats can't be all that creative, and elected officials truly don't understand the complexity of the system and so we're getting what we are getting. We are getting essentially, no, no, no, we'll just negotiate on price rather than fundamental shifts in the system. And I think that's what we've gotten for a good number of years. That's why we are partially in the state we're in."* (Former provincial drug plan manager)

6.4 Chapter summary

The research question pursued in the chapter asks about federal government roles. There was strong agreement among many participants that Ottawa could play several roles – funder, coordinator-facilitator, leader and relationship manager – perhaps all best summarized as leadership. Nation-building is probably exclusively federal in nature. Participants did not appear well-informed about social insurance as a structured and proven alternative to a single payer model. Social insurance is not likely on the short-list "decision agenda" so a window may open only if implementing a single payer option is once again stymied.

Many participants agreed that drug prices have driven concerns about future sustainability and affordability among payers but the drug industry is not a trusted collaborator. Payers favour more collaboration between them but many relationships are narrow, shallow and in a formative stage. With respect to NPh, a major provincial concern is adequate and permanent funding and the current federal proposal of $6 billion over four years for all its new health care objectives hardly passes that test.

One labour participant sparked the idea that creating a real-world NPh will primarily be a bargaining session. Before that table can be set, participants believe the federal government is the only party that can call the meeting to order. Against this hope is the

realization the federal government has not indicated it will step into any of those roles. One again, the political stream appears to be drying up quickly.

Chapter 7

Opinion Leader Interviews: The role of private insurance

Research Question 2

What advantages and disadvantages of our current shared-funding model are recognized by private and public drug plan opinion leaders?

b. Is private drug insurance acceptable and should it be included in national pharmacare policy?[225]

Chapter Overview

This chapter describes the current and potential role for private insurance in a national pharmacare program according to opinion leaders and influencers in public and private drug plans. Participant perceptions provide new and important real-world insights and evidence to determine what kind of plan is optimal for Canadians as both patients and payers.

Participants agree on the need to improve system sustainability and personal affordability, both driven by the high cost of drugs. The brand (vs. generic) pharmaceutical manufacturing industry is commonly viewed as untrustworthy. Poorly informed employers can lead to financial surprises, drug plan cancellation and a risk transfer to provincial liability. Somewhat surprising was the support expressed by provincial drug plan managers for the continuation of private insurance, largely as a safety valve to limit the cost to provincial treasuries.

A few concerns surfaced. First is the lack of trusted relationships and limited experience by provinces and private insurers in collaborating on drug plan policy or programs. A second concern is how payers can create a national standard for drug plans to ensure adequate universal coverage. Related to these problems is how to engage employers and unions. With OHIP+ fresh in mind (Sec. 4.6.1) there is concern about how to manage politics in administrative and operational decisions. This includes political decisions made without a practical understanding of private insurance and importantly, what assumptions are made about employer needs and preferences if a single payer NPh model is used. Finally, there is a need to educate in areas such as differing goals between payers, the Quebec model and the place of regulation to govern private drug insurance.

[225] Drawing from the literature, government opinion leaders, primarily senior bureaucrats responsible for provincial drug plan administration, have the tenure, organizational knowledge, network, and subject matter expertise to identify a suitable model(s) and exert significant influence on implementation. Similarly, private payer opinion leaders included also have the tenure, expertise, authority and network to effectively advocate for change and influence implementation.

A bright spot was the complementary use of technology – private plan services aimed at consumers and patients, and public plan expertise in health technology assessment – that could benefit everyone if both continue following introduction of NPh.

While there was no resistance to the need to change, there was an important divide in the place of private insurance in a new NPh plan. Both practical and ideological barriers must be overcome. Better relationships will encourage the collaboration needed to optimize change.

7.1 Results: Ideas from Experts

There is no qualitative research on how private and public drug plans experts and influencers with real-world experience see universal single payer national pharmacare. Their advice can help ensure that what happens actually works, and that we avoid theoretically pure but operationally impractical decisions on roles for the federal and provincial governments, private insurers and other important stakeholders.

The role of private insurance is among the most contentious and important decisions before us. It is the main difference between proponents of single payer and "fill the gap" solutions.

> *"If there is political momentum that builds and people, Canadians generally endorse this approach, there will still be considerable latitude to define what we all meant when we said we are endorsing single-payer universal pharmacare. I think the critical issue will be really on the insurance piece of it."* (Labour policy expert)

The main issues and discussion points derived from the interviews are listed below and described and illustrated with participant comments.

1. Most common problems
2. Practical considerations and the case of collective bargaining
3. Payer relationships
4. Opportunities and conditions for collaboration
5. Considering politics
6. Different philosophies: Private sector concerns about government
7. Emerging themes

After these sections are explored, the role of private insurance is distilled and discussed.

7.2 Most common problems

7.2.1 Financial risk

Even though each payer group has different sponsors, funding, structures, priorities and covered populations (**Table 4.1**) they generally agreed on sustainability[226] and affordability[227] as the two key issues. Equity and access were also frequently mentioned. Payers were generally worried about "the high cost stuff," meaning recurrent claims for high-cost specialty drugs and drugs for rare diseases (DRDs). Since these are system-level concerns beyond the control of either payer group, there may be opportunities to work more closely together to address those financial threats.

> *"I think the problem we're trying to solve is in our industry specifically, there is a question of sustainability in drug plans, in part because the lack of certainty in terms of employers. The payers of plans have very little ability to predict what their future costs are going to be any longer. Even in particular, the impact of rare disease drugs which hit them, right, as well as the growing use of biologics and the rise of chronic disease.*" (Insurance executive)

When asked about the major problems facing drug plan managers, one participant captured most of the major topics noted by other public and private participants. These are bolded for easier identification.

> *"I believe that it's **access**, access to the medications that people need. … So I think the biggest issue they faced, from a public policy issue, is how do I ensure there's fair, consistent, equitable access. Second issue then, as you look at that is **sustainability** of the healthcare system and so if you're going to give access, how are you going to give access [to] those that [are] going to go forward. The system seems to have the capacity to take all monies that are thrown at it [laughs], it's insatiable. And I think then the third aspect within this access and sustainability is **accountability**. We really don't have a good system in place to determine whether or not we are getting the outcomes that we desire from the medications that we approve.*" (Former provincial drug plan manager)

However, there was a counter-point:

> *"I would say, I mean, I can throw out the word sustainability but frankly people have been saying that for 25 years and the sky has not fallen yet. ... We do deal with*

[226] Sustainability can be generally defined as the ability to maintain a predictable course. For insurers, this means prior drug costs can reliably predict rates for the current period. For provincial drug plan managers, it means better ability to plan and control annual budgets. Environmental factors also affect drug plan sustainability, including the cost of new drugs and the rate at which they replace older therapies, as well as underlying demographic drivers like aging and higher rates of chronic disease.

[227] Affordability is typically used to describe a micro-level concern such as the cost of a drug or a person's ability to pay for it.

sustainability by making changes all the time [emphasis], and by managing the drugs that are listed on our formulary." (Provincial drug plan manager)

7.2.2 Drug insurance tied to employment

Traditional long-term careers underpinned the provision of group benefits during at least the first three decades of private insurance (1970s through 1990s). The employment relationship has now changed with more precarious work – temporary, part-time and "gig" jobs which significantly lessen the 'employment contract' between worker and employer. Almost always, those employees do not have a health benefit plan. The cost of drugs then shifts to the patient or to the government for catastrophic costs, if the drug is covered by the public plan.

One participant noted the voluntary and precarious nature of employer plans. Cancer drugs were noted as a sometimes tragic example of differences in provincial and private drug plans. In four provinces, newer, efficacious orally-administered cancer drugs are not covered by provinces except (possibly) through slow Exceptional Access programs.

"*And then my third major concern is the potential for the contraction of private benefits which would expose more Canadians to risks in terms of the cost of drugs. …Or, what happens if someone loses their job and receives a cancer diagnosis, right? Who's going to pay for the out-of-hospital drugs that they need as part of their treatment? And that varies across the country.*" (Academic policy expert)

The statement also supports the need for national standards so coverage does not depend on where you work or live. The risk of voluntary, employment-based drug insurance also concerned a second participant:

"*And the conversion of full-time to casual, part-time without coverage. There's been an enormous shift towards part-time employment just to avoid things like pensions and health benefits. … The job place has changed, so contract work has emerged. Part-time, casual work has been replacing full-time work. … I think it's just about a changing understanding of the employment model and what that means to the cost of drugs to Canadians and the affordability of drugs.*" (Federal politician)

This same federal politician also reported that people "inside the industry…the brokers…" advised that employers were already feeling the strain of providing drug plans:

"So about 36% of people have private drug plans.[228] *Let's just talk about those for a second now. …So if we are relying on employer-based private plans, they [employers] are already experiencing significant increases in the burden of [funding drug plans]. …My*

[228] The participant changed the number as this exchange continued. The CLHIA reports about two-thirds of Canadians have private drug plans. CIHI (2018) reports private insurance accounts for 37% of all prescription drug spending.

understanding is the private plans are starting to become quite at risk." (Federal politician)

In some ways this indicates anecdote becoming evidence of a major problem in access. CLHIA data show more and more Canadians covered by group benefit plans, although the industry's calculations are higher than survey data suggest and are not independently validated. There is no comprehensive national market data available on how employers have changed their drug plans in recent years.

7.3 Practical considerations and the case of collective bargaining

Participants in this section point out some specific, practical, real-world challenges. They include a specific tension between politicians and bureaucrats in delivering a comprehensive NPh plan in 2027 (Advisory Board, 2019b) and doing that within a sustainable budget. The potential impacts of collectively bargained drug plans is noted. While those who administer plans are familiar with these details, politicians who propose policy and programs are likely unaware of these possible stumbling blocks.

7.3.1 Transition: Reconciling differences

As noted, even the best provincial drug plan (QC) provides access to fewer drugs than most private plans. If public insurance was more comprehensive, there may be less interest in preserving private insurance. One labour participant acknowledged the challenge of balancing the goal of comprehensive coverage with the ability or willingness of governments to pay for it. He notes a side issue of what non-formulary drugs might be available to those who want and can afford them.[229]

"*We appreciate that people will understand that although we would call for a single-payer insurer for pharmaceutical products, that's not to suggest that you would be prohibited from purchasing pharmaceutical products out-of-pocket. Ideally, we're not going to suggest, we wouldn't promote a single-payer pharmacare plan and then say we'll negotiate supplementary insurance at workplaces to cover the gaps. We don't want to promote a system that from the beginning has gaps… although we realize there are gaps we're not going to set ourselves up to acknowledge that we will fail from the outset*." (Labour policy expert)

[229] Sometimes when CADTH reviews a new drug, its clinical value is accepted but its cost-effectiveness is not. For example, after considering the manufacturer's submission for Osimertinib (Tagrisso), CADTH reported it would recommend the drug for provincial reimbursement subject to two conditions: (1) Cost-effectiveness is improved to an acceptable level, and (2) Feasibility of adoption (budget impact) is addressed (E-Alert, January 4, 2019). An ethical and political question is whether a patient, wealthy or not, could buy a new, effective drug that a government plan will not cover unless or until it has negotiated a lower price.

Another participant acknowledged the reality that any budget-constrained public system will sometimes require a potentially unpopular political or bureaucratic decision. Resources are not unlimited so compromises are necessary and rationing of access will occur.

> "*I think all of these pieces fit together in the sense that where you have a publicly funded system to one degree or the other, you're always going to be faced with financial constraints and more demand than you can meet. So you know ultimately the Ministers or whoever is responsible has to ultimately make a tough decision.*" (Federal policy executive)

This sets up an important challenge for governments as they decide the structure and coverage NPh will provide, and how to transition from private coverage. Twenty-two million Canadians who are highly satisfied with their private drug plans (Sanofi, 2019) will not happily accept less than they already have. The Advisory Council (2019b) identified the Quebec formulary as its comprehensive drug plan. When the PBO costed a Quebec-based model for HESA cut $4 billion in drugs that were eligible under private plans. The original OHIP+ faced a similar issue when it did not grandfather patients on drugs that were formerly covered by their private drug plan. While these are administrative (bureaucratic) issues, they are exactly the type that is likely to create very important political headaches. Avoiding those may make create some impetus to consider a larger role for private insurance.

While choice is a common justification for having a private insurance option, the same participant as above was not convinced that the current competitive market is offering a compelling choice of plans and insurers.

> "*I don't know to what extent drug plans are a major component of their [insurer] revenues but I think that's where if you throw into the equation the benefits of single-payer, what are the off-setting benefits of a multi-payer system? And people will say, well there is freedom of choice, you can pick A, B or C. [laughs] Well in my line of work there isn't much distinction between A, B or C.*" (Labour policy expert)

7.3.2 A special case: Unions and collectively bargained benefits

One participant pointed out that a labour union sponsors a large health benefits plan (the asrTrust) for retirees of the former Chrysler Canada and General Motors.[230] Introduction of a single payer NPh plan would eliminate this trust, and likely cost some jobs and perhaps an operating profit for the union. More broadly, it is not clear how employers will manage their legal obligation to provide union members and sometimes retirees with a specific negotiated drug benefit plan that is very likely more generous than a NPh plan based on even the Quebec formulary. Would governments be willing to override collective

[230] See: https://www.asrtrust-cci.com/.

agreements? That would be a messy political and legal challenge, as well as generally disruptive to labour relations.

This situation would affect an important minority of workers: about one third of the labour force is unionized (Statistics Canada, 2016).[231] However, since the majority of those members are in the broader public service, governments would also be faced with a similar bargaining challenge with their own employees.

One participant felt strongly that civil servants would resist losing their richer private drug plan for a less generous fully public plan. (This consideration was briefly noted earlier.)

> "*There is a very, there is probably an intersect of those public-private worlds that doesn't get discussed enough that I think plays a very important part of the political economy and dynamic that contribute to an effective state of gridlock and confusion … In collective bargaining agreements that public-sector employees have negotiated …some of the most generous and broadest access to drug plans, to private employer-based drug plans … That creates a whole assortment of political dynamics and political issues associated with drug policy in Canada in the sense that a whole series of public drug plans exist that apparently aren't good enough for those people who are working for governments. They expect and do get access to better, more generous plans with improved coverage*." (Policy expert)

This situation again highlights the need for governments, employers and unions to anticipate the practical impact of a new public drug plan, and not just on collectively bargained contracts.

In a bit of a twist, one participant noted that private insurers could change their role from insurer and risk-bearer to an administrator contracted by governments. This option has not been discussed in the current NPh debate.

> *"I think ourselves and probably many other proponents of the single-payer pharmacare would prefer to go to the table and negotiate an appropriate role for existing insurance providers and plan administrators. … So we're mindful that it isn't a simple discussion about the single-payer, or for that matter the state, that we want to embolden the state to assume this responsibility when there could be agents in civil society that have the expertise. An example I would draw upon would be that the Ontario Drug Benefit Plan for the longest time was administered by Green Shield. The back office, out of sight as it were… It would I think materially be different if it was stated there would be no need for private insurance as opposed to there is no option for private insurance*." (Labour policy expert)

[231] *Labour Organizations in Canada 2015*. Available at: https://www.canada.ca/en/employment-social-development/services/collective-bargaining-data/reports/union-coverage.html.

7.4 Payer Relationships

Between private insurers and provincial health ministries, relationships are mostly positive but still quite narrow and weak. However, one provincial participant saw several opportunities to collaborate with private payers on problems of mutual interest. These are **bolded** for easier identification.

> "*It's tricky, but I think there's definitely been more and more engagement over the last few years on things like* ***expensive drugs for rare diseases*** *[EDRDs or DRDs]. Some of the joint things like pricing. Certainly when we did the* ***generic initiative****, we consulted because having transparent price reductions were very important for CLHIA and their members.* ***PLAs*** *[Product Listing Agreements – confidential contracts between payers and drug manufacturers generally reducing a drug's price or net cost to the payer] continue to create a challenge between [payers] because it [a drug's price] is not transparent…*"

This same participant continued:

> "*I think we've talked with [CLHIA executive] Stephen [Frank] about more* ***alignment with CADTH****. I think it would be interesting to start to consider should we be looking at more of a societal perspective [in CADTH's economic analyses] as opposed to strictly the public perspective as far as any difference that does make. I think there is opportunity on some of the big issues like SEBs [Subsequent Entry Biologics, or* ***biosimilars****] or EDRDs [Expensive Drugs for Rare Diseases], those kinds of things. I think there is good opportunity for collaboration.*" (Provincial drug plan manager)

Private plans fund access to drugs but the needs and priorities of private plan sponsors or members may not be considered as governments create policy and programs. The participant correctly noted CADTH's economic review of new drugs considers only the health system and not societal or workplace needs.

Two public sector participants expressed a lack of trust and respect for private insurers. One participant felt private insurers were trying to take advantage of access to public insurance.

> "*Private drug coverage, they de-list drugs. They don't add new drugs. They have co-pays, percentage co-pays with no annual max, and they just keep ratcheting that up to reduce either the employee's or the employer's [unclear] contribution. So if we're looking at filling the gaps, they're just going to keep taking and taking and taking and dumping and dumping. To me that's a losing battle.*" (Provincial drug plan manager)

Note that all provincial drug plans have cost-sharing for their general populations and in two jurisdictions (QC and MB) patient cost-sharing also increases every year. Similar problems, similar responses, no consultation.

One politician stated bluntly that private payers don't manage their plans closely or consistently. His general conclusion was that private insurers add no value over what provincial plans offer.

> *"There's no formulary, there's no restrictions. As costs go up those costs get transferred directly back to the employer. There is no negotiation for the private sector on the price of those drugs. It's really just a negotiation on the cost of the administration of the plan. Then as quite significant costs start to emerge like biogenetic [sic] drugs, some of the immunotherapy medicines, as they start to become more common in prescriptions. Those are for a small employer, they can be enormously punitive*." (Federal politician)

While relationships between public and private payers are limited in number and quality, a measure of trust exists although clearly there will be tensions. Still, it appears a reasonable foundation is in place that would allow collaboration.

7.4.1 Bureaucrat opinions on the role of private insurance

Economic modeling studies clearly state that a single payer NPh is certain to save money by lowering total costs. However, senior bureaucrats take a more narrow view, saying that private insurance should continue, in part, because it reduces their programs' cost to the provincial treasury. Private insurance limits both the number of beneficiaries and program cost for provinces and provides a 'safety valve' by spreading the financial risk to employers and patients. In the end, private insurance may also reduce the need for tax increases. This is demonstrated in the following exchange with a former provincial drug plan manager:

> "*And then the other thing is maintaining the private market. You know… I think we need to maintain the private market.*
>
> [Researcher] And why do you think that?
>
> "*Oh, they play a huge role in cost, in bearing some of the burden of cost. I think they want to maintain it too, and not just the insurers, but employers because it is something that they compete on in terms of hiring. I just think a system without private insurers will cost a lot more.*
>
> [Researcher] … why do you think the combination of public and private could create a lower cost program than a completely public plan?
>
> "*The cost for government would be higher if there was no… [private insurance]. … if all those costs, if that no longer existed, all of those people would now be on our public plan. The costs would increase and how would we get, how would we bear the cost of that [pause] without raising our taxes? I mean there's only two ways that government can get funding: raising taxes or cost share with patients*." (Former provincial drug plan manager)

Other public payers also favoured the continuation of private drug plans, although one participant said it could be better coordinated with public plans. Each of the first three comments below is from a different participant with provincial government experience.

> *"I personally think it would be challenging to simply replace or get rid of private drug insurance. I'm not sure how you would do that because I think the one thing they do provide is choice… I think there is value in private payers. I don't think it would necessarily benefit us to simply get rid of them."* (Provincial drug plan manager)

> "*Is there a role for a private insurance company's employee group plans to play? Yes*." (Provincial drug plan manager)

> "*I think there needs to be a more rationed and balanced approach as to how that will proceed. Maybe the best system then isn't a total public system, but rather is this blended model that we talked about but we just need to make sure that within the blended model, all aspects of it are working as effectively and as efficiently as they can. … What I think that they [the federal government] need to be able to do in this space is continue to have both those cash flows [public and private] in play. The trick isn't to move to all one or all of the other because I think that that's too much money. The trick is to figure out how to make both pools of those monies more efficient and effective. So I agree that employers… employers are used to paying for health benefits. How do you make it so that the spend that they have is a more effective spend?*" (Former provincial drug plan manager)

> *"We have a very healthy, robust private [drug] insurance market in place, so let's just determine what is the appropriate place for that insurance market. Let's maintain that, either to work in a truly parallel way with the public system or to act as the safety valve…*" (Former federal senior bureaucrat)

Some politicians may want to see private insurance eliminated or severely curtailed but in contrast many bureaucrats appreciate the role played by private plans as a safety valve for their budgets.

7.4.2 Payers and pharmaceutical manufacturers

The pharmaceutical (pharma) industry appears to be the main target of concerns about sustainability by all payers. The high prices (affordability) of newer medicines, particularly specialty and rare disease drugs, are of particular concern. From the pharma perspective, Canada's attempts to reduce prices, particularly since PMPRB reform was announced in 2016, have created significant uncertainty about the industry's future revenues and profits, as well as clinical trial activity in Canada and how quickly we will get access to the latest drugs. That noted, the industry here claims to have very little discretion on drug prices. They are set internationally based on several factors including national wealth, external price benchmarking, and our proximity to the US market which has the highest per capita drug costs in the world.

Neither payer group particularly likes or trusts the pharma industry.

"*So …the pharmaceutical industry are making, and I'll be just really blunt, no effort whatsoever to address the pricing concerns in this country. No effort whatsoever to address the evidence-based [unclear]. So, are they a partner? No, they're not. It's an adversarial relationship. Once we get the structure right in Canada then maybe we move to a partnership.*" (Insurance executive)

"*We have a long history that has led to that, a trust issue. And I do think that there is a role that [pharma] can play if we can get past that. We have had a very, I would say, long history of being, and I don't want to say adversaries because we do try to collaborate when we can, but it's often very one, from my perspective anyway, one-sided. [pause] And there's always a hidden agenda.*" (Former provincial drug plan manager)

One participant noted that the pharmaceutical industry must consider NPh along with new drug price controls proposed by the PMPRB and the potential effects they would have on research and development, company-sponsored patient support programs, and the timing of new product launches. These changes may impact access to new medicines.

"*But if you take a look at where they're tracking, if you take a look at the numbers that the previous Minister [Philpott] had indicated she was looking to save, although no one seems to know the basis of the denominator or the time horizon for her statement of saving $3.6 billion for Canadians. On the surface, that sounds like a good political message and an important one. Our industry would say okay, there's a bunch of ways to save that kind of money. Price is part of it but if you're going to try to do that only on price then that's going to have significant consequences, both for our business viability in Canada but as importantly for Canadians even ignoring individuals who work in the drug industry in Canada. It may in fact create a challenge on business decisions as to drugs that will come to Canada. So that's not very well understood.*" (Pharma industry executive)

The industry fears they will not have time to adjust to new pricing rules or explain them to their international headquarters. The consequences of narrow cost-centred decisions are "not very well understood," providing further evidence of a poor working relationship between payers and the pharma industry.

7.5 Opportunities and conditions for collaboration

Public payers have collaborated to address drug access, affordability and sustainability problems. In 2010, Canada's Premiers set up the pan-Canadian Pharmaceutical Alliance (pCPA) to lower brand drug prices in public plans.[232] Private payers are excluded from this

[232] See: http://www.canadaspremiers.ca/pan-canadian-pharmaceutical-alliance/. As at December 31, 2018, the pCPA had completed 262 price negotiations on new brand medicines.

forum although they have benefited because the pCPA has reduced generic drug prices and made biosimilar prices transparent for all Canadians. One insurer participant does not believe there should be a separate "pCPA" for private insurers.

> "*I don't think it makes sense for us to replicate the infrastructure the provinces are bringing. We will have different aims and different things we're trying to achieve but most can be, in my view, bolt-on or we do that incrementally. But our view, and this is what we say all the time, is we want to be at the table with pCPA. That's it!*" (Insurance executive)

Private insurers rarely use their collective buying power to negotiate prices or other listing conditions for new drugs due to concern about potentially violating the Competition Act. Some of the largest insurers do ad-hoc negotiations: the oldest example is Manulife's DrugWatch.[233] Private insurers want to be "price-takers" according to one insurance executive, and simply adopt pCPA prices after those price negotiations with brand drug manufacturers are complete. However, those prices are not publicly disclosed.

Collaboration among payers has important potential benefits but one public plan participant believes allowing private insurers at the pCPA table could potentially undermine existing solidarity against drug manufacturers.

> "*You have to ensure that private plans will be able to do similar [not list a drug until it goes through the pCPA process] if they want to be part of that [pCPA], because once you lose that solidarity then you lose a lot of leverage too…*" (Provincial drug plan manager)

At least one insurer is aware of the need to establish and grow trust between the payer communities based on one previous incident when insurers looked after their own interest without considering the larger long-term picture. This situation points out the need for clear rules of engagement.

> "*I think the pCPA work on Inflectra [biosimilar to Remicade, a high-cost specialty drug] where they shared pricing with the private payer is a good example of where that came together. You know the challenge is the private payers have somewhat betrayed that by them cutting deals with the originator [company] biologic which will cause I think some hesitation on the public side to keep collaborating with us. I think we've got some other opportunities coming up now where we're going to have to be a little more disciplined as an industry and say, look, if we're going to work together with the public side, we're going to have to make some commitments that we're all in and we are going to support that biosimilar more exclusively rather than just watering it down with deals on the originator side.*" (Insurance executive)

[233] For a description of *DrugWatch* and how private insurers negotiate new drug prices with drug manufacturers, see: http://www.pdci.ca/manulife-drugwatch-private-payer-product-listing-agreement-pla-series/.

7.5.1 Managing confidentiality

There are challenges in sharing information between governments and private insurers because of the need for confidentiality on both sides. For governments, information sharing is difficult because of the need for impartiality and giving no party an advantage. For insurers, certain information is proprietary and so carefully guarded. This is another operating rule to address before effective collaboration can occur

> *"Typically you are bound by confidentiality restraints in the budget process. What we would do is try to make a connection as soon as we were able to, but often it's really after-the-fact, which is unfortunate."* (Provincial drug plan manager)

7.5.2 The role of competition

Collaboration between governments and business would force consideration of how to manage competitive interests, including protecting intellectual property. Competition is a double-edged sword: while it drives innovation in private businesses, it can be a barrier for public organizations. This will be one of the greater challenges because insurers will not sacrifice their market position and billions in revenues for the sake of 'playing nice' with provincial drug plans. It could also be addressed through clear operating rules and boundaries on what defines anti-competitive behaviour.

> "*One of the issues with IMC [Innovative Medicines Canada, the industry association for most brand drug manufacturers] and you get this a little bit I'd say with the private insurers too, more so with IMC, that they come up with some very good things and some very good ideas and projects, and philosophies, but because they're all competitors, and they can all agree on it, but then when it's their drug or affects their bottom line, then you see, you see it kind of fall apart.*" (Former provincial drug plan manager)

Another participant suggested that private plans create important and unique value relative to public plans because they may be more willing to innovate and can open a channel to patients. Such innovation, borne of a competitive market, is a positive development for patients and all payers. Private insurers also make use of their access to plan members to provide direct assistance, also something ministries of health and drug programs do not do.

> "*What we're looking at, as just a sidebar, we're starting a pilot in June with [institution] and a genetic tester. We are then going to through our disability case management in the early stages of mental health where it's a challenge to stabilize, a person is not responding or stabilized in a current medication. We're going to cover the cost for that testing to help the physician make that determination of what is the best right drug. …That's a good example though of what we're talking about here. If we want to incorporate innovation such as that, that is one area where, because the private sector, we have access to the employer and employees which is a good channel of communication because government has difficulty reaching individuals that they are covering.*" (Insurance executive)

One participant suggested that combining the best of both public and private abilities could spark some creative solutions, and still avoid upsetting established roles.

> *"I'm not huge on any of those other* [single payer] *options but then we get to some sort of shared funding model. You've got provincial [and] employer insurance, the option to... Here things get interesting. Here's where we're talking about creative ways of making improvement to the existing set of arrangements without complicating vested interests wherever they might lie…"* (Policy expert)

While payer collaboration is possible careful planning is necessary to set ground rules and determine how best to use the strengths of both sides.

7.6 Considering politics

Politicians are unlikely to be drug policy or program experts. They will not always know the right questions to ask and some may not even be interested in alternative solutions, e.g., social insurance. That may change if NPh planning starts to consider implementation and funding.

Participants reported politics are a powerful influence in Canada (see Chapter 6). The massive funding needs and highly visible personal and national impacts will ensure that politicians must decide on the most appropriate role of governments and for private insurance.

In general, the right balance must be found between political opportunism and sound policy alternatives, ensuring problems are matched with appropriate solutions.

> "*But the other thing that's very significant in our healthcare system is politics, and how much of it is politicized. So much of policymaking is driven by, it appears to be driven as much by politics as by good policy*." (Former federal senior executive)

As evidence, at least two participants identified politics were a specific concern when the Ontario government unexpectedly announced in April 2017 that OHIP+ would provide free provincial drug coverage to all residents under age 25.[234] (See Section 4.5.1) The transition to almost any version of NPh will involve private insurers over a period of several years.

> "*The recent announcement in Ontario about the kiddie pharmacare program, well it's hard to argue against ensuring everybody has access to drugs. Basically, to address the one in 10 that might not have coverage to pay for the other nine in 10, doesn't make*

[234] The current government changed OHIP+ to make private drug insurance the first payer for any patient under age 25 who had a plan, most likely through their parents.

sense. Was there a problem in that age group? Was it acute? Was that the best investment of our limited resources to solve a problem? That's taking at a big hammer to, investment to solve what most would argue was probably, would require a more targeted program. That's, in my mind, a philosophical and political approach. It's more about elections than it is about providing good sound health policy." (Pharmacy executive)

"*I mean you'd have to ask Ontario. That to me was completely political.*" (Provincial drug plan manager)

Private insurers and all businesses must work within the confines of political policy, programs and persuasion. This is illustrated in the following exchange which identifies the Quebec government's three important motivations in introducing its unique drug policy in 1996-97: (i) filling coverage gaps, (ii) protecting private insurers and (iii) protecting its own budget. Two out of these three will almost certainly apply to the current federal government. To date, there has been no NPh discussion about the need to protect private insurers. A conversation with a former provincial drug plan manager noted those concerns:

[Researcher] Thinking back to the mid-1990s…Do you recall at that point any particular divisions or differences in how the political leaders and the bureaucratic leaders looked at the Castonguay report and then figured out what to do with it?

"*I think the main issue was related to people or patients who were not able to have access to a private insurance plan. The key issue was then what they will do with these patients and the final decision was that the government will be the insurer for them. That was the main issue, and how to manage costs also in terms of budget. The key was how to cover the working poor, I would say, who did not have access to a drug insurance plan by a private payer.*

[Researcher] Why did a social insurance model come up, because it's not one that's been introduced anywhere else in Canada. Clearly there are examples of it: the Canada Pension Plan is a social insurance model and clearly there are a number of similar models in Europe. Where did that idea come from?

"*I think the government had to protect the private insurers. They are an important employer in the province. So if you decide to stop or to replace the private plans by government plans, you create issues for all these employees and the private insurers too.*

[Researcher] OK, I get that. Do you think that the government also wanted to protect its own budget?

"*Yes.*" (Former provincial drug plan manager)

Insurers in Quebec

To illustrate their importance in Quebec, life and health insurers currently employ 31,700 people across all their operations, collectively pay $957 million in provincial taxes, and have $138 billion invested in the province including provincial ($29 bn) and municipal ($5.5 bn) bonds. (Source: CLHIA, 2019. *Provincial Facts and Figures* 2018)

It may be tempting for insurers, but also academics and politicians to speak for employers. This already occurs. But it's impossible to generalize across 1.1 million incorporated businesses, especially when 95% have fewer than 100 employees. Small businesses don't always speak as employers, they more often speak as personalities and so there is unlikely to be a consensus on the need for or form of NPh.

One benefits advisor working with small and mid-sized employers said his business clients did not hold just one view on the roles of government and employers in providing drug insurance.

> "*So there's no easy answer, no different than individually. We all have different feelings, political views about how this stuff gets handled and I would say employers are the same.*" (Private drug plan expert)

The last participant's statement is supported by one internet-based opinion survey that included large national samples of both employees and employers. It reported strong support for each of four alternative NPh models.

- The strongest support (87% from 1,505 plan members and 84% from 403 employers) was for a NPh model that would "fill gaps in coverage for Canadians who have no insurance or who are underinsured. The workplace plan would not be affected."
- However, the least popular choice still received 57% support from employers and 72% support from employees: "Replace all current provincial and workplace drug plans to ensure everyone gets the same coverage. Workplace drug plans would no longer exist." (Sanofi, 2019 p. 16).

7.7 Different philosophies: Private sector concerns about government

In addition to asking whether we need universal drug insurance, many people will translate NPh into a more fundamental question about the role and size of government (Kingdon, p. 133). This is particularly true in pharmacare where a very large, visible private industry has existed for decades and receives very high quality ratings from most plan members (Sanofi, 2019). There is also a strong national identity with our public healthcare system. Within NPh, the size of governments bounds the role for private insurance.

"*But you're right, we operate in a real world and in the realm of public, in the political world, there is a contest between how much we should allocate and how big government should be and how small it should be. And that's the argument we have*." (Federal politician)

"*So then, depending on the stripe of your governing power, they may think why would we take that on something the private sector does? That's a huge change*." (Provincial drug plan manager)

Ministers rarely start their Cabinet posts as subject-matter experts. Even still, one civil servant understands that political "masters" will decide priorities and resource allocation.

"*So in my mind the fundamental question that each province needs to answer …is should my residents share in the cost of my pharmaceuticals? If so, what should that share look like? And I think everyone's in a different time-space on working up that type of policy question. That's where the political framework comes in mind. What do the political masters value? Is there something they want to invest their time and space into and if so how does this rank amongst their other competing priorities, right?*" (Provincial drug plan manager)

A comment was made about government sincerity to actually make the kind of change this participant believes is needed:

"*I just don't know how realistic it is to re-do [the drug coverage model] [laughs]. Whether there ever would be the political will and courage to do it, I'm very cynical about [that]. Health care is the third rail, and we don't seem to like telling Canadians that some of this stuff needs to change. … we still seem unable to have an adult conversation about how to reform it*." (Insurance executive)

If progress is made, then some in the private sector are also concerned about how well F/P/T governments are likely to plan and execute pharmacare. They question stewardship and governance of our existing health system and its legacy of poor past performance.

Commonwealth Fund research demonstrates other national systems have better outcomes while spending less (Shoen et al., 2010; Davis et al., 2014; Schneider et al., 2017). At its worst, one participant sees government as inherently and perpetually wasteful and incompetent:

"Yeah, you might get a, some of the arguments or the opposing arguments might give you a taste of perhaps how a small business owner might think of this in terms of a publicly administered system. Basically, there is lack of trust or [fear of] *mismanagement and wasteful spending. All of that stuff is going to come up and there's [sic] tons of examples of course in the past that influence that kind of position."* (Business leader)

Competency is not a new concern. Boothe (2015) noted that around 2000 and the National Forum on Health: "Elites [had] high levels of concern about the problems of the existing system of hospital and medical insurance, such as wait times and overcrowded emergency rooms…" (p. 102) that were not being addressed. While fixing problems in the current system is a legitimate priority, the other concern here is trust in government's ability to manage and govern the system as it is, let alone how it might handle change and expansion.

One participant said that poor performance in health governance and planning does not warrant expanding the public system to absorb drug insurance.

> *Essentially if we believe the only solution to the problems that all Canadian healthcare is to expand the Medicare model, I think we're just being oblivious at the same time to the problems associated with the Canadian Medicare model in the first place and the fact that we get really poor value for money. I think that's probably the best way to describe it for all things, doctors and hospitals, the assumption that somehow things are going to dramatically change were we to just to add drugs to that."* (Policy expert)

This comment speaks loudly to the need to ensure good governance, oversight and competency to ensure a high-performing health system.

7.8 Emerging Themes

In addition to the general topics arising from the interviews noted in each section of this chapter, two higher-order themes emerge.

The first theme is collaboration, which emerges from the shared financial and reputational risk to both payer groups that is a product of the same broad market forces. The separate channels of public and private drug plans allow suppliers to 'squeeze-the-balloon', always attempting to make up financial losses on one side (usually public) from private payers, including directly from patients. While public bodies like pCPA deserve credit for more closely managing drug manufacturers, as a matter or equity private plan members should not be disadvantaged and pay higher prices.

Whether or not NPh is launched by the federal government, private and provincial payers could work together to lower drug prices and costs throughout the Canadian market. This would ensure continuing access to emerging drugs, many of which will cost thousands or hundreds of thousands of dollars annually. The presence of private sector organizations may also help address the innovation opportunity for pharmaceutical manufacturers to ensure effective new products are quickly launched in the Canadian market.

A standing advisory forum has already been proposed (Sec 5.3.5) that would report and make recommendations to Ministers of Health (or the pCPA or the new Canadian Drug

Agency), similar to Germany's Federal Joint Committee. This would operationalize two "projects" that stem from a broader commitment to work together:

1. The immediate needs are to develop a national policy for drugs for rare diseases and biosimilars, and perhaps to standardize new drug submissions and economic analyses. Making recommendations about a national formulary, limits to out-of-pocket costs and regulating private drug plans could be included. Longer term, consideration may be given to developing an actively managed national prescription drug policy that stays abreast of fast-moving developments in products and policies globally.

2. Second, the very practical issues arising from transition and implementation could be investigated, including topics such as competition, collective bargaining agreements and protection of confidential information. The Advisory Council did minimal work on this topic, awaiting policy direction from the federal government. This work requires the expertise of practitioners and sufficient time to plan and execute as recent experience with OHIP+ indicates.

The second theme includes philosophy and principles, perhaps more challenging because these involve personal values and a national health system that is loved despite its chronic under-performance relative to international peers. That noted, there is little disagreement on principles and the main questions are about definitions and how many are reasonable (Sec. 2.2.2). This theme stems from comments made about the size and role of government, trust in government competency (and by extension transparency and accountability and including the reverse concern about the need to control private sector behaviours that are not in the public interest), and the occasional intrusion of politics into administrative matters. While it is unlikely any substantive and prescriptive policy may arise from any such discussion, and political involvement cannot be controlled (nor should it be) perhaps guidelines or boundaries may be discussed and outlined.

7.9 Discussion: The role of private insurance

The role of private insurance is one of the most important questions related to national pharmacare, and the dividing line seems to be more ideological than rational. Even though our health system for hospital and physician coverage is public, participants who favour single payer NPh do not totally dismiss a role for private insurance.

Insurers are not without power, especially in Ottawa. They reportedly influenced the Quebec government in the late 1990s to maintain a robust role for employer-sponsored drug plans.[235] Twenty-two years later, insurers have massive investments and economic impact, as well as significant workforces across Canada.

[235] Personal communication, Claude Di Stasio, (former) Vice-présidente, Affaires québécoises, CLHIA. October 20, 2015.

That noted, the depth and diversity of opinion among employers who pay for private insurance is not well known. Since employer-sponsored plans are voluntary, they may be terminated or limited at any time to reduce exposure to uncontrollable high-cost drugs.[236] This means risk and cost transfer to patients, the government, or to other parties. Unfortunately, there are no public data to track the extent to which this is already happening. This threat can be overcome with an employer mandate to provide coverage and meet minimum standards, as in Quebec, but this will be loudly resisted by small businesses that do not already provide coverage. If a full employer mandate is not feasible, then the government could also decide to cover anyone without private insurance, again, similar to Quebec.

Funding has always been a central consideration to governments (Hall, 1964, Boothe, 2015). Unlike private plans that are usually renewed each year despite cost increases well in excess of general inflation, public plans operate under budgetary constraints and must sometimes ration access through administrative rules, failure to list, and lengthy new drug review processes.[237]

Neither payer group trusts the pharmaceutical industry, but its needs must also be considered because access to new, efficacious and cost-effective drugs is in the national interest and clearly in the patient's interest. The pharmaceutical industry believes other government decisions affecting cost, such as PMPRB reform and patient support programs, must be considered alongside NPh. Drug companies operating in Canada must negotiate domestic access and prices with their global headquarters as well as with pCPA.

Payer participants suggested a collaborative model including private insurance could ensure universal access and improve the sustainability of all drug plans by spreading risk and limiting public funding while still addressing cost and equity problems. A mixed payer model could also provide an option for additional coverage for those who can afford and qualify for it. However, collaboration requires higher levels of trust among payers and competition among health providers must be well managed.

While collaboration is noted as an important need, there is a risk that drug price discounts negotiated by the pCPA and given to F/P/T plans by pharmaceutical manufacturers would be smaller if the base was broadened to include all private prescriptions. Governments would therefore pay more than they do in the current model, assuming drug companies have a finite budget for price discounts. This would only affect future negotiations. However, equity would gradually be improved by having a single national price for all public and private payers.

Technology illustrates a complementary approach by public and private payers. Health technology assessment (HTA) used by CADTH and INESSS for public payers is superior to

[236] In unionized workplaces, no changes in health benefits are normally allowed throughout the duration of the collective bargaining agreement.

[237] Examples described in Part 1 include access to Avastin and no coverage for take-home cancer drugs in Ontario.

any used by private insurers. A single payer NPh may need to adapt its HTA to include employer, workplace and community interests. However, no public plan provides technologically sophisticated patient services like those provided by the largest private insurers. Their robust digital health technology platforms – the "omni-channel experience" according to one participant – are aimed at consumers and using various media platforms, i.e., web, smart phone, telephonic and call-centre available 24-7. These services include education on adherence to therapy, health promotion, pharmacy locators and internet-based cognitive behavioural therapy. If these services are terminated due to NPh, patients may reasonably demand that provinces develop comparable services. This will not come cheaply or quickly. A social insurance model could use or adapt the best technology from both payers.

Several participants noted that politics or the politicization of our health system generally is an important problem. The politics of drug insurance are unpredictable particularly for private payers 'outside the tent.' While a new single payer plan could potentially sideline private drug plans, employers would likely exchange insurer premiums for higher taxes. They would then lose control of the design and operation of drug plans that may no longer meet their needs or those of their employees. Ideally, politicians would have more practical knowledge of private drug insurance before they decide how or whether it ought to continue.

Not surprisingly, private insurers also have issues. The industry has been slow to fix problems of its own making such as requiring mandatory generic substitution and capping out-of-pocket costs. Their pooling system for high-cost drugs is limited and failed to progress even in the face of much client criticism. They have no policy on covering drugs for rare diseases. While a private plan may have far larger formularies than even the most generous provincial plan, better coverage will certainly be determined by some combination of formulary and protection from excessive out-of-pocket costs.

Employer drug plans have different goals and priorities than public plans. They should not be examined using the same criteria (see **Table 5.1**). Despite near-universal concern about prices and costs, most employers appear willing to pay for greater choice, technological sophistication and the unique customer service aspects of private insurance. They value competition to improve products and services. Many want to address organizational health issues such as absence, disability and presenteeism in concert with drug plan design and cost so they can better manage productivity and employee engagement and loyalty. These interests are rarely considered by governments in health policy or plan design.

Interviews uncovered two important knowledge gaps. First, almost no one had deep knowledge about how to apply Quebec's social drug insurance model across Canada.[238] Yet, this is the model costed by the PBO at the direction of HESA and proposed by the Advisory Council. It is not at this point a viable off-the-shelf alternative unless a single payer model

[238] Inability to fully review French language reports and research is a potentially important limitation. See Section 8.7.

again fails to launch. Second, no participant knew how regulation could be used to manage drug insurance and ensure private insurers meet the public interest. Regulation of private insurers (Sec 4.8) is central to a social insurance model, again highlighting this is an undeveloped option.

There are a handful of reports about social drug insurance in Canada but neither HESA (2018) nor the Advisory Council (2019b) demonstrated careful assessment and serious consideration as an alternative to a public single payer plan. Neither major report noted regulation of private insurance as a feasible alternative. These need to be explored now if social insurance is to be ready as an alternative solution.

Participant responses indicate private insurance is not generally seen as a problem in itself even though it likely adds unnecessary costs that can be better managed by public plans. Neither provincial and federal bureaucrats nor private payer participants considered a public single payer NPh to be a uniquely appropriate solution, though politicians, labour and academic participants favour it. The political and ideological appeal of this model must be reconciled with the practical knowledge and experience of those who plan and administer public and private drug plans.

If the federal government ultimately decides once again to not pursue NPh, then the status quo could be considered a victory for private insurers. This does not absolve them from making important improvements that would further the goal of ensuring adequate universal coverage. The insurance industry could establish a minimum standard private plan, including mandatory generic substitution, a cap on out-of-pocket spending and perhaps even a policy on biosimilars to serve as a benchmark for employers (and provinces). Insurers could propose approaches to managing drugs for rare disorders. They could certainly improve the high-cost claim pooling mechanism that falls far short of their clients' needs. Better access to private insurance claim data would also improve national drug policy and program development.
Not all the responsibility of leadership should fall on governments considering the hugely important role already played by insurers and employers.

7.10 Chapter Summary

In contrast to the discovery of a strong federal role (Ch. 6) the place of private insurance was known to be contentious and possibly tenuous given academic studies supporting only a single payer approach. My sensitizing concepts and questions specifically asked about this topic.

The research question for this chapter asked whether private drug insurance is acceptable and should be included in national pharmacare policy. A majority of participants agreed private insurance is important and wanted it to continue inside a NPh plan. This is likely a practical position although for some it is ideological based on personal values and how governments are perceived to manage the broader health system. For those who favour

private insurance, this likely means access to a larger formulary and adjunct services (including technology and disease management), and choice of plan design and funding amounts and sources. The somewhat higher cost is not a deterrent: risk can be mitigated because most plans have yet to introduce more active cost management tactics.

On a more strategic or policy level, insurers are often perceived to be more passive managers of their own destiny in contrast to the more activist approach taken by governments through the pCPA, CADTH, INESSS and the PMPRB. Insurer costs can usually be passed on to their employer clients. If “fill the gaps” evolves to more of a social insurance model, then stakeholders will need to better understand the Quebec approach and consider how regulation and far better risk sharing may help the industry operate preferentially in the public interest.

Two high-level themes have emerged from this chapter – those of collaboration and a need for some discussion on principles and philosophy.

A final comment is that employers provide the source funding for private drug plans. While understanding the role of private insurance and insurers is important, this research does not presume to fully explain the roles that employers (and unions) may want to play in NPh policy development and plan design.

Chapter 8

Theoretical Perspectives: Applying Kingdon's Model

8.1 Introduction

It is not clear yet if the recent resurgence in interest for NPh will provide a different outcome than in 2004-06 when the National Pharmaceutical Strategy last prompted discussion about important changes in Canada's drug policy and programs.

In Agendas, Alternatives and Public Policies, Kingdon (2011) explores the conditions that make policy change more likely. He identified three processes or streams: problem definition, policy solutions and politics. The convergence of these streams is signaled by a defined problem coupled with a pre-existing policy solution backed by a policy entrepreneur and high political interest. Convergence opens a window of opportunity, which is often short-lived. Action may or may not follow. The pattern for NPh is one of punctuated equilibrium.

The three streams will be discussed in turn, with convergence of the streams into potential windows of opportunity as the concluding section of this chapter.

8.2 The Problems

NPh has been repeatedly linked in the literature to two clear problems: drug prices are too high and not all Canadians have adequate coverage.

Inadequate drug insurance is recognized as an important problem, with two different models proposed to address it. A public single payer NPh was anticipated by the 1964 Royal Commission and more recently by the 1997 report of the National Forum on Health. It is the basis of most published academic studies (e.g., Morgan et al., 2015). Social insurance is not a new idea either but it has not been implemented in the Canadian health system except for Quebec's drug plan in 1997. The problem of under-insurance is likely to be far greater than the number of uninsured. Alberta and New Brunswick are the only provinces without protection from catastrophic drug costs but residents can access their voluntary plans (Non-Group Coverage and NB Drug Plan, respectively) with minimal delay and will be covered for future expenses within the respective provincial formularies. That leaves just 15,630 residents of Newfoundland and Labrador who had after-tax family incomes over $150,000 (2015) with no access to the NL Assurance catastrophic drug plan. NPh is well-suited to address the need for adequate universal drug insurance if it implements appropriate national standards.

However, it is the drug price-cost problem that has arguably received the most attention. Total prescription drug spending almost doubled between 2004 and 2018 (CIHI, 2018). In recent years, attention has shifted from traditional blockbuster drugs to several very costly

new specialty biologic drugs (especially for oncology) and drugs for rare diseases with six- and sometimes seven-figure annual or one-time costs.

Kingdon describes funding as a "special problem" (p. 105) for new public programs especially one with very high costs. But underneath, there are other important cost "problems" related to NPh as proposed, each presented below. Any of these could have stopped progress but the combination made implementation especially difficult.

National data and comparative international surveys have indicated cost and coverage challenges for many years, but Kingdon warns: "Thus the data do not speak for themselves. Interpretations of the data transform them from statements of conditions to statements of policy problems" (p. 94). The problems are often subjective interpretations, connected by chance or entrepreneurial skill to ready-made policy solutions and political opportunity.

Academic studies have produced large and attractive estimates of cost savings from NPh and for the most part, have presented them as highly likely, relatively simple ("bulk buying"), available quickly, and tied exclusively to a single payer system. Many studies have made a routine call to national pride, by beginning with a statement that Canada is the only OECD country with a universal health system that does not include coverage for prescription medicines. The best-known study (Morgan et al., 2015) was titled "Estimated cost of universal public coverage of prescription drugs in Canada. Its abstract reported: "Results: Universal public drug coverage would reduce total spending on prescription drugs in Canada by $7.3 billion (worst-case scenario $4.2 billion, best-case scenario $9.4 billion)." This paper made headlines and later won the CMAJ Bruce Squires Award.

The Morgan et al. article was published just a few months before the 2015 federal election. The problem of drug cost was now paired with the national pharmacare policy solution. Politicians had an opportunity to critically assess this and related studies, but many would not have sufficient time, skills or inclination to do so. This solution still became part of the government's "decision agenda" (Kingdon, p. 4) even though several drug program experts who participated in this research stated they did not fully accept the validity of this research.

The Liberals came from third place in June 2015 to win the October 2015 federal election,[239] energizing a progressive political agenda. Politicians like former federal Health Minister Jane Philpott were seriously focused on the cost control problem, echoing Boothe (2015). In a January 2017 CBC interview, Minister Philpott made it clear that "access to appropriate medications is absolutely essential" (00:40). She then remarked "we pay among the highest costs for drugs in the world" (01:15), but that "first of all, let's get those prices down" (04:10). In other words, lower prices and costs were essential for continued access, and NPh could only follow price reductions. Interestingly, it appears the Minister did not

[239] The CBC has compiled monthly polling averages since 2009. See: https://www.cbc.ca/news/politics/historical-federal-polling-data-1.4171977.

believe NPh could in itself lower drug prices or costs. After acknowledging an important problem of access (and equity), the Minister also framed the problem in financial terms.

Related to the cost of launching a drug program, a second problem is the underlying, long-term state of F/P/T finances. Half the provinces and the federal government were in deficit for fiscal 2018-19: collectively, costs exceeded revenues by almost $31 billion (RBC Royal Bank, 2019. p. 2). Deficits typically discourage funding of expensive new programs but the door may still be open to more narrow tactics that could still improve drug coverage. As Section 4.12 describes, it is only the federal government that has the fiscal capacity to act over the long term.

The Advisory Council's proposed comprehensive pharmacare phase (a Quebec formulary due January 2027) comes with a $15.3 billion estimated annual cost to the federal government (Advisory Council, 2019b, p. 14). Large annual federal deficits are forecast at least until 2024-25 according to the December 2019 Economic and Fiscal Update (EFU). Further, the PBO, in its analysis of the EFU, states: "Deficits in this range permit limited fiscal flexibility in the event of an economic downturn to maintain a declining debt-to-GDP, and limited fiscal room to implement additional electoral commitments in the near term" (p. 3). To the extent the federal government proceeds with NPh, less money will be available for other national priorities such as pipelines, defence and environmental investments unless taxes are increased.

Kingdon notes the reluctance of politicians and bureaucrats to implement a plan for which they have limited certainty of current cost and future growth. Indeed this concern was evident in the report of the 1964 Royal Commission and resulted in drug insurance being deferred until sometime following the introduction of medical insurance. Section 4.12 and Table 4.4 identify 16 different cost estimates and ten estimates of the number of un- and under-insured Canadians. None is current or complete, incurring financial, reputational and political risk to the government. Current and complete data are crucial to presenting a reliable, real-world NPh budget impact analysis. This is the third important cost problem that discourages NPh.

Health budgets and long-term funding are issues inextricably connected to F/P/T relations. This is the fourth major cost problem: despite the call for federal leadership, Ottawa cannot act alone. The federal government must negotiate health issues with the jurisdictions either as a group or bilaterally. The Constitution effectively gives provincial governments veto power in health and the current political dynamic indicates several Premiers are likely to opt out, at least initially. In addition, more than one mandate will be needed to achieve full implementation of NPh. Like the Netherlands, continued momentum will depend on the support of future F/P/T governments. For comparison, achieving NPh is orders of magnitude more complex than the four-year process of reforming the PMPRB.

All this suggests the "special problem" is particularly relevant for NPh.

8.3 Policy Options

Optimism reached new heights as the Advisory Council began its investigation into implementing NPh, even before HESA reported. A single payer NPh model had been the "pet solution" (p. 203), positioned as the only good choice by some academics and think-tanks. Every major public and private stakeholder was finally engaged at the highest levels. Polling indicated high public support for the idea. It was expected that the Advisory Council (2019b, p. 25) would finally settle how to implement and pay for NPh.

Interviews indicated some influencers favoured single payer (politicians, academics, labour), but payers and bureaucrats with experience administering public and private drug plans wanted private insurance to remain in a "fill the gaps" option.

Bureaucrats certainly understood the complexity of implementation and transition. Several participants in this thesis were in senior positions with knowledge and experience that would be recognized as centrally important to planning and administering NPh. However, they did not reveal that they had been actively consulted about the feasibility of launching NPh. "Sometimes, windows open quite predictably… At other times, windows open quite unpredictably" (p. 203). Perhaps no serious investigation of implementation issues had yet occurred, or other experts were consulted. This suggests that policy development can be random, the result of "a complex combination of factors [being] generally responsible for the movement of a given item into agenda prominence" (Kingdon, p. 76).

From conception through implementation, both political and bureaucratic support are essential to get things done. Speaking again of the US, Kingdon concluded that politicians were more powerful than bureaucrats with respect to agenda setting (p. 31). However, most legislators lack deep knowledge of a complex and high-cost policy issues. If NPh is approved, bureaucrats then become more likely to impact implementation and generate alternatives (p. 31). Both politicians interviewed for this thesis were keen to "sell" HESA's view of NPh but their limited knowledge of the details is consistent with Kingdon.

The government's animation of the HESA and its later creation of the Advisory Council signaled an important change in politics. In Kingdon's language, the politics stream appeared to be converging between 2016 and 2019 with the problem and the policy solution. Eventually key stakeholders that were largely outside the debate – insurers, retail pharmacy, brand drug manufacturers – began to research their risks and create public advocacy positions that aimed to influence political parties towards more industry-friendly ideas about what changes were needed and how best to achieve them.

Kingdon describes the "policy primaeval soup" (Ch. 6) as a broth of floating ideas and issues that either careen off each other or become attached to potential solutions that are created, shopped and championed by policy entrepreneurs. Other combinations can be shelved for more opportune times. It is difficult to identify a "focusing event" that triggered political interest in NPh. More likely, it may simply be a different group of politicians or a

different calculation of the political advantages of backing NPh which led the Liberals to establish HESA's NPh investigation and then the Advisory Council. These steps would blunt an NDP claim that only it could ensure NPh progress.

There is, however, an important cautionary note. Kingdon writes that sometimes, "solutions become attached to problems, even though the problems themselves did not necessarily dictate those particular solutions" (p. 177). If feedback from bureaucratic monitoring or public complaints indicates the fit between solution and problem is sub-optimal or conditions change, then those solutions may be short-lived. To those risks can be added public indifference and key stakeholder disagreement.

For any idea to survive, Kingdon suggests it must be technically feasible, promote acceptable values (equity, efficiency), have a tolerable cost and be acceptable to both the mass and specialized public, as well as to politicians (p. 131). As reasonable as these conditions may appear, he notes policy development is rarely rational: "Comprehensive rational policy making is portrayed as impractical for the most part, although there are occasions where it is found" (p. 19). Although both HESA and the Advisory Council claimed they had seriously reviewed alternatives to single payer, their reports present no indication about what they deliberated or how they came to dismiss alternatives such as "fill the gaps" and social insurance.

Kingdon defines technical feasibility as "all worked out and "ready to go (p. 131) and "heavily involved with implementation" (p. 132). Bureaucrats and other research participants who are familiar with drug plan administration indicated they did not accept the large cost savings projected by academic models. Those studies did not explore implementation or settle funding sources or amounts. Consequently, bureaucrats – those who are responsible for real-world implementation and are accountable for administration and budgets – may have had a braking effect on HESA and Advisory Council recommendations because they believed a single-payer plan failed a test of technical feasibility, one of Kingdon's criteria.

Kingdon warned that opportunities seldom linger, so stakeholders need to prepare ideas even when there is no sign of imminent change. Academics and more recently the Canadian Pharmacists Association (CPhA) and the Canadian Labour Congress heeded that advice and spent some years 'softening up' the political and policy environment with their advocacy for a single payer model and an appeal to cost-conscious politicians that billions of dollars could be saved.

But the unexpected revival of NPh after the 2015 election caught other interested parties, including senior-level career bureaucrats and private insurance participants by surprise. "Without the prospect of an open window, participants slack off. They are unwilling to invest their time, political capital, energy, and other resources in an effort that is unlikely to bear fruit" (p. 167). Insurers had no ready and 'qualified' alternatives, even though they had the most to lose. In the only drug policy paper issued by the CLHIA before 2015, the focus was lowering drug prices and costs and it did not specifically mention NPh

(see Section 4.6.8). Alone among those in the private payer community, the CPhA was engaged and had prepared policy documents but it is, however, a relatively small player.

Employers, as drug plan sponsors, were much larger and more important but were even more removed because their focus is on their core business interests. They would generally leave health system matters to others more qualified. As long as insurers and employers are seen to be "outside the tent" by bureaucrats and politicians, their role and goals would not be sufficiently understood and are less likely to be reflected in policy. A second important shortfall that weakened the policy argument was the federal government's failure to recognise, consult with and engage other important stakeholders that could have helped the government build credibility and momentum.

NPh had failed Kingdon's policy tests of technical feasibility, stakeholder engagement, and a tolerable cost, in this case, for the federal government. One may conclude the Liberal Party was not deeply committed to the big idea of NPh and launched HESA and then the Advisory Council without an appreciation of its complexity, cost and the need for supporting coalition.

8.4 Politics

Political interest in NPh has ebbed and flowed for 75 years. Boothe (2015, p. 68) noted the inclusion of drug coverage in a federal health insurance proposal made to the provinces in 1945. While there have been times when political support appeared, there has never been enough to implement a drug plan as bold as hospital or medical care decades ago.

Kingdon notes that politicians tend to resist contentious ideas, making political choices more difficult: "Issues of high controversy and low [public] salience are particularly unattractive to politicians" (p. 38). NPh has high public salience, though it may not be as deep and intense as needed, and NPh had strong support from within the Liberal Party at its 2018 Halifax policy convention. Still NPh has not yet gained enough attention from senior Liberal politicians. It may be that NPh struck influential Liberal (and Conservative Party) politicians as an idea with high and accelerating costs with the potential for significant and negative political consequences.

If cost savings were the main driving political force for NPh, the answer is now to be found in PMPRB reform. The cost of new patented drugs is to be reduced 15% to 20% by repricing them in line with the new group of 11 comparator countries. Without this initiative, savings are unlikely to occur for several years. One reason is that a comprehensive universal plan would quickly increase drug utilization from the un- and under-insured. Over time, new drugs are added which are invariably priced higher than older drugs. In the long term, many other environmental variables are likely to have shifted such as population, disease profiles, provincial policies, private insurance coverage, new drugs and indications and prescribing practices. Politicians would take considerable short-term risk with little assurance of long-term credit.

Small, incremental rational change is common for governments, especially when generating high-risk alternatives to existing programs. “People are sometimes reluctant to take big steps. Apprehensive about being unable to calculate the political fallout, politicians shy away from grand departures. Apprehensive about not fully understanding the unanticipated consequences that might ensue, specialists also avoid changes. Both worry about the budgetary implications of massive new programs” (p.80). Politicians generally retreat from solutions with larger-than-expected costs (p. 106).

High controversy, suspect public salience and uncertain costs create financial and reputational risk to governments. In response, governments are likely to slow down and undertake due diligence to ensure fit for purpose. High complexity often creates conditions for slow resolution. Speaking of the US, Kingdon writes: “Congress is easily fatigued” (p. 104) when legislation can’t pass and decisions aren’t made. The same limitation likely applies to Canada’s Parliament and provincial legislatures.

8.4.1 National Mood

Kingdon includes public or national mood as part of the political stream (Ch. 7). His interviews suggested that politicians “sense” public opinion and that this mood can either promote or constrain policy items. First, sensing is usually far more tangible than the word implies. It is usually narrowly defined as well, arising from direct interaction with only a small percentage of constituents, either as individuals or groups, or from advocates of certain ideas. Sensing may even arise from other sources or past experiences.

Kingdon states that “the mood does not necessarily reside in the mass public” (p. 148), minimizing the influence of the general public and its direct impact on the decision agenda. Public opinion surveys show high public support for NPh, but there is uncertainty about how to pay for it, concern about potentially lost coverage, and the meaning of this term may not be consistently or accurately understood by the general public or in fact by politicians (see Section 4.4.7). Polling has indicated public support is actually higher for other health and non-health priorities (Pollara, 2018).

Influential media outlets may have more sway since media reports the opinions of politicians, specialists and the public (e.g., though polling) and often provides their own editorials. This confluence of views makes it difficult to know which stakeholder influences or leads the others.

All in, it appears the political stream at this moment is essentially unchanged from past resurgences described by Boothe (2015). The problems of inadequate coverage and high drug prices and costs have again had added profile in recent years but this appears fleeting and superficial. Governments have resisted boldness and made only incremental change. Tinkering has avoided substantive improvement for those in greatest need, e.g., the

underinsured who would benefit from national standards for much reduced out-of-pocket costs.

8.5 Entrepreneurs, Coalitions and Streams

To recap, a window of opportunity did not exist from 2006 until late in 2015 but then suddenly opened wide with subsequent work done by HESA and the Advisory Council (2016-2019). Then, the window appeared to mostly close since the 2019 Liberal election platform offered only minimal support for NPh. The window for some form of universal coverage may remain open because the Liberal minority government needs NDP support and NPh was noted in the 2019 Speech from the Throne, albeit briefly and ambiguously: "The Government will take steps to introduce and implement national pharmacare so that Canadians have the drug coverage they need" (p. 12).

8.5.1 Policy Entrepreneurs

Kingdon identifies the need for alternatives that are politically and publicly attractive and for highly capable champions with broad support. These policy entrepreneurs can be found in many stations, including elected officials and academia (p. 204). Two policy entrepreneurs can be identified so far.

The first is Steve Morgan, a professor at the University of British Columbia. Dr. Morgan and his colleagues have for several years worked to develop a stream of advocacy research to both specialized groups and the public through general media communication (e.g., op-eds) supporting a single payer NPh. They have kept the issue "alive in lean times" (Kingdon, p. 130) and their work helped 'soften up' those communities (p. 127-130), likely with the intention to shape public values (p. 123). They have also done some of what Kingdon calls "negative blocking" (p. 49): playing the role of champion protecting our public medicare system against the incursion of private interests. Currently (February 2020), over 1,300 academics have endorsed this group's Pharmacare 2020 initiative but only a handful have published work on this topic. Research from this group has been adopted by the Canadian Labour Congress and some of its member unions (e.g., Unifor, CFNU).

Academics very rarely take such public advocacy positions. The group may share common policy values (p. 204) about NPh. However, their rigid support of only a public single payer plan and their lack of operational experience has limited their credibility according to some of my research participants. Kingdon notes that academic work is not always trusted: "…the value of the work is accepted, but practical people realize that its recommendations cannot always be implemented" (p. 57). "Feasibility," he writes, "is heavily involved with implementation" (p. 132).

The second visible policy entrepreneur is Eric Hoskins. As a former Ontario Minister of Health and Long-Term Care, he endorsed a public single payer drug plan and promoted it with his P/T peers. As Chair of the Advisory Council he accepted a small supporting role for

private insurance. Dr Hoskins may be motivated by his policy values, and potentially as a politician, by an interest in claiming credit for enacting OHIP+ and then expanding this template to across the country. However, the implementation of OHIP+, though not its principles, has been seen as rushed and flawed, and was easily unwound by the next government. Following tepid Liberal political support for the Advisory Council's final report, Dr. Hoskins has rarely spoken publicly on this topic. Kingdon notes the importance of "sheer persistence" (p. 205) as a quality of policy entrepreneurs.

Further evidence is needed that the implementation of either a public single payer or a social insurance model is feasible. That requires other experts which have so far not coalesced with the academic support group or with the core recommendation of the Advisory Council for a public single payer plan.

8.5.2 Coalitions

While a policy entrepreneur can build bridges, a coalition of organizations helps sort out conflicting or confusing priorities and preferences, and makes it easier for governments to ensure NPh progresses or at least that important changes occur. Kingdon describes this process as tipping: "…a process of coalition-building: bargains are struck, concessions are given in return for participation in a coalition, and as the bandwagon gains momentum people join out of fear of being excluded from participation in the goodies to be obtained" (p. 141).

For example, the core focus of a coalition could be maintaining a private insurance component. Initially this might engage pharmacists because their fee is higher in private drug plans. Patient groups may support a private alternative because they resist smaller formularies or higher barriers to access. To the extent a coalition exists right now, it is informal, such as speaking about consensus positions at conferences. There has been no follow-through to a more substantive and durable form. No concessions among potential members have been publicly disclosed because perhaps they are not yet necessary. A tipping point that would trigger coalition-building is not at all clear in this currently antagonistic F/P/T climate with its limited and scattered attention span and where the vast majority of Canadians have adequate coverage.

Neither entrepreneur has caught sustained attention among the general public nor has either united the array of interested parties – national and provincial political leaders, the general public, patients, business, health professionals and labour – on how to fund and implement NPh. No symbol or imagery has emerged that captures the public attention needed to animate and implement a feasible solution. As Kingdon notes: "The joining of the separate streams described earlier depends heavily on the appearance of the right entrepreneur at the right time" (p. 205). As the window apparent closes, perhaps neither entrepreneur is the "right" one.

8.5.3 Diverging Streams

Cracks in the window of opportunity have appeared. There was more than one problem and only one (inadequate drug insurance) was a good match for NPh. The policy idea and investigations by HESA and the Advisory Council of a public single payer model were too narrow in scope and did not account for administrative complexity, the high cost to the federal government and stakeholder resistance from the provinces, insurers, brand drug manufacturers, patient groups and pharmacy industry. Even as the Advisory Council was launched in February 2018, clear political support within the Liberal Party for a fully public single payer plan suddenly appeared limited or uncertain. The federal Minister of Finance stated: "We need a strategy to deal with the fact not everyone has access, and we need to do it in a way that's responsible, that deals with the gaps, but doesn't throw out the system that we currently have."

The comment about “responsible,” spoken by this powerful Minister, indicated that cost would be an important political consideration, Kingdon’s “special problem.” The solution needed only to fill gaps, not replace the existing system of mixed private and public funding. Single payer was no longer the only option and the phrase “fill the gaps” became the alternative even though it is not much more than an advocacy slogan. At that point, the three streams had either separated or never actually been joined, with several serious problems and an alternative policy solution (social insurance) that had not been seriously investigated by the government.

Was this too little too late? Kingdon notes that “years of effort” (p. 143) are required to strike when the window of opportunity opens. However, alternatives may still be seriously considered later on, as Kingdon notes, if major complexities make the original solution – a public single payer plan – untenable. Most often, those alternatives will not be completely new ideas, but a reworking and recombination of previously floating ideas.

8.6 Conclusions

The Kingdon model provided an early warning that any form of NPh would at best be delayed as policy, program and funding alternatives were considered. The failure to join or the ultimate divergence of the streams is reflected in the piecemeal approach taken by the Liberal government. Of the many HESA and Advisory Council report recommendations, only a Canadian Drug Agency, a national formulary, and a strategy for drugs for rare diseases has been funded. None of these three steps is expected before 2022-23 at the earliest and none guarantees adequate universal drug insurance.

It is possible that slow steady changes may also create a tipping point and get political attention and even priority in the future (Baumgartner, Jones and Mortensen, 2014, p. 63). Martin et al. (2018), citing broadcast journalist Steve Paiken, wrote: “[The health system] is thus most accurately described not as a system in crisis, but a system in stasis (p. 1726).” After punctuation, stasis is again emerging.

Baumgartner, Jones and Mortensen (2014) also point out that government policy or program neglect of environmental changes or an inability to adjust to them (i.e., stasis in the face of rapid change) can heighten the chance of punctuations (p. 84), perhaps led by business or professional interests that are no longer willing to wait for government action. A future trigger could be the continuing introduction of DRDs that are unaffordable to employers, or a growing focus on high-cost private drug plan claimants with complex health needs that demand a more responsive public health or workers' compensation system where care is presently outdated or rationed. An emerging industry/business coalition may advance NPh by introducing imagery and framing that contradicts a fully public NPh, e.g., highlighting the loss of "better" private coverage. Employers will then have to choose between unhappily paying more or terminating drug plans that then transfer risk to public plans.

Negotiating universal coverage of a comprehensive drug formulary with minimal and standardized cost-sharing will take considerable time, skill and consensus (Kingdon's tipping process). The combination of negotiation and high cost make it possible, even likely, that important compromises may eventually occur, such as different phasing or scope. The big-bang policy change may reduce to incremental change over several years so the bureaucracy can move it to implementation. "People are sometimes reluctant to take big steps. Apprehensive about being unable to calculate the political fallout, politicians shy away from grand departures. Apprehensive about not fully understanding the unanticipated consequences that might ensue, specialists also avoid changes. Both worry about the budgetary implications of massive new programs" (p.80).

Regarding government decisions and actions, Allison (1969) states: "what happens is not chosen as a solution to a problem but rather results from compromise, coalition, competition, and confusion among government officials who see different faces of an issue…" (p.708). Reflecting the random nature of government processes, it is a very challenging to predict and understand why something (or nothing) happens.

In summary, Kingdon provides a reliable model of typical government processes, but government action cannot be perfectly predictable or even rational. Even if convergence of the three streams occurred, that does not guarantee any outcome. The status quo would therefore remain unless more politically attractive, administratively feasible, publicly acceptable and likely lower cost alternatives emerge to replace the single payer NPh.

Chapter 9

In Search of Change: Conclusions, Lessons and Limitations

9.1 Introduction

A key question is how this roller-coaster issue of universal drug insurance has risen to the decision agenda and whether it stays there long enough to encourage an effective and feasible solution. There is broad public support for something called “national pharmacare” and now there is a better description of one version of that (Advisory Council, 2019b). This thesis has explored the issues using the literature, theory, three comparative jurisdictions and a relatively broad set of in-depth opinion leader interviews. Participants were clear that universal coverage is needed and generally believed private insurance should play an important role. The Advisory Council, and HESA before it, did not.

Since the vast majority of Canadians have adequate drug insurance, and participants expressed a strong consensus position that the federal government must lead change, NPh might be framed in value-laden language of fairness, equity and nation-building.

9.2 Theory-based Considerations Review and Application

Kingdon has written about incremental approaches that respect financial constraints and the place of regulation as a feasible and relatively inexpensive approach to improving policy and programs. Regulation of private drug insurance could help fill coverage gaps and national standards for formulary scope and out-of-pocket cost could be jointly developed by private and public payers. Even experts who participated in this research have poor knowledge of the Quebec social drug insurance model and many cannot separate the model from the policies that created a high-cost plan. Much more work is needed before the Quebec or a social insurance model can be considered for application across Canada.

Kingdon also notes that policy is often not rationally constructed and presents a primordial soup analogy to indicate a random coupling of time-worn solutions with the problem (soup) ‘du jour.’ Players and agendas often conflict and are messy. Both single payer and social insurance drug insurance models can provide adequate universal coverage. The latter is not well known even among a diverse group of well-informed opinion leaders, leaving it for all practical purposes as a fallback to be more carefully considered if a single payer plan again fails to launch. Both models meet Kingdon’s test of value acceptability and either is a better alternative to today’s coverage patchwork. In addition to familiarity, the two differ on technical feasibility, cost and political support. While the principle of NPh is very attractive in public opinion polls, what it means and what it can achieve in real-world terms is likely ambiguous to the general population. That may be by design.

NPh appears to still have problem status on the government’s decision agenda. Small, tactical changes have been announced and funded – the establishment of the Canadian Drug

Agency that will develop a national formulary (among other tasks), and the development of a strategy for drugs for rare diseases. This minimalist approach seems to be reinforced by the Advisory Council's interim 2022 solution of an Essential Medicines List (EML)[240] that will address a problem of far less significance than, for example, funding a national standard for catastrophic out-of-pocket loss. However, an EML is a simple, low-cost option and may create the impression that important progress is underway. The actual outcome will be important only to a very small number of Canadians because patients covered by existing drug plans already have access to these generic and over-the-counter products and their cost is very rarely a barrier.

While a policy entrepreneur may have appeared, it is odd there is not yet a coalition to champion an alternative solution even one as thin as "fill the gaps." A key consideration is where common ground lies, and whether progress can be negotiated. The argument that system sustainability is at risk may be a focusing event (Kingdon, p. 94), although one participant likened it to crying wolf given its long run and limited bite. Every year more money is found.

Relationships are critical to organizing the actors and trying to articulate and align national goals and political objectives. However, participants report that relationships are either weak (i.e., between provincial and private payers), antagonistic (all payers and the brand pharmaceutical industry, or potentially either symbiotic or dysfunctional (politicians and bureaucrats). Tuohy (2013) strongly supports the importance of relationships but aims at an alternative solution of a public-private mixed funding approach.

> "The challenge for policy makers is to identify entrepreneurial allies within the health care arena and to create opportunities for these allies within the public system. …In the case of prescription drug coverage, models that incorporate the existing base of private insurance into an integrated model of public and private finance could make private insurers allies of reform (as in Quebec and the Netherlands)." (p. 305)

Three important applications arise from Kingdon's work and the information in this thesis.

9.3 Application 1: Exploring Coalitions and Collaboration

At the highest level, our drug insurance governance model presents an opportunity for collaboration. Germany's Federal Joint Committee provides a very feasible approach that pools intellectual and financial resources and brings complementary expertise to bear on complex and technical problems. However, this depends on a willingness by politicians to acknowledge certain limitations in our current approach and share information and a measure of power.

[240] The EML proposed by the Advisory Council follows the CLEAN Meds model (cleanmeds.ca) which includes 128 therapies (Jan 2020), mostly generic drugs, with some vitamins and over-the-counter drug products. That list currently includes just three specialty drugs, including adalimumab and short- and long-acting insulin.

In recent years, the language of First Ministers' annual communiqués remains what Boothe (2013) describes as tactical, i.e., focused on affordability and lower drug prices. In 2016, the Premiers issued a vague statement with no sense of urgency: "Our governments will also consider a range of other measures to reduce pharmaceutical prices and improve prescribing and appropriate use of drugs, while striving to improve health outcomes. We also agree to explore approaches to improving coverage and access to prescription drugs for Canadians."[241]

In 2019, sensing opportunity from the Advisory Council report, the Premiers became far more specific: national pharmacare must remove patient cost barriers, have a clear and compelling business case (i.e., "benefits, risks, costs, and reliability of supply") and ensure the jurisdictions retain responsibility for drug plan design and delivery. Funding must be "long-term, secure, flexible and fully offset present and future cost pressures…". Jurisdictions must be able to "opt out unconditionally, with full financial compensation" if the federal government decides to fund NPh (Canada's Premiers, 2019 Final Communiqué, p. 2).[242] NPh requires a negotiation between federal and provincial governments, since the latter have veto power.

It must be acknowledged however that the provinces do not always act in solidarity. A simple and common example is that even when the pCPA has negotiated a manufacturer rebate, a province has no obligation to list that new drug. Beyond that, the significant variations in provincial drug plan design and eligibility mean that any new federal funding that sets a national standard will advantage some provinces more than others.

The most glaring problem arises if the Quebec formulary is used as the national standard. In that case, Quebec would not receive any additional funding. However, if there is also a national standard to significantly lower out-of-pocket spending, then Quebec will gain because its cost-sharing is very high relative to other provinces (see Sec. 5.5.1 and 5.5.2). This means, notionally at least, that provinces that have chosen minimal public drug plans (i.e., Atlantic Canada) will stand to gain the most by new federal money that allows them to offer, for example, a Quebec formulary and an Ontario out-of-pocket cap.

To overcome these disparities, the federal government has at least two polar choices. They can provide a flat per capita subsidy (equal and simple) or they can propose an equalization formula (equitable and complicated). The latter could be similar to risk-sharing models used in the Netherlands or Germany that adjust for chronic disease loads and socio-economic status. The answer is likely in-between with some limited adjustments for provincial variations, and a promise to monitor effects and make adjustments over time. The question of what provincial politicians believe is a "fair" subsidy, one they can sell to

[241] The Communique, *Statement of the Federal-Provincial-Territorial Ministers of Health*, January 21, 2016, is available at: http://news.gc.ca/web/article-en.do?nid=1029069.
[242] Available at: https://www.canadaspremiers.ca/premiers-committed-to-healthcare-sustainability-call-on-federal-government-to-be-full-partner/.

their own residents as a "win", and what the federal government is willing to pay is a crucial determinant of progress.

A second option is for the provinces to revert to their 2004 Council of the Federation request that the federal government take over all public drug plan administration. The normally fractious state of F/P/T relationships make that much less likely.

Given their importance as funders, any coalition ought to include both the business community and the health insurance industry. It remains a mystery why these groups are not inside the drug policy "tent." Polling a representative sample of employers to determine their willingness and under what conditions is a particular challenge.

For its part, the private payer community did not anticipate that NPh would be an important part of the federal government's decision agenda after the 2015 election. Health insurers are reasonably well organized through the CLHIA and unlike the pharmaceutical industry, insurers have high cards to play in the level of both employment and investment in this country. One executive participant made it clear insurers have ready access to the federal Department of Finance which has to be heavily involved if the NPh agenda is to advance. The pharmacy industry and brand pharmaceutical industry were also caught unaware, although the pharmacy professional association (CPhA) had already addressed some of the single payer policy agenda before 2015. All these groups are now in regular contact and no doubt recognize a certain synergy of NPh goals. Each gains when any one of them advocates for an alternative to a single payer model. The caveat is that insurers express little trust of the brand pharmaceutical industry, so any coalition including pharma is likely more a marriage of convenience.

Crucial to coalition-building will be establishing a consistent set of ethics and values between members. Kingdon speaks to value acceptability (p. 131). Issues must be carefully framed to allow key stakeholders to identify with and support the issue over a lengthy implementation period. More work on establishing shared values and constructive narratives will be helpful to bring together parties with more in common than they may realize.

Perhaps the private payer community could again be prodded to action by governments. Prior to implementing its new drug plan on January 1, 1997, the Quebec government reportedly gave insurers only about six months to develop a mutually agreeable approach to ensure private drug plans would continue in that province.[243] Nationally, private payers are likely to accept an employer mandate, some grudgingly,[244] which could help "fill the gaps"

[243] Personal communication, Claude De Stasio, formerly VP Quebec Affairs, CLHIA, October 20, 2015. The RAMQ plan was implemented January 1, 1997.

[244] The Canadian Federation of Independent Business (CFIB) generally resists any increase in administration or taxation of its small business members. While perhaps half its members already offer a good drug plan, The CFIB's anti-tax and "red-tape" position remains true in its polling of members on NPh. See: https://www.cfib-fcei.ca/en/media/national-pharmacare-must-not-impose-new-costs-and-taxes-small-business.

with an adequate formulary. As provincial participants noted, spreading the financial risk and cost among both major payer groups protects each from excessive exposure.

Drug policy work on generic drugs which began in 2010 and was last updated in April 2018[245] shows common ground exists between the pCPA and the CLHIA. This begs the question why these two groups should not collaborate to address brand drug pricing, a national strategy for drugs for rare diseases (DRDs) and a national drug formulary. National standards could also be developed to ensure both formulary and cost-sharing are improved and equitable across Canada regardless of the source of insurance. Participating in this research expressed significant goodwill and may welcome the chance to work together. Notionally, either the CLHIA or the pCPA could initiate this work.

9.4 Application 2: Funding

Concern about drug prices and costs has been accentuated by higher levels of many chronic diseases, low treatment adherence, waste and inappropriate prescribing. Specialty drugs and now the massive cost of personalized gene and cell medicines have exacerbated funding challenges for all payers, even governments. While provinces are therefore reluctant to introduce improved drug programs, federal funding for universal drug insurance, or selected key features such as a national formulary or out-of-pocket cost limit or DRD access, could make an important difference. If NPh cannot proceed as a comprehensive package of services and reforms, then at least we ought to fix important problems on the road to a national strategy. Medicare advanced only when the federal government provided matching-dollar incentive funding for hospitals (1957) and physician services (1966).

Including private insurance within a social insurance framework may be more compelling to politicians and bureaucrats than having governments fully absorb up to $19 billion in private drug spending. Selling a smaller public formulary than what 22 million private plan members now have will not be easy. Lower out-of-pocket costs will help but some patients will prefer paying more to get more.

Too many NPh plan designs and costing assumptions (Sec. 5.10) have been proposed to have certainty. NPh may not initially have much effect on total spending but it will likely change the allocation between payers. We are left with many "ifs." If the massive cost reductions that have been promoted by academics actually occur without patients being medically disadvantaged, then no additional funding will be needed for many years. If there is a continuing role for employer-sponsored plans, their premium payments to insurers might be replaced by a payroll tax of roughly the same amount. If the federal government by design pays more, then presumably individuals would pay much less per claim.

[245] A five-year plan to reduce the cost of generic drugs was announced on January 29, 2018. See: https://canadiangenerics.ca/news-release62/a-joint-statement-from-the-pan-canadian-pharmaceutical-alliance-and-the-canadian-generic-pharmaceutical-association/

Social insurance requires employers and employees to share significantly in drug cost but this is already typical. Governments would top-up funding through general taxation. In exchange for up-front contributions, patients would have minimal cost for the drugs they buy. A dedicated payroll tax would also be more visible and perhaps trusted to deliver a specific, high-value program. Over time such a tax will suffer as it has in Germany and elsewhere from changes in labour market structure. Other administrative changes could include cost control through a reference drug system as exists in Germany (widespread) or in British Columbia (eight therapeutic classes). There are many, many ways to influence drug prices and costs, although there is no unified strategy to do this in Canada.

Funding amounts and sources will remain contentious. It will be important to anticipate where opposition to funding reforms may arise. Some companies with minimal drug coverage will have to upgrade their plan to meet a minimum standard, but most businesses already have high quality drug plans to help attract and retain scarce, skilled talent. Based on New Brunswick's experience in 2014 when it proposed a mandatory New Brunswick Drug Plan, the Canadian Federation for Independent Business[246] is very likely to oppose an employer mandate. One senior bureaucrat noted the political importance of identifying potential losers from policy change and attempting to mitigate their losses early. The greater problem may be in the more limited formularies, restricted eligibility and high thresholds for catastrophic protection provided by provinces in Atlantic Canada.

Perhaps the major challenge in financing universal drug insurance is agreeing on the cost, timing and burden-sharing of change especially for patients, the jurisdictions and for employers. The plan design must first be finalized. With various studies forecasting either billions of savings or billions in cost shifting, cost uncertainty makes change impossible, especially for risk-averse bureaucrats and politicians who are intent on re-election.

Success relies on the ability of F/P/T governments to compromise in areas where each has undisputed strength. The federal government must decide to deploy its fiscal capacity to provide the jurisdictions with stable and long-term funding. For their part, the provinces must be willing to trust a funding commitment from Ottawa (despite its past withdrawals of health funding) and accept national standards in coverage quality. This climate of trust is rare but has appeared in the past, most recently in 2003-04 with two multi-billion-dollar health accords introduced under Prime Ministers Chretien and Martin (Tuohy 2018. p. 398-409).

9.5 Application 3: Leadership through Discovery and Transition

Beyond funding is a need for federal leadership, and the importance of this factor, or its dearth, cannot be overstated. It is here that perhaps the biggest challenge lies in terms of attracting individual leaders, assembling coalitions, and engaging the public. Ministers of

[246] CFIB papers and positions on this issue are available at: http://www.cfib-fcei.ca/english/article/4028-building-a-drug-plan-for-uninsured-new-brunswickers-a-small-business-perspective.html.

Health are typically transient as are the governments that appoint them. Participant interviews did not identify any policy entrepreneurs or "insiders" with potential to lead change. However, it is now possible that Eric Hoskins, former Ontario health minister and past Chair of the Advisory Council between February 2018 and June 2019 may step into this role.

While significant financial and access pressures continue to build, there seems to be little agreement beyond the need for "change." Germany has invested in a steady stream of legislation over the last thirty years to address the stream of market developments. The Netherlands took twenty years to implement its reform vision of market-oriented universal health insurance. One could struggle to find any similar initiative in Canada, other than a series of commissions and studies over the same period that have failed to spark the actual process of modernizing strategy. Even the Advisory Council recommended their vision of NPh be introduced inside the (1984) Canada Health Act with no changes in its five governing principles. Given the short tenure of Ministers and of politicians generally, it would seem that such a long view requires the support of the professional bureaucracy and external stakeholders.

Kingdon identifies academics as a constituency who can play an important supporting role and be a source of policy alternatives. (The role of Pharmacare 2020 has ben previously noted.) Up until 2016, NPh likely remained of much greater interest to some in the academic community than it did to government leaders or to the general population. Evaluating how research is structured or translated to better meet the practical needs of governments and the business community may help the general and specialized publics make sense of academic research.

The policy community has still not framed a solution that is acceptable to large private sector stakeholders. Perhaps that is not crucial but the chances of implementation would improve if there is consensus on this complex and technical subject by politicians, key stakeholders and the public. Driven by the federal Liberal party, HESA and the Advisory Council have developed a fairly consistent public single payer policy model which to date (December 2019) has yet to be endorsed as Liberal Party policy. Key gaps exist in the role of private insurance, in funding sources and amount, and the extent of national standards beyond a formulary.

While somewhat lower cost, single payer is more complex. Even the Advisory Council which was to focus on implementation sketched this task out only in broad terms, leaving key features to be determined by others. The only feature generally agreed upon is that NPh will be universal. The Advisory Council has proposed a phased approach to a formulary with this first tactic fully two years away. We should ask why more progress cannot be made.

Actions by the federal government since the Advisory Council report and the last federal election indicate an unwillingness to implement a comprehensive approach to NPh. It now appears that changes are likely to come in smaller, tactical form and take longer to

implement. Still, windows of opportunity are likely to open again since fundamental problems of adequate universal access are not yet resolved.

Kingdon's discussion of policy provides a number of instructive ideas to influence the direction and pace of change. Policy advocates must start or continue to soften up other leaders both within government and in other influencer communities, as well as the public (Kingdon, p. 128). Single payer advocates such as Pharmacare 2020 have a significant advantage with political, academic, labour and some media audiences given the time already invested. However, insurers and employers have direct access to at least 22 million individual drug plan members and could provide "fear-of-loss" messages about having less coverage, or longer wait times to get access to the newest drugs, or the lack of customer service competency in provincial drug plans. Insurers, pharmaceutical and professional associations may develop and promote more sophisticated advocacy material for general and specialized media. They may prepare and test "trial balloons" (p. 129) with various stakeholders that might include ideas from comparative international drug system research. Organizations representing employers (i.e., CFIB, Chambers of Commerce) can study the breadth and depth of employer opinion about NPh. Insurers, not well known in health ministries across Canada, could develop those relationships and propose projects that allow payer communities to jointly address policy issues such as standardized formularies and drugs for rare diseases. There are many options that can prepare the ground and ensure a more coherent and even unified approach that could make political action easier.

Related to these efforts is the need to identify, encourage, equip and promote one or more policy (Kingdon, 179-83) or institutional (Tuohy 2018, 437-48) entrepreneurs who may choose to lead advocacy work. Any significant delay in progress or a change in focus may require new policy entrepreneurs (Sec.8.5). A new focus is in fact preferable at this stage. Acknowledging previous work, expertise is now needed to negotiate funding amounts and sources, fill in research gaps, and plan the implementation of some form or phases of NPh, including the transitional bridge from today to a better future strategy.

9.6 Two Considerations

Right now, payer groups do not fully understand each other's plans and priorities. Situations and announcements too often catch other parties by surprise. Decisions vary by province, insurer and employer. There is a perception that each party acts only out of self-interest and happily stays in its own lane and silo. Patients have been disadvantaged by poor consultation, piecemeal responses and a patchwork of coverage.

The first potentially more effective approach is to create a national prescription medicines strategy to link appropriate solutions to a broader array of access, quality and cost problems. This would include but not be limited to national pharmacare. In addition to identifying and beginning to integrate goals, processes, funding and outcomes, a strategy would help Canada 'future-proof' our system against rapid evolution in products, patient expectations and third-party willingness or ability to pay.

Modeled after Germany, a second idea is to establish a standing forum of public and private payers (governments, insurers, employers and patients) to advise pCPA, the only body that includes all the jurisdictions, or the new Canadian Drug Agency (CDA). Greater transparency could help engage the public and overcome purely political considerations and institutional inertia. At a tactical level, stronger payer relationships would help identify and support national opportunities such as improved economic analyses of new drugs, increased use of biosimilars and creating a framework for drugs for rare diseases (DRDs). A secretariat could be equipped (or expanded if within pCPA or CDA) to sponsor rigourous practical research and consultation. For example, it could investigate the costs and opportunities of implementing a real-world Quebec drug insurance model across Canada.

These ideas would encourage trust, understanding and an appreciation of each party's role and symbiotic relationship. It would broaden inputs to reflect the considerably more complex, expensive and highly technical environment that permeates drug insurance. Each idea would reinforce a pan-Canadian approach, help integrate drugs with other health services and potentially overcome system inertia.

Two other specific opportunities emerged from the interviews:

1. The pCPA / CDA mandate should negotiate a single national price for new brand drugs. At least between now and 2027, private insurers could contribute to operating costs in exchange for benefiting from price discounts negotiated on their behalf.

2. While the CLHIA is well-organized it does not include representation from employers, employer organizations, benefit advisors, pharmacy benefit managers or patient groups. A broader coalition could more effectively and credibly recommend a private drug insurance framework to governments (or the pCPA or CDA) for NPh.

9.7 Strengths of this Study

This research is centred on exploring an alternative model – social insurance – to break the impasse of achieving adequate universal drug insurance. Today's private insurance is somewhat more expensive to administer over the proposed single payer model because it provides choice in plan design, technological improvements over public plans, pays over $1 billion in taxes, and because it is administered by 24 for-profit and not-for-profit. private insurers. A new social insurance model is a viable alternative though a workable model has yet been fully developed. It could also achieve adequate universal drug insurance while eliminating one of the main barriers to implementation – high additional cost to governments. Social insurance would retain an important role for private insurance and should regulate the industry to achieve policy goals such as acting in the public interest, competitive innovation and equitably spreading risk and cost between private and public payers.

The combination of a comprehensive literature review, comparative analysis of social health and drug insurance systems in two European countries and Quebec, and detailed interviews with a diverse, national panel of opinion leader experts in public and private drug plans provides a unique and practical composite perspective on planning, implementing, managing and governing national pharmacare.

This thesis adds to very limited research on how private insurance operates and has become institutionalized in Canada over the last five decades. It provides detailed descriptions of the operations and goals of two European health systems to identify what Canada could learn and implement. This thesis uses qualitative research to explore for the first time the perceptions and opinions of experienced, senior-level drug plan experts on NPh and reveals different priorities and concerns. More specifically, this thesis also collected and assessed current information on key NPh decision points, described below.

1. Principles for a national approach to drug insurance are proposed that reflect current concerns. NPh should be affordable, effective, efficient, equitable, integrated and sustainable. This consolidates work from previous published papers.

2. Eight reasons why nothing has changed are explained: (1) cost, (ii) limited policy ideas, (iii) resistance to change, (iv) impractical principles, (v) indifference of policy elites, (vi) political interpretations of the Canada Health Act, (vii) patients feel protected and (viii) insurer strategy. To the author's knowledge, these reasons have not been consolidated or compared in previous published works.

3. Kingdon's three streams theory provides astute observations of how the US federal government may act or not act. To the author's knowledge, Kingdon has not been applied in the Canadian context of achieving adequate universal drug insurance. The theory was very useful in identifying a lack of convergence in problem, policy and politics streams which suggests continued problems in implementing a comprehensive NPh model. Kingdon and the original work in this thesis provide largely complementary explanations.

4. This thesis proposes a rationale for 11 key plan design considerations. This led to a submission to the Advisory Council by the author (cited in Advisory Council 2019b) and an essay published in January 2019 by Longwoods.com.[247] The publisher has featured this essay at least three times in its weekly emails to subscribers.

5. Contrary to common messaging that a single payer model is the only viable approach to implement NPh, there does not appear to be an established relationship between system model and system performance or quality. This thesis concludes the

[247] Available at: https://www.longwoods.com/content/25723//recommendations-for-the-advisory-council-on-the-implementation-of-national-pharmacare

system is not the main determinant of health system success, and either model can achieve our most likely goals once they are clearly articulated.

6. The summary of 15 studies (**Table 4.4**) that provided estimated costs for different versions of NPh is new. The estimates vary widely over time and in part because all use different assumptions, many of them unrealistic and misunderstood by politicians and the public who have no relevant operational experience. Other mechanisms to control costs are better matched to this goal, e.g., PMPRB reform, setting up the new Canadian Drug Agency, and creating a more inclusive and transparent governance structure.

7. There are ten different estimates provided of the number of Canadians uninsured and underinsured for prescription drugs (Sec 4.10). None is current and complete.

Oddly, numbers 6 and 7 combine to show there is no authoritative study that accurately identifies the costs and beneficiaries of one of the major problems NPh is supposed to solve – adequate universal access. This is a crucial information gap.

9.8 Limitations and Further Study

Chapter 4 captures three health systems at a point in time. While slow progress in Canada may provide greater currency and longevity, legislation, regulation and structure in Germany and the Netherlands seem to change more quickly to reflect a rapidly evolving market. While both European systems fortunately publish considerable information in English, other information in German and Dutch was not accessible to this author. This is also true for Quebec where most government information and an unknown volume of other work on the Quebec drug plan is available only in French and therefore inaccessible to a researcher with limited fluency in French. This was partially redressed by interviewing one bilingual former Quebec drug plan manager and exchanging views with a bilingual consultant resident in Quebec who has written extensively on the Quebec drug plan.

The opinion leaders interviewed may or may not be representative of all provincial and private drug plan managers and executives and influencers, but the author believes their experience, opinions and perspectives are accurately presented. A purposive sample is necessary because there are so few people with deep knowledge of private insurance and NPh. All participants are highly experienced and qualified in their respective areas and were conversant in reasonable depth on universal drug insurance. Some demonstrated unusual insight. Their information and interpretations should be considered directionally valid and reliable at the time, but may have changed since the interviews occurred.

Participants were not speaking primarily as employers, and it is employers that pay insurers to administer private drug plans. This is a very important constituency but one that is very hard to reach directly given the sheer number of private businesses (over 1 million) and the number of employer-sponsored drug plans (about 110,000).

I am relying on limited and possibly biased information provided by the private life and health insurance industry association to inform my discussion of the NPh debate. For example, the CLHIA's methodology for counting health plan beneficiaries is not disclosed and its estimate is much higher than what large national surveys report (Law, 2018). Important comparative research would be possible in the future if the CLHIA provided CIHI with industry drug expenditures by province. Insurer investment in constructive public policy research, including appropriate access to data by qualified independent researchers, would help ensure private payer perspectives were included in the implementation of adequate universal drug insurance.

The author's personal experience in the private payer community was both helpful and likely a hindrance at times. Familiarity enabled me to get interviews with a broad range of well-informed people. My long work and volunteer experience may provide a better foundation of knowledge than a much younger person, but it may have shaped my own opinions and perceptions in ways that biased the way I asked questions and reported results. In the course of transcribing the interviews I came to appreciate that in a couple of the early interviews I may have expressed my own opinions more than is appropriate. However, given that the participants are very experienced and knowledgeable, I do not believe the impact was consequential.

Six areas are suggested for further study:

1. The effects and potential design of regulation on private Canadian health insurers needs to be understood. Kingdon notes this is a less expensive way to achieve policy change and insurers already have experience with light drug plan regulation and reporting in Quebec. Public plans could benefit as well if this includes the development of minimum standards for coverage and cost-sharing.

2. A more effective national drug insurance governance model based on Germany's Federal Joint Committee should be investigated. Involving patients and other important stakeholders would ensure a more dynamic approach to "future proof" our system.

3. The Netherlands has achieved a truly remarkable reduction in prescription drug prices and average per capita costs while almost every other OECD member has seen steady and significant increases. While their market-based SHI system is beyond our grasp, there are government enablers and insurer behaviours that may be adapted for use here.

4. The deep and lingering mistrust between payers and drug manufacturers needs to be resolved. While the pharmaceutical industry should introduce a more socially responsible pricing model, this innovative industry could build on Canada's high-performing biomedical research capacity and establish a more meaningful role in research and development. Several collaborative frameworks have been launched

between European governments[248] and at least one between a government (Belgium) and its drug industry.[249] These agreements may be examined for use in Canada.

5. Further research on the health system needs, preferences and priorities of employers is needed, especially if they are asked to pay directly for any version of a new NPh plan. Even if a single payer plan is ultimately implemented, the employer contribution to prescription drug spending already totals $12 billion and would increase if there was an employer mandate.

6. Finland has a hybrid financing system that combines single payer hospital and physician coverage and a social drug insurance model (Gagnon, 2017). This is similar to what this thesis and others have proposed for Canada and so requires further investigation.

[248] Grubert N, 2018. *A landmark for international collaboration on HTA and pharmaceutical pricing*. Available at: https://www.linkedin.com/pulse/landmark-international-collaboration-hta-pricing-neil-grubert/.

[249] The three-year *Pact of the Future* was launched in July 2015 by the Belgian Minister of Social Affairs and Public Health. I have not found any published evaluation and it appears the agreement was not renewed. Available at: https://pharma.be/nl/focus/bronnen/publicaties/159-pact-of-the-future-with-the-pharmaceutical-industry.html.

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Appendix A

Incenting Change and Innovation

Changing the health system has been called "the third-rail of Canadian politics"[250]: touch it and you die politically. Change does not come easily in drug policy and programs (Morgan & Daw, 2012; Boothe, 2013).

As change is considered, innovation will be required. Work by E.M. Rogers' and Greenhalgh et al. may be helpful to consider how to get key stakeholders to adopt the important changes needed to sustain adequate universal drug insurance.

There have been thousands of uses of Rogers' generalized Diffusion of Innovation model (Rogers, 1962; Rogers, 2004). While supporting Rogers' theory, Dearing (2004) proposes a five-part integrated strategy for change which I have adapted and annotated with examples for the purposes of this thesis:

1. Demonstrate the social and economic advantages.
    - Quantify and explain the gaps in drug coverage and the need for change that is more responsive to patient needs while respecting fiscal limits. Pick best practices from, for example, the existing Quebec social insurance model, or from outside Canada. [251]
2. Communicate 'features and benefits' of a new funding model to mass media, social media and to opinion leader networks.
    - Distill complexity to clear, crisp, common principles, values and language.
3. Focus adoption at informed intermediaries who serve clients with the greatest needs.
    - Highlight current inequities to health professionals, patient advocates and cancer drug navigators.
4. Advocate a set of solutions that fit the problem.
    - A complex problem requires closer collaboration including a continuum of regulatory options.
5. Manage risk and resistance to change.

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[250] The "third-rail" analogy has been used by many, but this comment is by David Naylor, former President, University of Toronto, quoted by Jeffrey Simpson, Globe and Mail, January 4, 2010. Available at: http://www.theglobeandmail.com/globe-debate/the-great-canadian-health-care-evasion/article794642/#dashboard/follows/.

[251] In this thesis, Germany and The Netherlands.

- Show compatibility with values and current practices to reduce the perceived risk of change. Demonstrate "trialability" in Canada by reviewing the Quebec model.

These steps are similar to those described by Katz (1963) who suggested innovation occurs more successfully when four dimensions are addressed: (i) communicability (easy explanation), (ii) pervasiveness (apparent impacts), (iii) risk (difference from status quo), and (iv) profitability (cost-effectiveness).

Greenhalgh et al. (2004) provided a systematic review that used thirteen different research traditions to examine how health organizations assess, spread and sustain innovation. Their conceptual model acknowledges system antecedents (structure, absorptive capacity for new knowledge and a receptive context for change) and system readiness for change. Three initial observations are:

1. The fit between the innovation and the system in which it is nested is generally more important than the attributes of the innovation itself. "…the attributes are neither stable features of the innovation nor sure determinants of their adoption or assimilation. Rather, it is the interaction among the innovation, the intended adopter(s) and a particular context that determines the adoption rate" (p. 598).

2. The evidence supporting a change may be seen as ambiguous, contestable, continuously (re-)interpreted and reframed according to local issues. There will likely be a lengthy period of negotiation that will involve power struggles. Assimilation, should it occur, will be "…variously punctuated by shocks, setbacks and surprises" (p. 601).

3. Adoption will be affected by the absorptive capacity of the organizations involved, including information technology and whether or not leaders are receptive to experimentation, risk-taking and change. The large scale of governments and insurers is likely positive in terms of resources, but their desire for stability may discourage the capture, sharing and creation of new knowledge.

While the goal is to successfully identify a more feasible and useful approach to enhance coverage and administrative efficiency, it will be just as important to try to identify why innovation may not take hold.