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High Drug Prices, Big R&D Spenders and "Free Riders": Canada in the Topsy Turvy World of Pharmaceuticals

Drug prices and R&D spending vary greatly in developed countries, with the US ranking highest on both counts. How can Canada avoid being a "free rider" on the US while keeping drug prices reasonably low?

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The Study In Brief

The main reason why health and general living standards in the world's developed countries are so much better than in earlier eras is that today's technology is much more advanced. But new technology does not come for free. Most of it, in healthcare and elsewhere, comes about because large amounts of resources are spent on R&D. All countries, especially those with high per-capita incomes, face an inevitable tension between their obligation to contribute their fair share to global pharmaceutical R&D financing and their desire to save money for the taxpayers, private insurers and patients who pay for drugs.

In this *Commentary*, we compare how patent law and pharmaceutical regulation help determine drug prices in Canada, the US, and major countries in Europe and Australasia. Different countries respond in different ways to balancing the need to contain drug spending with contributing to the development of new pharmaceutical technologies that improve our ability to treat previously untreatable conditions. Government policy in many other countries plays a more comprehensive role than it does in Canada, either in the form of direct regulation of drug prices or via the government's role, direct or indirect, in the process under which insurance plans negotiate with pharmaceutical companies about drug purchasing and pricing.

Specifically, we examine what policies Canada should pursue to help overcome criticism that it is a free rider while avoiding paying more than its fair share. With complex interactions between regulations, patent laws, and R&D tax incentives and subsidies, it is difficult to determine whether Canada's contributions to global pharmaceutical R&D are "optimal." It is clear, however, that Canada is less of a free-rider than some other countries that employ restrictive drug pricing policies. Conversely, evidence suggests that US consumers pay more than their fair share towards pharmaceutical R&D due to high prices. Though lower than in the US, published prices of patented pharmaceuticals in Canada are comparable to or higher than in many other developed nations, as are our contributions to business R&D through direct funding and tax expenditures.

We recommend that Canada pursue a two-track strategy. In the short run, we benefit from and, therefore, should aim for the lowest drug prices that we can get without inviting opposition from our main trading partners. But we should simultaneously work with our trading partners and international agencies toward a model of global R&D funding that overcomes the free-rider problem and moves us closer to a more efficient management of this aspect of the global commons.

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The tension between the objectives of controlling healthcare costs, on one hand, and incentivizing the research and development (R&D) that is necessary to develop new drugs, on the other, is evident in healthcare policy debates in Canada and elsewhere.

To incentivize R&D, all industrialized countries have patent laws that enable developers of new drugs to temporarily charge higher prices and earn a higher profit than they otherwise would, but the drug patent laws and regulations that accompany them differ considerably from country to country.[1]

In this *Commentary*, we compare the way patent law and regulation help determine drug prices in Canada, the US, and major countries in Europe and Australasia. We discuss the incentives for some countries, especially smaller ones, to act implicitly as free riders who benefit from the drugs developed as a result of global R&D but don't contribute their fair share toward financing it. Specifically, we examine what policies Canada should pursue to help overcome criticism that we are a free rider.

Although the current Canadian model of paying for pharmaceuticals through a mixture of government and private insurance resembles that in the US, our regulatory policies also have many similarities with those in Europe and Australasia. With the exception of the US and Canada, all the countries we consider have some form of universal pharmacare. If Canada also moves to universal coverage, it should draw on the experiences of these countries. Still, universality is not incompatible with a mix of public and private insurance, so aspects of the US model might still remain relevant.

We end the *Commentary* with a recommendation that Canada pursue a two-track strategy. In the short run, we benefit from and, therefore, should aim for the lowest drug prices that we can get without inviting opposition from our main trading partners. But we should simultaneously work with our trading partners and international agencies toward a model of global R&D funding that overcomes the free-rider problem and moves us closer to a more efficient management of this aspect of the global commons.

FINANCING R&D AND THE LOGIC OF THE PATENT SYSTEM

The main reason why health and general living standards in the world's developed countries are so much better than in earlier eras is that today's technology is much more advanced. But new technology does not come for free. Most of it, in healthcare and elsewhere, comes about because large amounts of resources are spent on R&D. Technological progress can take different forms: finding new and better ways to produce existing goods and services, developing new products that consumers value and enabling us to alleviate health problems that previously could not be treated effectively.

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1 Intellectual property rights protection includes not only patents but also elements such as data protection and copyright. Since patent rights can be bought and sold, patent protection applies to the patent owner, who may not be the creator.

Some pharmaceutical R&D consists of basic research that is funded by governments and is typically carried out in universities and specialized research institutes. But most of it is undertaken by private firms in the hope of making a profit from breakthroughs and new technology. The patent legislation that exists in all advanced countries today is intended to encourage private sector R&D. It does this by making it illegal, for a time, for anyone other than the patent holder to market the product or use the technology it has developed. That is, it gives the patentee a period of market exclusivity; i.e., a monopoly during which no competitor can legally sell the new product or use the new technology that is covered by the patent. With no legal competition, the price that the patent holder can charge is likely to be higher than it otherwise would be, and all the profits from the new product or technology will accrue to the patent holder.

Conventional static microeconomic analysis tells us that in a market where a monopolist sells a product at a price that is substantially higher than the marginal cost of producing it, there will be some loss of economic efficiency. However, if sellers of new products could not charge a price above their production costs, they would never be able to recoup their R&D expenses. This would lead to another form of inefficiency – valuable new products or technology would never be developed. In the long run, this form of inefficiency – sometimes referred to as dynamic inefficiency – would be a great deal more damaging. On balance, therefore, the modest static efficiency losses that arise from allowing patent holders a period of market exclusivity can be considered a small price to pay for the long-run benefits of the continuing development of new technology.

Medicine, in general, and pharmacology, in particular, are examples of sectors where the patent system has contributed to dramatic improvements in human welfare. Patients, or more often their insurers, may complain about the high prices that patent holders charge, and critics may argue that the profits that pharmaceutical companies earn on some of the most successful drugs are much larger than the cost of the R&D that went into developing them. But the new drugs have also saved countless lives and alleviated a large amount of the pain and suffering among patients with serious and debilitating health problems. While the pharmaceutical companies have made large profits on some of the most successful drugs, they have also spent a lot of money on R&D that has not been successful. Overall, it seems clear that in past years, the world at large has received good value for the resources used in the pharmaceutical industry.[2] However, although R&D investment by pharmaceutical companies has increased substantially over time, the productivity of such investments has been declining, (Pamolli, Magazzini and Riccaboni 2011).

Pricing in Pharmaceutical Markets

The logic of the patent system is based on the idea that when a new product sells at a high price and generates profits, it is because it is truly valuable to consumers. Unless it were, consumers would not be willing to pay a high price for it. In healthcare, however, critics have argued this may not be so. Markets that provide people with products and services that cure or improve health problems have special characteristics that may enable sellers to charge prices that substantially exceed the true value to patients of the benefits from using these products or services.

Patients looking for healthcare or medicines typically don't have the information that is necessary to make good purchasing decisions. They must rely instead on the advice of health

2 In the healthcare sector, value, in human welfare terms, means the years of life gained or deaths and disabilities prevented by pharmaceutical technologies.

professionals such as doctors or pharmacists. As well, most (though not all) patients don't pay for services or drugs out of their own pockets since some or all of these costs are covered by public or private insurance plans. As a result, when a doctor writes a prescription for a particular medicine, patients are likely to buy it, even if the price is high: they fear the consequences of not taking it or of using a less expensive substitute. If all or most of the expense is paid by an insurance plan, they have even less reason to pay attention to the cost of the drugs they have been prescribed.

While these features suggest that sellers of patented drugs potentially have a great deal of pricing power, they do face moderating factors. Prescribing doctors may pay attention to prices when choosing among possible alternatives, though in most cases they do not have a strong incentive to do so.[3] More importantly, the insurance plans that pay at least a portion of the drug costs in all industrialized countries may refuse to cover drugs whose prices they consider too high. Indeed, as we discuss below, in healthcare systems where most drugs are paid for by one or a few large plans, the pricing power on the seller's side may be quite limited, even for drugs that remain under patent.

Global R&D and the Free-RidingIssue

Technology, including pharmaceutical technology, is global. Patent legislation in different countries generally recognizes not only patents granted for technologies or products developed by domestic firms but also in other countries. The multinational enterprises that carry out most of the R&D to develop new drugs derive revenue from sales in countries all over the world. For this reason, patent legislation often figures prominently when countries negotiate international trade agreements. Most recently, new Canadian patent rules relating to the class of drugs known as biologics were an important element included in the new trade agreement with the US and Mexico to replace NAFTA.[4]

In international economic negotiations, the pattern tends to be that countries with large amounts of pharmaceutical patents and R&D activities support stronger patent protection such as longer monopoly periods and more restrictive rules that define patent infringement and govern competition from generics when a patent runs out.

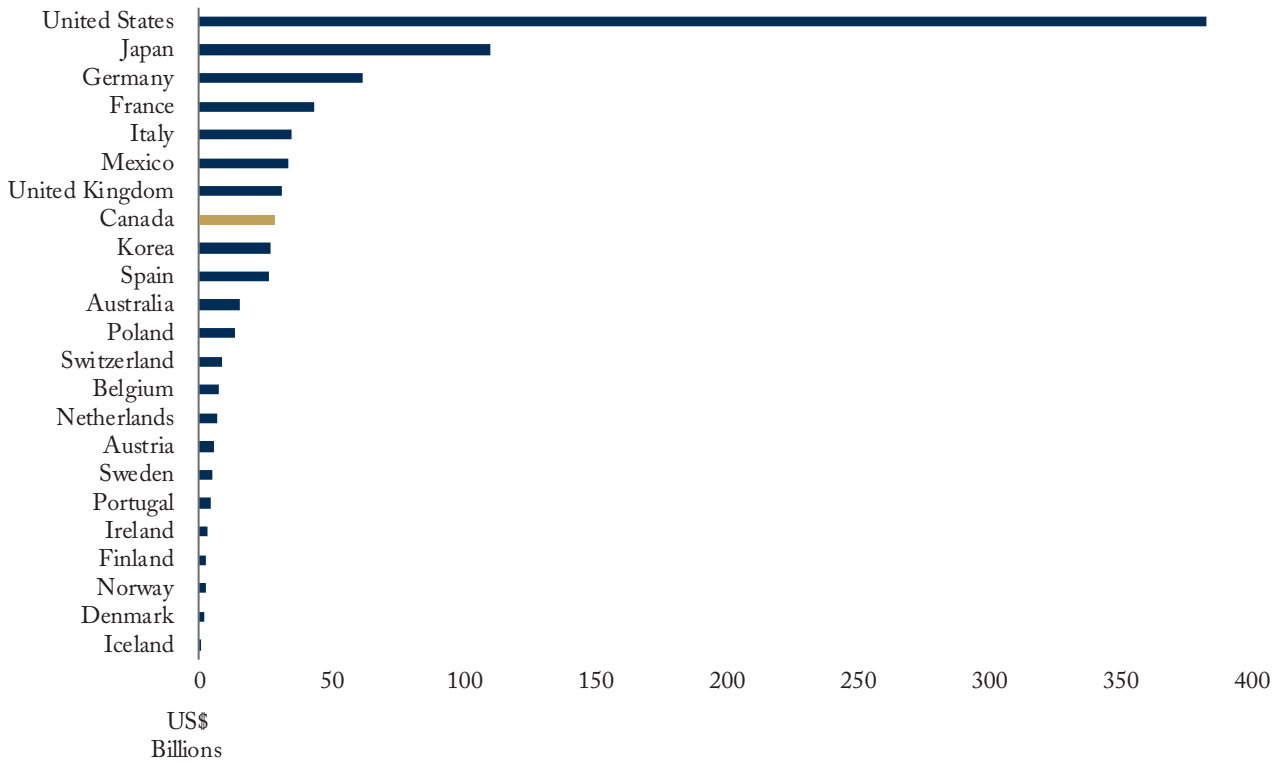
This is not surprising. In looking at its *domestic* patent legislation and drug-pricing policies, a country must balance the interests of pharmaceutical firms (who benefit from high prices) against those of patients and payers who benefit from low prices.

In *international* negotiations about rules that influence drug prices in other countries, however, there is no such ambiguity. From the viewpoint of a country with a large pharmaceutical industry, high drug prices in other countries clearly are beneficial since they tend to increase the profits of domestic firms that produce these drugs while the high prices are borne by foreign residents. In international negotiations, countries that pursue policies that lower drug prices are sometimes described as "free riders": they benefit from the new drugs developed through R&D elsewhere but are unwilling to pay their share of the development costs in the form of high drug prices.

3 In Canada, doctors have no such (US) incentives, but in many other countries tools such as drug budgets (UK) or salary withholds in managed-care plans are used to create an incentive for prescribing doctors to pay attention to cost (Rashidian et al 2015).

4 A recent newspaper report, however, suggests that this provision is meeting opposition in the new US Congress as it considers ratification of the agreement (Wiseman 2019). The extension of patent and data protections could be costly for Canadians, but this is moderated to some extent by the Patented Medicine Pricing Review Board, for which there is no analogous US counterpart.

Figure 1: Total Pharmaceutical Spending, 2015



Source: OECD Health Expenditure and Financing.

This creates several problems. First, it may lead to policies that reduce the resources devoted to global pharmaceutical R&D, resulting in lower – perhaps substantially lower – investment than what would be efficient from a global perspective.[5] Second, the free-riding incentive may shift a disproportionate share of the R&D financing burden to large countries.

The incentive to be a free rider is strongest in small countries that account for only a small share of the global profits re-invested in R&D and, therefore, have little impact on the global pharmaceutical industry. For example, even if such a country, like Norway or New Zealand, pursued a policy that entirely eliminated the expected profits from patented drug sales, it would be unlikely to produce a significant reduction in global R&D or in the progress of pharmaceutical technology. On the other hand, decision makers in countries that account for a relatively large share of the global market for pharmaceuticals, such as Japan, Germany and the US (Figure 1), must recognize that their decisions could have a significant impact on global R&D and reduce the expected future benefits for everyone, including their own residents. Therefore, jurisdictions that account for a large share of global demand can be expected to have patent and pricing

5 The free-riding incentive might more than offset the pricing power that sellers in healthcare markets have because of the factors discussed earlier: imperfectly informed consumers and third-party payment.

policies that allow relatively high price markups and profits and, therefore, carry a disproportionate share of global R&D financing.[6]

This effect is most obvious in the US, which despite being the largest purchaser of pharmaceuticals, also pays the highest prices. Among OECD countries, the US market accounts for nearly half (46 percent) of all brand name drug sales and 70 percent of patented pharmaceutical profits, despite accounting for only 34 percent of GDP (Council of Economic Advisors 2018). This concentration of sales and profits of patented pharmaceuticals in the US is due in part to higher prices and in part to earlier access to these medicines. A large market, higher prices and lack of lengthy centralized-buyer price negotiations all contribute to the launch of more pharmaceutical products with shorter delays. In contrast, Danzon, Wang and Wang (2005) find that countries with lower expected prices or smaller expected market size have fewer launches of new pharmaceuticals and longer launch delays.[7]

All countries, especially those with high per-capita incomes, face an inevitable tension between their obligation to contribute their fair share to global pharmaceutical R&D financing and their desire to save money for the taxpayers, private insurers and patients who pay for the drugs. Different countries respond in different ways. In the following sections, we first describe the main elements of the Canadian approach. We then consider various policies in other high-income countries in Europe and Australasia whose systems are different from those in Canada and the US, in part because they all have some form of universal government health insurance that includes the cost of drugs.

THE CANADIAN MODEL

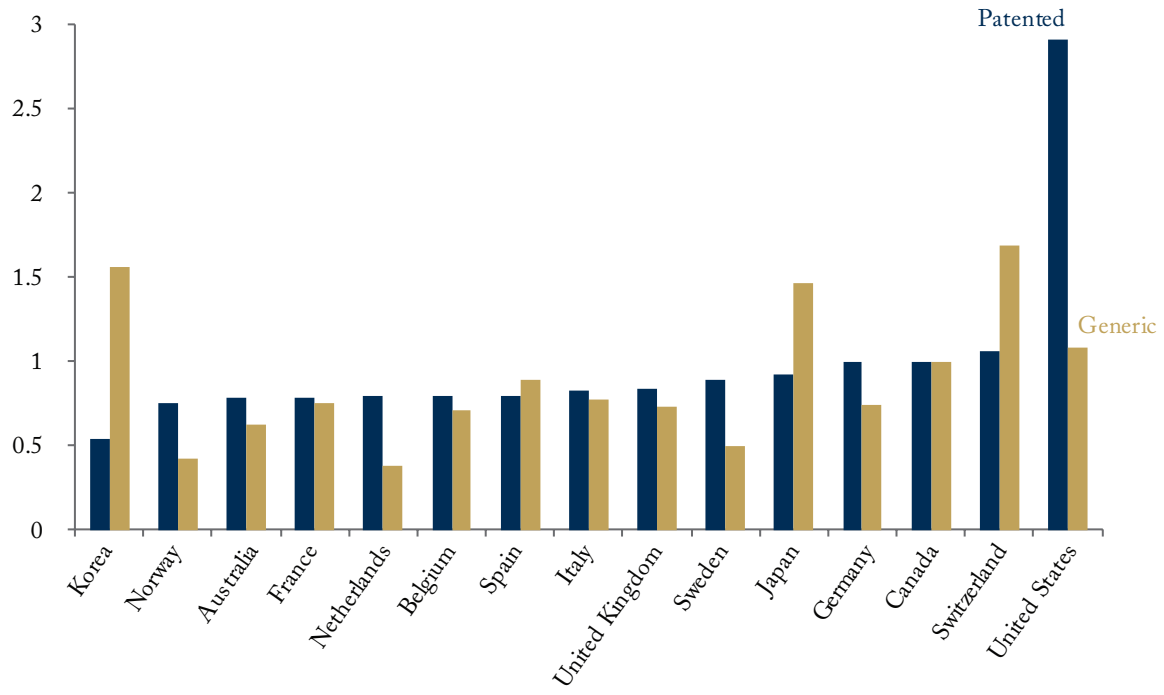
In Canada, the regulatory process that a new drug must undergo begins with an application to Health Canada for permission to market it. Health Canada will approve the drug if there is a low enough risk of adverse side effects, based on the clinical testing undertaken by the patentee. Earlier Canadian patent legislation contained provisions for "compulsory licensing," which limited the rights of owners of pharmaceutical patents to some extent, but these provisions were eliminated when the *Patent Act* was revised in the 1980s and 1990s. Following these revisions, the current Canadian *Patent Act* gives the owners of drug patents a period of market exclusivity during which they are the only legal sellers of the drug. While this gives them a monopoly position that in many cases could enable them to charge a very high price, the Act also specifies that the prices of patented medicines are subject to regulation by the Patented Medicine Prices Review Board (PMPRB).

The PMPRB's mandate is to ensure that patented medicine prices are not "excessive." Functionally, this means that the PMPRB regulates the drug's maximum price in Canada. The Act does not define excessive but says that the Board shall consider the prices of "other medicines in the same therapeutic class" and the prices at which the medicine has been sold "in other countries." These are often referred to as "internal" and "external" reference comparisons. As we discuss below, both are used extensively in regulation of pharmaceutical prices in other countries. Comparing prices paid for patented medicines shows that Canada generally pays more than other countries, with some exceptions (US and Switzerland).

6 For more on the inefficiencies created by centralized pricing policy, the global nature of medical innovation and the international interactions between them, see Egan and Philipson (2013).

7 A more recent study that reaches a similar conclusion is Danzon and Epstein (2012). We discuss a possible reason for these findings in a later section.

Figure 2: Average Foreign-to-Canadian Drug Price Ratio, 2016



Source: PMPRB 2017, 2018.

Current PMPRB regulations contain a list of comparator countries to be used for external reference comparisons.[8] However, that list could change as a result of proposals to amend the regulations.[9] If the proposed changes come into force, the PMPRB's external reference comparison would see the elimination of two of the seven listed countries, US and Switzerland. Seven new ones would be added, resulting in the following list of 12: Australia, Belgium, France, Germany, Sweden, Italy, Japan, the Netherlands, Norway, South Korea, Spain and the UK.

In addition, the PMPRB would also be required to consider several new factors intended to reflect a drug's "pharmacoeconomic value" as well as measures of Canada's "willingness and ability to pay for patented medicines" based on expected market size for the drug and Canada's GDP per capita. As we discuss below, these changes would bring Canada's regulatory regime closer to those in most other high-income countries, other than the US.

The federally regulated prices in Canada are ex-factory prices; i.e., the prices at which medicines are sold to large buyers such as wholesalers, pharmacies, or hospitals. The ex-factory prices that sellers charge cannot be higher than those established by the PMPRB. They can be, and frequently are, lower, sometimes substantially so. Typically, price adjustments take the form of discounts and rebates that sellers grant the provincial insurance plans that

8 Additional detail about how the PMPRB arrives at the maximum prices patentees are allowed to charge is contained in its Compendium of Policies, Guidelines and Procedures (PMPRB 2017).

9 The proposed regulatory changes are well described in Government of Canada (2017).

pay a large share of the cost and to the hospitals and pharmacies that distribute their drugs. Often the amounts of these discounts are confidential.

The universal health insurance plans in Canada's provinces do not cover pharmaceuticals, so drugs are paid for by patients alone and/or by various public and private plans for specific population groups. About two-thirds of Canadians have some health insurance beyond the basic coverage offered by government plans (Allin and Rudoler). Government plans that cover retirees, social assistance recipients and some First Nations and Inuit peoples[10] account for a large share of total drug spending. There are also public backup plans that provide at least some coverage for other population groups, such as Ontario's OHIP+, which pays the prescription drug costs for persons under 25.[11]

In 2016, public dollars covered 43 percent of prescription drug costs in Canada. Even though the provincial government plans do not cover the entire population, they typically are the largest plans in each province. They have been increasingly active in negotiating price discounts from the pharmaceutical companies when deciding whether or not a drug is eligible for reimbursement. In previous years, each province negotiated these discounts separately. Since 2010, the provincial plans conduct these negotiations jointly, through the pan-Canadian Pharmaceutical Alliance (pCPA),[12] which now also includes the federal plan for First Nations and Inuit. Under the new system, all the participating plans are eligible for the same discount. So far, private insurance plans have not been allowed to join the pCPA in negotiating discounts for patented brand-name drugs.[13]

In making their listing decisions, insurance plans can draw on the cost-effectiveness analysis that another federal-provincial agency, the Canadian Agency for Drugs and Technologies in Health (CADTH) routinely carries out for new drugs. Like its counterparts in other countries such as the UK and Australia, CADTH's main analytical tool is a form of cost-utility analysis where a new drug's benefit is expressed as an estimate of the additional quality-adjusted life years (QALY) for those who use it. By comparing the estimated benefit with the proposed cost of the drug, one can then calculate a cost-effectiveness ratio, the cost per incremental QALY. The ratio is often referred to as an incremental cost-effectiveness ratio (ICER). The lower a drug's ICER, the more attractive it is, in the sense that it yields a larger amount of health benefits per dollar. Other things equal, insurers are more likely to list drugs with lower ICERs than existing or proposed alternatives.[14]

A drug's ICER estimate is based on information that sellers supply about the results from the clinical testing it has undergone and on the proposed price. Since sellers have a strong interest in seeing their drugs included on insurance plans' lists, and are well informed about the CADTH's methodology, it is in their interest that their proposed prices, net of the confidential discounts they offer, come close to whatever threshold ICER values that the provincial insurance plans like to see as a condition for listing a drug. It should also be noted that even

10 The federal Non-insured Health Benefits Program provides extended medical coverage for First Nations people registered under the *Indian Act* and Inuk recognized by an Inuit land claim organization. Inuk not recognized by an Inuit land claim organization, First Nations people without status and Métis are ineligible.

11 At the time of writing, the Ontario Government had announced plans to restrict OHIP+ coverage to those who do not have coverage under a private health insurance plan but had not yet implemented the changes.

12 Formerly known as the pan-Canadian Pricing Alliance.

13 The pCPA has also negotiated discounted prices for generic drugs. In contrast to those for brand-name drugs, the discounted prices for generic drugs are available to all Canadian payers – public, private and out-of-pocket – because the negotiated prices are transparent and listed on public websites.

14 The classic reference on economic evaluation in healthcare is Drummond et al. (2015).

though pharmacoeconomic value measures (such as a drug's ICER) currently play no role when the PMPRB sets its maximum allowable price, this will change if the proposed new regulations are adopted. Again, this would bring the Canadian model closer to those in other countries (except the US), where "value-based pricing" often is an important element in the regulatory regime (see below).

PHARMACEUTICAL PRICING POLICIES IN OTHER COUNTRIES

When it comes to the funding of hospitals and physician services, Canada's model of universal provincial health insurance is much more similar to those in Europe and Australasia than to the US system where coverage is not yet universal. However, since we do not have universal pharmacare, the way Canadians pay for pharmaceuticals is, in many respects, more similar to the US model. Still, current US pharmaceutical policy is different from Canada's in that it does not have an agency, like the PMPRB, that regulates drug prices.

Meanwhile, government policy in other countries plays an even more comprehensive role than it does in the US or even Canada, either in the form of direct regulation of drug prices or via the government's role, direct or indirect, in the process under which these plans negotiate with pharmaceutical companies about drug purchasing and pricing. Since Canada is likely to move toward some type of universal pharmacare in the coming years, we focus in this section on a comparison between Canada and countries other than the US. (A brief description of the US drug-pricing system is in the Appendix.) Many of these countries' techniques and approaches to drug-pricing policy are similar to those used in Canada, or have featured in the discussion about revised regulations governing the PMPRB's role in the process (Table 1). However, while many of the underlying ideas are similar, the precise way in which they are combined and applied differs a great deal. Some countries use other instruments (such as national drug budgets) to affect prices and aggregate pharmaceutical expenditure.

International comparative surveys of drug pricing systems also suggest that, like Canada, many countries are in the process of modifying their approach (Babar 2015). In part, this reflects the fact that policies that may have worked reasonably well in the past may no longer be appropriate, as many new kinds of potentially very expensive medicines, particularly biologics, are becoming a larger component of total pharmaceutical spending. Rather than trying to describe particular countries' current and past policies in detail, we will instead briefly review recent approaches and techniques before turning to a discussion of lessons that Canada may draw from their experience.

Internal and External Reference Pricing

Most European countries have regulatory agencies that impose maximum drug prices and do so in part on the basis of internal and external price comparisons; i.e., comparisons of the proposed price of a drug either with similar drugs being sold in that country or with the prices at which the given drug is sold in other countries.

Internal price referencing is applied in cases where a new drug is considered comparable to one or more existing ones with respect to chemical composition and to the patient categories and health problems it is intended to address. Frequently, the World Health Organization's Anatomical, Therapeutic, Chemical (ATC) classification system is used to define comparability. As in Canada, regulatory agencies may then specify a maximum price for a new drug that can be no higher than a value that depends on prices of other drugs in the same class. Such internal comparisons are also used by insurance plans when they negotiate with pharmaceutical companies about discounts, even when prices are not formally regulated.

Table 1: Summary of International Healthcare Systems and Strategies for Regulation and Containment of Pharmaceutical Expenditures

	Government Role in Health System	Private Insurance role	Price Regulation and Cost Containment
Australia	Regionally administered, joint (national & state) public hospital funding; universal public medical insurance program.	~47% buy complementary (e.g., private hospital, dental care, optometry) and supplementary coverage (increased choice, faster access for non-emergency services, rebates for selected services); 56% had general treatment coverage.	Pharmaceutical subsidies are provided through the Pharmaceutical Benefits Scheme (PBS). To be listed, drugs need to be approved for cost-effectiveness by the independent Pharmaceutical Benefits Advisory Committee. Consumers pay the full price of medicines not listed on the PBS. Pharmaceuticals provided to inpatients in public hospitals are generally free.
Canada	Regionally administered universal public insurance program that plans and funds provision	~67% buy complementary coverage for non-covered benefits (e.g., private hospital rooms, drugs, dental care, optometry, etc.)	CADTH's Common Drug Review assesses drugs' clinical- and cost-effectiveness and provides common, non-binding formulary recommendations to the publicly funded provincial drug plans (except in Quebec) to support greater consistency in access and evidence-based resource allocation.
Denmark	National system. Regulation, central planning and funding by national government; provision by regional and municipal authorities.	~39% have complementary coverage (cost-sharing, non-covered benefits such as physiotherapy); ~26% have supplementary coverage (access to private providers).	Policies to control outpatient pharmaceutical expenditures include generic substitution, prescribing guidelines and regional assessment of deviations in prescribing behaviour. Pharmaceutical companies report a monthly price list to the Danish Health Authority, and pharmacies are obliged to choose the cheapest alternative with the same active ingredient, unless a specific drug is prescribed. Patients may choose more expensive drugs, but they have to pay the difference. Inpatient pharmaceutical expenditure is controlled through national guidelines and clinical monitoring combined with collective purchasing. The purchase of medicine takes place through tendering by a joint regional organization.
England	National Department of Health provides stewardship for the overall healthcare system, but day-to-day responsibility rests with a separate public body, NHS England.	~11% buy supplementary coverage for more rapid and convenient access (including for elective treatment in private hospitals). In 2015, 90 percent of prescriptions were dispensed free of charge.	The costs of prescription (branded) drugs are contained by the Pharmaceutical Price Regulation Scheme that regulates the profits that drug companies make selling drugs to the NHS. It is a voluntary scheme, negotiated between the UK government and the pharmaceutical industry, with new medicines to be introduced at prices set by the manufacturer as long as they remain within the profit cap. This scheme runs parallel with cost-effectiveness appraisals that tend not to recommend new drugs as cost-effective if they exceed US$28,900–US$43,350 per Quality Adjusted Life Year.

Source: The Commonwealth Fund – *International Health System Profiles.*

Table 1: Continued

	Government Role in Health System	Private Insurance role	Price Regulation and Cost Containment
France	Statutory health insurance system, with all insurers incorporated into a single national exchange	~95% buy or receive government vouchers for complementary coverage (mainly cost-sharing, some non-covered benefits); limited supplementary insurance.	Lists of covered procedures, drugs and devices are defined at the national level and apply to all regions. The health ministry and a pricing committee set these lists, rates of coverage and prices. The increasing cost of drugs is addressed in two ways: 1) by using earmarked funds and capping the total cost of treatments at EUR700 million (US$843 million) in 2015, thus providing treatment to successive waves of patients by decreasing severity; and 2) by negotiating price-volume agreements and undisclosed rebates with manufacturers.
Germany	Statutory health insurance system, with 124 competing insurers ("sickness funds" in a national exchange); people can opt out for private coverage.	~11% opt out from statutory insurance and buy substitute coverage. Some role for complementary (minor benefit exclusions from statutory scheme, co-payments) and supplementary coverage (improved amenities).	All prescription drugs are covered except those excluded under the law ("lifestyle drugs") and those excluded following a benefits assessment. All drugs, both patented and generic, are placed into groups with a reference price serving as a maximum reimbursement level, unless they can demonstrate added medical benefit. For drugs with added benefit, the Federal Association of Sickness Funds negotiates a rebate on the manufacturer's price that is applied to all patients. In addition, rebates are negotiated between individual sickness funds and pharmaceutical manufacturers to lower prices below the reference price.
Italy	National system. Funding and definition of minimum benefit package by national government; planning, regulation, and provision by regional governments.	Patients buy complementary (services excluded from statutory benefits) or supplementary coverage (more amenities in hospitals, wider provider choice); ~5.5% buy additional coverage (1.33 million families), while ~2.5 million people have group coverage.	Prescription drugs are divided into three tiers according to clinical effectiveness and, in part, cost-effectiveness. The first tier includes lifesaving drugs and treatments for chronic conditions and is covered in all cases; the second contains all other drugs and is not covered. There is an additional tier comprising drugs that can be delivered only in a hospital setting. The three tiers are updated regularly by the National Pharmaceutical Agency based on new clinical evidence. For some categories of drugs, therapeutic plans are mandated, and prescriptions must follow clinical guidelines.

Source: The Commonwealth Fund – *International Health System Profiles.*

Table 1: Continued

	Government Role in Health System	Private Insurance role	Price Regulation and Cost Containment
Japan	Statutory health insurance system, with >3,400 non-competing public, quasi-public and employer-based insurers. National government sets provider fees, subsidizes local governments, insurers and providers.	Majority of population has coverage for cash benefits in case of sickness, usually together with life insurance. Limited role of complementary and supplementary insurance offered separately from life insurance.	The Central Social Insurance Medical Council defines the benefit package and fee schedule. Pharmaceuticals and medical devices are reviewed for quality, efficacy and safety by a governmental agency. The criteria for coverage include clinical effectiveness but not costs. Recently, the agency has been implementing trials to use comparative cost-effectiveness studies in its decision making. Patients pay 30 percent for most services. The fee schedule is revised every other year, following formal and informal stakeholder negotiations. The price revisions for pharmaceuticals and medical devices are based on a market survey of actual current prices (which are usually less than the listed prices). Drug prices can be revised downward for new drugs selling in greater volume than expected and for brand-name drugs when generic equivalents hit the market.
Netherlands	Statutory health insurance system, with universally mandated private insurance (national exchange); government regulates and subsidizes insurance.	Private plans provide statutory benefits; 84% buy complementary coverage for benefits excluded from statutory package such as dental care, alternative medicine, physiotherapy, eyeglasses, contraceptives and co-payments.	The Medicines Evaluation Board oversees the efficacy, safety and quality of medicines while the Dutch Health Care Authority has primary responsibility for ensuring that the health insurance, healthcare purchasing and care-delivery markets all function appropriately. Cost control relies on market forces while regulating competition and improving efficiency of care. In addition, provider payment reforms, including a shift from a budget-oriented reimbursement system to a performance- and outcome-driven approach, have been implemented. Reimbursement for expensive drugs has to be negotiated between hospital and insurer, and there is some concern that this and other factors may limit access to expensive drugs in the near future.
New Zealand	National system. Responsibility for planning, purchasing and provision devolved to geographically defined District Health Boards.	~33% buy complementary coverage (for cost-sharing, specialist fees and elective surgery in private hospitals) and supplementary coverage for faster access to non-urgent treatment.	For drugs prescribed by GPs and private specialists, co-payments are required only for the first 20 prescriptions per family per year (US$3.40, per item). The Pharmaceutical Management Agency uses mechanisms such as reference pricing and tendering to set prices for publicly subsidized drugs dispensed through community pharmacies and hospitals. If a patient prefers an unsubsidized drug, they must pay the full cost.

Source: The Commonwealth Fund – *International Health System Profiles.*

Table 1: Continued

	Government Role in Health System	Private Insurance role	Price Regulation and Cost Containment
Sweden	National system. Regulation, supervision and some funding by national government; responsibility for most financing and purchasing / provision devolved to county councils.	~10% of all employed individuals ages 15-74 get supplementary coverage from employers for quicker access to specialists and elective treatment. In 2014, about 16 percent of all health expenditures were private. Most out-of-pocket spending is for drugs.	Individuals pay the full cost of prescribed medications up to US$120 annually, after which a subsidy gradually increases to 100 percent. County councils and municipalities are required by law to set and balance annual budgets for their activities. For prescription drugs, the central government and county councils form agreements on the levels of subsidy paid by the government to the councils. The central government's Dental and Pharmaceutical Benefits Agency also employs value-based pricing for prescription drugs, determining reimbursement based on an assessment of health needs and cost-effectiveness.
Switzerland	Mandatory health insurance system, with universally mandated private insurance (regional exchanges).	Private plans provide universal core benefits; some people buy complementary (services not covered by mandatory insurance) and supplementary (improved amenities and access) coverage	The main national player is the Swiss Federal Office of Public Health that, among other tasks, supervises the legal application of the mandatory system, authorizes insurance premiums offered by statutory insurers, and governs statutory coverage (including health technology assessment) and the prices of pharmaceuticals.
US	Medicare: age 65+, some disabled; Medicaid: some low-income. For those without employer coverage, state-level insurance exchanges with income-based subsidies; insurance coverage mandated, with some exemptions (~10% of adults uninsured)	Primary private voluntary insurance covers ~66% of population (employer-based and individual); supplementary for Medicare.	Payers have attempted to control cost growth through a combination of selective provider contracting, price negotiations and controls, utilization control practices, risk-sharing payment methods and managed care. Recently, both public and private payers have focused more attention on value-based purchasing and other models that reward effective and efficient healthcare delivery.

Source: The Commonwealth Fund – *International Health System Profiles.*

In several countries where the government insurance plan allows for patient co-payments, the plan specifies a basic reimbursement price within each therapeutic class. If a patient chooses a drug with a higher price, he or she has to pay the difference. In France, for example, co-payment rates for drugs range from zero to 100 percent (Durand-Zaleskind). This is similar to the method used by US pharmacy benefit managers to induce competition among sellers and obtain lower prices.

Internal price referencing is controversial when it is used in price regulation. Different agencies divide drugs into classes in different ways, and there can always be subjective disagreements with respect to which drug within a class is likely to work best for a given patient. Moreover, the official ATC classification has different levels, and agencies differ in terms of which level they use to classify drugs as being in the same class (Zuidberg 2010).

External price referencing, of the type the PMPRB engages in, is used by many countries in Europe. It also plays a significant role in Australia and New Zealand. Most commonly, comparisons with prices in other countries are used when government regulatory agencies set maximum ex-factory or wholesale prices, but they

are also used in a less formal way when insurance plans or purchasing agencies negotiate with pharmaceutical companies about listing decisions and reimbursement rules. In the comparative literature on pharmaceutical pricing systems, only a few countries, particularly the UK and Sweden, are generally described as not using external reference pricing (Vogler and Martikainen 2015). However, some discussions distinguish between European countries where external price referencing is formally used as the main determinant of regulated prices and others, such as Germany and Italy, in which such comparison is only one among many factors that determine regulated prices.

Even among countries that use external price referencing in a more formal regulatory sense, there is a great deal of variation in which countries are included on the comparator list and how foreign prices are used in setting maximum domestic prices. The comparison, for example, could be with the lowest international price, the average or the median price among comparator countries, and so on.

Generally speaking, the regulated or negotiated prices that pharmaceutical companies and government agencies or insurance plans agree on and that are publicly available are considered as more or less official list prices. As in Canada, an issue that has become increasingly relevant in other countries is the fact that the real transaction prices paid by insurance plans or pharmacies are often considerably different from these list prices. As a result, there appears to be a gradual trend in pharmaceutical policy toward less emphasis on international comparisons and more on alternative approaches such as value-based pricing. Another response to this issue has been more active attempts to pressure pharmaceutical sellers to reveal more information about rebates and discounts that currently are confidential.

Value-Based Pricing

A general definition of value-based pricing is that the decisionmaker relates a proposed price to a quantitative estimate of the additional benefit that the medicine is expected to yield in comparison with a specified alternative. The benefit measure used in most cases is the incremental QALY in the relevant patient population. Simpler benefit measures can also be referred to as a form of value-based pricing. As discussed above, if the QALY is the benefit measure, the key metric is the drug's estimated ICER expressed as a number of dollars per unit of incremental benefit.

Value-based pricing is now a factor in pharmaceutical reimbursement and pricing decisions in most OECD countries, except for the US (Paris and Belloni 2013). In several countries, including Australia, the UK and Sweden, various versions can be said to be the main criterion, especially for new drugs in therapeutic classes where patients have few alternatives. In Canada, the ICERs that are estimated by assessment agencies such as the federal-provincial Canadian Agency for Drugs and Technologies in Health or Québec's Institut national d'excellence en santé et en services sociaux (INESSS) are used by insurers in negotiations about prices and for making listing decisions, but have so far not been used by the PMPRB to set maximum prices.

In countries where most pharmaceutical costs are paid for by a nationwide publicly managed universal drug plan, the distinction between regulated and negotiated prices essentially becomes irrelevant, since that plan is the only buyer. In Canada, where pharmaceutical companies can sell their drugs at different net prices to public and private insurance plans and individuals, the distinction still matters. However, proposals to allow the PMPRB to use cost-utility analysis as an element in the regulation process have been criticized on the grounds that it typically is not explicitly used elsewhere as part of price regulation.

The idea that the price paid for a given drug should be no higher than what can be justified by its health benefits in comparison with other medicines or health system interventions is intuitively appealing, and the use of cost-utility

analysis has become more widespread over time. However, many of its aspects remain controversial. For example, estimates of the QALY gains from curing or managing different non-life threatening conditions require quantification of the relative losses of life quality associated with many different kinds of health problems. Clearly, such comparisons remain imprecise and subjective. Measuring health gains in terms of remaining life expectancy implies that it is considered more valuable to save the life of a young person than that of an elderly one, a principle that many will disagree with.

Estimates of a new drug's ICER at a given price also depend on what costs other than that of the drug itself are considered in the analysis, and whether it is carried out from the viewpoint of the healthcare system budget or society as whole. There is no generally accepted methodology for defining exactly what should be included in the cost measure if additional costs beyond the price of the medication itself are considered. None of these issues have easy answers, and disagreements about them will inevitably spill over into the debate about the proper role of cost-utility analysis and value-based pricing. At the end of the day, however, value-based pricing is an approach that has a better-established conceptual basis than any proposed alternative, and the trend toward more reliance on it seems well established.

Budget-Impact and Managed-Entry Agreements

For managers of insurance plans, an important consideration when negotiating prices and making decisions about which drugs their plans should cover is whether or not a given drug is likely to be prescribed for a small or large number of patients or, equivalently, have a large or small impact on the plan's total drug budget. In some countries, "budget impact" (also referred to as "market size") is explicitly listed as a factor to be taken into account when regulating or negotiating a new drug's price (Paris and Belloni 2013).

Market size, of course, is uncertain when a drug is first introduced. One way of dealing with this unknown is for the buyer and seller to agree to risk-sharing where the price the buyer pays depends on the quantity of the drug that is supplied. Under such a price-volume agreement, the buyer may agree to pay a relatively high price per unit up to a specified quantity (per year, or as a cumulative total), but a lower price for each unit beyond that threshold. In comparison with a fixed-price contract, a price-volume agreement provides both parties with some degree of risk protection. If utilization is lower than expected, the seller benefits from higher profits per unit, while payers are assured that if utilization is higher than expected a volume-price discount moderates the impact on overall expenditures.

When a new drug is introduced, there is uncertainty not only about the extent to which it will be prescribed and utilized, but also with respect to its treatment effectiveness. The results of clinical trials don't always assure similar effectiveness in real-world settings. In response to this uncertainty, a number of countries have entered into some form of managed-entry agreements, under which the initial price can be adjusted as more evidence becomes available after the drug has been launched. A case study of managed-entry agreements in four countries (Belgium, the UK, the Netherlands and Sweden) found well over 100 such contracts. Their exact form varied: while some of the price adjustments were conditional on total expenditure, others provided for systematic collection of patient outcome data post-launch, or monitoring the restrictions on the patient categories for which the drug was prescribed (Ferrario and Kanavos 2015). Some agreements were described as having "payment by results," where the drug price paid depends on observed patient outcomes.

Aggregate Drug Budgets and Profit Controls: The UK Case

Several countries with universal health insurance plans, including the UK and New Zealand, have at times set upper limits on their plans' aggregate pharmaceutical spending and tried to enforce these limits in various ways. The UK is a particularly interesting model since its drug prices are not directly controlled by government (Morrison and Webb 2015). However, the major pharmaceutical companies have all elected to belong to what is called the Pharmaceutical Price Regulation Scheme under which they negotiate with the Department of Health about the prices that they charge for the outpatient pharmaceuticals prescribed by general practitioners in various clinical commissioning groups.[15] Although each clinical commissioning group establishes its own list of drugs that it will subsidize, all of them are obliged to include all drugs that the National Institute of Care Excellence (NICE) has evaluated and recommended for coverage.

As discussed above in regard to other drug-approval bodies, NICE makes recommendations based on a pharmacoeconomic evaluation of new drugs. The prices charged by companies that are party to the Pharmaceutical Price Regulation Scheme are expected to reflect the relative value of the medicines' health benefits as estimated by NICE. Each company must also set its prices in such a way that its aggregate profits in the UK don't exceed a specified upper limit. Companies must report both their profits and total revenues each year, and if the NHS exceeds its aggregate drug budget, the companies must return a fraction of their revenue to the NHS, calculated so that total spending is retrospectively brought within the budget. Effectively, therefore, UK pharmaceutical policy does not focus directly on drug prices, but instead on controlling total pharmaceutical spending and the major drug companies' profits.

LESSONS FOR CANADA FROM OTHER COUNTRIES

National pharmaceutical-pricing policies must balance two conflicting objectives: making efficient use of medicines and medical technologies that have already been developed, and providing incentives for firms to develop new ones. As long as we use the patent system for the latter purpose, there will be tension between the two. Allowing pharmaceutical patent holders to charge prices that are substantially higher than what it costs to produce the medicines creates monopoly profits that incentivize R&D, but these high prices deter patients and payers from using patented medicines to an economically efficient extent. The task of finding a good balance between these two objectives in a country like Canada is also complicated by the temptation to be a free rider; i.e., to take advantage of new technology that has been developed through R&D in other countries, without paying the high prices that serve as an incentive to undertake more of it.

Looking elsewhere, it is clear that different countries have arrived at different compromises. In New Zealand, restrictive policies have led to very low drug prices, saving the healthcare system a great deal of money but leaving the country open to the charge that it is acting as a free rider (Ragupathy, Kilpatrick and Babar 2015). In the US, at the other extreme, the high prices that patentees have been able to charge have imposed heavy costs on taxpayers and contributed to high premiums in

15 In order to be eligible for National Health Service coverage, a UK resident must register with one (and only one) general practitioner (GP). Each GP practice, in turn, is part of one of the UK's more than 200 clinical commissioning groups. Each group is responsible for managing most of the budgets that the NHS makes available to pay for the health services in the area covered by its GP practices.

Box 1: Government Policies Affecting Pharmaceutical Research and Development

Enforcing patent legislation, purchasing drugs and regulating prices are not the only ways that governments affect the funding and development of new pharmaceuticals. Governments use many different policy tools to affect R&D activities, including direct funding, tax incentives and procurement practices. These policies and activities affect the incentive to innovate and contribute to the global creation of knowledge, as does the funding of academic research.

Canadian taxpayers and those in other countries fund education and university research laboratories that are a valuable input to pharmaceutical research. To some extent, pharmaceutical companies capture and profit from the public good of taxpayer-funded research through incremental innovation and commercialization.

Market imbalances in the form of information asymmetries, inelastic demand on the part of patients and principal-agent problems in the stewardship of public funds provide an argument that strengthening the buyer's price-negotiation power is desirable. In addition, since taxpayers fund some R&D activities, there is an argument that pharmaceutical companies should not be allowed to earn unrestricted monopoly profits, which strengthens the rationale for increasing buyer-side power or reducing prices in other ways.

Canada's contribution to business research and development (BERD) through direct subsidies and tax relief, as a percentage of GDP, is comparable to many peer nations (Figure 3). Comparative drug price data suggest that they are clearly lower in Canada than in the US, but more than comparable with those elsewhere. On balance, it is hard to argue that Canada currently contributes less than its fair share to global R&D inputs, in comparison to most other countries.

Whether this contribution is optimal from the perspective of efficient global funding of R&D activities would require considering not only pricing policies in each country but also patent-enforcement mechanisms, government supports for R&D, regulations and purchasing institutions.

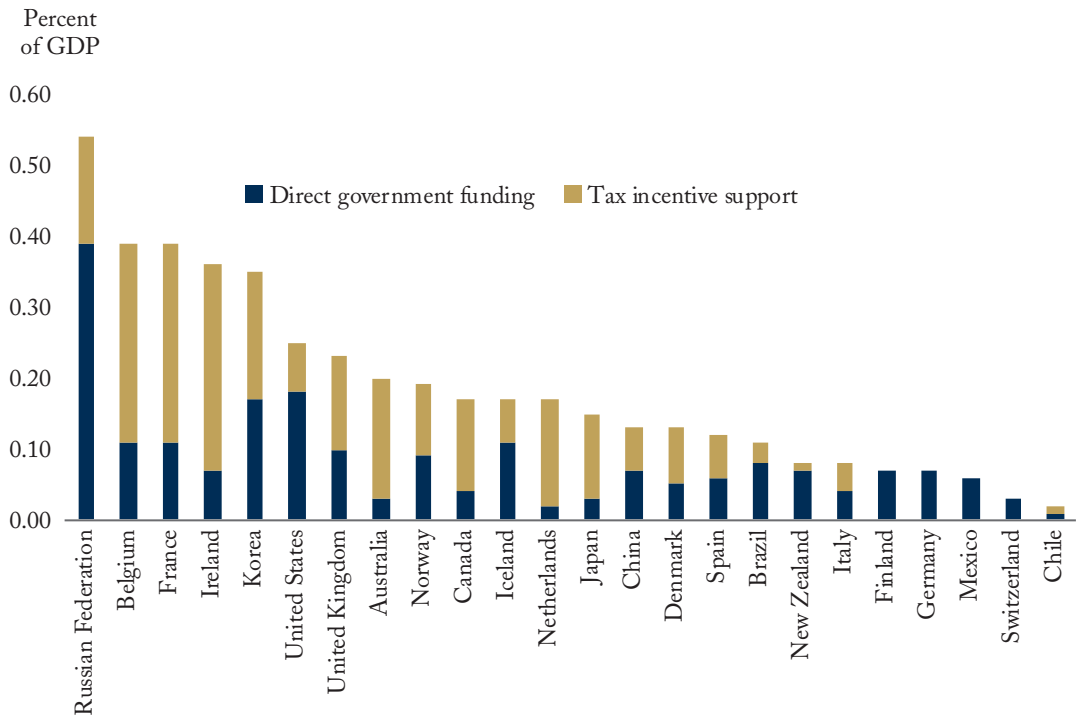
private insurance plans. They may also have led to adverse health outcomes for uninsured patients or those with insurance plans that have denied them access to potentially beneficial drugs. But they have also supported a leading-edge pharmaceutical industry whose R&D spending has led to new breakthrough drugs that have been of immense benefit to patients with problems that could not be effectively treated in the past. Canada clearly falls between these two extremes. This makes it less clear whether Canada is free riding or not, especially when considerations are made for other policies that affect R&D (Box 1).

Given these complications, defining the Canadian "national interest" that should be the guide in designing our pharmaceutical pricing policy is not easy. What we propose is a two-track approach. On one hand, Canada should work with other countries in developing a good set of international rules that entail a more efficient and equitable sharing of the global cost of pharmaceutical R&D. On the other, it should refine its short-term policies that focus on controlling pharmaceutical costs and ensure that Canada does not end up carrying a larger share of those costs than other countries, within the context of the current international system.

The Short-Term Strategy: Meeting International Expectations

In the Canadian debate about creating a nationwide pharmacare plan, a prominent theme has been that by doing so, Canada could also create an agency that essentially would be the single buyer of patented medicines. Such a single buyer would

Figure 3: Direct Government Funding and Tax support for Business R&D, 2016



Note: Tax expenditures are deviations from a benchmark tax system and countries use different national benchmarks. Available estimates typically reflect the sum of foregone tax revenues – on an accruals basis – and refunds where applicable, with no or minimal adjustments for behaviour effects.
Source: OECD R&D Tax Incentive Database, http://oe.cd/rdtax, November 2018.

have a great deal of bargaining power: unless a seller was willing to quote an acceptable price, its sales in Canada would be zero.[16]

But even though a centralized buying agency would have a great deal of bargaining power, in practice it could not use it to negotiate drug prices that were substantially lower than in peer countries. If it did, other countries would label us free riders and be less willing to treat us favourably in negotiations about other issues of common interest such as trade agreements, shared defence spending and the cost of reducing greenhouse gas emissions. Such lower prices would also likely delay the launch of new medicines in Canada.

One way in which a country can make the case that it *is* contributing its fair share is by aiming for prices that are comparable to those in peer countries. This, in fact, is the ultimate rationale for the external reference pricing (ERP) model. ERP is a natural way for regulatory and buying agencies to defend themselves against the accusation of trying to be free riders, something that probably is the main reason why it has been so widely practised in the past.

16 This is already effectively the case for generic medicines in Canada. While there are many purchasers, discounts negotiated by the pan-Canadian Pharmaceutical Alliance are publicly disclosed.

The ERP model, however, has become less effective over time, in part because of how pharmaceutical sellers have responded to it. For sellers, ERP poses a dilemma. If many countries use it, sellers will be reluctant to accept a relatively low price in public negotiations with any one country (for example, a country with a low per-capita income or one with a particularly cost-conscious buying agency). Agreeing to charge a low price in country A would influence regulatory or buying agencies in other countries whose list of comparator countries included country A. In the terminology of economic theory, these spillover effects would reduce, or even eliminate, the seller's ability to charge different prices to different buyers. Differential pricing – "price discrimination," in the terminology of economic theory – generates larger net profits for a monopoly seller than it can generate without it.

As a result, the pharmaceutical industry has responded in several ways, the two most significant ones being delays in the launching of new patented medicines in countries with strict drug price controls and the use of confidential discounts and rebates in their negotiations with buyers.

ERP and the Launching of New Drugs

In the debate about drug pricing in Canada and elsewhere, considerable attention has been paid to the relationship between the level of a country's drug prices and the speed with which its population has had access to new valuable drugs. Specifically, there is empirical evidence to show that there is a tendency for new drugs to be available later in countries that pursue policies that result in relatively low drug prices (Danzon, Wang and Wang 2005).

At first glance, this relationship is not easy to explain. As long as the maximum allowable price in a particular country is higher than the costs of producing the patented medicine, the patent-holder has an incentive to begin selling it there as quickly as possible. The launching of new drugs may be delayed by the need to satisfy government regulations of various kinds, but there is no reason to expect that these delays should be longer in countries where drug prices are relatively low.

However, when many countries practice ERP, the observed pattern makes more sense. Clearly, such countries can make price comparisons only with countries where the drug in question has already been launched. Therefore, sellers can increase their net revenue by first introducing a new drug in a country with relatively high drug list prices, and where ERP is not practiced (e.g., the US), but delay launching in countries with low-price policies (e.g., New Zealand). That way, the low prices there don't enter into the regulatory decisions or price negotiations in countries that fall between the extremes, at least until the low-price countries are offered and approve the drug.[17]

Confidential Discounts

Sellers can also try to blunt ERP's impact by granting price reductions through confidential discounts and rebates. When they do, the effective price paid by the wholesale buyer is the public list price, less the discount. In countries where a single government plan buys most drugs, all or most of the sales will then be at the price net of the discount. There will be no or few sales at the public list price. However, since the discount is confidential, it is not known by the regulatory authorities in other countries. Hence, while a reduction in the seller's official list price might lead to lower regulated prices in other countries that use ERP, a price reduction in the form of a confidential discount

17 Danzon and Epstein (2012) suggest that this form of strategic behaviour by sellers may be one explanation for the observed relationship between strict regulation of pharmaceutical prices and delays in the launching of new drugs in individual countries.

does not have this effect. For this reason, the price reductions that buying agencies with substantial bargaining power have been able to obtain in many countries have typically been confidential, to the point where the official public list prices now give increasingly misleading information about the real net prices that buyers actually pay for patented medicines.

Proposals to require discounts and rebates to be made public are typically resisted both by the sellers, because it would reduce their ability to charge different prices in different countries and by those countries and buying agencies who believe that they are paying lower net prices than others. In countries where many public and private buyers pay different net prices for given drugs, buying agencies that represent one or more large public plans are able to negotiate substantial confidential discounts causing an increasing discrepancy between the net prices they pay and those paid by uninsured consumers or smaller insurance plans with less bargaining power. In the pharmacare model in Québec, where residents are allowed to choose either a public plan or private coverage, the higher prices paid by private plans put them at a competitive disadvantage, suggesting that if this model is extended to Canada as a whole, any confidential discounts granted to government plans should be available to private plans as well.

CONCLUSION: TOWARD A TWO-TRACK POLICY

In the short and medium term, Canadian policy toward pharmaceutical pricing should continue to focus on trying to seek lower prices for the patented drugs used in our healthcare system. However, Canadian prices should be consistent with those charged in our peer countries, so as not to lay us open to the charge that we are not contributing our fair share to global R&D financing. To do so effectively, we should continue to move in the direction of more centralized pricing and purchasing policy through an agency such as the pCPA, and seek price concessions in the form of confidential discounts to this agency, rather than through explicit, less flexible, price regulation. At the same time, Canada should also try to obtain as much information as possible about the confidential discounts granted to buyers in other countries.

If we are going to move toward a national pharmacare model with a continued role for private insurance and public provincial plans, private insurers should be allowed to join the pCPA and have access to the same discounts and rebates as the provincial plans. As part of this trend, the PMPRB's regulatory function should become more closely integrated with that of CADTH and pCPA, so that over time, the Canadian system more closely resembles those in the UK and Australia where the price-regulation function has been largely integrated with the assessment and price negotiation functions and delegated to a single centralized buying agency.

Canada should also continue to strengthen its expertise in health technology assessment and move toward a greater role for value-based pricing based on pharmacoeconomic evaluation, as a tool for both regulation and price negotiation. Efforts should be made to negotiate with pharmaceutical companies not only about pricing but also about avoiding delays in the launching of new drugs. In these negotiations, more reliance could be placed on the methods used in some European countries such as price-volume, managed-entry or risk-shared agreements.

The second track that we believe Canada should pursue over the longer term consists of working with other countries and international agencies toward helping design a more efficient and equitable mechanism for global sharing of pharmaceutical R&D costs. Such international R&D cost sharing should be consistent with a country's ability to pay for new drugs, and in that sense residents in the world's high-income countries should carry a proportionately larger share of the burden.

The design of such a mechanism falls outside the scope of this *Commentary*, but the goal should be

to make the system more efficient and transparent rather than being based on confidential discounts. Since confidential discounts are a consequence of strategic responses to the use of external reference pricing, there should be a more prominent role for other factors such as internal referencing and value-based pricing based on pharmacoeconomic evaluations.

One way of moving in the direction of a collaborative approach would be for participating countries to establish an international agency that would undertake health technology assessments of new pharmaceuticals. Countries that join the agency would be obliged to provide complete information about domestic prices of pharmaceuticals. In countries with universal pharmacare programs, these would typically be the prices at which drugs were supplied to these programs' buying agencies. In exchange, participants would receive transparent drug pricing information from other countries and enjoy reduced domestic costs associated with health technology assessments. Each country could then set maximum prices based on the assessed value of the new medicine, perhaps in accordance with an agreement under which countries with lower ability to pay (as measured, for example, by per capita income) could set lower prices than more affluent ones. Insurance plans within each country would then make listing decisions based on domestic policies and regulations. Such a system would not eliminate the tension between reducing costs and funding future innovation. But, it would remove the inefficiency created by external price referencing that can result in delayed access to new medicines in countries with lower drug prices, and a negotiated transparent agreement could go a long way toward eliminating the free-riding problem.

In principle, it would also be possible to change the way pharmaceutical R&D is funded so that it becomes less dependent on the patent system, by separating the rewards of innovation from the price of the resulting product. One way of doing this is to establish prizes for new breakthrough drugs, but allow anyone to produce them once they had been developed. This could be an effective tool for encouraging innovation in areas that are less likely to be commercially profitable - medicines to treat illnesses that predominantly affect people in developing nations, for example. This approach has already received some attention as a way of encouraging development of new antibiotics (Servick 2015).

The complex interactions between countries' intellectual property rules, drug pricing regulations and R&D funding mechanisms presents significant challenges in working towards sustainable financing for both pharmaceutical R&D and drug budgets. As said by Hollis (2016) "Fundamentally, we lack information on how much the world, or any country, should spend on supporting medical innovation, and we don't know how to allocate a given budget across different potential or existing therapies. The result is a continuing competition between different ideas and institutional structures. […] it seems that the best hope for 'sustainable' financing for innovative therapies is a continuing evolution of the structure of how we pay for new therapies." Negotiating and implementing the drastic changes to the international system that would be required in order to construct a workable version of a more collaborative structure of the kind we favour would obviously be difficult, but we believe there is growing support for reform of current approaches. As in other cases involving the global commons, the potential benefits could be very large, and consideration of what an ideal model would look like may provide inspiration for small steps that would at least improve on the status quo.

Appendix – US Drug-Pricing Policy

While Canada's healthcare system differs dramatically from that in the US in other respects, they are somewhat similar when it comes to pharmaceuticals.[18] Like Canada, the US has large government programs that provide coverage for most retirees and persons with low income, while private insurance plans cover most working age people. In the US, government pharmaceutical plans are large enough so that they pay for as much as roughly one-half of total drugs costs (Morton and Kyle 2012); in Canada, about 36 percent of total drug costs (43 percent of prescription drug costs) are covered by public spending (CIHI, NHEX 2018 – Series C, G).

Like Canada, the US heavily regulates the marketing of pharmaceuticals. A new drug can only be sold if the Food and Drug Administration (FDA) approves it. The FDA specifies in detail what information the pharmaceutical companies must supply in order to show that a drug is safe and effective in dealing with the health problems of the patients for which it is intended.

But while the US has a highly developed system for supervising and regulating drugs with respect to safety and effectiveness, it has no direct government regulation of drug prices. There is no counterpart to Canada's PMPRB or agencies with a similar role in most other countries. Pharmaceutical companies, even when selling patented drugs, are free to sell them at whatever prices buyers are willing to pay.

As discussed above, prescription drug purchasing decisions involve not only patients, but also the doctors who prescribe them and the insurance plans that pay most of the cost. In the US system, the sellers' most important consideration are the choices made by the pharmacy benefit managers (PBM) and prescription drug plans (PDP). PBMs design and manage the rules for coverage in the employment-related group insurance plans, which cover most Americans of working age and often their families. PDPs cover a majority of American seniors under what is known as Medicare Part D. Favourable decisions by these managers regarding coverage and required patient co-payments are key determinants of the revenue that sellers can expect from a given drug.

PBMs and PDP managers try to negotiate price reductions from pharmaceutical companies by creating incentives for plan members and their doctors to select lower-priced drugs where several choices are available. These incentives consist in designating lower-priced drugs as "preferred" and in requiring lower patient co-payments when a preferred drug is chosen. Although data suggest that US drug prices continue to be higher than elsewhere, there is little doubt that these strategies have had a substantial moderating influence, especially in therapeutic areas where patients and their doctors have meaningful choices among several competing drugs. They will be less effective, however, in cases where a patented "breakthrough" drug is introduced in a therapeutic class where few or no alternatives already exist. In such cases, the only option that is open to insurers is simply to refuse to cover the drug if they find the seller's price too high. However, this is not an option for Medicare Part D plan formularies, which are required, by law, to include at least two non-therapeutically equivalent drugs (if they exist) in each therapeutic category and class covered. This effectively means that Part D plan sponsors have almost no price negotiation ability for medicines in therapeutic categories with fewer than three treatments, since pharmaceutical companies know they are legally required to cover it, regardless of price (Council of Economic Advisers 2018).

As discussed above, new drugs in Canada undergo a cost-effectiveness evaluation before

18 A detailed survey of the funding and pricing of pharmaceuticals in the US is Morton and Kyle (2012). The material in this section draws heavily on its exposition.

provincial plans decide whether to cover them. This approach does not appear to have any US counterpart, even for their public plans. The reasons for this difference are not obvious. In part, US insurers' reluctance to exclude even very expensive drugs may be because doing so might be perceived as a form of rationing, a concept that is deeply unpopular in the US, especially in the context of healthcare. Pharmaceutical companies and insurance plans may also prefer a negotiated compromise for public relations reasons: a public dispute about insurance coverage for a high-priced drug does not generate favourable publicity for either the seller or the payer. For pharmaceutical companies, the fear that such disputes might ultimately lead to new forms of government price regulation may also be a consideration that makes them more willing to compromise on price.

US Medicare and Medicaid

Medicare and Medicaid are the two government programs through which most elderly Americans and those with low incomes have pharmaceutical coverage. Under Medicare, the federal US program that offers health insurance for seniors, pharmaceutical coverage is available either as an add-on (Medicare Part D) to the basic plans that cover physician and hospital services[19] or as part of a private substitute health insurance plan that a senior can opt for as an alternative to the regular Medicare plans. In the latter case, Medicare pays a subsidy that covers all or part of the premium that the private plans charge.

In contrast to Canada's provincial plans that pay most of the cost for the drugs of seniors, Medicare does not directly engage in price negotiations with pharmaceutical companies. To the extent that the sellers offer discounts or rebates for drugs supplied under specific plans, these are negotiated between the sellers and the plans or with the PBMs that represent them. Although Medicare imposes certain restrictions on the patient co-payments that plans can require, or on the formularies that govern which drugs are covered, these can differ from plan to plan, as can the discounts or rebates that plans are able to negotiate with pharmaceutical companies.

Medicaid provides insurance coverage for the cost of pharmaceuticals, as well as hospital and physician services, for persons with low income. Medicaid plans are administered by the states, not by the US federal government. However, federal regulations aim at lowering the prices charged for medicines supplied to Medicaid beneficiaries, for example the Medicaid Drug Rebate Program. Specifically, in order for Medicaid to cover a drug, the seller must supply information about both the average price at which they sell this drug in the retail sector, net of any discounts, i.e., the average manufacturer's price (AMP), and on the best price they offer any non-federal buyer. They must then offer Medicaid either a 13 percent to 23.1 percent discount off the AMP, or this best price, whichever is lower.[20] In the case of Medicaid, therefore, the federal government has effectively allowed the states to join together to obtain lower prices in somewhat the same way as happens through the joint negotiations about pricing by the provincial and federal government plans in Canada that belong to the pan-Canadian Pharmaceutical Alliance.

19 Under Medicare Part B, drugs administered in physicians' offices and hospital outpatient departments are reimbursed based on a 4-percent to 6-percent markup above the average sale price, net of any discounts (Murrin 2017). This creates an incentive for doctors to prescribe drugs that are more expensive – reimbursement for administering a US$10,000 drug is US$600 but only US$60 for a US$1,000 drug. Since doctors do not pay for the medicines themselves and receive larger payments for administering more expensive medications, they directly benefit from prescribing the more expensive option.

20 The percentage discount required depends on the type of drug and ranges from 13 percent for non-innovator drugs to 23.1 percent for innovator drugs.

However, the Medicaid Drug Rebate program does create some perverse incentives that may inefficiently increase drug prices in the US. If a large share of a given drug's market is enrolled in Medicaid, a pharmaceutical firm has an incentive to inflate prices in the private sector to increase the post-rebate Medicaid price. Similarly, lower-income, private-patient populations would not be charged lower prices, as this would then become binding as the reference price for Medicaid rebates.

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