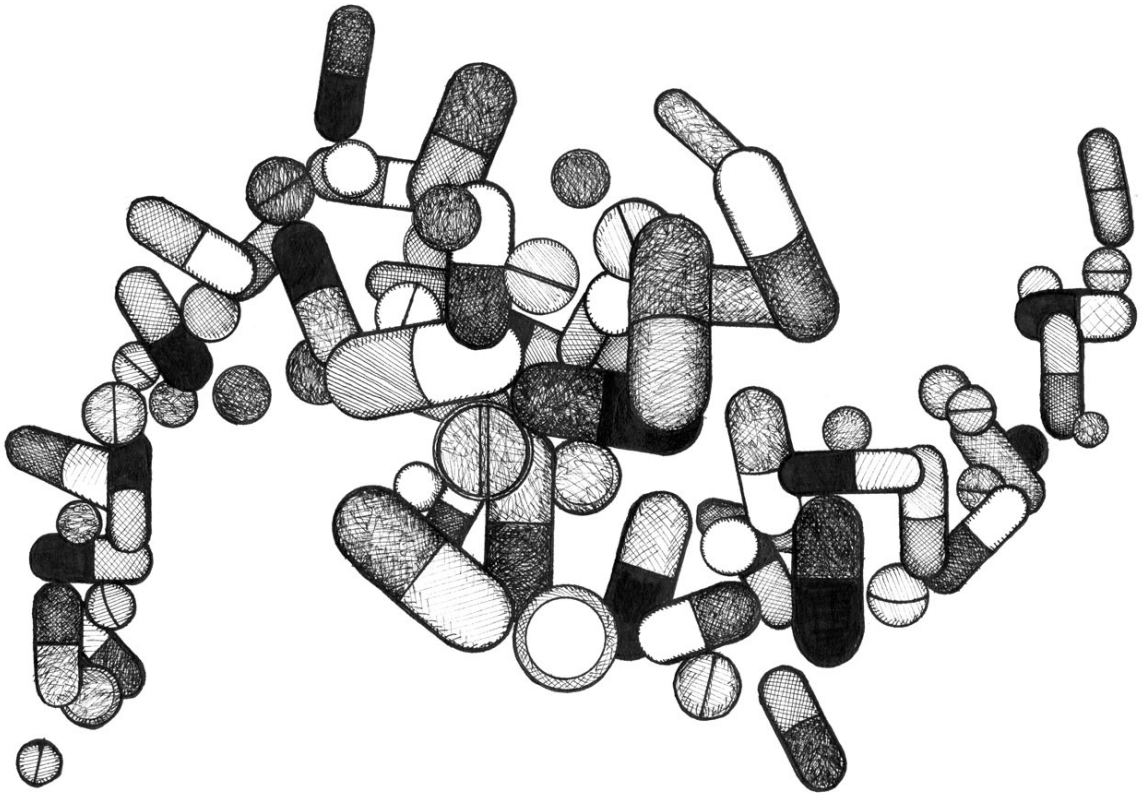

Controlling Drug Costs for People Living with HIV/AIDS:

Federal Regulation of Pharmaceutical Prices in Canada

prepared by
Richard Elliott

Canadian Strategy on HIV/AIDS

CANADIAN HIV•AIDS LEGAL NETWORK | RÉSEAU JURIDIQUE CANADIEN VIH•SIDA

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The opinions expressed in this document do not necessarily reflect the views or policies of Health Canada or the Canadian HIV/AIDS Legal Network.

Cover illustration by Luke Nicholson

In memory of Glen Hillson,
activist, leader, inspiration

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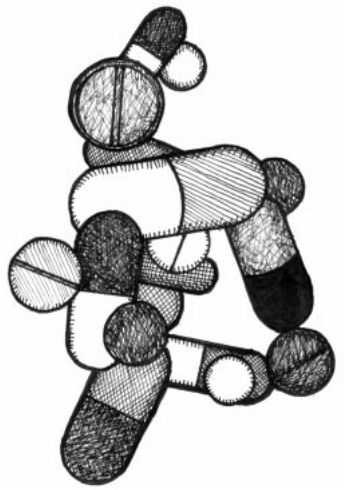

Executive Summary

Why a paper on the legal regulation of pharmaceutical prices?

This paper is the second in a series of occasional papers by the Canadian HIV/AIDS Legal Network on priority legal and ethical issues related to HIV/AIDS care, treatment, and support. It forms part of a multi-year project to examine such issues. The issue of drug pricing was identified as a priority by a project advisory committee, and complements and supports advocacy already initiated by other HIV/AIDS organizations in Canada. The question of pharmaceutical prices is also receiving considerable international attention, and related questions are on the political agenda in Canada in the context of rising spending on drugs and an ongoing national debate on the future of health care. Review of some aspects of federal policy on drug pricing has recently been completed, while other issues remain outstanding. The cost of medicines is of obvious concern to people living with HIV/AIDS. An analysis of federal policy on drug price controls, with recommendations for strengthening or reforming policy where appropriate, can help protect the interests of people living with HIV/AIDS, and Canadians more generally, in accessing affordable health care.

What does the paper contain?

There are many factors that affect drug prices ultimately paid by Canadians – whether paying out of their own pockets, or enjoying full or partial coverage of their spending on drugs through public and/or private insurance schemes. These include the behaviour of drug manufacturers themselves, as well as that of patients and prescribers, and the actions of drug wholesalers, retailers, and pharmacists. Similarly, the laws, regulations, and policies implemented by the federal government (eg, protection of patents, barriers to market entry and competition by generic drug manufacturers, direct intervention to control prices), provincial governments (eg, different rules and mechanisms for paying for medicines through public health insurance plans), and various regulatory bodies (eg, the guidelines for assessing prices

applied by the independent federal regulator, the regulations governing the conduct of health-care professionals such as physicians and pharmacists), as well as measures implemented by private insurance companies to control drug claims, all have an impact.

It is beyond the scope of this paper to address all these factors. This paper focuses on the specific question of how Canada, through legislation at the federal level, regulates the prices charged by manufacturers for their medicines. This is only one aspect of the policy puzzle, but it is nonetheless an important one. Furthermore, as it is a matter of federal jurisdiction, policy in this area affects all Canadians.

The paper:

- highlights the significance of policy on pharmaceutical pricing, given increasing costs and spending on medicines as part of overall healthcare spending in Canada;
- identifies recent developments that are important because they inform current debates in Canada over regulating drug prices, or our policies in general relating to pharmaceuticals;
- outlines current federal law and policy on the regulation of pharmaceutical manufacturers' prices; and, finally,
- makes recommendations for reform of federal regulation of pharmaceutical prices in Canada.

What are the recommendations?

The paper presents a number of recommendations regarding Canada's policy approach to regulating the price of medicines in Canada. In summary form, the recommendations are as follows:

Remedies for excessive pricing

1. Parliament should consider possible mechanisms for compensating private purchasers, particularly individual Canadians paying out of pocket, for prices of medicines determined to be excessive by the Patented Medicine Prices Review Board.
2. Parliament should amend the Patent Act (section 83) to authorize the Patented Medicine Prices Review Board or, alternatively, the Commissioner of Patents, to issue a compulsory licence as a remedy for excessive pricing by a manufacturer of a patented medicine.

Excessive Price Guidelines

3. In its upcoming analysis of how to define the "value" of drugs, the Patented Medicine Prices Review Board should consider the relevance and applicability of that analysis for the permissible pricing of Category 2 new drug products (breakthrough drugs).
4. The Patented Medicine Prices Review Board should revise its Excessive Price Guidelines to limit the introductory price in Canada for Category 3 new drug products (those that offer moderate, little, or no therapeutic advantage over existing medicines) to either (i) the median (or, alternatively, the lowest) international price charged by the manufacturer for the same product in comparator countries, or (ii) the highest price in Canada among all therapeutically comparable products, whichever of these two prices is *lower*. Alternatively, the Guidelines could be revised to cap the introductory price for a Category 3 product to either the median or the average of Canadian prices for all the drugs in the same therapeutic class. Consideration should be given to further differentiating between new drugs such that those offering "little or no therapeutic advantage"

might be limited to an introductory price that is the lowest Canadian price of existing drugs in that therapeutic class, while those new drugs that offer "moderate" therapeutic advantage might be allowed a maximum introductory price that is either the median or the average of prices of existing drugs in that therapeutic class.

5. The Patented Medicine Prices Review Board should review the appropriateness of using an index based on retail price increases to limit the increases in factory-gate manufacturers' prices on patented medicines.
6. The Patented Medicine Prices Review Board, and the federal departments of Health and Industry, should identify and assess options for amendments to the Patent Act, the Patented Medicines Regulations, and/or the Board's Excessive Price Guidelines that would result in a closer correlation between overall Canadian price levels for patented medicines and levels of spending in Canada by patentees on pharmaceutical R&D.
7. The Patented Medicine Prices Review Board should undertake a review, involving public consultation (including with consumer representatives), of the basket of countries currently used for the purposes of international price comparisons. The review should identify the relevant bases on which these countries are similar and dissimilar, for the purpose of comparing pharmaceutical prices, to Canada. The review should also identify other OECD countries, not currently included on the list of countries for price comparison purposes that could be suitable for inclusion on this list, and assess the relevant similarities to and differences from Canada. The report of that review should be made available in draft form for public comment and then finalized. Based on the conclusions of that report, the Patented Medicine Prices Review Board should then consider whether to recommend to the Minister of Health and the federal Cabinet that the Patented Medicines Regulations be amended to revise accordingly the list of countries used for international price comparisons.
8. The Patented Medicine Prices Review Board should revise its Excessive Price Guidelines such that maximum non-excessive prices allowed to manufacturers of patented medicines bear a reasonable relationship to the cost of their development and manufacture, and allow a "reasonable" profit margin beyond those costs.
9. Parliament should amend the Patent Act and/or the Patented Medicines Regulations to provide for a mechanism for interim or conditional pricing of a new patented medicine upon its introduction to the Canadian market, which price would be automatically reviewed at appropriate periods over the life of the medicine to take into account new evidence regarding its therapeutic merits and its merit relative to comparator medicines. The Patented Medicine Prices Review Board should be given the mandate and necessary powers to conduct such reviews and to revise the maximum "non-excessive" price of a medicine upward or downward as warranted by such new evidence.

Jurisdiction of the PMPRB to regulate medicine prices

10. Depending on the outcome of current litigation over the definition of a "medicine" in the Patent Act, which definition controls the jurisdiction of the Patented Medicine Prices Review Board to regulate patented-medicine prices, Parliament should amend the Patent Act to expressly affirm and clarify the broad scope of this term to preserve the objective of preventing excessive pricing by manufacturers of any invention pertaining to a medicine. By the same token, Parliament should also amend the Patent Act to extend the scope of the Board's jurisdiction to encompass regulating the prices of patented medical devices, which should be accompanied by the additional resources necessary to carry out this extended mandate.

11. Parliament should amend the Patent Act to expressly clarify that the Patented Medicine Prices Review Board has jurisdiction to regulate the prices of medicines during the period of time that grant of a patent is pending.
12. In line with the recommendation of the Commission on the Future of Health Care in Canada, Parliament should enact a national legislative scheme for the regulation of prices of generic medicines to prevent excessive pricing, complementing Canada's existing scheme of regulating prices of patented medicines. If necessary because of jurisdictional questions, the federal government should undertake this in collaboration with provincial governments, to secure the implementation of a system that is consistent across the country. Provincial governments should collaborate with the federal government in designing such a scheme, drawing upon lessons learned to date from various provincial policy measures aimed at controlling prices for medicines, including generics, covered under provincial drug insurance programs.
13. The jurisdiction of the Patented Medicine Prices Review Board to regulate the prices of patented non-prescription medicines should be maintained.

Spending in Canada on pharmaceutical R&D

14. Parliament should amend the Patent Act to require manufacturers of non-patented medicines to report annually, to the Patented Medicine Prices Review Board or other designated body deemed appropriate, their revenues and details of the source of the revenue, whether direct or indirect, from sales of medicine in Canada, and their expenditures in Canada on R&D relating to medicine. This would complement similar obligations currently applicable to manufacturers of patented medicines.
15. Parliament should amend the Patent Act to create requirements for R&D spending in Canada that legally bind pharmaceutical patentees, in the form of an annual levy on all patentees that do not meet a specified minimum ratio of R&D to sales, based on the discrepancy between their actual ratio and the minimum specified ratio. In addition, sales of all patented medicines should be subject to a levy, revenues from which would be dedicated to publicly funding basic research and research into "neglected diseases," in particular those prevalent in developing countries.

Patentees' reporting obligations

16. The federal government should amend the Patented Medicines Regulations to require a patentee to include, in its annual report to the Patented Medicine Prices Review Board, a description of the type of promotional activities carried out and its expenditures on each type of promotional activity.

Next steps

A working draft of this paper was sent to a variety of people from government, industry, and the community to provide comments. Feedback received has been considered and, where appropriate and relevant, taken into account in preparing the final document. The final paper will be sent to selected individuals and organizations working in the areas of HIV/AIDS and pharmaceutical policy in Canada. It will also be sent to appropriate government policymakers, the Patented Medicine Prices Review Board, consumer organizations, pharmaceutical industry associations (both originator and generic), and other interested parties. Those who receive the paper will be asked for their comments and input on the paper, in particular its recommendations, and their views on how best to pursue implementation of these recommendations.

In addition, info sheets on the federal regulation of pharmaceutical prices in Canada will be prepared and disseminated. The info sheets will summarize the contents of the paper in an easy-to-read format, making the report more accessible to a wider audience and providing useful tools for education and discussion on the issues raised in the report.

For further information…

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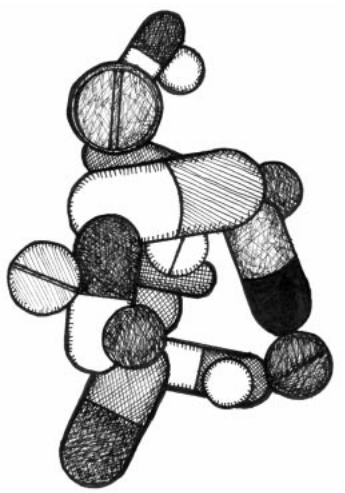


Introduction

History of the project

This is the second in a series of occasional papers by the Canadian HIV/AIDS Legal Network as part of a project on Legal, Ethical and Policy Issues Related to HIV/AIDS Care, Treatment and Support.[1] Work by the Legal Network on care, treatment, and support issues continues, beyond the confines of this particular project, both within Canada and internationally.

> The primary objective of drug policy should be to ensure optimal drug therapy (the right drug for the right patient) at an affordable level of expenditure.
>
> – The Hon David Dingwall, Minister of Health
> Brief to the House of Commons Standing Committee on Industry
> for the Review of the *Patent Act Amendment Act, 1992*, March 1997

A national advisory committee for the project was struck to provide input to the Legal Network as to which legal, ethical, and policy issues related to HIV/AIDS Care, Treatment and Support it should examine as part of this project. Input received from the advisory committee through a workshop and other means led to the conclusion that, because of the significance of drug costs for people living with HIV/AIDS, the Legal Network could make a contribution by analyzing legal issues related to the pricing of medicines in Canada.

Not only was this issue the highest priority for a majority of the advisory committee; it complements and supports the advocacy already initiated by other HIV/AIDS organizations in Canada. The question of pharmaceutical prices is also receiving considerable international

attention – particularly in the wake of the International AIDS Conferences held in Durban, South Africa in July 2000 and in Barcelona, Spain in July 2002, where the question of global pharmaceutical policy and prices, and the impact on access to medicines globally, was high profile.

Closely connected, the question of pharmaceutical prices and access to medicines is on the political agenda in the United States – always a significant influence on Canadian law and policy – where that country's federal laws affecting prices in the pharmaceutical market are being debated. As the Chair of Canada's agency tasked with regulating prices of patented medicines recently put it:

> Although we can take some comfort in knowing that our approaches have resulted in drug prices in line with most of our trading partners, we must recognize that the disparity with the US continues and may even be growing.… If pharmaceutical manufacturers [in the US market] are concerned about the possible re-importation of [less expensive] drugs from Canada, they are probably even more concerned about the possible importation of policies and ideas that might limit their current flexibility in pricing and marketing their products in the US. These concerns may well result in efforts to put upward pressure on prices in Canada and efforts to open the doors for increased promotion of drugs. Left unchecked, these actions may cause even greater increases in drug expenditures and put more pressure on private and public drug plans. Canadian consumers and policymakers must continue to be vigilant in such an environment.[2]

Simultaneously, Canada's own policy approach to regulating drug prices is under scrutiny – including in the context of a national debate on the future of health care. These discussions in North America parallel ongoing debate over pharmaceutical policy in most developed, and some developing, countries.

Drug pricing and HIV/AIDS

AIDS activists in the United States have condemned the growing upward pressure on drug prices being pursued by manufacturers, labelling it "a new scourge [that] might best be called opportunistic pricing."[3] As an article in *POZ Magazine* reported, these concerns escalated in 1995 with the introduction of protease inhibitors and dramatically increased pricing by manufacturers.[4]

For people living with HIV/AIDS, the final cost of drugs to them as purchasers – only part of which is the result of manufacturers' prices – is of obvious concern, even in wealthy, developed countries such as Canada. For example, research from Alberta shows that costs of treatment with antiretroviral drugs have increased significantly since the introduction of highly active antiretroviral therapy (HAART) due to the rising costs of drugs, increased use of therapy, and increase in multi-drug regimes.[5] An Ontario study from 1999 reported that data from 1997 showed that the average cost for antiretroviral treatment (ART) in that province was $11,000 per year, representing approximately 43 percent of the direct health-care costs for HIV.[6] Researchers also found that:

> Overall HIV treatment costs have increased due to the cost of the new antiretrovirals. For 1997, the average annual HIV-related cost per PHA in the care of a physician is estimated at about $18,000. An analysis released in 1998 of the economic burden of HIV/AIDS in Canada estimated the lifetime costs of treating someone living with HIV infection at about $153,000. Formal and informal

> health care, medications and patient out-of-pocket costs are included in this estimate. Inpatient care now accounts for only 10 percent of this cost.[7]

A report released in 1998 with estimates of national costs related to HIV/AIDS in Canada also reported a similar shift away from hospitalization costs toward spending on pharmaceuticals:

> Direct cost estimates produced in the late 1980s reflected an episode that was dominated by inpatient hospital costs. Over the past five years, the natural history of HIV disease and treatment patterns have evolved and changed rapidly and a new HIV/AIDS episode has emerged. Drugs now outstrip inpatient hospital costs in the episodic resource consumption profile.[8]

While costs of treatment for people living with HIV/AIDS are increasing, and spending on pharmaceuticals represents the most significant component of those costs, treatment with HAART remains cost-effective. The 1998 study calculated that "if HAART treatment increases the period of productive life for those people living with HIV/AIDS by 15%, the savings in indirect costs will cover the increased costs of treatment. These indirect costs of HIV/AIDS far outweigh the costs of care and treatment, and prevention."[9]

In the absence of universal, public insurance coverage for pharmaceuticals, people living with HIV/AIDS rely upon a patchwork of private and/or public, full or partial, coverage to purchase prescription drugs.[10] The same 1999 Ontario study, for example, reported that:

> In spite of the number of different private and public insurance programs, many PHAs [people living with HIV/AIDS] need to pay for some, or all, of their drug costs themselves. This research shows that although many PHAs receive ART at little or no cost, at least 25 percent are carrying a substantial financial burden in terms of annual expenditure, as well as how much they spend relative to their income. As a result, some PHAs do not get the drugs they need, and others are doing so at a substantial financial sacrifice.
>
> The average out-of-pocket expenditure for a patient receiving ART in the province was $1629 a year, but this figure can vary quite widely depending on who the payers are.… High out-of-pocket expenses may occur for PHAs who have high deductible payments, who do not qualify for the benefit programs, or who are using drugs not approved by the benefit programs.[11]

"[E]vidence suggests that costs have a direct impact on whether or not people comply with their prescriptions."
– Romanow Commission, 2002

For the minority of people living with HIV/AIDS in Canada who lack some form of coverage, high drug prices may push the cost of medicines, particularly for combination antiretroviral therapy, out of reach. It is estimated that 12 percent of Canadians, or some 3.5 million people, lack any form of insurance coverage for pharmaceuticals.[12] In the case of those with coverage (generally tied to current or previous employment) through private insurers or provincial public insurance plans, high prices put pressure on those payers to deny coverage, raise premiums or deductibles, or scale back their purchase and provision of certain drugs. As the Romanow Commission on the Future of Health Care in Canada reported:

> Under current drug insurance plans, evidence suggests that costs have a direct impact on whether or not people comply with their prescriptions. For example,

people may stop taking both essential and non-essential medications when they are faced with onerous co-payments, deductibles or co-insurance. People with lower incomes are most affected by these out-of-pocket charges. If people refuse to take necessary drugs because of the costs, it affects not only the individuals involved but also their families, their communities, and the overall health of the population. It also can increase costs in the longer term.[13]

Recent developments and current context

Given the constitutional division of responsibility for health care between federal and provincial/territorial governments in Canada, as with all things related to health care since the introduction of a universal public healthcare system across the country, the question of spending on pharmaceuticals is one in which both federal and provincial/territorial governments have a large economic stake and both have roles to play. The question of managing, and containing, these expenditures has been one of increasing significance in Canada – and has, as expected, been on the agenda of government, industry, and patient advocates in the context of current debates over the future of health care. Questions related to pharmaceutical policy have therefore been raised in a variety of fora in which health care is being debated. For example:

- In 1997, the National Forum on Health addressed numerous issues related to pharmaceutical policy in Canada.[14]
- In 1998, a Conference on National Approaches to Pharmacare included discussion of cost-control issues as a critical challenge facing the introduction of national pharmacare.[15]
- In 2001, a survey conducted by the Patented Medicine Prices Review Board showed that one of the principal concerns of stakeholders other than the pharmaceutical industry was the rising cost of drugs. Stakeholders in general also identified the need to balance price regulation of drugs and the need for research and development.[16]
- In 2002, the federal government established the Commission on the Future of Health Care in Canada (the "Romanow Commission"). The Commission reported that many Canadians have raised their concerns about pharmaceuticals, particularly on the affordability and accessibility of necessary medications.[17] The Commission presented a number of recommendations for Canada's approach to regulating the pharmaceutical sector, including expanding price controls beyond patented medicines to include generic drugs[18] and even "vaccines and some over-the-counter medications,"[19] as well as a coordinated national approach to purchasing and reimbursement of prescription medicines, through public formularies, so as to more effectively contain costs.
- In June 2003, the House of Commons Standing Committee on Industry, Science and Technology held a few days of hearings into provisions of Canada's patent legislation that are used to inhibit the entry of generic drugs into the market even after patents on the original drugs expire. Delaying market competition means delaying the emergence of lower drug prices. A complaint about the abuse of these provisions has been filed with the Competition Bureau of Canada by a group of unions, seniors' organizations, patient advocates, and healthcare activists. In June 2002, the Bureau announced that it would investigate the complaint, its first direct inquiry into the issue.[20]

As is to be expected, the issue of pharmaceutical prices is also before the Patented Medicine Prices Review Board (PMPRB), the national body tasked with regulating the prices of

patented medicines in Canada. The PMPRB is in the midst of ongoing work examining its price review process. In addition, in 1999, the Federal/Provincial/Territorial Pharmaceutical Issues Committee, an intergovernmental body, received a report from its task force on pharmaceutical prices recommending some improvements to the work of the PMPRB in monitoring prices, and recommended additional research into other outstanding issues.[21] Also in 1999, as a result of public consultations in 1997 and the release by the PMPRB of its "Road Map for the Next Decade" in 1998, the PMPRB established a Working Group on Price Review Issues; by 2002, that working group had addressed a number of issues, and recommended additional research and analysis on others, which is currently underway.

Finally, in the context of international debates about patents and access to medicines, and ongoing negotiations in various fora dealing with international trade and investment agreements, Canada has come under increased pressure to weaken its regulation in the area of pharmaceutical policy, and to leave such matters to the operation of market forces.

For example, in June 2003 it was revealed that the Pharmaceutical Research and Manufacturers Association of America (known as PhRMA), the industry group representing patent-holding pharmaceutical companies in the US, will spend US$17.5 million "to fight price controls and protect patent rights in foreign countries and in trade negotiations," and "allocates US$1 million to change the Canadian health care system and US$450,000 to stem the flow of low-price prescription drugs from online pharmacies in Canada to customers in the United States."[22] PhRMA has long objected to Canada's mechanisms for controlling the prices of patented medicines, be it compulsory licensing in the 1980s or, more recently, direct price regulation, and this continues. For example, again in 2003, PhRMA included Canada among the countries on its annual "priority watch list," in which it urged the US Trade Representative to place Canada on its "Special 301 Priority Watch list" for the same year, a precursor to potential retaliatory trade measures by the US against countries that fail, in its estimation, to "adequately" protect the interests of US intellectual property owners.[23] PhRMA's submission explicitly mentions its objection to Canadian price controls. Also in 2003, US-based pharmaceutical companies intensified criticism of pharmacies located in Canada selling medicines to consumers in the US who seek to benefit from lower Canadian prices; some companies took steps to "cut off" supplies of their products to Canadian pharmacies that continue to fill such orders,[24] and some commentators, such as a former federal Minister of Industry, predicted that unless Canada took steps to curb this cross-border trade, pressure would intensify for revisions to Canada's measures to control drug prices.[25] Some observers have expressed concern that US-headquartered pharmaceutical companies may refuse to market their new products in Canada, as a pressure tactic aimed in part at Canadian price regulations but perhaps more importantly in order to send a message to US lawmakers considering introducing price controls.[26]

The size and political influence of the industry are considerable. In 2002, in the US the industry hired 675 different lobbyists, nearly seven lobbyists for each US senator, and spent a record US$91.4 million on lobbying activities.[27] In Canada as well, concerns have been raised about the extensive connections between the brand-name pharmaceutical industry and the leadership of the party currently forming the federal government.[28] Experience in negotiations at the World Trade Organization (WTO) dealing with intellectual property and access to generic medicines in developing countries has also demonstrated that the brand-name pharmaceutical industry has considerable influence with both the US and Canadian governments. It is therefore important that Canadians understand the strengths and limitations of our national policy regarding pharmaceutical pricing in order to preserve and improve its functioning in the greater public interest.

Given the cost pressures from within the country, the political attention currently focused on healthcare issues generally and pharmaceutical policy in particular, and the external threats to weaken Canada's existing policies, as well as the significance of this issue for people living with HIV/AIDS, an analysis of Canada's approach to controlling pharmaceutical prices is timely.

Scope and outline of this paper

There are many factors that affect drug costs ultimately borne by Canadians – whether paying out of their own pockets, or enjoying full or partial coverage through public and/or private insurance schemes. These include the behaviour of drug manufacturers themselves, as well as that of patients and prescribers, and the actions of drug wholesalers, retailers, and pharmacists. Consequently, the laws, regulations, and policies implemented by

- the federal government (eg, protection of patents, barriers to market entry and competition by generic drug manufacturers, price regulation);
- provincial governments (eg, rules and mechanisms for deciding which drugs are placed on formularies, and on what terms, for coverage by provinces' public health insurance plans);
- various regulatory bodies (eg, the guidelines for assessing prices applied by the independent federal regulator, the regulations governing the conduct of healthcare professionals such as physicians and pharmacists); and
- private insurance companies (eg, various limits on coverage for pharmaceuticals, premiums charged to policyholders)

all have an impact on the final costs of medicines to Canadians, and on national healthcare spending.

The basic division of responsibility was put succinctly by the chair of a commission inquiring into the pharmaceutical industry in the 1980s:

> The particular features of the intervention of these [federal and provincial] governments have varied over time, but the fundamental pattern is constant: the federal government regulates the prices of patented medicines by its use of the *Patent Act* for which it is responsible, while provinces affect the prices of medicines through their reimbursement programmes.[29]

At the federal level, there are three key elements to national policy affecting the prices of pharmaceuticals and hence the ultimate costs to purchasers:

- mechanisms for controlling prices of medicines;
- provisions in patent law that facilitate or hinder competition in the marketplace between patented medicines and generic medicines, and therefore affect prices indirectly;[30] and
- regulations on the marketing of medicines, which influence the consumption of medicines and which medicines get prescribed and purchased.[31]

At the provincial/territorial level, key policy mechanisms for influencing the prices of medicines, and ultimately the costs borne by purchasers, include:

- extent of coverage for pharmaceuticals through public health insurance programs using "drug formularies" to include and exclude certain drugs;
- the conditions placed on such coverage by provincial/territorial governments, including measures aimed at promoting the use of less expensive medicines or capping reim-

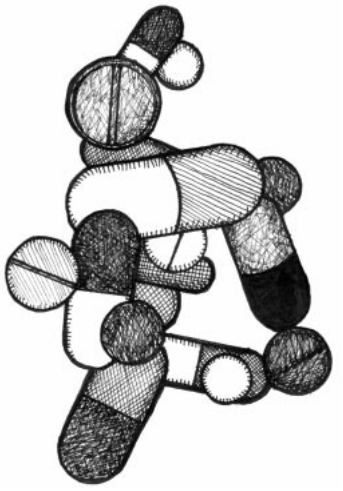
bursement levels (such as substituting generic drugs for brand-name ones, "reference pricing" approaches, etc);[32] and
- to a much lesser extent, monitoring of prescribing by physicians and dispensing by pharmacists.

It is beyond the scope of this paper to address this panoply of regulatory provisions, across Canadian jurisdictions, that affect the costs of medicines to consumers and total spending on pharmaceuticals. It is recognized that provincial governments' policies and decisions regarding their public health insurance plans play a very significant role in containing drug prices in Canada, through their power as major purchasers of pharmaceuticals in the market. Given the variations in approach among jurisdictions, and their significance in affecting final costs and total spending, a full analysis of these policies and their implications for drug costs for people living with HIV/AIDS would be a useful complement to this paper.

This paper focuses on the first of the elements identified above – namely, the specific question of how Canada, through legislation at the federal level, regulates the prices charged by manufacturers for their medicines. While this is only one aspect of the policy puzzle, it is nonetheless an important one, as the initial price charged by a manufacturer accounts for a significant portion of the final price paid by purchasers (eg, it was estimated in 1997 that the manufacturer's selling price amounts on average to almost two-thirds of the final cost[33]). Furthermore, as a matter of federal jurisdiction, policy in this area affects all Canadians.

The first goal of the paper is to assist Canadians, including those living with HIV/AIDS and their advocates, in understanding this element of Canada's approach to controlling medicine prices. The second goal is to provide policymakers with an analysis of that approach, and recommendations for its improvement, so as to protect the interests of Canadians living with HIV/AIDS and Canadians in general. To this end, the paper:

- highlights the significance of policy on pharmaceutical pricing, given increasing costs and spending on medicines as part of overall healthcare spending in Canada, and its significance for people living with HIV/AIDS;
- identifies historical and recent developments that are important because they inform current debates in Canada over regulating drug prices, or our policies in general relating to pharmaceuticals;
- outlines current federal law and policy on the regulation of pharmaceutical manufacturers' prices; and, finally,
- makes recommendations for reform of federal regulation of pharmaceutical prices in Canada.



Healthcare Spending and Pharmaceuticals in Canada

Pharmaceutical spending in Canada

For the last two decades, spending on pharmaceutical products has been the fastest-growing component of total spending on health care in Canada, such that Canadians now spend more on drugs than on physician services, and in the country's total expenditure on health care, drugs are second only to spending on hospitals.[34] Over the 1990s, the amount spent on pharmaceutical products by provincial and territorial governments (the principal public sector purchasers of pharmaceuticals) increased by 87 percent, which is by far the largest increase in any component of healthcare spending.[35] Since 1990, Canadian pharmaceutical spending per capita has doubled, from $191 annually in 1990 to $386 annually in 2000.[36]

Canadians now spend more on drugs than on physician services. In the country's total expenditure on health care, drugs are second only to spending on hospitals.

Significant increases in spending have also been seen in the seven countries used by the Patented Medicine Prices Review Board (PMPRB) for price comparisons to determine whether Canadian drug prices are excessive;[37] at last assessment, Canada was roughly in the middle in terms of the percentage increase in spending on pharmaceuticals.[38] Across Europe, all countries are facing significant increases in drug expenditures, leading to "constant evolution in public policy throughout Europe related to the pricing of drugs and reimbursement under public programs. On the pricing side, these initiatives include reference-based pricing, foreign price comparisons, and mandated price reductions…. Some countries are negotiating volume agreements with manufacturers to limit total expenditures."[39] Across member countries of the Organization for Economic Cooperation and Development (OECD), pharmaceutical expenditure has been rising steadily as a share of GDP since 1970.[40]

Increased spending on pharmaceuticals results from at least three major factors:

- the increased use of drugs on a per capita basis;
- the use of more expensive, new drugs rather than older, less expensive drugs; and
- the rising prices of existing drugs.[41]

Research has shown that "[t]he most important component of these rising drug expenditures [in Canada] is spending on *prescription* medicines, which currently account for some three quarters of total drug spending."[42] (See Figure 1 below with 1997 data, and Figure 2 tracking expenditures on prescription and non-prescription drugs from 1985 to 2002).

Figure 1: Drug Expenditures by Type of Drugs and Sector, Canada, 1997[43]

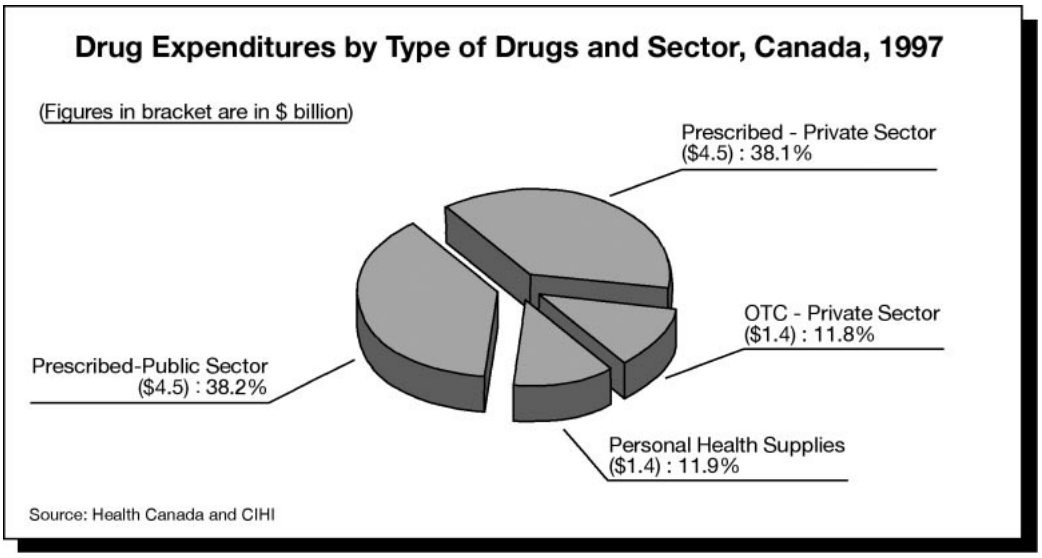
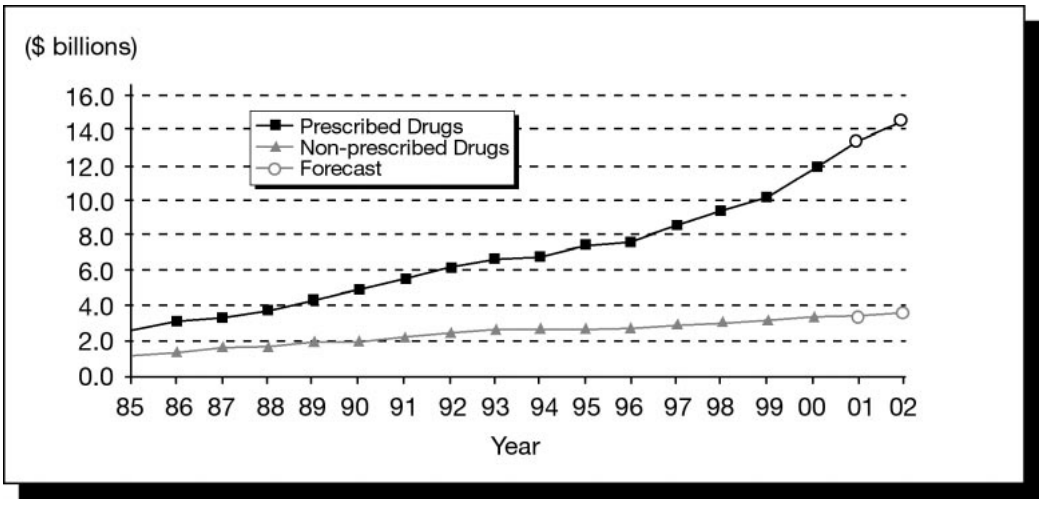
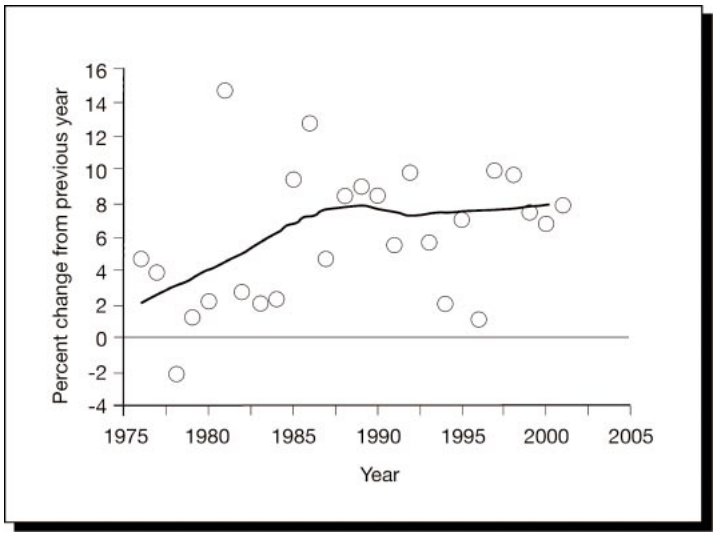


Figure 2: Total Drug Expenditure by Type, Canada, 1985-2002[44]



Adjusting for inflation, Lexchin has tracked the annual percent change in retail prescription drug spending over a longer period (1975-2001) as shown in Figure 3.

Figure 3: Percent change in retail prescription drug expenditures in Canada, 1975-2001 (constant dollars, 1992 = 100)[45]



Sources: Canadian Institute for Health Information. National health expenditure trends, 1975-2001, report. Executive summary.

Bank of Canada. Inflation calculator, at www.bankofcanada.ca/en/inflation_calc.htm.

Recently, the Canadian Institute for Health Information, an independent, non-profit organization established by federal and provincial/territorial ministers of health, released a detailed analysis of trends in national health spending over the last 17 years. The CIHI estimates that:[46]

- Canada remains among the highest healthcare spenders in the industrialized world: in 2000, Canada's total healthcare expenditure accounted for 9.1 percent of its gross domestic product (GDP), the fourth highest ratio among G-7 countries, and in 2001 this had claimed to 9.3 percent of GDP.
- In 2002, while spending on hospitals represented the largest share (31.3 percent) of total healthcare expenditure, spending on drugs outside hospitals[47] (prescription and non-prescription) remained the second largest component: for 2002, spending on drugs is estimated to be $18.1 billion, or 16.2 percent of total health expenditure in that year.
- Since the early 1990s, the share of spending on prescribed drugs from *private* sources (eg, private insurers, patients themselves) has been over 50 percent, ranging from 52.3 percent to 57.6 percent during those years. CIHI estimates that the figure is approximately 55.0 percent in 2002.

Increased spending on pharmaceuticals is not problematic per se and, indeed, in some cases may be cost-effective in delivering improved therapeutic benefits to patients and avoiding or reducing other costly medical interventions. Pharmaceuticals have made, and will continue

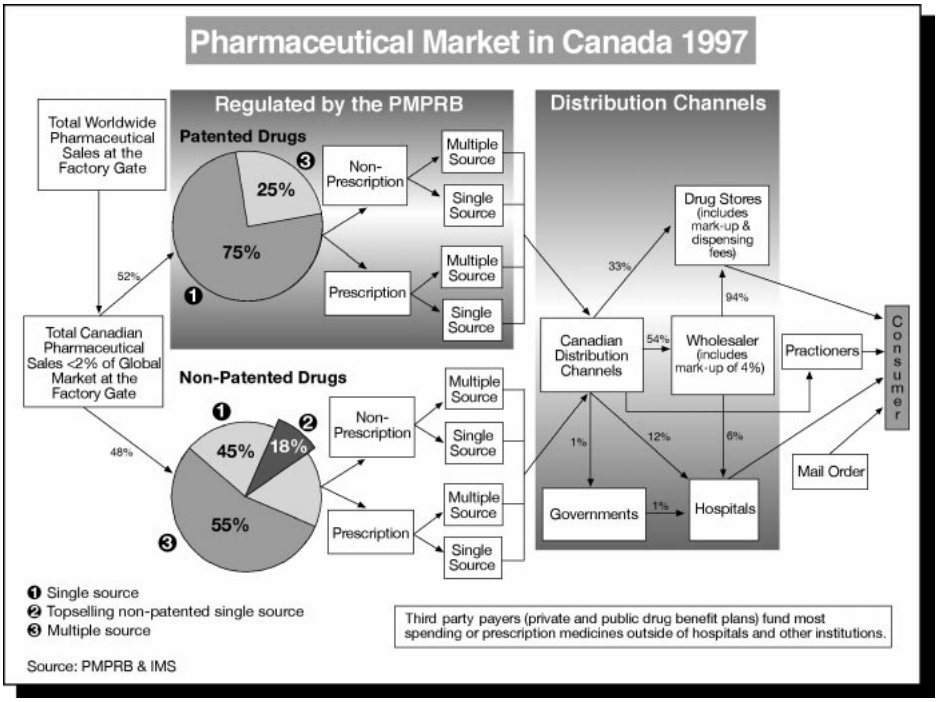
to make, significant contributions to improving life expectancies and improving quality of life.[48] However, these benefits are not obtained by increased use of those new medicines that offer little or no therapeutic advantage over existing medicines but are priced more expensively. It is therefore important that Canadian policy seek to best use healthcare dollars for maximum health benefits. Policy in numerous areas, and at different levels of jurisdiction, needs to be informed by this ultimate objective – such as reducing unnecessary prescription and overutilization of medicines through regulating marketing by manufacturers or influencing physician practice, setting criteria for placing medicines on provincial drug formularies based on data showing value for money, etc. One area that should reflect this is Canada's federal system for regulating prices of new medicines; several of the recommendations in this paper are aimed at improving federal policy to this end.

Pharmaceutical industry in Canada

Although a few years old, the 1999 report of the Federal/Provincial/Territorial Pharmaceutical Issues Committee analyzing drug prices and costs in Canada from 1990-97 provides a succinct, introductory overview of the pharmaceutical industry in Canada. That description is excerpted here in full:[49]

> The supply side of the pharmaceutical market is comprised of approximately 130 manufacturers of prescription medicines in Canada; these manufacturers can be broken down into those producing brand name drugs and a smaller sector of manufacturers who produce generic copies of these medicines after patent expiry. For the large part, the Canadian brand name drug industry is comprised of foreign multinational companies that have Canadian subsidiaries. These subsidiaries benefit from Canadian patent law and undertake the vast majority of research and development of innovative pharmaceutical products in Canada. Most of the pharmaceutical industry is situated in Ontario (i.e., Toronto) and Quebec (i.e., Montreal). The generic industry is largely comprised of domestic companies, with a few of these generic companies beginning to invest in the research and development of new innovative pharmaceutical products.
>
> The demand side of the sector includes hospitals and other institutions, a mix of publicly (mainly provincial) and privately funded insurers, and individuals paying for drugs out of pocket. Intermediaries acting in the prescription drug market include physicians, pharmacists and drug wholesalers and retailers.
>
> The following figure [Figure 4] illustrates the operation of Canada's pharmaceutical market. In 1997, Canada's pharmaceutical sales represented approximately $7 billion at the factory gate. In 1997 this $7 billion sales figure is divided into approximately 52% for patented drugs ($3.7 billion) and 48% for non-patented medicines ($3.3 billion); only prices of patented medicines are directly regulated in Canada. Pharmaceutical products are distributed either directly from the manufacturers, or through wholesalers, to either the hospital sector or to community pharmacies. The following figure demonstrates the complexities of this sector.

Figure 4: Pharmaceutical Market in Canada 1997[50]



> This spending on prescription medicines can be further broken down by those drugs that are currently protected by patents and whether the medicine is available from a single manufacturer, or from multiple (e.g., competing) sources. Note that patented medicines can be multiple source products; in particular, older patented medicines with competing generic medicines manufactured and sold under compulsory licence. Note also that single source products may face indirect competition from alternative therapies.

Concerns have been raised about the nature of the pharmaceutical industry in Canada. One analyst has pointed out that in the last two decades, and largely since the weakening and then the almost complete abolition of compulsory licensing (described in detail below), Canada has become overwhelmingly dependent on imports to supply our pharmaceutical needs:

> In 1983, imports were 18% of the Canadian market, in 1993 they were over 35% and by 2000 over three-quarters of the market were [sic] made up of imports. Most imports are fine chemicals that form the active ingredients in the medications that we use. Therefore, coincident with the change in the Canadian patent laws, there has been a failure to develop a fine chemical industry and pharmaceutical manufacturing has taken on more of an assembly line nature whereby ingredients are combined into their final form.[51]

Data presented at a national symposium hosted in October 2002 by the PMPRB highlighted that pharmaceutical sales generally, and the sales of *patented* medicines in particular, continue to increase:

Since the PMPRB was created in 1987, retail spending on drugs in Canada has increased from about 10% of total health expenditures to more than 15%. Total sales by drug manufacturers have grown by close to 400% to reach $11.5 billion in 2001. The sales of *patented* drugs have increased even faster so that they now represent 65% of total drug sales as compared to 45% just a few years ago.[52]

These increases are graphically illustrated in the figures below from the PMPRB:

Figure 5: Manufacturers' Sales of Drugs, 1990-2001[53]

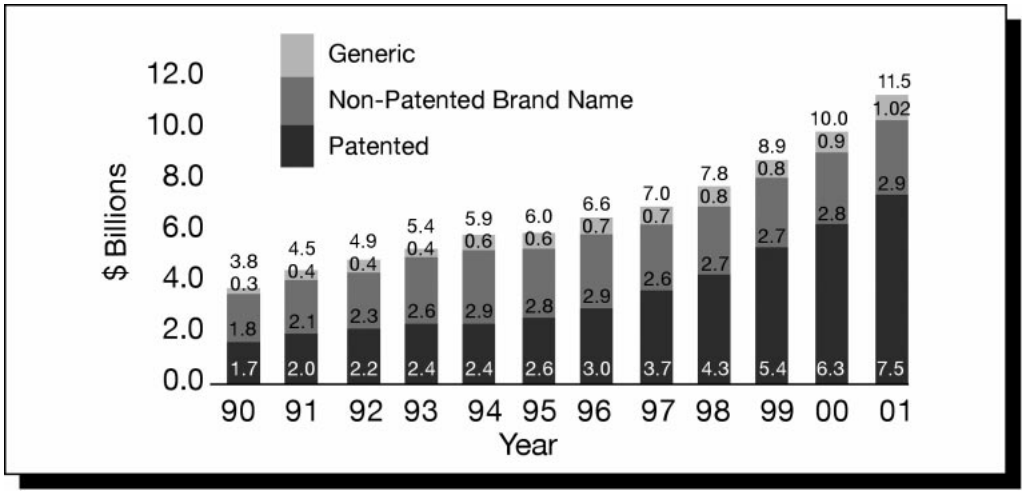
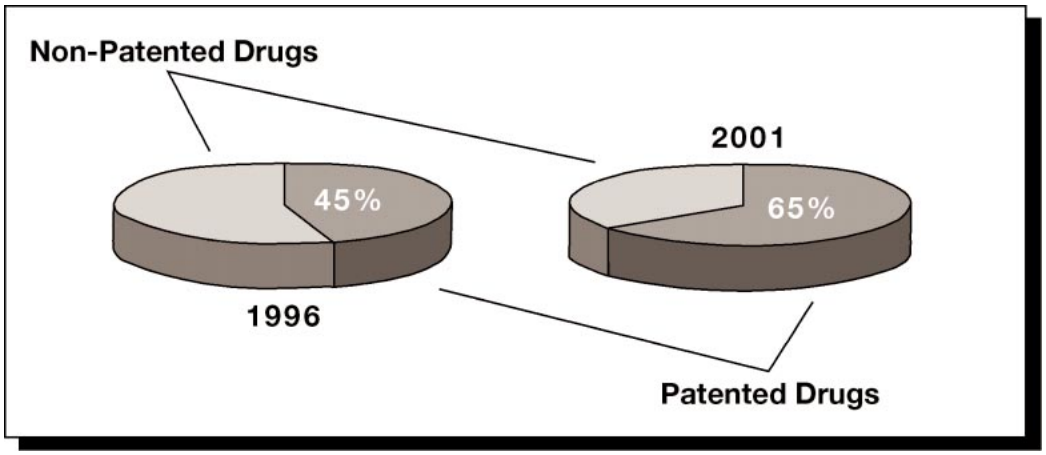


Figure 6: Patented Drugs – Share of Total Drug Sales[54]



Figures released even more recently in the latest annual report of the PMPRB indicate these increases are continuing, such that for 2002:

- total sales in Canada by drug manufacturers of pharmaceuticals for human use grew by 13.9 percent from the previous year, to an estimated $13.1 billion for the year; and

- the share of *patented* drugs within total drug sales rose 17.3 percent from the previous year, and now accounts for $8.8 billion for the year, or over 67 percent of total drug sales in Canada. Patented drugs' share of total drug sales has increased in every year since 1996.[55]

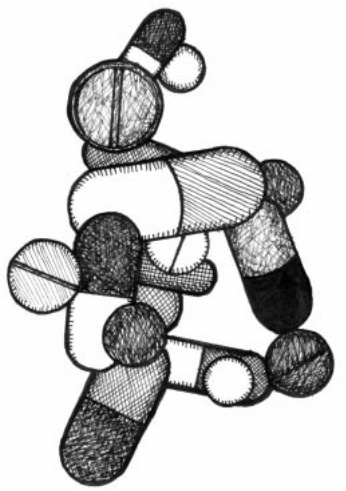
Notwithstanding this, pharmaceutical sales in Canada in 2002 represented only 2.6 percent of total worldwide sales by pharmaceutical manufacturers, which is estimated at CAD$638.8 billion in the year ending October 2002. (In contrast, US sales represented 53.4 percent of total global sales, more than twice the combined sales in Canada, France, Italy, Germany, and the UK.)[56] The PMPRB reports, however, that over the last three years pharmaceutical sales have grown faster in Canada than in other major markets, including the US, the UK, Germany, Italy, and France.[57]

The Canadian patented pharmaceutical industry has also seen healthy profits. As Lexchin pointed out in 1997:

> Even prior to Bill C-22 the industry in Canada was among the most profitable industries in the country. Over the eight years ending in 1987 the pre-tax rate of return on equity for drug manufacturers averaged 36.8% compared to an average for all manufacturing industries of 14.0%. Since the enactment of Bills C-22 and C-91 [see discussion below] the pharmaceutical industry has, if anything, been even more profitable relative to all manufacturing industries than it was before, with pre-tax profit margins on equity of 29.6% and 10.7%, respectively.[58]

These figures on the rapid, sustained growth of patented pharmaceutical sales and profits in Canada are paralleled by the global growth in sales and profit of the brand-name pharmaceutical industry generally. Researchers at the Université du Québec à Montréal (UQAM), analyzing financial data from the nine largest pharmaceutical companies principally marketing innovator drugs over 1991-2000, found that:

- over the decade, the average after-tax return on capital for the companies was 41 percent, whereas inflation averaged around 2 to 3 percent over the same period;
- the average after-tax return on capital for the nine companies for the year 2000 was 45.3 percent; by comparison, according to *Fortune* magazine, the next highest rate of return that year was 16.7 percent (in the banking industry), and the average rate of return over 48 industries in the same year was 15.6 percent;[59]
- net profits for the nine companies were US$31 billion, up from US$11 billion in 1991, representing an increase of 182 percent in 10 years, or a net profit margin of 19 percent over the decade as a whole.[60]



Evolution of Canadian Law on Pharmaceutical Pricing

Like Australia, New Zealand, Japan, and most European countries, Canada has implemented public regulation of drug prices. Of major developed countries, the United States, Germany, and Denmark do not have some comprehensive national system of price control.[61] As the lead researcher on a recent, comprehensive survey points out:

> Pharmaceuticals … have been subject to extensive and wide ranging price-fixing policies in OECD countries, for several decades. Today, pharmaceutical prices are free in only a minority of OECD countries, even if these include some major players such as the United States, Germany and Denmark.… Price fixing has been chosen as a public policy when:
>
> - Prescription pharmaceuticals are considered as belonging to the goods provided by a universal health care system;
> - Patient access is not to be deterred for financial reasons, but public funds are limited.[62]

But public programs in the United States that cover some drug costs for certain groups are increasingly adopting some price control and cost-containment mechanisms previously used in Europe and elsewhere, and some US states are introducing or examining broader price-control measures, often invoking the lower drug prices seen in Canada as a result, in part, of price regulation.[63]

Canadian law regulating the price of pharmaceuticals has always been tied to the question of patent protection for pharmaceuticals.

However, in some respects, Canada's approach to regulating the price of pharmaceuticals is "unique" among comparably developed countries.[64] Canadian law regulating the price of pharmaceuticals has consistently, throughout its evolution over the past century, been tied to Canadian law and policy on

patent protection for pharmaceutical inventions. This remains very much the case today. This section outlines, in broad strokes, how Canadian policy regarding medicine prices has evolved over the last several decades; this historical overview is important for understanding the current state of affairs.[65]

In general, at the national level, Canada has adopted two principal approaches in its efforts to maintain the prices of (patented) medicines at "reasonable" levels. First, from the 1920s to the 1980s, it constrained market monopolies by limiting the scope and extent of patent rights on medicines, relying on market competition to manage prices. In the mid-1980s, the federal government changed course and began to strengthen and extend exclusive patent rights and, as a political compromise, introduced a scheme for direct regulation of the prices charged by manufacturers of patented medicines, to prevent patent holders from abusing those rights by engaging in "excessive" pricing. This is the regime that remains in place today. But pharmaceutical policy regarding both patents and prices remains controversial and a source of ongoing tension and debate. This is particularly so given the value Canadians overwhelmingly place on equitable, universal access to health care and the pressures of international trade and investment agreements that constrain, or threaten to constrain, the room for governments to make policy choices that balance broader public interests against private interests.

Canadians value equitable, universal access to health care.

1923: Introduction of compulsory licensing for medicines

Compulsory licensing for pharmaceutical products was first introduced into Canadian law in 1923.[66] A patent on an invention (such as a new medicine) grants the patent holder the right to exclude others from making, using, or selling that invention for a defined period of time, and to sue someone who makes, uses, or sells the invention without permission. A "compulsory licence" is legal authorization for someone other than the patent holder to make use of an invention; in effect, it removes the patent holder's exclusive rights in the invention, preventing the patent holder from holding a monopoly on the invention and thereby charging inflated, monopoly prices.

At the time of the 1923 legislation, the Patent Act limited permissible patent claims for inventions relating to medicines only to *processes* for making a particular medicine (and to products produced by such a patented process). A medicine itself could not be covered by a patent independently of the process used to make it. This meant it was legal for others to make and sell their own version of the final medicine as long as they manufactured it using a different, unpatented process. This limited the scope, at least in theory, of the market monopoly of the patent holder.

The Act also established that compulsory licences could be obtained almost as of right. It stated that, in the case of inventions related to medicine, the Commissioner of Patents "shall" grant a compulsory licence to an applicant in the absence of "good reason not to grant such a licence."[67] In granting a licence, the Commissioner was required to set the terms of the licence and fix the amount of the royalty or other compensation to be paid to the patent holder, taking into account "the desirability of making the medicine available to the public at the lowest possible price consistent with giving the patentee due reward for the research leading to the invention and for such other factors as may be prescribed."[68]

Canadian courts repeatedly affirmed the legitimacy of Parliament's objectives in promoting competition in the pharmaceutical market through compulsory licensing. In one leading case, the trial judge ruled:

> In my view, the objective of the provision is to bring about competition. On balance, in most fields, competition is regarded by Parliament as being in the public interest ... and also because competition tends to bring about greater efficiency, better service, and further research. The monopoly granted to an inventor is an exception to this general principle in our law. [The compulsory licensing provision] was passed because, in the field to which it applies, "the specific public interest in free competition" was deemed to be more important than the maintenance of the patentee's monopoly rights.[69]

On appeal to the Supreme Court of Canada, the Court affirmed the ruling. Writing for a unanimous court, Abbott J stated:

> In my view the purpose of [the section authorizing the Commissioner to issue compulsory licences] is clear. Shortly stated it is this. No absolute monopoly can be obtained in a process for the production of food or medicine. On the contrary, Parliament intended that, in the public interest, there should be competition in the production and marketing of such products produced by a patented process, in order that as the section states, they may "be available to the public at the lowest possible price consistent with giving to the inventor due reward for the research leading to the invention."[70]

While the 1923 Patent Act introduced the possibility of obtaining compulsory licences on inventions related to medicines, such licences could only be issued to authorize the *use* within Canada of patented processes and the *manufacture* within Canada of products manufactured through patented processes. There was no provision to issue compulsory licences authorizing the *importation* of patented medicines, or their active ingredients, into Canada. However, for reasons that are disputed, few applications for compulsory licences were filed over the several decades that followed – until significant changes to the law were introduced in 1969.[71]

1969-87: High prices, growing concern, and expansion of compulsory licensing

High prices for drugs became a growing concern in Canada in the 1960s. Several federal government inquiries reported that drug prices in Canada were among the highest in the world, and identified Canada's patent regime as a major cause, prompting them to recommend reform to Canada's patent laws. One commission recommended that Parliament abolish completely the possibility of obtaining medicine-related patents,[72] while two others recommended maintaining patents related to medicines but extending compulsory licensing to include importation, rather than being limited to authorizing local production.[73]

The federal government followed the latter recommendation. Before 1969, compulsory licences were available for patented medicines, but only to authorize the manufacture of the medicine in Canada. Amendments in 1969 to the Patent Act extended the scope and availability of compulsory licences to allow someone other than the patent holder to *import* medicines or the ingredients.[74] Judicial interpretation of the Act "extended the licensing provisions to embrace chemical intermediates. Chemical intermediates are substances intended for, and necessary to, the synthesis and production of medicines, but which are not medicines in and of themselves."[75]

Combined with the pre-existing provision that the Commissioner "shall" issue a compulsory licence unless there was a "good reason" not to, the amendments prompted a dramatic

increase in the number of compulsory licences issued in Canada, leading to greater competition in the pharmaceutical market and the growth of a significant generic pharmaceutical industry in Canada. Between 1969 and 1987 (when the Patent Act was amended again), some 765 applications for compulsory licences had been filed and some 400 licences had been issued, almost all of which were licences to import.[76] As noted by one court:

> The 1969 amendment resulted in the licensing of brand name patented products by generic firms, which then produced and marketed their own brand or copy of the patented medicine. Compulsory licensing to import medicines resulted in increased competition by generic firms against patent-holding firms. This competition was further encouraged by the provincial policy of generic substitution under their respective pharmacare plans. The result has been the growth of large and profitable Canadian-owned generic pharmaceutical firms, which in turn led to lower prices. Needless to say, this aspect of compulsory licensing permitting a competitor (generic firm) to import and produce a copy of the patent holder's product (brand name) has been the object of intense political lobbying by the patent-holding firms.[77]

As could be expected, patent-holding pharmaceutical companies opposed the 1969 amendments expanding compulsory licensing. Soon began a period of frequent litigation over Canadian patents and patent laws, which trend continues today.

For example, the courts repeatedly rejected claims that these provisions fall outside the legislative jurisdiction of the federal government or offend provisions on property rights, liberty, or equality in either the Canadian Bill of Rights or the Canadian Charter of Rights and Freedoms.[78]

One particularly contentious issue was the question of the compensation for patent holders accompanying compulsory licensing. As has always been the case with compulsory licensing, some form of compensation to the patent holder is required. According to one source, before the 1969 amendments, the royalty paid to the patent holder "was typically 5 to 15% of the net selling price of the active medicine or drug in bulk form which is the form prior to processing into unit dosage forms such as tablets."[79]

However, under the new legislation, a different practice emerged. Recall that the Patent Act granted the Commissioner of Patents the authority, and obligation, to fix the terms of a compulsory licence, including compensation. In the case of the first licence issued after the 1969 amendments, the Commissioner fixed a four percent royalty on sales, which figure became standard in the Commissioner's practice – although there seems to be little clarity as to how this figure was reached and why it became a standard.[80] While this first post-1969 decision by the Commissioner was challenged, the court ruled it would not interfere.[81] This first judicial decision following the 1969 amendments

> established the royalty figure of 4% of the net selling price of the drug in final dosage form, that it was for the Commissioner of Patents to determine the weight to be attributed to particular matters on which he would rely in order to reach a proper determination, and that a balance was to be arrived at between giving to the patentee due reward for the research leading to the invention and making medicine available at the lowest possible price.
>
> The origin of the figure of 4% is unclear, it does not seem to have been derived from any detailed study or understanding of costs associated with the research and development of the particular drug, of the risks involved, or the benefits

> achieved.… In any event the mysterious 4% has remained unaltered.… [B]y whatever mystical route the figure of 4% was arrived at, the Commissioner of Patents has not considered it necessary to justify or alter this figure, and the Courts have taken the position that it is for the Commissioner of Patents to decide on the royalty to be awarded, although evidence is to be presented so that he can make the award.[82]

While four percent was the royalty rate "routinely applied in most pharmaceutical cases," in the early 1990s, in the dying days of compulsory licensing provisions in Canadian law, this practice of applying an automatic royalty rate eventually came in for criticism from one appellate court as legally insufficient, and higher royalties were ordered in two subsequent cases.[83]

1980s: Bill C-22 weakens compulsory licensing, but introduces price regulation by PMPRB

By the 1980s, there was pressure on Canada from the patent-holding pharmaceutical industry and the United States government to weaken or eliminate compulsory licensing. Eventually, this pressure, combined with the policy directions of Canada's own government, led to drastic changes in Canada's pharmaceutical policy at the federal level with the passage of Bill C-22 in 1987.

In 1984, the federal Liberal government had established the Commission of Inquiry on the Pharmaceutical Industry (Eastman Commission) to examine a range of questions, including the cost of medicines in Canada. The Commission's 1985 report concluded that the liberal use of compulsory licensing provisions since the 1969 Patent Act amendments had saved Canadian consumers some $211 million in a single year (1983), had not adversely affected the Canadian research pharmaceutical industry, and had had little effect on the decisions of multinational pharmaceutical corporations regarding investments in research and development.[84] In fact, Lexchin notes, "even prior to Bill C-22 [in 1987] the industry in Canada was among the most profitable industries in the country. Over the eight years ending in 1987 the pretax rate of return on equity for drug manufacturers averaged 36.8% compared to an average for all manufacturing industries of 14.0%."[85]

The 1984 Commission of Inquiry on the Pharmaceutical Industry concluded that Canada's regime of compulsory licensing had spurred the growth of a generic drug industry.

The Eastman Commission also concluded that Canada's regime of compulsory licensing had spurred the growth of a generic drug industry in the country.[86] The Commission concluded "that compulsory licensing as it exists in Canada today under … the Patent Act is an effective component of an appropriate patent policy for the pharmaceutical industry."[87] While the Commission recommended that Canada retain compulsory licensing provisions in its patent laws, it also recommended revisions aimed at improving the compensation received by innovator companies whose patents are licensed in this fashion. Three recommendations in particular stand out:

- First, it recommended that it be possible to patent a pharmaceutical product itself, independent of the process for producing it.
- Second, the Commission recommended that a new drug should be guaranteed four years of market exclusivity from the time it is authorized for marketing in Canada, such that no compulsory licence could be issued during this time.

- Third, it recommended that a Pharmaceutical Royalty Fund be set up, which would be financed by generic companies receiving compulsory licences. The amount of a given generic company's levy would depend on both the value of its sales in Canada of products sold under compulsory licence and the patent-holding company's worldwide ratio of R&D to sales. Patent-holding companies whose products were compulsorily licensed would periodically receive payments from this Fund, based on the Canadian sales of the generic versions of their products and their own ratio of R&D spending in Canada to their total sales of patented medicines.

These recommendations, aimed at striking an overall balance between public and private interests, were largely ignored by the federal government. To the extent that some of the ideas were implemented, the direction was overwhelmingly to strengthen private patent rights.

In 1987, the federal government enacted Bill C-22,[88] which represented "the beginning of the end"[89] of compulsory licensing in Canada and a shift to a new approach to controlling the prices of patented medicines. Four principal features of the amendments should be noted:

- First, the bill amended Canadian law to recognize patents on medicines themselves, independent of a patented process for creating them.
- Second, it extended the term of patent protection. Until then, the Patent Act provided patent protection for 17 years from the date that the patent was granted by the patent office. Bill C-22 amendments changed the patent term to 20 years from the date of filing the patent application; this change came into effect in 1989.
- Third, the bill introduced staggered periods of protection against the possibility of compulsory licensing for new medicines. The Eastman Commission had recommended market exclusivity for only a four-year period. Under the Bill C-22 amendments, generic drug manufacturers could still obtain compulsory licences during the patent term, but these could not be used until some period of market exclusivity for the original, patented medicine had expired. To encourage domestic pharmaceutical production, in the case of a medicine invented *outside* Canada, a compulsory licence to *manufacture* within Canada could be used after seven years of market exclusivity for the original patented drug, but a licence to *import* could ever be used only after 10 years.[90] In other words, the generic manufacturer could obtain a compulsory licence earlier if it were to manufacture the generic drug within Canada, but would have to wait longer if it were simply going to import the generic product. In the case of a patented medicine that had been "invented and developed" *in* Canada, a compulsory licence could only be issued for manufacturing the medicine domestically, after seven years; no compulsory licence could be obtained to import a medicine invented in Canada during the patent term.[91] In exchange for this boon to the patent-holding industry, the Pharmaceutical Manufacturers Association of Canada (PMAC), the patent-holding industry association (since renamed "Rx&D – Canada's Research-Based Pharmaceutical Companies"), promised to increase its spending on research and development (including basic research) in Canada, to increase employment in the R&D sector, and to keep price increases in line with inflation.
- Fourth, Bill C-22 created the Patented Medicine Prices Review Board (PMPRB), an independent body with the mandate to monitor drug prices and impose penalties in cases of excessive pricing by patent holders. The creation of the PMPRB as a quasi-independent body to prevent excessive monopoly pricing by patent holders was a response to acrimonious parliamentary and public debates about the impact on patients of weaken-

> ing compulsory licensing and strengthening monopolies on medicines. Since then, the PMPRB has been the sole mechanism for regulating manufacturers' prices of patented medicines. One power held by the Board was that, in cases of excessive pricing or non-compliance with statutory obligations or Board orders by a patentee, the Board could withdraw from the patentee the protection against compulsory licensing, exposing the patentee to the possibility of the Commissioner of Patents issuing such a licence.[92] (The PMPRB's powers were revised in 1993; the Board is discussed in more detail below.)

While compulsory licensing was dramatically weakened, it nonetheless remained in Canadian law. Despite ongoing challenges by patent-holding pharmaceutical companies, Canadian courts reaffirmed the validity of compulsory licensing in its new modified form, and its objective of reducing drug prices through market competition.[93] Courts also continued to accept a four percent royalty rate as standard.[94]

The external political pressures of the "free trade" model of globalization played a significant role in this dramatic shift in Canadian law – a pressure that has only increased in the last decade with the advent of other trade and investment agreements. The federal Conservative government of the day was in the process of negotiating the Canada–USA Free Trade Agreement (FTA) eventually concluded in 1988. Sharing some of the ideological inclinations of the US government, and under pressure from the US to strengthen patent protections for pharmaceutical companies and weaken compulsory licensing, the Canadian government responded with the amendments in Bill C-22. The FTA did *not* require, in its text, any such amendments, and the Canadian government

> continually and vigorously denied that there was any connection between the free trade agreement and changes in compulsory licensing, but the facts make their denials hard to credit.… [T]he US deputy chief negotiator in the free trade talks said: "Ottawa didn't want it [intellectual property] to be in the free trade negotiations. They didn't want to *appear* to be negotiating that away as part of the free trade agreement. Whatever changes they were going to make, they wanted them to be *viewed* as, quote, 'in Canada's interest.' … It was a high priority issue for us. We were not above flagging the importance of resolving the issue [to the Canadian negotiators] for the success of the overall negotiations."[95]

Indeed, the US President raised the issue of pharmaceutical patents directly at a summit with the Canadian Prime Minister, the US Trade Representative described Canada's compulsory licensing provisions as a "trade irritant" and criticized the Canadian government for not making changes, and the US Vice-President publicly complained about the issue on a state visit to Canada.[96] The US Trade Representative placed Canada on the first "Special 301 trade watch" list dealing with intellectual property protection that it issued, the first step toward possible trade sanctions for failing to, in the view of the US government, "adequately protect" the intellectual property of US companies.[97] Finally, the US Trade Representative released a summary of the FTA in October 1987 which stated that the two countries had agreed to address the compulsory licensing provisions of Canada's Patent Act.[98] While the patent-holding pharmaceutical industry lobbying for this aggressive US stance did not have a large financial stake, relatively speaking, in the Canadian market (which accounts for about two percent of world sales[99]), they were "horrified that compulsory licensing would set a precedent"[100] and therefore campaigned vigorously for its abolition in Canadian law.

1990s: Bill C-91 largely abolishes compulsory licensing, new trade agreements signed

The industry's efforts, and those of the US government, to abolish compulsory licensing in Canada largely succeeded several years later, with the passage of further amendments in the Patent Act Amendment Act, 1992 (also known as Bill C-91), which came into force in 1993.[101] These amendments completed the shift away from compulsory licensing as a measure for controlling the prices of patented medicines. The Federal Court of Appeal has characterized the 1993 amendments as "a reversal of government policy adopted by Parliament in 1923."[102] The bill, and regulations made under it, made four key changes to Canadian laws regarding pharmaceutical patents:

- largely abolishing compulsory licensing;
- creating certain limited exceptions to the patent holder's exclusive rights;
- linking marketing approval for a generic drug with the patent claims on the original brand-name drug; and
- reforming the Patented Medicine Prices Review Board.

In 1992, the federal government abolished Canada's special regime for compulsory licensing of patented medicines. Only limited options for obtaining a compulsory licence on a medicine now remain.

Abolition of compulsory licensing

First, Bill C-91 abolished Canada's special regime for compulsory licensing of patented medicines entirely, meaning that patent holders enjoy market exclusivity until their patents expire at the end of the 20-year term. It also significantly reduced compulsory licensing generally in Canada. At present, three possibilities for compulsory licensing remain in Canadian law but are heavily circumscribed – two of these exist under patent laws, the third under competition law.

- The principal variant that remains is found in the Patent Act provisions on "use of patents by government."[103] Under those provisions, the federal or a provincial government may apply to the Commissioner of Patents for authorization to use a patented invention without the patent holder's consent. Any such authorization is subject to a variety of conditions required by international trade agreements.[104]
- Second, it remains the case that compulsory licensing (and even forfeiture) of a patent may be ordered by the Commissioner of Patents to remedy a patent holder's "abuse" of its patent rights.[105] "Abuse" is made out where "the demand for the patented article in Canada is not being met to an adequate extent and on reasonable terms"[106] or, alternatively, where the patent holder's conduct causes "prejudice" to the trade or industry of Canada or "unfairly" prejudices the manufacture, use, or sale of non-patented materials used in a patented process.[107] In such a case, three years after a patent has been granted in Canada, the federal Attorney General or "any person interested" may file an application to the Commissioner alleging abuse of exclusive patent rights and seeking a remedy under the Patent Act.[108] One remedy the Commissioner may provide is to grant a compulsory licence "on such terms as the Commissioner may think expedient," but the licence cannot authorize importation of the patented invention into Canada.[109]
- Third, under the Competition Act,110 if a patent holder uses its patent rights in a manner that "unduly" prevents or lessens competition, the Federal Court may order the grant of a licence to use a patented invention "on such terms as it deems appropriate" (or may revoke the patent). While this remedy is theoretically available, it can be invoked only

by the federal Attorney General. In practice, compulsory licences have only been authorized under the Patent Act.[111]

As with the passage of Bill C-22 in 1987, trade pressures were again at play – but this time, the federal government was forthright in invoking "free trade" agreements as "obliging" Canada to amend its domestic legislation to further strengthen private patent rights over pharmaceuticals, although this claim is largely inaccurate. However, the federal government (first Conservative, then Liberal) had for some time been in the process of negotiating a trade agreement with the United States, this time the North American Free Trade Agreement (NAFTA), which came into effect in January 1994. Seeking to completely eliminate compulsory licensing of pharmaceuticals in Canada, the US Trade Representative put Canada on its "trade watch list" again each year from 1989 to 1991.[112] Simultaneously, it had been an active participant in the decade-long Uruguay Round of negotiations under the General Agreement on Tariffs and Trade (GATT), which ultimately led to the creation of the World Trade Organization (WTO) in 1994. That new body included the first multilateral treaty tying the protection of intellectual property to "free trade" obligations and the possibility of authorized trade retaliation for failing to adequately protect private intellectual property rights – namely, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

These new treaties – NAFTA in particular – were said to require the abolition of compulsory licensing.[113] Yet as one commentator points out:

> What makes the passage of Bill C-91 so ironic is that despite all the government protests to the contrary, Canada was then under no obligation to amend its patent system. The GATT negotiations were still ongoing, and in fact would last more than two years. The US Congress had not approved the NAFTA implementing legislation, and, as Congressional Democrats raised concern over jobs and the environment, looked less likely to do so with each passing day. The Canadian government, which had [in 1987] so vehemently denied the obvious linkage between Bill C-22 and the Canada–US Free Trade Agreement, now argued that an as-yet nonexistent free trade agreement compelled them to pass Bill C-91. Ultimately, of course, both the GATT and NAFTA would come into effect. At the time the Canadian Parliament passed Bill C-91, however, there was no international mandate for it to do so.[114]

It is correct to point out that Canada was under no international legal obligation, at the time of enacting the provisions of Bill C-91, to do so. But this observation is still true, even after both NAFTA and the WTO's TRIPS Agreement have come into effect – it is simply *not* the case that these two treaties require Canada to do what was done with Bill C-91. NAFTA, and subsequently the TRIPS Agreement containing almost identical language, do not prohibit compulsory licensing, although they do impose certain restrictions.[115] A ministerial Declaration on the TRIPS Agreement and Public Health, adopted unanimously by WTO member countries on 14 November 2001, expressly reaffirms that, under TRIPS, countries are free to use compulsory licensing and to determine in their domestic legislation the grounds upon which they will authorize compulsory licences.[116]

Notwithstanding this, several years later, during the period of a statutorily mandated review of the Patent Act by Parliament, both the Industry minister and the Health minister continued to assert that NAFTA required Canada to maintain the Bill C-91 amendments.[117] Industry Canada and Health Canada maintained, in a package put together "to provide

factual background material for the review" of Bill C-91 by the House of Commons, that a regime of compulsory licensing, such as existed in Canada before Bill C-91 in 1993, "would be contrary to Canada's international treaty obligations under the WTO and the NAFTA."[118] It is true that Canada's pre-1993 provisions on compulsory licensing did not conform exactly to NAFTA and WTO/TRIPS obligations, which are more restrictive. But the implication that compulsory licensing of any sort is prohibited by NAFTA or the WTO is incorrect and misleading.

The pressure for further strengthening protection for pharmaceutical patents, and further restricting government regulation, continues in current negotiations for a Free Trade Area of the Americas (FTAA), which would encompass all countries in the hemisphere save Cuba. The United States in particular is pursuing even stronger protections for intellectual property, exceeding those already found in either NAFTA or the TRIPS Agreement (also known as "TRIPS-plus" measures). The Canadian government has officially indicated to Parliament that

> The Government will participate in continuing international negotiations covering intellectual property rights, including the FTAA, and will develop negotiating positions that are consistent with our domestic intellectual property policies and that advance Canadian IP interests as they evolve through ongoing consultations with Canadians.[119]

This official response does little to clarify the negotiating position(s) being taken by Canada, or Canada's "bottom line" on intellectual property in the FTAA negotiations process. The government has also publicly stated that "Canada's goals regarding intellectual property within the FTAA are to maintain and support the improvements achieved within the WTO while also pursuing areas of specific interest to Canada."[120]

"Each member [of the WTO] has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

– Ministerial Declaration on the TRIPS Agreement and Public Health, adopted at Doha, Qatar, 14 November 2001

This still falls well short of a clear statement that Canada will reject any TRIPS-plus measures in the final FTAA. Government negotiators have, in private, indicated that Canada itself is not pursuing TRIPS-plus measures on intellectual property in the FTAA.[121] It remains to be seen whether Canada, under pressure from the US during FTAA negotiations, will not only refrain from pursuing TRIPS-plus measures but will also actively insist that, in protecting private patent rights and limiting governments' regulatory options, FTAA provisions on intellectual property not go beyond the provisions already in TRIPS. The implications for Canada and particularly for the many developing countries in the hemisphere are serious.

Limited exceptions to patent rights: "early working" and "stockpiling"

The second major reform introduced by Bill C-91 was to create two limited exceptions to exclusive patent rights, which allowed some use of a patented drug during the patent term but still preserved the patent holder's market exclusivity for the full 20-year patent term. An "early working" exception allows a generic company to use a patented medicine for the purposes of developing their version of the medicine and seeking approval for its eventual marketing in Canada as a safe, effective alternative. A "stockpiling" exception authorized generic companies to manufacture and stockpile their own version of the drug within the last six months before patent expiry, enabling them to market their generic drug immediately upon patent expiry; but they were still prevented from selling their generic product until the patent

had expired at the end of the 20-year term. As a result of a complaint by the European Communities, a WTO tribunal ruled in 2000 that Canada's "early working" exception was permissible, but that its "stockpiling" exception was contrary to its obligations regarding patents under TRIPS.[122]

Linking generic marketing approval with patent claims on brand-name drugs

Third, Bill C-91 and the accompanying regulations introduced under the amended Patent Act[123] introduced a link between marketing approval of generic drugs and the patent rights over originator drugs. While, as the preceding overview shows, federal law in Canada has always conceptually linked patent policy with the question of price controls on pharmaceuticals, these regulations created another form of linkage: under the regulations, the Minister of Health may not grant approval for marketing (called a Notice of Compliance) to a generic drug unless the patent on the original, brand-name drug has expired, notwithstanding that the generic drug has been shown to be safe and effective and therefore may be permitted to be sold in Canada. This new linking of two separate schemes, governing two separate areas of pharmaceutical regulation, represented a dramatic shift from the previous state of the law:

> Before Bill C-91 amended the *Patent Act* in 1993, the considerations in relation to the grant of a patent or of a compulsory license for a patented medicine and those in relation to the grant of an NOC [Notice of Compliance, ie, approval for sale in Canada] were unrelated, and they were undertaken independently by the Commissioner of Patents and by the Minister of National Health and Welfare, respectively.[124]

The "NOC regulations," as they are commonly known, go quite far in linking marketing approval for a generic drug to the patent status of the original drug. Upon merely filing an allegation that the generic drug will infringe any of its patents, a patent-holding company automatically obtains what amounts to a de facto injunction blocking the Minister from approving the generic drug for sale for up to 24 months. (Originally the period had been 30 months, but this was reduced to a maximum of 24 months by amendments to the regulations in 1998.[125]) Such a provision for automatic injunctions does not exist elsewhere in Canadian law, where ordinarily a party seeking an injunction prohibiting some action must show, among other things, that there is some "irreparable harm" that will follow if the injunction is not granted preemptively.

The Supreme Court of Canada has described the regulations linking marketing approval of a generic drug to the patent status of the originator drug as "draconian" in their effect on generic manufacturers. Canada and the US are the only two developed countries with such laws.

As might be expected, this arrangement provides a strong incentive for a patent holder to take out multiple patents on a medicine (even for minor variations) and to claim potential infringement even if there is no sound basis for the claim, thereby automatically blocking the generic competitor from getting marketing approval and extending the patent holder's market exclusivity for additional months or years. The additional profits thus generated by delaying competition in the market can easily exceed legal costs of even ultimately unsuccessful claims of patent infringement.[126]

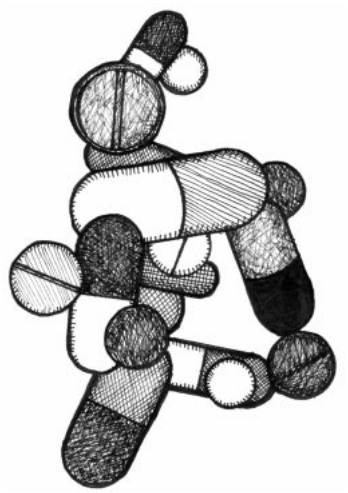
The Supreme Court of Canada has described the regulations as "draconian" in their effect on generic manufacturers,[127] but they have been upheld as being within the legislative jurisdiction of the federal Parliament.[128] Other courts have criticized the regulations as being difficult to interpret and have questioned the "linkage" they make:

> In large measure, the difficulty is due to the fact that those regulations, whose clear intention is to facilitate the protection of private property rights, have been grafted onto a regulatory scheme whose sole purpose is the protection of public health and safety. The union is not a happy one.[129]

A similar provision in US law provides for automatic injunctions of up to 30 months, although as of June 2003, legislative proposals to amend this regime were still under consideration by the US executive and Congress.[130] In Canada, the House of Commons Standing Committee on Industry, Science and Technology held hearings in early June 2003 into the NOC Regulations.[131] Canada and the US are the only two developed countries to have such "linkage" provisions that tie marketing approval of generic drugs to patents claimed on an originator drug.

Reforms to the PMPRB

Finally, Bill C-91 reformed the powers of the PMPRB to monitor drug prices and prevent "excessive" pricing. While it is generally stated that Bill C-91's amendments strengthened the Board, this is only a partial account. As part of the overall agenda of abolishing special compulsory licensing regimes for pharmaceuticals, Bill C-91 actually removed the Board's power to revoke protection against compulsory licensing of medicine patents as a penalty for excessive pricing. On the other hand, the amendments strengthened the Board's capacity to impose fines and even to order imprisonment for failure to comply with its orders.



Current Canadian Law on Pharmaceutical Price Controls: The Patented Medicine Prices Review Board

As the preceding historical review has illustrated, Canadian federal policy regarding the regulation of drug prices has generally been linked with policy on patent protection for pharmaceuticals. This continues to be reflected in current Canadian law and policy: in essence, the political trade-off has been to strengthen and expand protection of patent rights while implementing a system aimed at preventing patent holders from abusing those rights by charging "excessive" prices. That system is implemented by the Patented Medicine Prices Review Board (PMPRB). This section provides an overview of Canada's legislative framework for controlling prices of (patented) pharmaceuticals and the PMPRB as the body responsible for administering that framework. In the course of this discussion, it offers several recommendations for improving Canada's policy approach to regulating pharmaceutical prices.

Federal legislative framework

The federal legislative framework governing prices of (patented) medicines in Canada consists of:

- the Patent Act;
- the accompanying Patented Medicines Regulations; and
- the Guidelines, policies, and practices developed by the PMPRB.[132]

This section provides an overview of the Board, its mandate, and the regulatory framework it implements under the Patent Act and the Patented Medicines Regulations.

Composition of the PMPRB

As noted above, the PMPRB is a quasi-judicial body created by the federal Parliament in 1987 as part of a series of amendments to the Patent Act. It is independent of government, but reports annually to Parliament through the federal Minister of Health. The Board consists of five members appointed by the federal Cabinet, based upon recommendations from the Minister of Health and an advisory panel consisting of representatives of provincial health ministers, consumer groups, the pharmaceutical industry, and others appointed by the Minister.[133] Board members serve on a part-time basis and for five-year terms, but may be removed by the Cabinet at any time.[134] The Board is supported by a staff.

PMPRB's mandate and functions: regulation and reporting

The PMPRB "protects consumer interests and contributes to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive."[135] In fulfilling its mandate, the PMPRB carries out both *reporting* and *regulatory* functions:

- it monitors, and reports to Canadians on, drug pricing, pharmaceutical sales, and the expenditure of patent-holding pharmaceutical companies on research and development (R&D) in Canada; and
- it regulates the prices charged by manufacturers of patented medicines to ensure they are not "excessive."

The Board's monitoring and reporting function is important because it provides a mechanism, albeit weak, for holding the patent-holding pharmaceutical industry to its stated commitments to increase spending in Canada on R&D, commitments given in exchange for the Patent Act amendments described above that enhanced patent protection and therefore industry profits. It also provides useful information for government and civil society organizations to monitor the profitability and performance of the patent-holding pharmaceutical industry, and can therefore inform policymaking in the longer term. (This function of the PMPRB is discussed in more detail in the final section of this part of the paper.)

The Patented Medicine Prices Review Board is an independent, quasi-judicial body that protects consumer interets and contributes to Canadian health care by ensuring that prices charged by manufacturers of patented medicines are not excessive.

The Board is tasked with submitting two reports annually to the federal Minister of Health, which are then to be submitted to Parliament, in which the PMPRB reports on pricing trends in the pharmaceutical industry, and also monitors sales of patented medicines in Canada as well as the spending of patent-holding pharmaceutical companies on R&D.[136] (In practice, these two reporting requirements are addressed in a single, combined "annual report" from the PMPRB.) This information is to be compiled for each company and as an aggregate across the sector of patented medicines.[137] The Patented Medicines Regulations set out what patent-holding pharmaceutical companies must report to the PMPRB, for the purposes of compiling this report, regarding their revenues and expenditures (including on R&D) in Canada.[138] Each company's report on its R&D expenditures must describe the type of R&D and the expenditures in respect of each type of R&D,[139] and the "source and amount" of the funds for its expenditures toward R&D[140] (which language would seem to encompass any public subsidies received for this purpose). For purposes of reporting to the PMPRB, "research and development" is defined as "those activities for

which expenditures qualify for an investment tax credit in respect of scientific research and experimental development" under the Income Tax Act.[141]

It should also be noted that the Patent Act gives the federal Minister of Health the authority to refer matters to the Board for inquiry and reporting; the Act does not impose any particular limits on the Minister in setting the terms of reference for an inquiry by the Board.[142] This provides an additional, potentially important mechanism for generating research, analysis, debate, and reform of Canadian policy relating to pharmaceutical pricing and related issues. The Minister has used this provision to authorize the PMPRB to conduct research in support of federal/provincial/territorial initiatives, such as the National Prescription Drug Utilization Information System.[143]

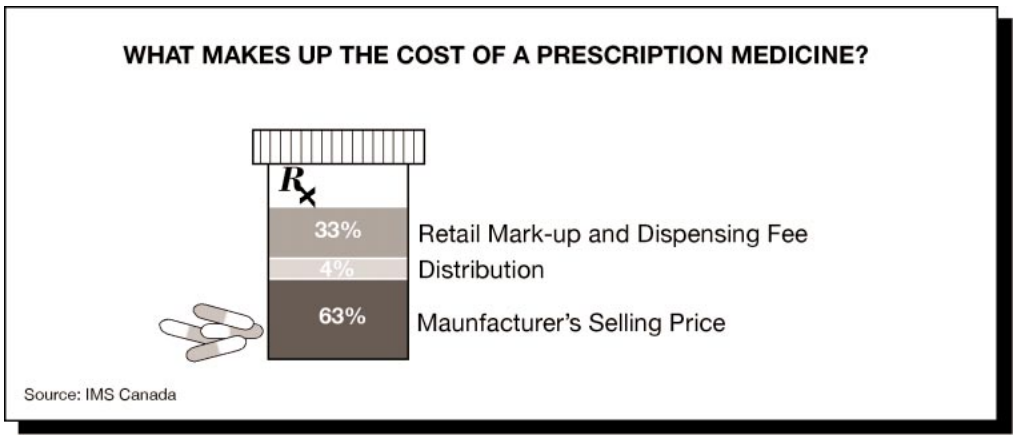
PMPRB's regulatory function: limiting pharmaceutical prices for new and existing drugs

Of more immediate significance is the PMPRB's other function – regulating manufacturers' prices on patented medicines. Commenting on the changes to the PMPRB's powers introduced in 1993 with Bill C-91, one court has stated: "The purpose of these changes is to empower the Board to influence the pricing of patented medicines much to the same extent that the competition fostered by compulsory licensing used to influence it."[144]

The manufacturer's selling price accounts for almost two-thirds of the ultimate cost of a medicine to the purchaser. This highlights the importance of controlling these prices.

As the figure below illustrates, the manufacturer's selling price accounts for almost two-thirds of the ultimate cost of a medicine to the purchaser. This highlights the importance of controlling manufacturers' "factory gate" prices (ie, the price the manufacturer charges to distributors, wholesalers, hospitals, and pharmacies), although other elements may be subject to regulation to safeguard the public interest in enjoying reasonable overall drug prices.

Figure 7[145]



In order to regulate medicine prices, the PMPRB collects data from drug manufacturers and applies a series of criteria, set out in both legislation and its own guidelines, in determining whether prices are "excessive." The PMPRB monitors and regulates both:

- the introductory price of a new patented medicine; and
- increases in the price of patented medicines after they enter the market.

This subsection describes the mechanisms by which the PMPRB regulates medicine prices through investigations and enforcement of price controls.

Reporting and gathering information on drug prices

The Patent Act requires a patentee of a medicine to notify the PMPRB of its intention to introduce a medicine into any Canadian market. If the PMPRB orders the patentee to provide information and documents respecting the intended price of the medicine, the patentee must comply.[146] This provides information for the PMPRB to assess the prices of new medicines as they are introduced into the Canadian market.

The PMPRB also monitors prices of patented medicines, and increases in those prices, on an ongoing basis after they enter the Canadian market. Under both the Patent Act and the Patented Medicines Regulations,[147] the patentee is required to report, within 60 days of the first sale of the drug, and every six months thereafter as long as the drug remains patented, the "publicly available ex-factory price" and average net transaction prices for the medicine sold to each class of customer in Canada and in each of the seven countries the PMPRB uses for price comparison purposes when assessing whether a Canadian price is excessive. Those seven countries are specified in the Patented Medicines Regulations as Germany, France, Italy, Sweden, Switzerland, the United Kingdom, and the United States.[148] The obligation on the holder of the Canadian patent to report this price information includes those cases where the patented medicine is being sold in another country by another company – as may be the case, for example, under a licensing agreement between the patentee and that other company.

In assessing whether a Canadian price for a medicine is "excessive," the PMPRB also considers the price in seven other developed countries: Germany, France, Italy, Sweden, Switzerland, the United Kingdom, and the United States.

There have been some problems with patentees complying with their filing requirements. In April 2002, the PMPRB reported that as of 31 January 2002, 48 percent of reporting patentees had not filed their semi-annual report on price and sales information.[149] It should be noted that the Patent Act grants the Board the powers and rights vested in a superior court.[150] It also allows for criminal proceedings against a patentee who contravenes or fails to comply with its filing requirements or any order of the Board regarding production of information: failure to comply with a Board order may result in an offence punishable on summary conviction, for which an individual may be liable to a fine of up to $5000 and/or six months' imprisonment, while a corporation may be liable to a fine of up to $25,000.[151] Where the offence is committed or continued on more than one day, the person who committed it may be convicted for a separate offence on each day it is committed or continued.[152] Enforcement options exist in law; it may be that the PMPRB needs to resort to them to ensure compliance.

Compliance and enforcement procedures

Under the Board's Compliance and Enforcement Policy, Board staff investigate concerns about possible excessive pricing. If Board staff conclude that a price appears to have exceed-

ed the Board's Excessive Price Guidelines (discussed in more detail below), the company is given an opportunity to make a Voluntary Compliance Undertaking (VCU), in which it undertakes to take steps to rectify the problem – such as reducing the price of its medicine, advising customers of the reduction as a result of the undertaking, offsetting excess revenues already received by making a payment to the federal government, and/or ensuring the price of its medicine remains within the Guidelines in future. A company's VCU must be approved by the Chairperson of the PMRPB, in which case the need for formal enforcement proceedings is avoided.

The PMPRB has the power to investigate allegations of excessive pricing by manufacturers of patented medicines.

If no VCU is forthcoming, or a company's VCU is not approved by the PMPRB Chairperson, the Board may commence formal proceedings into the matter of the drug's pricing by issuing a Notice of Hearing, which may ultimately lead to a formal order to remedy a price determined to be excessive. Before the Board makes any order to remedy excessive pricing, it must give the company a "reasonable opportunity" to be heard,[153] which shall be done through a public hearing unless the company convinces the Board that disclosure of information or documents in a public hearing will cause "specific, direct and substantial harm" to the company.[154] The federal Minister of Industry, another federal minister who may be designated by regulation, and health ministers of the provinces are entitled to receive notice of any hearing and to appear and make representations to the Board.[155] There is no statutory provision for representatives of patients/consumers affected by potentially excessive pricing to obtain standing in PMPRB hearings regarding manufacturers' prices. However, the Board "may," with the approval of the federal Cabinet, make "general rules" for regulating its "practice and procedure."[156] The Board's draft Rules of Practice and Procedure, including those that have been issued with Notices of Hearing to date, state that a person who claims an interest in the subject matter of the proceeding may apply to intervene.[157]

After a hearing, the PMPRB may order a pharmaceutical manufacturer to reduce its maximum price in Canada to a level that is not "excessive."

If, after such a hearing, the Board finds that a company is selling the medicine "at a price that, in the Board's opinion, is excessive," it may order the company to reduce its maximum price to a level the Board considers is not excessive.[158] The Board also has the authority to address past excessive pricing: if it finds that a company has sold a patented medicine at an excessive price, it may take steps to "offset" the amount of the excess revenues that the Board estimates were gained from selling the medicine at the excessive price. To do this, it may order the company to do one or more of the following:

- reduce the price at which it sells that medicine in any Canadian market, to such an extent and for such a period of time as the Board orders;
- reduce the price at which the company sells one other medicine; or
- pay a specified amount to the federal government.[159]

The Board's orders carry the same force and effect as those of the Federal Court of Canada, and a Board order may be made an order of that court or any provincial superior court.[160] The company must begin complying with a Board order within one month unless the Board grants a longer period of time to comply.[161] If the Board orders the company to pay an amount to the federal government, the government may enforce this debt by court order.[162] Contravening, or failing to comply with, an order by the Board to remedy excessive pricing is a criminal offence punishable on summary conviction; an individual is liable to a fine of up to $25,000 and/or one year of imprisonment, while a corporation may be fined up to

$100,000.[163] Where the offence is committed or continued on more than one day, the person who committed it may be convicted for a separate offence on each day it is committed or continued.[164]

This remedy of ordering the patentee to pay a sum to the federal government is in recognition of the fact that a significant portion of spending on patented medicines in Canada comes from the public purse that, through federal and provincial insurance programs, covers a significant portion of prescription drugs used by Canadians. As a condition of eligibility for federal transfer payments, provincial/territorial health insurance plans must pay for "medically necessary" drugs dispensed in hospitals. Furthermore, some federal programs pay prescription drug costs for certain populations (eg, veterans, First Nations and Inuit people, refugee claimants), and most provinces/territories provide some coverage of prescription drugs outside of hospitals for at least certain segments of the population, such as senior citizens and social assistance recipients on fixed incomes (and some provinces provide more extensive coverage). In some cases, provinces also operate supplementary public insurance programs, usually geared to beneficiaries' income in some fashion, that also cover a portion of the expenditures of those with "catastrophic" drug costs.

Therefore, the PMPRB has been granted the power to compensate the public purse for excessive drug pricing by ordering the manufacturer to make payments to the federal government. Under the Patent Act (s 103), the federal Minister of Health may enter into agreements with any province respecting the distribution of any monies collected as a result of offset orders made under the Act. "Pursuant to agreements between federal and provincial ministers of health, 100% of those funds are transferred to the provinces on a per capita basis in recognition of the fact that public funding now represents close to 50% of prescription drug spending in Canada and about 73% of total health spending."[165]

However, as noted above, for the last decade *private* spending has accounted for over half of all spending on drugs each year.[166] An offset that compensates government for spending on excessively priced drugs therefore only provides partial redress to Canadians; it does not address the excess costs incurred by private payers (including patients purchasing medicine out of their own pockets). There would be logistical and administrative difficulties in implementing a system that provided redress for individual private purchasers in the event of excessive pricing of a given drug, and it would likely be the case that only a handful of claimants might ultimately benefit in any given case. Nonetheless, it may be possible to design a streamlined administrative system for reimbursements to private purchasers who can establish proof of purchase at excessive prices; given the high proportion of private spending on pharmaceuticals, in the interests of fairness it is worth exploring the possible mechanisms that could be implemented.

RECOMMENDATION #1

Parliament should consider possible mechanisms for compensating private purchasers, particularly individual Canadians paying out of pocket, for prices of medicines determined to be excessive by the Patented Medicine Prices Review Board.

Should the remedial and enforcement powers of the PMPRB be further enhanced? As noted above, before the Bill C-91 amendments in 1993, the PMPRB had the power to remove a patentee's protection against compulsory licensing of a medicine patent in cases of excessive

pricing or failure to comply with statutory obligations or a Board order. While the special regime for compulsory licensing of pharmaceutical patents that existed in Canada until Bill C-91 in 1993 was not, in all its features, compatible with Canada's obligations under NAFTA and the TRIPS Agreement, those treaties do not contain a blanket prohibition on integrating compulsory licensing into domestic law – and indeed, as noted above, general compulsory licensing provisions continue to exist elsewhere in Canadian law.

As long as Canada complied with the various conditions attaching to compulsory licensing required under NAFTA (Article 1709) and TRIPS (Article 31), it would be entitled to allow for compulsory licensing of pharmaceutical patents. (It is arguable that Canada could also define this as an "exception" to patent rights as envisioned in TRIPS Article 30.) This could be re-inserted into the Patent Act by granting the PMPRB the authority to issue a compulsory licence as a remedy for excessive pricing by patentees. If necessary to avoid a trade challenge that such a regime "discriminates" against holders of *pharmaceutical* patents (as opposed to patents in other fields of technology), the same standard could be applied as is already found in the provisions of the Patent Act granting the Commissioner of Patents the authority to grant a compulsory licence in the event of "abuse" of patent rights.[167] In essence, this would maintain the same standard of protection in Canadian law for all patent holders, but would expressly grant the PMPRB, as an independent, quasi-judicial body and as the national entity tasked with preventing excessive pricing, the same authority currently enjoyed by the Commissioner.

RECOMMENDATION #2

Parliament should amend the Patent Act (section 83) to authorize the Patented Medicine Prices Review Board or, alternatively, the Commissioner of Patents, to issue a compulsory licence as a remedy for excessive pricing by a manufacturer of a patented medicine.

Determining "excessive" pricing: statutory factors

In deciding whether there is, or has been, excessive pricing of a patented medicine in any market in Canada, the Board is required by the Patent Act to first consider the following factors (to the extent that information is available):

- the prices at which the medicine has been sold in the relevant market;
- the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
- the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
- changes in the Consumer Price Index; and
- such other factors as may be specified in any regulations.[168]

If, *after* considering these factors, the Board is unable to determine whether a price is excessive, the Board *may* consider the costs of making and marketing the medicine, and "such other factors that may be specified in any regulations or the Board considers relevant."[169] If the Board does consider these additional factors, it may only take into account "the Canadian portion of the world costs related to the research" that led to the invention of the medicine or to the development and commercialization of that medicine. This "Canadian portion" of total

worldwide research costs is deemed to be the same proportion as the ratio of sales of that medicine in Canada to total world sales of the medicine.[170] In other words, Parliament intended "that Canadians pay their international share, but not more, of the cost of discovering and developing new medicines."[171]

It has been pointed out that, while PMPRB's guidelines on excessive prices (described below) have allowed average Canadian prices of patented medicines to fluctuate around the median of price levels in a "basket" of seven other developed countries used for international price comparisons, "R&D spending in Canada by patent-holding pharmaceutical companies tends to be at the lower levels of our foreign basket, not the median."[172] If Parliament's objective was that Canadians pay for their fair share of global pharmaceutical R&D, and not more, this discrepancy between prices and R&D levels in Canada would suggest that either pharmaceutical patentees must increase their Canadian spending on R&D, or that Canadian prices on patented pharmaceuticals should be lowered, perhaps through a revising of the criteria applied by the PMPRB and/or the countries it uses for international price comparisons. (The question of these price comparisons is discussed in more detail below.)

Parliament intended "that Canadians pay their international share, but not more, of the cost of discovering and developing new medicines."

– Harry Eastman, former PMPRB Chairperson, 1998

Determining "excessive" pricing: Board guidelines

Based on these price-determination factors set out in the Patent Act, and exercising its authority under the Act,[173] the Board has adopted Excessive Price Guidelines.[174] Although these Guidelines are not legally binding on patentees, patentees have generally complied with them. The Guidelines are applied by Board staff in reviewing the introductory prices of all *new* patented medicines entering the Canadian market, as well as in reviewing price increases by manufacturers on *existing* medicines already on the market. A review includes a comprehensive scientific analysis, often including advice from the Human Drug Advisory Panel (HDAP), and comparisons of the price and cost of the drug against other therapies and other countries. "The PMPRB reviews the average price of each strength of an individual dosage form of each patented medicine."[175]

The PMPRB applies its Excessive Price Guidelines in assessing whether a manufacturer's price on a patented medicine is excessive.

As articulated by the PMPRB itself, "in summary, the Guidelines provide that:

- prices for most new patented drugs are limited such that the cost of therapy for the new drug does not exceed the highest cost of therapy for existing drugs used to treat the same disease in Canada;
- prices of breakthrough [new] patented drugs and those which bring a substantial improvement are generally limited to the median of the prices charged for the same drug in other industrialized countries listed in the Regulations (France, Germany, Italy, Sweden, Switzerland, UK and US);
- price increases for existing patented medicines are limited to changes in the Consumer Price Index (CPI) [ie, inflation]; and
- [for all drugs], the price of a patented drug in Canada may, at no time, exceed the highest price for the same drug in the foreign countries listed in the Regulations."[176]

The following subsections describe the price controls applied for (1) new drugs and (2) existing drugs, and then (3) the international price comparison applied to the price of all drugs, whether new or already existing on the Canadian market.

Assessing the introductory prices of new drugs

An intergovernmental committee has recently highlighted the significance of controlling the prices of new patented medicines:

> PMPRB's review[s] of introductory prices of new patented drugs are particularly important. About 80 new patented drug products come on the market every year. In 1997, newer drugs, on the Canadian market for five years or less, accounted for over half of the sales of patented drugs.… [A] full analysis of prices requires not only an examination of price changes but also an examination of price levels. The price of a given medicine at any point in time (ie, its price level) is a function of both its introductory price and its price increases following introduction (ie, its price trend). Analysing price levels, and in particular introductory prices, is important given the dominant role newer medicines play in drug plan spending.[177]

"Analysing price levels, and in particular introductory prices, is important given the dominant role newer medicines play in drug plan spending."
– Federal/Provincial/Territorial Committee Pharmaceutical Issues Committee, 1999

The PMPRB's experience also shows the need for monitoring of manufacturers' introductory prices. In 2002, 94 new patented drug products were introduced to the Canadian market. As of the end of March 2003, of the 60 that had been reviewed, about one-quarter were priced at levels apparently exceeding the Guidelines, and therefore investigations were commenced.[178]

The test to be applied in determining whether the introductory price for a new drug is excessive depends on how the drug is categorized. The Guidelines classify each new drug into one of three categories, and then apply the relevant tests. The three categories are:

- Category 1: new formulations of an existing medicine;
- Category 2: new drug products representing a therapeutic "breakthrough" or "substantial improvement" over existing products; and
- Category 3: a new drug or new dosage form of an existing medicine providing moderate, little, or no improvement over existing medicines.

A review of PMPRB's categorizations of new patented drugs over a recent five-year period showed that "Most new drugs do not offer any significant improvement over existing therapies. Out of 455 new patented drugs introduced into Canada from 1996 to 2000 only 25 were major improvements or breakthroughs."[179] This means that about five percent of the new drugs over this period were major improvements or "breakthroughs."[180] Data from the PMPRB's most recent annual report indicate that over the last five years, breakthrough drugs have accounted for between 8 and 24 percent of "new active substances" patented in Canada and entering the Canadian market; in each year, over three-quarters of the new active substances were Category 3 drugs offering moderate, little, or no therapeutic advantage over existing drugs.

Category 1: new formulations of existing medicines

For "new" drug products that are new formulations of existing medicines (eg, a different release formulation such as a buffered coating), the PMPRB applies a *reasonable relationship test*: the introductory price will be presumed to be excessive "if it does not bear a reasonable relationship to the average price" of other versions of "the same medicine in the same or comparable dosage forms."[181] In other words, for a "new" drug that is merely a

reformulation of an existing drug, the price of the new formulation should not be higher than other formulations of the same strength.

The Board may not consider this *reasonable relationship test* adequate or appropriate if, for example, the new formulation "has a therapeutic use or dosage regime that differs materially from the other [versions] of the same or comparable dosage forms of the medicine."[182] In such a case, it may conduct a *therapeutic class comparison test* to determine if the introductory price of the new formulation is excessive. This test

> compares the price of the drug product with the price of drug products that are clinically equivalent and sold in the same market at prices the Board considers not to be excessive.… The Board will make these price comparisons in terms of the price per day or price per course of treatment, whichever is more applicable. Generally, the price per course of treatment will be applicable to acute indications, whereas price per day (based on maintenance dose) will be applicable to chronic situations.[183]

Category 2: "breakthrough" drugs

New drugs fall into Category 2 if they are "breakthrough" drugs or offer a "substantial improvement" over comparable existing drugs. While these drugs are generally only a small minority of new drug products in a given year, they are often the most costly. Furthermore, breakthrough drugs "may establish new therapeutic classes and often set the standard for introductory prices of all subsequent (non-breakthrough) drugs within their therapeutic class,"[184] having a knock-on effect on costs to consumers.

Most new drugs do not offer any significant therapeutic improvement over existing drugs. Data from the PMPRB show that, over the last five years, only 8 to 24 per cent of "new active substances" patented in Canada were "breakthrough" drugs.

Under the PMPRB's current Guidelines, the introductory price of "breakthrough" drugs can be as high as either of the following, whichever is the *higher* price:

(1) the median of the prices charged for the same drug in the seven countries used by the PMPRB in its *international price comparison test*, or
(2) the highest Canadian price among all comparable drug products, using the *therapeutic class comparison test*.

However, as noted below, no patented drug can ever have a Canadian price that exceeds the highest international price, so this operates as an absolute ceiling on any price for a breakthough/substantial improvement new drug. In other words, even if the Canadian introductory price is higher than the median international price, whatever the prices being charged already in Canada for comparable drugs, the new drug's price can never exceed the highest international price.

The PMPRB has announced that it plans to review the appropriateness of the "median price" test for Category 2 drugs.[185] In late 2002, the PMPRB's working group on price review issues recommended, with regard to price reviews for Category 3 drugs (see below), that greater consideration should be given to the "relative value" of drugs. (The working group did not define what was meant because of lack of agreement between industry and non-industry members.) The PMPRB has committed to undertake further analysis on this point.

Presumably that work could also inform how it reviews the prices of Category 2 drugs as well, since the "value" of a drug is an equally relevant consideration for both "me-too" drugs (Category 3) and for breakthrough drugs (Category 2).

RECOMMENDATION #3

In its upcoming analysis of how to define the "value" of drugs, the Patented Medicine Prices Review Board should consider the relevance and applicability of that analysis for the permissible pricing of Category 2 new drug products (breakthrough drugs).

Category 3: drugs offering moderate, little, or no therapeutic advantage

Category 3 drugs are "new chemical entities" that provide "moderate, little or no therapeutic advantage" over comparable existing drugs, and are sometimes referred to as "me-too" drugs. The maximum introductory price allowed by the PMPRB for one of these new products is the highest price of all comparable products, based on the *therapeutic class comparison test*. If it is inappropriate or impossible to conduct this test, the Board "will give primary weight to the median of the international prices" charged by the manufacturer for that product in the seven comparator countries, using the *international price comparison test*.[186]

As of 1997, Category 3 drugs accounted for the largest sales and number of newer drugs over the preceding decade, and in 1997 itself accounted for about 47 percent of total sales of patented drugs, close to four times the percentage represented by Category 2 drugs.[187] In 1999, the F/P/T Pharmaceutical Issues Committee reported that, according to PMPRB data, almost one-quarter of the Category 3 drugs continued to be priced above median international levels. The Committee therefore suggested that the PMPRB consider changing its guidelines to ensure that the introductory prices of non-breakthrough drugs do not exceed the median international price. Adding this rule would mean that the introductory price in Canada for a new drug that offers moderate, little, or no therapeutic advantage over existing medicines would be capped at the *lower* of:

(1) the highest Canadian price of comparable drugs; and
(2) the median international price being charged by the manufacturer for the new product.[188]

Another alternative would be to cap the introductory price of a Category 3 new drug product at the median Canadian price of all drugs in the same therapeutic class or, alternatively, the average of Canadian prices of all drugs in that class.

In October 2002, a PMPRB working group reported on its review of the Guidelines for new drug products in Category 3. The working group primarily approved of the Board's current practice, and did not recommend substantive changes to the Guidelines. However,

> On the issue of the price test, … the Working Group indicated that it would be appropriate for the Board to consider the relative value of a new drug to a greater extent than it currently does in the category 3 Guidelines, but they did not go so far as to define what is meant by "value" and how "value" could be linked to price limits.[189]

The working group did identify that determining the "value" of a new drug could take into account factors such as the drug's efficacy, effectiveness, side effect and safety profile, contribution to scientific knowledge base, future effects on incentives to innovate, and therapeutic choice.[190] In response, and given the range of comments raised during its previous consultations, the PMPRB has decided to further research and analyze this area, including clarifying what is meant by "value."[191]

RECOMMENDATION #4

The Patented Medicine Prices Review Board should revise its Excessive Price Guidelines to limit the introductory price in Canada for Category 3 new drug products (those that offer moderate, little, or no therapeutic advantage over existing medicines) to either (i) the median (or, alternatively, the lowest) international price charged by the manufacturer for the same product in comparator countries, or (ii) the highest price in Canada among all therapeutically comparable products, whichever of these two prices is *lower*. Alternatively, the Guidelines could be revised to cap the introductory price for a Category 3 product to either the median or the average of Canadian prices for all the drugs in the same therapeutic class. Consideration should be given to further differentiating between new drugs such that those offering "little or no therapeutic advantage" might be limited to an introductory price that is the lowest Canadian price of existing drugs in that therapeutic class, while those new drugs that offer "moderate" therapeutic advantage might be allowed a maximum introductory price that is either the median or the average of prices of existing drugs in that therapeutic class.

Regulating the prices of existing drugs

Once a new drug has entered the Canadian market and had its introductory price reviewed by the PMPRB, the Board's jurisdiction to regulate its price continues over the life of the patent term and the manufacturer has ongoing obligations to report its price on that drug to the Board every six months. This reporting allows the Board to cap price increases by the manufacturer while it enjoys market exclusivity because of its patent on that product.

Under the Guidelines, the increase in the Canadian price of a patented medicine is presumed to be excessive if it exceeds the rate of inflation as measured by the increase in the Consumer Price Index (CPI). The Guidelines limit price increases to increases in the CPI measured over a three-year period. However, the Board will accept one-year price increases based on forecast changes in the CPI, as long as they do not exceed 1.5 times the forecast change;[192] this cap prevents a manufacturer from trying to "catch up" in one year on unused price increases from previous years. If the patent holder ceases to sell a patented drug in the Canadian market, but that drug is sold by another (eg, through a licensing agreement transferring marketing rights to another company), the Guidelines continue to apply to the new seller for the duration of the patent term.

But as some analysts have pointed out, this approach may be comparing apples and oranges:

> For *existing* patented drugs, the PMPRB uses the Canadian consumer price index (CPI) as the basis for limiting price increases. However, since the CPI is based on retail consumption, some find it curious that factory-gate prices are limited using this index.[193]

This approach – allowing manufacturers' factory-gate prices to increase at the rate of *retail* prices – thus potentially "frontloads" an increase into the base price, which is then further marked up along the wholesaling and retail chain, compounding over time the inflation of

final drug prices. (While the potential for this effect exists, it should also be noted that in practice the PMPRB's price index for patented medicines has, to date, risen less than the CPI.)

The Patent Act does not mandate that the PMPRB must directly and strictly apply the CPI as the sole cap in limiting the price increases of patented medicines; it merely says that the Board, in making its determinations regarding excessive pricing, "shall take into consideration … changes in the Consumer Price Index."[194] It is up to the Board to decide how it will take this factor into consideration. Indeed, in its Guidelines as currently formulated, the Board does not strictly limit price increases precisely to the CPI in a given year, but rather compares price increases with CPI increases over a three-year period and has determined that, in any given year, the maximum price increase may be up to 1.5 times the forecast change in the annual CPI.[195] The point is that it is open to the PMPRB to revise its Guidelines on price increases to take changes in the CPI into consideration in a different fashion. Therefore, it is open to the Board to revise how it uses an index based on retail price inflation to control the inflation in manufacturers' factory-gate (ie, non-retail) prices.

RECOMMENDATION #5

The Patented Medicine Prices Review Board should review the appropriateness of using an index based on retail price increases to limit the increases in factory-gate manufacturers' prices on patented medicines.

International price comparisons applied to all patented drugs

In addition to the specific price tests applied to *new* drugs and *existing* drugs already on the Canadian market, under the PMPRB's Guidelines the price of any patented medicine sold in Canada, whether new or existing, "will be presumed excessive if it exceeds the prices of the same medicine sold in all" of the seven comparator countries.

It should be remembered that, under the Patented Medicines Regulations, the seven countries to be used by the Board for international price comparisons in controlling Canadian prices of patented drugs are Germany, France, Italy, Sweden, Switzerland, the United Kingdom, and the United States.

Generally, in conducting international price comparisons, the PMPRB will compare the manufacturer's Canadian price of the drug under review with the simple average of the prices the manufacturer is charging for the same strength and dosage form in each of these seven comparator countries.[196]

However, questions have been raised about the details of the international price comparison test used by the PMPRB in controlling Canadian prices of patented drugs. For instance, Canada lags behind many of these countries in the average time it takes to approve a new drug for marketing; this means prices are often set in comparator countries before they are in Canada. This is of particular concern in the case of countries that generally have higher pharmaceutical prices, such as the US and Germany (which lack price regulation). Several researchers have also pointed out that the Board's approach to international price comparisons may produce artificial results:

> With respect to the prices of *new* drugs, the PMPRB base their factory-gate (as opposed to retail) price comparisons on international prices in an effort to deter-

> mine whether or not prices are reasonable. Since the industry is strongly multinational, this may be an artificial form of price control.[197]

Indeed, as one commentator has pointed out:

> Regarding drugs for which no equivalent or similar product exists – the true "innovation" – there will be nothing to guide the Board except the international price of the drug. This is as a result of the somewhat limited jurisdiction of the PMPRB, which is obliged to measure the reasonableness of new products relative to the prices charged for those patented drugs worldwide. Thus, while Canadians will therefore pay no more – and indeed, often less – than people in other countries, the reasonableness or otherwise of drug prices is – to some extent – dependent on the prices the industry charges internationally. Thus all the industry really is obliged to do is to ensure that they treat Canada no worse than other countries in setting prices. Consistency in pricing does not eliminate the possibility of consistent profiteering.[198]

In September 1998, the PMPRB reported on consultations with its stakeholders, including that

> among other things, many were concerned about the … countries used for comparison purposes.… Some stakeholders expressed concerns about comparing drug prices in Canada to those in the US. Recently, the US Department of Veterans Affairs (DVA) has begun publishing information on the prices it pays for drugs. The Board has decided that patentees should be filing information on their prices to the US DVA and the Board is consulting with stakeholders on how it should use that information in conducting international price comparisons.[199]

In 1999, the Federal/Provincial/Territorial Pharmaceutical Issues Committee reiterated concerns about the appropriateness of the basket of seven countries used in price comparisons:

> While it may be appropriate to use median international prices to establish limits on introductory prices of new medicines, the impact of such a rule may depend entirely on which countries are applied.… It is important to ensure that the countries included in this basket for price review purposes be appropriate and support health, industry, and trade policy objectives. Criteria that may be used to assess the appropriateness of comparator countries include health status, comparability of health care systems, standards of living, research and development spending, and similarity of medicines available in these countries to those available in Canada.
>
> By way of example, for the research and development (R&D) criteria, a recent analysis comparing the ratios of R&D expenditures to domestic sales in these countries … suggests that research spending in Canada, while greatly improved over the last decade, ranks behind all countries used by the PMPRB for price review purposes, with the exception of Italy. This result may not be unexpected given that the countries included in this comparison are headquarters to the large brand name pharmaceutical companies. It is important to note, however, that the R&D expenditures are not part of the Board's Excessive Price Guidelines used to assess the appropriate pricing level of a patented product.

> This comparison demonstrates there is merit in conducting an in-depth examination of the current basket of countries used by the PMPRB to review prices of patented medicines to ensure its continuing appropriateness to Canadian policy objectives.
>
> Finally, the PMPRB applies this basket in order to have breakthrough medicines priced no higher than the median of prices in these countries. It is observed that how this basket of countries is applied by the Board is an equally important issue that merits careful examination by the PMPRB in its continuing review of its role, function, and methods.[200]

One leading expert on Canadian pharmaceutical policy has questioned the basis on which these countries were selected by the federal government when it introduced the Patented Medicines Regulations in 1994:

> Comparing Canadian prices to those in the seven selected countries might not tell the complete story about the cost of drugs in Canada relative to other industrialized countries. It is interesting to speculate how the comparison group of countries was chosen. None of the documents that I have examined ever mention the criteria used to select this specific group of seven countries, but it is relatively common knowledge that prices in Germany, Switzerland and the United States tend to be among the highest in the industrialized world. Choosing a different group of countries could dramatically alter the Canadian introductory price.
>
> A recent survey by Consumers International gives some hints of the magnitude of the differences between countries. Prices for 13 common brand name products were gathered from a group of developed countries. The average price in France, Germany, Italy, Switzerland, United Kingdom and United States (six of the seven countries that the PMPRB uses) was more than 50% greater than in another group of six developed countries: Australia, Belgium, Finland, Greece, The Netherlands and New Zealand. While the survey covered only a small number of products and has other methodological flaws it does suggest that perhaps the comparison group of countries the PMPRB uses was chosen specifically to allow relatively high introductory Canadian prices.
>
> These high introductory prices are one reason that the cost of a prescription has risen dramatically since 1987. The average price per prescription (excluding the dispensing fee) in Ontario has risen from $12.48 in 1987 to $24.09 in 1993, a rise of 93% compared to an increase in the Consumer Price Index of 23.1%. Over half the rise in prescription costs is due to the introduction of new drugs, specifically new (since 1987) patented medications. Prices for prescriptions containing new patented medications rose at a rate of 13.4% per annum since 1988 compared to 7.6% for prices for prescriptions using nonpatented drugs.[201]

"[T]here is merit in conducting an in-depth examination of the current basket of countries used by the PMPRB to review prices of patented medicines to ensure its continuing appropriateness to Canadian policy objectives."

– Federal/Provincial/Territorial Pharmaceutical Issues Committee, 1999 Report

Lexchin has also questioned whether the seven comparator countries are representative of countries belonging to the Organization for Economic Cooperation and Development (OECD) as a whole:

> To answer this question we need to turn to an economic measure called purchasing power parities (PPPs), rates of currency conversion that equalize the purchasing power of different currencies. When they are used to compare drug prices in the 7 reference countries that the PMPRB uses with those in all 24 OECD countries, it turns out that prices are more than 6% higher in the PMPRB's reference group of countries.… Even if the Board has had an effect, introductory prices are kept artificially high because of the PMPRB's definition of an international price.[202]

While the patented pharmaceutical industry dislikes the presence of price controls at all, they have argued that Canadian prices should be permitted to fall anywhere within the range of prices charged among the seven comparator countries. But even using the median international price standard, it is questionable whether the current guidelines are appropriate; at least the list of countries used for comparisons should be reformed. As the PMPRB's executive director has noted:

> Some [non-industry stakeholders] argue that the median allows too high a price because of inclusion of the US. The US is the only country in the basket without significant public drug coverage; there is also considerable price dispersion in that country; confidential discounts complicate efforts to make a meaningful price comparison. These stakeholders also often argue that the basket should include other countries that have more similarities to Canada – countries like Australia and New Zealand. These stakeholders also point to evidence that R&D spending in Canada tends to be at the lower levels of our foreign basket, not the median.[203]

Indeed, the PMPRB's most recent annual report indicates that average Canadian prices of patented medicines have been slightly below the median international prices for the decade since the 1993 amendments to the Patent Act (with the exception of 2002, in which they were about one percent higher).[204] Meanwhile, a PMPRB study found that, in terms of total spending on pharmaceutical R&D, Canada continues to rank behind other industrialized countries (most of whom also have pharmaceutical price controls of various sorts) by several measures: "Most importantly, the ratio of R&D to domestic sales in Canada remained well below values observed in Europe and the US. The Canadian ratio stood at 10.1% in 2000, whereas the aggregate ratio for the seven countries [used by the PMPRB for international drug price comparisons] was 19.0%. Among these countries, only Italy had a lower ratio than Canada in 2000."[205] In other words, patent-holding companies are spending on R&D in Canada only just over half of what they are spending on average in the seven other countries Canada uses to assess the reasonableness of Canadian drug prices.[206]

With the exception of one year, average Canadian prices of patented medicines have been slightly below the median international prices for the decade since the 1993 amendments to the Patent Act.

The PMPRB study also compared the Canadian R&D-to-sales ratio to the same ratio in a number of smaller European countries (ones not used by the PMPRB for international price comparisons) and again found it to be "well below the average value" in these countries.[207] The PMPRB has concluded that "Canada accounts for a share of total pharmaceutical R&D that is roughly one-half of its share of total pharmaceutical sales."[208]

When Bill C-91 was brought into force in 1993, in exchange for the almost complete abolition of compulsory licensing and the increased profits that would flow from 20-year

patent-protected periods of market exclusivity, the commitment was made by patent-holding companies that they would increase R&D spending in Canada to 10 percent of sales. Most recent figures indicate that industry has more or less achieved this level. However, this is but one part, albeit important, of the story, and there are legitimate concerns that remain about the level of industry's commitment to R&D in Canada in exchange for profits made here. In 2001, the ratio of R&D expenditures to sales revenues for the patented pharmaceutical industry as a whole was 9.9 percent, and for member companies of Rx&D, the industry association for patent-based pharmaceutical companies in Canada, the ratio was 10.6 percent. These figures prompted the PMPRB to observe that the ratios "were lower in 2001 than in any year since 1992"[209] (when Bill C-91 was enacted). In 2002, the PMPRB reports that the ratio for the patented industry as a whole remained unchanged at 9.9 percent, while it had worsened for companies that are Rx&D members, dropping down to 10.0 percent, again prompting comment from the PMPRB that "the R&D-to-sales ratios for the past three years have been lower than any year since 1992."[210] It should also be noted that, according to the Conference Board of Canada, Canada offers "one of the most competitive tax systems for research and development (R&D) in the world,"[211] but "the commitment of the business sector to R&D – as measured by the proportion of industry-financed R&D (excluding public funds) – is growing, but is still low by international standards."[212]

Spending on R&D in Canada by patent-holding pharmaceutical companies is falling well below the international median. Therefore, it is difficult to justify rules that produce Canadian prices clustered around the median of international prices. Canadians are paying more than their fair share of global pharmaceutical R&D.

Recall as well that, as noted above, Parliament's objective when enacting Bill C-91 in 1993 was to ensure that Canadians pay their fair share of global pharmaceutical R&D, and not more.[213] Given that spending on R&D in Canada by patent-holding pharmaceutical companies is falling well below the median, it seems difficult to justify international price comparison rules that produce Canadian prices clustered around the median of international price levels. As long as this discrepancy continues, Canadians are paying more than their fair share of global pharmaceutical R&D – a situation that is not to Canadians' benefit nor, given that Canadians account for only 2.6 percent of the world pharmaceutical market, one that seems to provide any significant incentive to spur overall global levels of investment in R&D by patent-holding pharmaceutical companies.

RECOMMENDATION #6

The Patented Medicine Prices Review Board, and the federal departments of Health and Industry, should identify and assess options for amendments to the Patent Act, the Patented Medicines Regulations, and/or the Board's Excessive Price Guidelines that would result in a closer correlation between overall Canadian price levels for patented medicines and levels of spending in Canada by patentees on pharmaceutical R&D.

The PMPRB has indicated that over 2003-2004, it will review the Excessive Price Guidelines with regard to three aspects of international price comparisons: (1) the appropriate test to be used when a drug is sold in fewer than all seven of the comparator countries;

(2) the appropriateness of the "highest price rule"; and (3) the methodology for calculating the average price in a foreign country.[214] It does not appear, however, that the planned review will examine whether the basket of seven countries set out in the Patented Medicines Regulations are appropriate and desirable comparators for the purposes of regulating Canadian medicine prices.

RECOMMENDATION #7

The Patented Medicine Prices Review Board should undertake a review, involving public consultation (including with consumer representatives), of the basket of countries currently used for the purposes of international price comparisons. The review should identify the relevant bases on which these countries are similar and dissimilar, for the purpose of comparing pharmaceutical prices, to Canada. The review should also identify other OECD countries not currently included on the list of countries for price comparison purposes that could be suitable for inclusion on this list and assess the relevant similarities to and differences from Canada. The report of that review should be made available in draft form for public comment and then finalized. Based on the conclusions of that report, the Patented Medicine Prices Review Board should then consider whether to recommend to the Minister of Health and the federal Cabinet that the Patented Medicines Regulations be amended to revise accordingly the list of countries used for international price comparisons.

Pricing of HIV/AIDS drugs

To date, activists with the Canadian Treatment Action Council (CTAC), a national organization directed by people living with HIV/AIDS working on access to treatment and health care, have sought to contain the introductory price of four antiretroviral drugs. The first two cases have been unsuccessful; the latter two remain outstanding at the time of writing.

Efavirenz

Efavirenz is a non-nucleoside reverse transcriptase inhibitor (NNRTI) for the treatment of HIV-1 infection. NNRTIs such as nevirapine and delavirdine already existed on the Canadian market, at an annual cost of about $3000 per patient. Before efavirenz (brand name Sustiva) had received final approval for marketing in Canada, DuPont Pharma advised the PMPRB that it intended to charge an introductory price of about $5000 for a year-long course of treatment for this new NNRTI, obviously considerably higher than the prices of existing NNRTIs and in the range of prices for protease inhibitors (PIs), another class of antiretrovirals for treating HIV, which sell at $5000-$6000 annually per patient. This represented the first time an HIV drug in Canada was priced substantially outside the established range for its own class of drugs.[215]

The PMPRB had provided non-binding advice to DuPont Pharma that its intended introductory price for its drug efavirenz would be acceptable. In July 1999, CTAC filed a formal complaint regarding this advice and the manufacturer's intended price.[216] The BC Centre for Excellence in HIV/AIDS also objected to DuPont's pricing strategy. The BC Centre for Excellence in HIV/AIDS is the sole public payer for HIV/AIDS drugs in that province and

operates under a capped budget. It determined that it would restrict its purchase of efavirenz to supply it only to patients who were already on the drug as a result of the company's "expanded access" program pending its marketing approval[217] or for "salvage therapy" (ie, when all other drug regimens have failed). The medicine was, therefore, effectively priced out of the hands of most other people living with HIV/AIDS in the province. Subsequently, with the patent still pending, the PMPRB advised DuPont that it should price efavirenz within the price range of existing NNRTIs in Canada. DuPont rejected the advice as non-binding and maintained its original, higher price.[218]

"Prices should be based on the costs to the manufacturer for research, development and manufacturing and should reflect a reasonable profit."

– Glen Hillson, AIDS treatment activist, 1999

In 2002, the PMPRB concluded its price review of efavirenz as a Category 3 new drug – ie, one providing moderate, little, or no therapeutic advantage over comparable medicines. DuPont, however, argued that efavirenz is more effective in combination therapy than even PIs and can be an alternative to them; it should therefore be allowed to price it at the level of protease inhibitors rather than at a price comparable to that of other, cheaper NNRTIs. The PMPRB accepted DuPont's argument that both NNRTIs and PIs could be used as appropriate "therapeutic class" comparators; therefore DuPont should be allowed to compare its efavirenz price not just to that of other NNRTIs, but also to PIs.

"We must not accept the notion that better drugs = higher prices. To do so would condone an upward spiralling of prices and even fewer people will have access to state of the art treatments than do now."

– Glen Hillson, AIDS treatment activist, 1999

This determination effectively disposed of CTAC's complaints. As discussed above, for Category 3 drugs, the PMPRB's Guidelines indicate the price will be excessive only if it exceeds both the prices in Canada of all comparable drug products *and* the prices of the same medicine in the seven comparator countries. Taking into account PIs as well as NNRTIs, DuPont's price for efavirenz was not "excessive" using these tests: it did not exceed the highest existing price for these medicines in Canada, and DuPont was charging even higher prices for efavirenz in each of the seven other countries.[219]

While there is clinical evidence to support DuPont's claim of greater efficacy, treatment activists argue that:

> From a consumer perspective these arguments about whose pill is better are completely irrelevant to any rational and responsible discussion about pricing. Even if, for the sake of argument, we accept DuPont's assertions about the effectiveness of efavirenz, it hardly justifies their pricing strategy. This direction runs contrary to an intelligent philosophy of how pricing should work. Activists argue that prices should be based on the costs to the manufacturer for research, development, and manufacturing and should reflect a reasonable profit.
>
> We must not accept the notion that better drugs = higher prices. To do so would condone an upward spiralling of prices and even fewer people will have access to state of the art treatments than do now.[220]

Abacavir

In August 1999, CTAC filed a formal complaint with the PMPRB alleging that the introductory price charged by Glaxo Wellcome (now GlaxoSmithKline) on its patented drug abacavir (marketed under the brand name Ziagen) is excessive.[221] Abacavir is a nucleoside

reverse transcriptase inhibitor (NRTI) that Glaxo chose to price approximately 30 percent higher than other NRTIs.

As with efavirenz, the PMPRB classified abacavir as a Category 3 drug providing moderate, little, or no therapeutic advantage over comparable medicines. And as with efavirenz, the Board concluded that the evidence showed abacavir, although an NRTI, was an alternative to NNRTIs or PIs in combination therapy with other NRTIs. Therefore, it concluded that NNRTIs and PIs could be used as appropriate "therapeutic class" comparators, and so the price review of abacavir could take prices for these other classes of drugs into account. Again, this determination effectively disposed of CTAC's complaint. Taking into account Canadian prices for NNRTIs and PIs, the price of abacavir was higher than the prices of all other NRTIs, higher than one NNRTI, and lower than the prices of all PIs. Glaxo's Canadian price for abacavir was the second lowest among the comparator countries.[222]

Didanosine and lopinavir

In January 2002, CTAC also filed formal complaints with the PMPRB regarding the prices of the Videx EC (an "enteric coated" formulation of the pre-existing drug ddI, an NRTI manufactured and patented by Bristol-Myers Squibb) and Kaletra (the PI lopinavir, patented by Abbott Laboratories).[223] In both cases, CTAC alleges that the price set by the manufacturer fails the "reasonable relationship" test under the PMPRB's Excessive Price Guidelines, as the price is considerably higher than other medicines in the same class of drugs used to treat HIV-1 infection. [At the time of writing, both complaints remained outstanding.]

Revising the Excessive Price Guidelines?

Based on its experience to date with the pricing of Sustiva (efavirenz) and Ziagen (abacavir), CTAC has pointed to the dangers of basing prices of drugs on the comparative potency of one drug vis-à-vis another, regardless of its therapeutic class or R&D costs, including the possible outcome that access to some drugs will be denied to Canadians. They point out that provincial drug formularies will resist adding new drugs in a class where cheaper, approved drugs already exist, but people living with HIV/AIDS need all drug options because a one-size-fits-all approach does not work in treating this disease.[224] To put it simply: "How can we possibly accept the notion that if these new drugs are better, they should cost more? All that means is that fewer of us than now will have access in the future to the drugs we need."[225] Therefore, CTAC has recommended that drug pricing should be based on the actual costs of R&D, manufacturing, and other relevant costs plus a reasonable profit.

Canada's system for regulating drug prices could be improved by creating a mechanism for interim or conditional pricing of a new medicine, with the price automatically reviewed at appropriate periods as a more complete picture of its therapeutic merit emerges.

CTAC has also pointed out that the data used by the PMPRB in considering the potential therapeutic benefit of a new antiretroviral and determining whether it should be allowed to command a higher maximum price is incomplete and does not fully reflect all the factors that should be considered in regulating prices. Clinical trial data relied upon often come from trials that are of relatively short duration and include small numbers of participants who are not necessarily representative of the actual population that will use the drug. Consequently, longer-term, more generalizable data on the durability and benefits of the drug, and on long-term toxicities, are not available.[226]

In all probability, Canada's system will continue, in setting maximum "non-excessive" prices for new patented drugs, to take the therapeutic value of a drug into account to some

degree. This suggests the system could be improved by creating a process for interim or conditional pricing of a new medicine upon its introduction to the Canadian market, which price would be automatically reviewed at appropriate periods over the life of the drug as a more complete picture of the drug's merits, and its merit relative to comparator drugs, emerges. The PMPRB could be empowered to implement such a scheme and the periodic reviews, with consequent authority to revise the maximum "non-excessive" price upward or downward as warranted.

RECOMMENDATION #8

The Patented Medicine Prices Review Board should revise its Excessive Price Guidelines such that maximum non-excessive prices allowed to manufacturers of patented medicines bear a reasonable relationship to the cost of their development and manufacture, and allow a "reasonable" profit margin beyond those costs.

RECOMMENDATION #9

Parliament should amend the Patent Act and/or the Patented Medicines Regulations to provide for a mechanism for interim or conditional pricing of a new patented medicine upon its introduction to the Canadian market, which price would be automatically reviewed at appropriate periods over the life of the medicine to take into account new evidence regarding its therapeutic merits and its merit relative to comparator medicines. The Patented Medicine Prices Review Board should be given the mandate and necessary powers to conduct such reviews and to revise the maximum "non-excessive" price of a medicine upward or downward as warranted by such new evidence.

Jurisdictional issues regarding PMPRB regulation of drug prices

Under the Patent Act, the PMPRB's jurisdiction is limited to regulating prices charged by *manufacturers* of all *patented* medicines, both prescription and non-prescription (over-the-counter, OTC). This includes regulating the price of each dosage form in which a patented medicine is sold in Canada. The PMPRB also has jurisdiction to regulate the prices of generic copies of patented medicines if they are marketed or distributed in Canada under a licensing arrangement with the patent holder (ie, entering into a voluntary licence arrangement with a generic or other company does not evade the Board's authority to control the price of the medicine during the patent term).

The price charged by the manufacturer is often referred to as the "factory-gate" or "ex-factory" price, which is:

> The price established for the first sale of the product to distributors, wholesalers, hospitals and pharmacies. This price always excludes sales taxes, and wholesale mark-ups when the wholesale function is not carried out by the patentee. The factory gate price is generally the "list price" for medicines. The factory gate price can also be the price that is agreed on between the patentee and the regulatory body of the country [in] which it is sold by the patentee.[227]

The PMPRB cites estimates that the manufacturer's factory-gate price accounts for about 65 percent of the final price paid by consumers;[228] hence the importance of government regulation at this point in the market.

However, it is important to understand that the PMPRB has no jurisdiction over the prices of non-patented drugs, including generic drugs sold in Canada under compulsory licence.[229] Nor does the PMPRB have any authority to control mark-ups on the factory-gate price by drug wholesalers or retailers (eg, retail pharmacies), which can significantly increase the final price paid by the purchaser. Nonetheless, prices of non-patented drugs are still influenced by provincial and hospital formularies and reimbursement policies. Whether the prices of non-patented drugs should be subject to regulation by the PMPRB is discussed in more detail below.

The PMPRB has authority to regulate prices charged by manufacturers of patented medicines. It has no jurisdiction over the prices of non-patented drugs, over mark-ups to the price added by wholesalers or retailers, or over pharmacists' dispensing fees.

Similarly, pharmacists' dispensing fees, another factor that can add significantly to the final cost of a drug to the purchaser, are also beyond the purview of the PMPRB. As a matter of constitutional division of legislative authority, these matters are within the jurisdiction of provincial governments to regulate.

Challenges to PMPRB's jurisdiction over patented medicines

Patent-holding companies have attempted to avoid the jurisdiction of the PMPRB over their prices in several ways. These attempts have been largely unsuccessful. The Board itself has been assertive in staking out its jurisdiction, guided by the historical understanding that Canada's legislative scheme for price controls has been substituted for a previous regime of compulsory licensing and therefore should strive to achieve a similar level of consumer protection. Canadian courts have generally approved of this approach on those few occasions where they have been called upon to decide challenges to the PMPRB.

Interpretation of what constitutes a "medicine"

First, in the 1997 *ICN Pharmaceuticals* case, a patent holder argued that the PMPRB lacked jurisdiction because the patented invention did not "pertain to a medicine," as required by the Patent Act. Under the Act, the PMPRB has jurisdiction to regulate the price of any "invention pertaining to a medicine," and the Act states that "an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine."[230] In this case, the medicine sold under patent was Virazole, for the treatment of respiratory infections in children. The only active ingredient is ribavarin, which was patented by ICN. The Federal Court of Appeal agreed with ICN that "there must be a rational connection or nexus between a patent and the medicine in question in order for the Board to acquire jurisdiction," but also found that "because of the broad scope of the terms 'pertaining to' and 'pertains to' as used in [the Patent Act], the nexus can be one of the merest slender thread."[231] This purposive approach, giving a liberal construction to the term "medicine" in the statute so as to preserve the statute's underlying objectives, should effectively close down this avenue for evading the Board's jurisdiction.

The question of what constitutes a medicine, and whether a patent pertains to a medicine, was again raised in 1999 in the *Hoechst Marion Roussel Canada* case (also known as the Nicoderm case).[232] There, HMRC argued that its patented "transdermal patch" containing nicotine, used to assist in quitting smoking by partially relieving symptoms of nicotine withdrawal, was not subject to the Board's jurisdiction. HMRC argued that the Nicoderm patch was not a medicine but a "delivery device for the administration of nicotine." HMRC point-

ed to a court decision (*Glaxo* v *Novopharm*) that inhalers used to administer medicines in aerosol form were medical devices, and not medicines,[233] and argued that its nicotine patch was similar. The Board rejected this argument, noting that:

Patent-holding companies have been largely unsuccessful in their attempts to avoid the jurisdiction of the PMPRB to regulate the prices of their products.

- the Federal Court of Appeal had stressed in *ICN Pharmaceuticals* that the term "medicine" in the Patent Act "was to be interpreted broadly and in its ordinary sense";
- the patch could also be analogized to an ointment delivering topical medications;
- HMRC itself referred to Nicoderm as a "medicine" in the labelling on its packaging and in its product monograph;
- companies holding patents on other nicotine transdermal patches, and similar patches delivering other drugs, had considered their patches to be medicines subject to the PMPRB's jurisdiction;
- Health Canada had considered Nicoderm a drug, and not a medical device, in determining to approve it for sale in Canada, and regulated it as such; and
- the decision of the Federal Court of Appeal in the *Glaxo* case was about the interpretation of the term "medicine" in a different legislative scheme (dealing with the approval of medicines for marketing in Canada), and the same court had, in its *ICN Pharmaceuticals* decision, made it clear that the interpretation of the word "medicine" in that other scheme was not relevant to the interpretation of the same word under the Patent Act for the purposes of Canada's price-control scheme.

The Board therefore found that the Nicoderm patch itself constituted a "medicine" and that the patents held by HMRC that were at issue here "pertained" to that medicine. It therefore asserted jurisdiction to regulate HMRC's price for the Nicoderm patch in Canada. HMRC's application to the Federal Court for judicial review of this decision remained outstanding at the time of writing.[234]

RECOMMENDATION #10

Depending on the outcome of current litigation over the definition of a "medicine" in the Patent Act, which definition controls the jurisdiction of the Patented Medicine Prices Review Board to regulate patented-medecine prices, Parliament should amend the Patent Act to expressly affirm and clarify the broad scope of this term to preserve the objective of preventing excessive pricing by manufacturers of any invention pertaining to a medicine. By the same token, Parliament should also amend the Patent Act to extend the scope of the Board's jurisdiction to encompass regulating the prices of patented medical devices, which should be accompanied by the additional resources necessary to carry out this extended mandate.

Jurisdiction of PMPRB when patent is "pending"

It has also been argued that the PMPRB does not have jurisdiction regarding the price of a medicine for which a patent is "pending." As the Executive Director of the PMPRB recently explained:

> The issue of the Board's jurisdiction during patent pending situations arises more often than one might expect. Of the new patented products reported to the Board in 1999, 24% had been on the market for some time prior to the issuance of the first patent. For several years, the Board has encouraged manufacturers in such circumstances to comply with the [Excessive Price] Guidelines during the patent pending period and has made it clear that it intends to assert its jurisdiction for new patents retroactively during the patent pending period.[235]

This issue of the PMPRB's jurisdiction over medicines for which a patent is pending was one of the points raised in *Hoechst Marion Roussel Canada* (the Nicoderm case). The Board panel found that HMRC had been enjoying de facto patent protection on its nicotine patch Nicoderm during the "patent pending" period (ie, between the date the patent application is "laid open" for public inspection and the date the patent is actually granted). The question for the Board, therefore, was whether "a person who has applied for, but not yet been granted, a patent [could] be a 'patentee' within the meaning of the patented medicine pricing provisions of the Act." The Board panel noted:

> The very purpose of the patented medicine pricing provisions of the Act was to balance the enhanced patent protection being simultaneously enacted, with a process for ensuring that the resulting pricing power did not result in excessive prices for medicines. If the Board does not have jurisdiction to avoid the excessive pricing of medicines where patent applications can be presumed to have given the applicants pricing power, the Act will not in those circumstances achieve the purpose for which it was enacted.[236]

Under the Act, a patentee is defined as "the person for the time being entitled to the benefit of the patent" for an invention.[237] The Act also allows for patentees to retroactively benefit from patent protection, once the patent is granted, by seeking compensation for patent infringement back to the date of the patent application.[238] Noting these factors, the Board concluded that

> the combination of these sections of the Act in the context of the situation facing the Board give[s] the Board the ability to fulfil its mandate by ensuring that medicines are not excessively priced during the patent pending period.[239]

The Board therefore asserted its jurisdiction to regulate the price of Nicoderm during the patent pending period. As noted above, HMRC's application to the Federal Court for judicial review of this decision remains outstanding.

RECOMMENDATION #11

Parliament should amend the Patent Act to expressly clarify that the Patented Medicine Prices Review Board has jurisdiction to regulate the prices of medicines during the period of time that grant of a patent is pending.

Institutional bias and the right to a fair hearing

In the Nicoderm case, the patentee also challenged the jurisdiction of the Board on the grounds that, because the Board is a single entity with the multiple responsibility of investigating, prosecuting, and adjudicating cases of alleged excessive pricing, this gives rise to a

"reasonable apprehension of bias" in the Board's decision-making and therefore deprives patentees of their right to a fair hearing under the Canadian Bill of Rights. The Board rejected these arguments, pointing to numerous other examples of tribunals with overlapping functions created by legislatures and the procedures introduced by the Board to separate its adjudicative functions (carried out by a panel) from its monitoring and investigative functions (carried out by staff).[240]

Avoiding PMPRB jurisdiction through patent dedication

At least one company has sought to avoid the jurisdiction of the PMPRB through "patent dedication." In the 1992 *Genentech* case, the company was informed that the PMPRB would hold a public hearing into its price for a medicine that dissolved blood clots. Genentech responded by irrevocably "dedicating" its patent to the public. It then argued that, because it no longer benefited from exclusive patent rights on its medicine, it was not a "patentee" under the Patent Act and therefore the Board had no further jurisdiction over the price charged for that medicine. The Board took a dim view of this conduct, ruling that under the Patent Act,

> the only Canadian medicine patentees exempted from the Board's price review jurisdiction are persons exercising rights under a compulsory patent licence.… In the Board's view, its regulatory powers form one element of the Parliament's scheme to deter abuse of patent and to provide offsetting relief to the public where such abuse occurs.… The Board does not accept the argument that it was Parliament's intention to permit medicine patentees to abuse their patent rights by charging excessive prices and then, once the regulatory machinery created by Parliament to provide a public remedy for such action is activated, to avoid those regulatory consequences by dedicating the relevant patents.[241]

Genentech succeeded in getting the Federal Court to stay the PMPRB's proceedings pending its appeal of the Board's decision.[242] However, Bill C-91 was pending at the time, and it was anticipated that the Bill would amend the Patent Act to expressly extend the PMPRB's jurisdiction for up to three years after a patent was dedicated or expired. Genentech's appeal of the Board's decision was adjourned, and was then abandoned following the passage of Bill C-91.[243]

In 1995, the PMPRB adopted a policy that asserts its jurisdiction over the price of a patented medicine following dedication of the patent to the public.[244] Since then, the policy has not been challenged and the PMPRB is not aware of any attempts to avoid its jurisdiction through patent dedication.[245]

Regulating prices of non-patented drugs

Of developed countries that regulate drug prices, Canada is the only country that restricts itself, in its national regulatory approach, to regulating only the price of *patented* drugs. As one set of researchers points out:

> While there is evidence that the PMPRB has succeeded in keeping pharmaceutical costs in line with those in other industrialised countries, the effectiveness of this cost-control strategy is limited by the fact that the PMPRB exercises authority only over patented medicines, not non-patented … medicines.[246]

Indeed, the Federal/Provincial/Territorial Pharmaceutical Issues Committee reported in 1999 that non-patented drugs represented about half the spending in provincial drug plans over the

1990-97 period.[247] (More recent data show that between 1996 and 2002, sales of non-patented brand-name drugs by patentees have fallen by more than half, accounting for only 22.1 percent of pharmaceutical sales in 2002 by patent-holding companies.[248] This means that patent-holding companies have shifted their sales increasingly to medicines that are still patent-protected, and therefore generally more expensive and profitable.)

"Non-patented medicines include all products for which patents have expired, those that are not yet or never will be patented, and generic copies."[249] Non-patented medicines may be single-source (eg, the patent-holding company may still, after the patent expires, be the only manufacturer) or multiple-source (eg, one or more generic companies is producing the medicine after the patent has expired, and the originator company may still be selling its brand-name product after patent expiry). As the Chairperson of the PMPRB has pointed out: "Not all non-patented drugs have generic alternatives; some of these non-patented drugs are single source and escape both the discipline of market competition and the oversight of the PMPRB."[250] Given the regulation of prices for patented medicines, and the fact that the public interest in reasonable drug prices exists independent of whether a medicine is or is not patented, there have been calls to extend pharmaceutical price regulation to non-patented medicines as well.

Of developed countries that regulate drug prices, Canada is the only country that restricts itself, in its national regulatory approach, to regulating only the price of *patented* drugs.

In 1994, the Prime Minister of Canada created the National Forum on Health, as an advisory body, "to involve and inform Canadians and to advise the federal government on innovative ways to improve our health system and the health of Canada's people." As part of its process, the NFH held a National Stakeholder Conference in 1996, during which some participants "expressed concerns about the limitations of the Patented Medicine Prices Review Board's mandate." Notwithstanding the concerns, the final report of the Forum stated that

> there is room for some difference of opinion as to the effectiveness of the Patented Medicine Prices Review Board (PMPRB) in regulating the price of patented drugs. The Forum believes that the PMPRB can continue to play a useful role, though as noted above the critical stage in drug pricing is at the point of first listing. In any case, given the *jurisdictional issues* surrounding the regulation of non-patented drugs, and given the absence of any hard *evidence* pointing to excessive prices in this area, the Forum does not recommend that the Board's mandate be expanded to incorporate non-patented drugs.[251]

However, the conclusion adopted in the report from the National Forum on Health is being revisited. In 1997, the parliamentary committee reviewing the impact of the Bill C-91 amendments in 1993 reported that "most witnesses wanted the Board to be able to look at the prices of generic drugs as well as patented ones."[252] While jurisdictional questions remain, there is an increasing body of evidence identifying concerns with rising prices of non-patented medicines. In 1997, according to Canada's then Minister of Health, Statistics Canada reported "that the prices of non-patented drugs increased on average about 3.2 per cent per year between 1989 and 1994" and that the PMPRB's overall index for prices of non-patented medicines had increased at a higher annual rate since 1987 than the index for prices of patented medicines.[253] In September 1998, the PMPRB reported on the outcomes of year-long consultations with its stakeholders, including that: "Among other things, many were concerned about the lack of price regulation for non-patented drugs and the countries used for comparison purposes."[254]

Single-source non-patented drugs

Recent studies show that prices of single-source non-patented drugs "continue to be well above the median foreign prices today."[255] The analysis by the F/P/T Committee for the 1990-97 period

> illustrated that Canadian prices for non-patented single source drug products were, on average, substantially higher than the median international price of the seven countries. The overall ratio of Canadian prices to median international prices was 1.30. In other words, Canadian prices for non-patented single source drugs were, on average, 30% higher than the median international price. In contrast, by 1997 Canadian prices of patented drugs were, on average, 11% below the median of their foreign prices in these countries.… An ongoing detailed assessment of the introductory prices of these medicines would provide the information necessary to determine whether such concerns can only be addressed through price regulation.[256]

On average, the prices of single-source, non-patented drugs are higher in Canada than in all of the seven other countries used by the PMPRB for assessing whether Canadian prices are excessive. They are higher only in the US.

Updating that figure, the PMPRB Chairperson reported in late 2002:

> [Federal, provincial and territorial] governments have asked us to compare the prices of these nonpatented single-source drugs in Canada with other countries. What we have found is that, on average, they are higher in Canada than in all other countries except the US. In fact, in 1999, the prices in Canada for these drugs were estimated to be 28% higher than the median of prices in the [seven] countries we use for comparison purposes; in contrast, the prices of patented drugs were 5% below the median foreign price last year [2001].[257]

Multiple-source non-patented drugs

In the case of multiple-source non-patented drugs, there is direct price competition, unlike the case where a drug is available from a single source only. Indeed, Canada's Minister of Health reported to Parliament in 1997 data illustrating competition's effect on prices:

> IMS data for the years 1990 to 1995 suggests that, on average, a generic drug will be priced at approximately 77.6 per cent of the corresponding brand name drug price, in cases where there is only one generic on the market. Where there are two generics on the market, the generic prices on average are approximately 65.3 per cent of the corresponding brand name drug price. This ratio declines to 62.6 per cent when there are three or more generics on the market. Generic drugs represent about 12 per cent of pharmaceutical manufacturers' sales revenues.[258]

Greater competition leads to lower prices. The more generic versions of a medicine are on the market, the greater the reduction in price.

In 2002, generic drugs accounted for just under 14 percent of total drug sales in Canada.[259] Given the relatively small proportion of total expenditures, addressing the prices of generics will not generate very large savings. Nonetheless, it is one area where law reform could be considered.

Notwithstanding that competition brings overall drug prices down, the F/P/T Pharmaceutical Issues Committee's analysis of the 1990-97 period found "a clear trend

towards higher generic drug prices relative to their brand name equivalents."[260] Since provincial formulary reimbursement policies would have the greatest influence in constraining drug prices, the Committee analyzed the experience of several provinces. However, the results were inconclusive and the Committee recommended further analysis to assess (1) the role of competition among multiple-source medicines in helping to contain drug costs, and (2) the appropriateness of the introductory prices of the first generic version of a medicine to enter the market and the effect of competition by the market entry of subsequent generic competitors.[261]

In 2002, generic drugs accounted for just under 14 percent of total drug sales in Canada.

Conclusion regarding price regulation of nonpatented drugs

In early 2003, the PMPRB's executive director confirmed that while all developed countries with publicly funded healthcare systems (ie, all developed countries except the US) appear to have been able to control the rate of inflation in the prices of existing drugs,

> More recently, studies have shown a different trend in Canada for non-patented drugs. On average, Canadian prices for non-patented brand name drugs, both single source and multiple source drugs, and for generic drugs, are about 24% to 40% above median prices for the same drugs in the other countries.[262]

In a study conducted on behalf of the Federal/Provincial/Territorial Working Group on Drug Prices and released in June 2003, the PMPRB analyzed the prices of top-selling multiple-source medicines in Canada. The study found that, while prices for patented drugs were on average 8 percent below median prices (among the seven comparator countries used for price comparisons) in 2000 and 5 percent below in 2001, the prices of brand-name multiple-source drugs in Canada exceeded the median of foreign prices by 28 to 33 percent.[263] In other words, while efforts to control drug prices during their patent term might arguably be moderately successful, after patent expiry and the end of the PMPRB's regulatory jurisdiction, manufacturers of brand-name products have been successful in increasing prices even when faced with the legal possibility of competition from other, generic manufacturers.

Efforts to control drug prices during their patent term might arguably be moderately successful. But after patent expiry, and the end of the PMPRB's regulatory jurisdiction, manufacturers of brand-name products have succeeded in increasing prices even when faced with the possibility of competition from other, generic manufacturers.

This sort of data on the costs of non-patented medicines, and the concerns of Canadians consulted by the Romanow Commission on the Future of Health Care in Canada, prompted the Commission to recommend the creation of a new National Drug Agency whose responsibilities would include those currently assigned to the Patented Medicine Prices Review Board, among others. The Commission recommended further that: "The new agency should include the price control functions of the Patented Medicine Prices Review Board, but be expanded beyond patented drugs to include generic prescription drugs as well in order to ensure that the price of *all* prescription drugs is fair to consumers."[264]

Questions remain as to how such regulation would be implemented. Jurisdictional issues need to be addressed. The federal government has jurisdiction over the marketing approval of drugs and over patent law; the latter has been the basis for it to introduce price regulation for patented medicines, particularly given the historical trade-off in Canadian law in which price controls were implemented in exchange for the almost complete abolition of compulsory licensing. Yet in the case of non-patented medicines, the link with federal jurisdiction

over patent matters is more tenuous. Absent this connection, regulation of prices would likely be within the purview of provincial legislatures, which have jurisdiction over "property and civil rights" under Canada's constitutional division of powers between the various levels of government. It would, of course, be open to provincial governments to implement price controls on non-patented medicines more directly than they already do via their decisions about whether to include certain drugs on provincial health insurance formularies and under what pricing conditions. The PMPRB could collaborate with provincial governments to examine options for implementing such controls.

RECOMMENDATION #12

In line with the recommendation of the Commission on the Future of Health Care in Canada, Parliament should enact a national legislative scheme for the regulation of prices of generic medicines to prevent excessive pricing, complementing Canada's existing scheme of regulating prices of patented medicines. If necessary because of jurisdictional questions, the federal government should undertake this in collaboration with provincial governments, to secure the implementation of a system that is consistent across the country. Provincial governments should collaborate with the federal government in designing such a scheme, drawing upon lessons learned to date from various provincial policy measures aimed at controlling prices for medicines, including generics, covered under provincial drug insurance programs.

Regulating prices of non-prescription drugs

Non-prescription drugs account for approximately $2.9 billion in sales annually in Canada.[265] Under the Patent Act, the PMPRB has jurisdiction to regulate the prices of *all* patented medicines, which includes both prescription and non-prescription drugs. It has been suggested by manufacturers that this regulation is inappropriate in the case of non-prescription drugs, but the jurisdiction of the PMPRB has been preserved since its inception, including through the 1997 parliamentary review of the Bill C-91 amendments to the Patent Act in 1993.

The Nonprescription Drug Manufacturers Association of Canada (NDMAC) is "the national association representing manufacturers, marketers and distributors of self-care products including nonprescription medications, herbal remedies/natural health products, nutritional supplements, home diagnostic kits and other personal care products."[266] The NDMAC has argued for several years that all non-prescription drugs should be exempted from Canada's system of price controls and the jurisdiction of the PMPRB.[267] Its principal argument is that the dynamics of the non-prescription drug market (in which drugs are marketed to, and purchased by, consumers directly) are "entirely different" than those of the prescription drug market (in which drugs are promoted to and prescribed by physicians, dispensed by pharmacists, and consumers lack the same autonomous decision-making power). The NDMAC argues that "these differences effectively remove any rationale for PMPRB involvement in non-prescription drug price monitoring."[268]

Yet the NDMAC's arguments fail to address the critical point that price controls on medicines in Canada arose principally out of a concern to prevent profiteering by those holding patents on medicines and thereby enjoying market exclusivity. This fundamental concern

exists regardless of whether the patented medicine in question is available only by prescription or over the counter. It is true, as the NDMAC maintains, that little attention has been paid to the question of non-prescription medicines in the drafting, implementation, and review of legislation in Canada dealing with pharmaceutical patents and price controls.[269] But this does not make the basic principle underlying the PMPRB's jurisdiction over all patented medicines irrelevant or inapplicable.

"The new [National Drug Agency] should include the price control functions of the Patented Medicine Prices Review Board, but be expanded beyond patented drugs to include generic prescription drugs as well in order to ensure that the price of *all* prescription drugs is fair to consumers."

– Romanow Commission, 2001

What is the experience in other countries? The question is moot for the US, as that country has no system of national price controls. Within the European Union, a high-level intergovernmental working group examining pharmaceutical policy reported that in some member states "there are controls on prices of medicines sold into private health care markets, on OTC [over-the-counter, ie, non-prescription] medicines and on medicines that are not reimbursed by Member States (i.e. in parts of the market where the State is not the purchaser)."[270] The working group did not, in its recent report, make any recommendation to exempt non-prescription drugs from price regulation. Canada would be acting consistently with practice in other developed countries in maintaining the jurisdiction of the PMPRB to regulate prices of non-prescription drugs.

RECOMMENDATION #13

The jurisdiction of the Patented Medicine Prices Review Board to regulate the prices of patented non-prescription medicines should be maintained.

PMPRB's monitoring and reporting function: price trends, sales, and R&D spending

As noted above, in addition to its principal function of preventing excessive pricing of new and existing patented medicines, the Board has a second, reporting function. It is tasked with submitting reports annually to the federal Minister of Health, which are then submitted to Parliament, in which the PMPRB reports on:[271]

- pricing trends in the pharmaceutical industry;
- sales of patented medicines in Canada; and
- spending in Canada on R&D by patent-holding pharmaceutical companies.

The information on sales and R&D spending is to be compiled for each company and as an aggregate across the patented-medicines sector.[272]

Price trends: impact of regulation on Canadian prices of patented medecines

Patented medicines

The evidence from within Canada and from other countries indicates, not surprisingly, that regulation can contain medicine prices, although such measures do not always translate into containing ultimate expenditures on pharmaceuticals and are insufficient on their own to achieve this objective. "In terms of trends, prices have increased less than inflation in all countries with significant price control [but t]he picture is more mixed for other countries."[273]

"Data from industrialized countries confirm that price controls can lower individual drug prices and reduce price growth. However, because of substitution effects and other factors, the impact of price controls on total individual and national drug expenditures is not at all certain."[274]

In Canada, when the PMPRB was created in 1987 "to enforce new legislation on controlling prices of patented drugs, Canadian prices were 23% higher than the median international prices, second only to price levels in the United States; since the mid-1990s, prices in Canada have remained consistently at about 10% below median international prices and in the mid-range of European countries used as comparators."[275] More recently, the PMPRB has reported for 2002 that:

- Since the mid-1990s, Canadian prices for patented drugs have remained between 5-12% below the median of foreign prices. In 2002, the prices of patented medicines in Canada were about 1% higher than the median of foreign prices in the seven countries used for price comparison purposes – lower than prices in the UK, Switzerland and the US, but higher than those in Italy, France, Sweden and Germany. As in previous years, US prices appear to be substantially higher than prices in Europe and Canada.
- The manufacturers' prices of patented drugs, as measured by the Patented Medicine Price Index (PMPI), fell by 1.2% in 2002. This result continues the pattern of declines and near-negligible increases in the PMPI that began in 1993.[276]

Some analysts have pointed out that the PMPRB's regulations may have only moderate or minor effect, in part because a significant number of drugs may not price at the maximum that would be permitted by federal regulations because of efforts on the demand side to control spending by provincial governments and other major purchasers extracting price reductions from manufacturers.[277]

Price regulation has been moderately successful. However, there is room for improvement in Canada's approach to dealing with both introductory prices of new products and annual price increases on existing products.

Nonetheless, the figures above are encouraging to some degree, and indicate that price regulation can have, and has had, at least some impact and should be considered moderately successful public policy, albeit not ideal. However, as the preceding discussion has shown, there is room for improvement in Canada's approach, with respect to both introductory prices of new products and annual price increases on existing products. The discussion above has highlighted the importance of adequately regulating manufacturers' introductory prices for *new* patented medicines because:

- the manufacturer's introductory price accounts for about two-thirds of the final price paid by the purchaser;
- patentees' sales (and their promotion to prescribing physicians) are increasingly shifting away from non-patented products to newer, patented, and generally more expensive drugs,[278] while evidence indicates that only a small proportion of these new drug products are Category 2 ("breakthrough") drugs and the bulk are Category 3 drugs offering moderate, little, or no therapeutic advantage over existing products; and
- even though subsequent annual increases in price are limited to the rate of inflation, high introductory prices set a high baseline for these future increases.

Lexchin's analysis of prescription drug costs in Ontario also highlights the operation of all three of these factors in generating an ongoing increase in real costs to consumers:

> These high introductory prices are one reason that the cost of a prescription has risen dramatically since 1987. The average price per prescription (excluding the dispensing fee) in Ontario has risen from $12.48 in 1987 to $24.09 in 1993, a rise of 93% compared to an increase in the Consumer Price Index of 23.1%. Over half of the rise in prescription costs is due to the introduction of new drugs, specifically new (since 1987) patented medications. Prices for prescriptions containing new patented medications rose at a rate of 13.4% per annum since 1998 compared to 7.6% for prices for prescriptions using nonpatented drugs.[279]

With respect to increases in the price of *existing* patented medicines, the advent of the PMPRB and Canada's system of price controls has also had an impact. As the then Minister of Health reported to Parliament in 1997:

> Prior to the creation of the PMPRB, from 1982 to 1987, when there was no direct regulation of drug prices, price increases for all drugs, as measured by the IPPI (pharma), averaged 8.96 per cent per year as compared to [an] increase in the CPI of 5.60 per cent per year. The *decline in the rate of increase* of all drugs relative to the CPI coincided with the introduction of federal price regulation of patented drugs, which represent about 44 per cent of manufacturers' sales of all drugs.[280]

More recently, the PMPRB has reviewed the increases in patented drug prices over the last 15 years and reported that:

> Increases in the prices of patented drugs, as measured by the PMPI, have been less than increases in the CPI in almost every year since 1988, the sole exception being 1992. This pattern continued in 2002, with consumer prices increasing by 2.3% while the PMPI fell by 1.2%.[281]

Yet the discussion above has also highlighted some concerns with the existing approach adopted in the Patent Act and by the PMPRB in controlling cumulative increases in the price of patented medicines. While Canada's intervention to ensure the interest of Canadians in reasonable drug prices is to be welcomed, our approach can be reformed to better protect the public interest while still adequately protecting the private interests of pharmaceutical manufacturers. The recommendations in the preceding sections aim to improve this balancing in Canadian law, policy, and practice.

Non-patented medicines

Because prices of non-patented drugs are not regulated in Canada, and the PMPRB has no jurisdiction over them (see discussion above), there is no legally mandated, national system for gathering such data either regarding drugs that are off patent or about the generic pharmaceutical industry in Canada. Aside from data gathered by pharmaceutical companies themselves (brand-name and generic) on their sales of off-patent medicines, the data that are available are inconsistent and scattered among various entities, such as provincial health insurance schemes and private insurance companies, or private market-research companies. Nonetheless, some data are gathered. As discussed above, the data that have been collected show increases in the price of non-patented drugs high enough to cause concern and prompt calls for extending some form of price regulation to non-patented drugs as well (eg, the recommendation of the Romanow Commission).

In September 2001, federal, provincial, and territorial ministers of health announced the creation of a joint PMPRB/CIHI project to monitor national expenditures on drugs. The National Prescription Drug Utilization Information System (NPDUIS) will provide more comprehensive monitoring of trends in price, utilization, and costs of pharmaceuticals, at least across public drug plans. This will generate some information for both patented and non-patented medicines. However, it is desirable that some more across-the-board mechanism be in place to provide as comprehensive data as possible about the entire pharmaceutical industry in Canada, including generic companies, and not just data limited to the observable end results of price, utilization, and costs of drugs.

RECOMMENDATION #14

Parliament should amend the Patent Act to require manufacturers of non-patented medicines to report annually, to the Patented Medicine Prices Review Board or other designated body deemed appropriate, their revenues and details of the source of the revenue, whether direct or indirect, from sales of medicine in Canada, and their expenditures in Canada on R&D relating to medicine. This would complement similar obligations currently applicable to manufacturers of patented medicines.

Sales and R&D spending by the patented pharmaceutical industry

Patentees' obligations to report revenues and R&D spending

The Patented Medicines Regulations set out what patent-holding pharmaceutical companies must report to the PMPRB, for the purposes of compiling this report, regarding their revenues and expenditures (including on R&D) in Canada.[282] Each company's report on its R&D expenditures must describe the type of R&D and the expenditures in respect of each type of R&D,[283] and the "source and amount" of the funding for its expenditures toward R&D[284] (which language would seem to encompass any public subsidies received for this purpose). For purposes of reporting to the PMPRB, "research and development" is defined as "those activities for which expenditures qualify for an investment tax credit in respect of scientific research and experimental development" under the Income Tax Act.[285] There is some concern regarding patentees' compliance with these obligations: according to the PMPRB, as of 2 March 2002, 56 percent of reporting patentees had not filed their annual R&D report.[286]

It should also be noted that the Patent Act gives the federal Minister of Health the authority to refer matters to the Board for inquiry and reporting; the Act does not state any particular limits on the Minister in setting the terms of reference for an inquiry by the Board.[287] This provides an additional, potentially important mechanism for generating research, analysis, debate, and reform of Canadian policy relating to pharmaceutical pricing and related issues. This provision was used to mandate the PMPRB to participate in the National Prescription Drug Utilization Information System (NPDUIS) that was established following an agreement in September 2001 between federal, provincial, and territorial ministers of

health. The NPDUIS will generate critical analyses of price, utilization, and cost trends of prescription drugs.

Pharmaceutical R&D in Canada

Recall that in 1992 the patented industry in Canada gave its collective commitment to invest in R&D in Canada in exchange for strengthened and lengthened patent protection introduced by Bill C-22 and Bill C-91. One analyst has observed that R&D spending in Canada by multinational pharmaceutical companies increased from 1987 to 1997, but has been declining ever since as a percentage of their total sales.[288] It should be noted that 1997 was the year in which a parliamentary review of the Bill C-91 amendments was statutorily mandated, as a means of holding the patented pharmaceutical industry accountable for its commitments to increased R&D in Canada. Since that hurdle was passed, with no revisions to the Patent Act forthcoming as a result of that review, the patented industry's ratio of R&D to sales has declined every year. As has already been noted, this has meant that Canada consistently falls behind the US and Europe in pharmaceutical R&D levels:

Since a parliamentary review of Canada's drug pricing laws in 1997, the ratio of spending on R&D by the patented pharmaceutical industry to its sales has declined every year. In 2002, Canada was benefiting from only about half as much R&D spending by the industry as the industry was benefiting from Canadian purchases of its products.

> Since 1995, Canadian investment in R&D, as a percent of sales, has remained significantly below the levels in six of the seven countries that the Patented Medicine Prices Review Board uses for price comparison purposes (France, Germany, Italy, Sweden, United Kingdom, United States). Not only are we behind these major industrial countries but Canadian R&D is also lower than most smaller European countries.[289]

According to the PMPRB, in 2002 patent-holding pharmaceutical companies reported total R&D expenditures of $1.18 billion, an increase of 11.6 percent from the previous year, but that over the same period, sales of all patented drugs rose by 17.3 percent.[290] This means that the R&D-to-sales ratio overall in the pharmaceutical industry remained at 9.9 percent in 2002, unchanged from 2001 for all patent-holding companies; in the case of member companies of Rx&D, the industry association for brand-name pharmaceutical companies in Canada, the ratio actually declined from 10.6 percent in 2001 to 10.0 percent in 2002.[291] As a result, a comparison between Canada and the seven countries used for price comparison purposes showed that, while total sales in Canada of brand-name drugs accounted for 3.4 percent of total sales in these eight countries, R&D spending in Canada by patent-holding pharmaceutical companies accounted for only about 1.8 percent of the total pharmaceutical R&D spending in these same eight countries.[292] In other words, Canada was benefiting from only about half as much R&D spending by the patented pharmaceutical industry as the industry was benefiting from Canadian purchases of its products.

Amendments to Canadian patent law in 1987 and 1983 gave patentees stronger, legally enforceable patent rights over pharmaceuticals. In exchange, they made non-binding commitments to increase R&D spending in Canada. Stronger measures are required to ensure fair levels of R&D spending in Canada.

Beyond a concern about overall levels of pharmaceutical R&D spending by patentees in Canada, attention has been drawn to the small proportion of that spending that is directed toward "basic research," defined as "work that advances scientific

knowledge without a specific application in view."[293] In 2001, the share of total R&D consisting of basic research had fallen to 16.1 percent, prompting the PMPRB to report: "This is the lowest proportion of total R&D spending on basic research ever reported by patentees since the Board began reporting such information in 1988."[294] In that same year, basic research amounted to 24.5 percent of spending in the UK and 36 percent in the United States, and the Canadian level fell behind even smaller European countries.[295] This decline was reversed in 2002, and the share of total R&D spending represented by basic research rose to 17.6 percent.[296]

High R&D costs are regularly invoked as the primary justification for strong patent protections on medicines and the accompanying high prices. But concerns remain about how much companies spend on marketing their products in relation to their spending on R&D.

Amendments to the Patent Act in 1987 (Bill C-22) and 1993 (Bill C-91) gave patentees stronger, legally enforceable protections for their intellectual property rights in pharmaceuticals. In exchange, non-binding commitments were made to increase R&D spending in Canada. Since the 1997 statutorily required review of the enhanced patent protections has passed, R&D spending in Canada by the patented industry has declined almost every year and is consistently well behind levels in all other comparable countries. Spending levels on basic research is an area of particular concern.

This suggests that stronger measures are required to ensure fair levels of R&D spending in Canada as the quid pro quo for enhanced profits for patentees. Indeed, in 1997 the House of Commons Standing Committee on Industry recommended that pharmaceutical companies (both generic and brand-name) be given the option of voluntarily participating in a program to fund biomedical research or to pay "a levy of 1% of sales on the manufacturers' price of patented, generic and non-patented drugs." The fund envisioned would be administered by what was then Canada's Medical Research Council (since replaced by the Canadian Institutes for Health Research) through normal peer-review procedures, to support collaboration in health research broadly defined, pharmaceutical-research needs that are not being currently met, and projects strengthening the research base needed by a self-sustaining pharmaceutical industry.[297]

Canada also has an opportunity to demonstrate its concern for global health, and its solidarity with those in developing countries, by increasing R&D into "neglected diseases." These are diseases principally afflicting poor people and the developing world, where the lack of adequate purchasing power means there is insufficient profit incentive for private pharmaceutical companies to invest in developing treatments for these diseases.[298]

These two objectives could be pursued through a variety of mechanisms. The recommendation offered below is one such mechanism.

RECOMMENDATION #15

Parliament should amend the Patent Act to create requirements for R&D spending in Canada that legally bind pharmaceutical patentees, in the form of an annual levy on all patentees that do not meet a specified minimum ratio of R&D to sales, based on the discrepancy between their actual ratio and the minimum specified ratio. In addition, sales of all patented medicines should be subject to a levy, revenues from which would be dedicated to publicly funding basic research and research into "neglected diseases," in particular those prevalent in developing countries.

R&D spending vs marketing and promotion

Ongoing concerns also remain about the extent to which drug prices are elevated by companies' expenditures on marketing their products, rather than reflecting the cost of researching and developing those medicines, especially when high R&D costs are regularly invoked as the primary justification for strong patent protections and accompanying high prices.

This phenomenon has been most studied in the United States, in part because it is one of only two developed industrialized countries (the other being New Zealand) to permit direct-to-consumer advertising of medicines. Some analyses have revealed the following:

- A 1992 study by the US Senate concluded that 22.5 percent of prescription drug costs were based on promotional and marketing expenses, compared with only 16 percent based on R&D.[299]
- Research conducted by the Kaiser Family Foundation in the US found that "between 1990 and 2000, the percent of overall revenues that major pharmaceutical manufacturers spent on production costs declined somewhat from 29.6% to 24.9%, and the percent for R&D increased from 10.9% to 13.7%. The proportion of revenues for marketing and administrative expenses remained nearly constant (about 34%), while profits fluctuated but with little net change over the decade (from 24.8% to 23.6%)."[300]
- Data from company annual reports and US tax returns for 1999 showed that in the US, for 14 of 19 pharmaceutical companies analyzed, spending on marketing and administration ranged from 1.27 to 4.75 times the spending on R&D.[301]
- In 2000, an analysis of the annual reports of the 15 largest pharmaceutical companies found that their spending on marketing, advertising, and administration was three times more than spending on R&D and, specifically, direct-to-consumer advertising is increasing at a rate three times more than R&D spending.[302]
- Researchers at the Université du Québec à Montréal (UQAM) analyzed financial data from the nine largest pharmaceutical companies principally marketing innovator drugs over 1991-2000, and found that over the decade, the nine companies spent US$316 billion on marketing and administration, which amounts to 2.8 times as much as the US$113 billion spent on research and development.[303]
- In 2001, the US industry association PhRMA reported that it increased its overall budget to more than US$50 million in order to spend more on public relations, including an "education and image" campaign anticipated to cost in excess of US$40 million.[304]

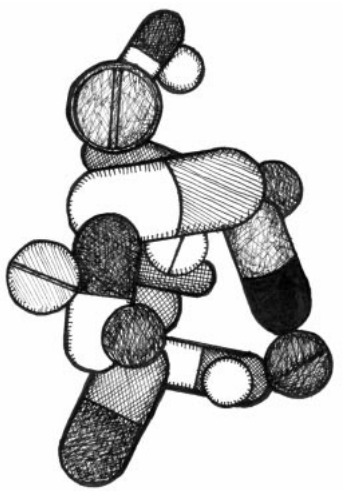
In the Canadian context, less data appear to be available. Direct-to-consumer advertising of prescription medicines is more circumscribed in Canada than in the US, so it would be reasonable to expect advertising spending by patentees to be lower, although spending on other forms of marketing and promotion (in particular, to prescribing physicians) could perhaps be consequently higher on a proportional basis. Although the data for a precise comparison in the same year were not available, Lexchin has reported that the brand-name pharmaceutical industry employed 3580 people engaged in R&D in Canada in 2000, while it also employed 4000 sales representatives as of 1995.[305] A more recent report suggested that the member companies belonging to Rx&D, Canada's Research-Based Pharmaceutical Companies, the association for the patented pharmaceutical industry, currently employ an estimated 23,000 people, including 9600 engaged in pharmaceutical marketing (or roughly one for every six doctors).[306]

Canadian patentees are required, under the Patent Act and the Patented Medicines Regulations, to report their revenues from sales and their spending on R&D. They are even

required to describe the "type" of R&D carried out, the name of the person or entity who carried out each type of R&D and the amount they spent, their capital expenditures on buildings and equipment, and the source and amount of the funds they spent on R&D.[307] However, there is no statutory requirement that they report to the PMPRB their other expenditures on marketing and promotional activities. Such data would, however, assist in weighing claims about the costs incurred by patentees in doing R&D versus promotional expenditures.

RECOMMENDATION #16

The federal government should amend the Patented Medicines Regulations to require a patentee to include, in its annual report to the Patented Medicine Prices Review Board, a description of the type of promotional activities carried out and its expenditures on each type of promotional activity.



Summary of Recommendations

Remedies for excessive pricing

1. Parliament should consider possible mechanisms for compensating private purchasers, particularly individual Canadians paying out of pocket, for prices of medicines determined to be excessive by the Patented Medicine Prices Review Board.
2. Parliament should amend the Patent Act (section 83) to authorize the Patented Medicine Prices Review Board or, alternatively, the Commissioner of Patents, to issue a compulsory licence as a remedy for excessive pricing by a manufacturer of a patented medicine.

Excessive Price Guidelines

3. In its upcoming analysis of how to define the "value" of drugs, the Patented Medicine Prices Review Board should consider the relevance and applicability of that analysis for the permissible pricing of Category 2 new drug products (breakthrough drugs).
4. The Patented Medicine Prices Review Board should revise its Excessive Price Guidelines to limit the introductory price in Canada for Category 3 new drug products (those that offer moderate, little, or no therapeutic advantage over existing medicines) to either (i) the median (or, alternatively, the lowest) international price charged by the manufacturer for the same product in comparator countries or (ii) the highest price in Canada among all therapeutically comparable products, whichever of these two prices is *lower*. Alternatively, the Guidelines could be revised to cap the introductory price for a Category 3 product to either the median or the average of Canadian prices for all the drugs in the same therapeutic class. Consideration should be given to further differentiating between new drugs such that those offering "little or no therapeutic advantage" might be limited to an introductory price that is the lowest Canadian price of existing drugs in that therapeutic class, while those new drugs that offer "moderate" therapeutic

advantage might be allowed a maximum introductory price that is either the median or the average of prices of existing drugs in that therapeutic class.

5. The Patented Medicine Prices Review Board should review the appropriateness of using an index based on retail price increases to limit the increases in factory-gate manufacturers' prices on patented medicines.
6. The Patented Medicine Prices Review Board, and the federal departments of Health and Industry, should identify and assess options for amendments to the Patent Act, the Patented Medicines Regulations, and/or the Board's Excessive Price Guidelines that would result in a closer correlation between overall Canadian price levels for patented medicines and levels of spending in Canada by patentees on pharmaceutical R&D.
7. The Patented Medicine Prices Review Board should undertake a review, involving public consultation (including with consumer representatives), of the basket of countries currently used for the purposes of international price comparisons. The review should identify the relevant bases on which these countries are similar and dissimilar, for the purpose of comparing pharmaceutical prices, to Canada. The review should also identify other OECD countries not currently included on the list of countries for price comparison purposes that could be suitable for inclusion on this list and assess the relevant similarities to and differences from Canada. The report of that review should be made available in draft form for public comment and then finalized. Based on the conclusions of that report, the Patented Medicine Prices Review Board should then consider whether to recommend to the Minister of Health and the federal Cabinet that the Patented Medicines Regulations be amended to revise accordingly the list of countries used for international price comparisons.
8. The Patented Medicine Prices Review Board should revise its Excessive Price Guidelines such that maximum non-excessive prices allowed to manufacturers of patented medicines bear a reasonable relationship to the cost of their development and manufacture, and allow a "reasonable" profit margin beyond those costs.
9. Parliament should amend the Patent Act and/or the Patented Medicines Regulations to provide for a mechanism for interim or conditional pricing of a new patented medicine upon its introduction to the Canadian market, which price would be automatically reviewed at appropriate periods over the life of the medicine to take into account new evidence regarding its therapeutic merits and its merit relative to comparator medicines. The Patented Medicine Prices Review Board should be given the mandate and necessary powers to conduct such reviews and to revise the maximum "non-excessive" price of a medicine upward or downward as warranted by such new evidence.

Jurisdiction of the PMPRB to regulate medicine prices

10. Depending on the outcome of current litigation over the definition of a "medicine" in the Patent Act, which definition controls the jurisdiction of the Patented Medicine Prices Review Board to regulate patented-medicine prices, Parliament should amend the Patent Act to expressly affirm and clarify the broad scope of this term to preserve the objective of preventing excessive pricing by manufacturers of any invention pertaining to a medicine. By the same token, Parliament should also amend the Patent Act to extend the scope of the Board's jurisdiction to encompass regulating the prices of patented medical devices, which should be accompanied by the additional resources necessary to carry out this extended mandate.

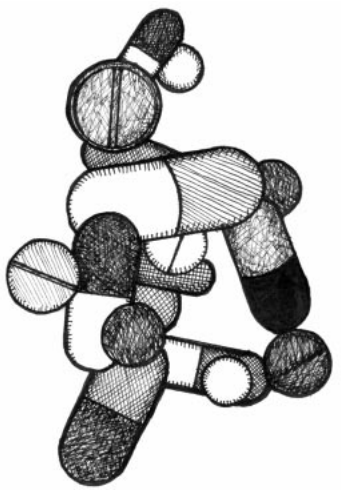
11. Parliament should amend the Patent Act to expressly clarify that the Patented Medicine Prices Review Board has jurisdiction to regulate the prices of medicines during the period of time that grant of a patent is pending.
12. In line with the recommendation of the Commission on the Future of Health Care in Canada, Parliament should enact a national legislative scheme for the regulation of prices of generic medicines to prevent excessive pricing, complementing Canada's existing scheme of regulating prices of patented medicines. If necessary because of jurisdictional questions, the federal government should undertake this in collaboration with provincial governments, to secure the implementation of a system that is consistent across the country. Provincial governments should collaborate with the federal government in designing such a scheme, drawing upon lessons learned to date from various provincial policy measures aimed at controlling prices for medicines, including generics, covered under provincial drug insurance programs.
13. The jurisdiction of the Patented Medicine Prices Review Board to regulate the prices of patented non-prescription medicines should be maintained.

Spending in Canada on pharmaceutical R&D

14. Parliament should amend the Patent Act to require manufacturers of non-patented medicines to report annually, to the Patented Medicine Prices Review Board or other designated body deemed appropriate, their revenues and details of the source of the revenue, whether direct or indirect, from sales of medicine in Canada, and their expenditures in Canada on R&D relating to medicine. This would complement similar obligations currently applicable to manufacturers of patented medicines.
15. Parliament should amend the Patent Act to create requirements for R&D spending in Canada that legally bind pharmaceutical patentees, in the form of an annual levy on all patentees that do not meet a specified minimum ratio of R&D to sales, based on the discrepancy between their actual ratio and the minimum specified ratio. In addition, sales of all patented medicines should be subject to a levy, revenues from which would be dedicated to publicly funding basic research and research into "neglected diseases," in particular those prevalent in developing countries.

Patentees' reporting obligations

16. The federal government should amend the Patented Medicines Regulations to require a patentee to include, in its annual report to the Patented Medicine Prices Review Board, a description of the type of promotional activities carried out and its expenditures on each type of promotional activity.



Endnotes

[1] Funding for the project was provided by Health Canada under the Canadian Strategy on HIV/AIDS.

[2] R Elgie. Drug Pricing: A Comparison between Canada and Other Countries. Notes for an address to IRPP Conference "Toward a National Strategy on Drug Insurance: Challenges and Priorities," Toronto, 23 September 2002, at 11-12.

[3] Project Inform. Opportunistic pricing: a new scourge, a new call to action. *PI Perpective No. 26*, December 1998, at www.projectinform.org/pdf/pip26.pdf.

[4] B Mirken. The high cost of living. *POZ Magazine* April 1999: 48-51, 66-67.

[5] Eg, HB Krentz et al. Cost of antiretroviral drugs before and after the introduction of HAART. *Canadian Journal of Infectious Diseases* 2001; 12 (Suppl B).

[6] P Millson, D McMurchy. Who pays for antiretroviral therapy in Ontario? A HOOD Report on the Cost of HIV in Ontario. Toronto: HIV Ontario Observational Database (HOOD), July 1999, at 1.

[7] P Millson, D McMurchy. Inpatient costs of HIV/AIDS: a HOOD report on the cost of HIV in Ontario. Toronto: HIV Ontario Observational Database (HOOD), July 1999.

[8] T Albert, G Williams. *The Economic Burden of HIV/AIDS in Canada*. CPRN Study No. H/02. Ottawa: Canadian Policy Research Networks, 1998 (available via www.cprn.org). Research in the US has yielded similar conclusions about the increase in spending on medications and a corresponding decline on other components of health care: eg. SA Bozzette et al. Expenditures for the care of HIV-infected patients in the era of highly active antiretroviral therapy. *New England Journal of Medicine* 2001; 344: 817-23; P Keiser et al. Long-term impact of highly active antiretroviral therapy on HIV-related health care costs. *Journal of Acquired Immune Deficiency Syndromes* 2001; 27: 14-19.

[9] T Albert, G Williams. *Reflexion – The Economic Burden of HIV/AIDS in Canada: Summary of the Findings and Policy Implications*. Ottawa: Canadian Policy Research Networks, 1997, at 4. Research in the US has also concluded that HAART is cost-effective: eg, KA Freedberg et al. The cost effectiveness of combination antiretroviral therapy for HIV disease. *New England Journal of Medicine* 2001; 344: 824-31; BR Schackman et al. Cost-effectiveness of earlier initiation of antiretroviral therapy for uninsured HIV-infected adults. *American Journal of Public Health* 2001; 91(9): 1456-1463.

[10] In addition to provincial/territorial plans that cover medicines for some groups (eg, social assistance recipients, seniors, and in some jurisdictions, some portion of expenditures for those with "catastrophic" drug costs), the federal government covers prescription drug needs of registered First Nations people and eligible Inuit people that are not covered by provincial/territorial plans, through the Non-Insured Health Benefits Program (NIHB). The federal government also provides prescription drug coverage for members of the Armed Forces and eligible veterans.

[11] Millson & McMurchy, supra, note 6 at 1-2.

[12] William M Mercer, Ltd. Supplementary Health and Dental Programs for Canadians: Assessment of Coverage and Fairness of Tax Treatment, November 1995, cited in J Lexchin. A National Pharmacare Plan: Combining Efficiency and Equity. Ottawa: Canadian Centre for Policy Alternatives, March 2001, at 2 (available via CCPA website at www.policyalternatives.ca).

[13] Commission on the Future of Health Care in Canada. *Building on Values: The Future of Health Care in Canada – Final Report*, November 2002, at 207 (available via www.healthcarecommission.ca), citing: AS Adams et al. The case for a medicare drug coverage

benefit: a critical review of empirical evidence. *Annual Review of Public Health* 2001; 22: 49-61; R Tamblyn et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *Journal of the American Medical Association* 2001; 285: 421-429; SB Soumeri et al. A critical analysis of studies of state drug reimbursement policies: research in need of discipline. *Milbank Quarterly* 1993; 71(2): 217-252; AL Kozyrskyj et al. Income-based drug benefit policy: impact on receipt of inhaled corticosteroid prescriptions by Manitoba children with asthma. *Canadian Medical Association Journal* 2001; 165: 897-902. See also: N Freemantle, K Bloor. Lessons from international experience in controlling pharmaceutical expenditure: I. influencing patients. *British Medical Journal* 1996; 312: 1469-1471.

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[15] Health Canada and Saskatchewan Health. *Proceedings of the Conference on National Approaches to Pharmacare*. Saskatoon, 18-20 January 1998, available at www.hc-sc.gc.ca/htf-fass/english/pharma1.htm.

[16] Results of the Environmental Scan and Performance Evaluation for the Patented Medicine Prices Review Board. *PMPRB NEWSletter* January 2002; 6(1): 10-11 at 10.

[17] Remarks of Dr Robert McMurtry, Special Advisor to the Commission on the Future of Health Care in Canada, at PMPRB Symposium 2002, as reported in: PMPRB Symposium 2002 – Highlights. *PMPRB NEWSletter* October 2002; 6(4): 3-5 at 4.

[18] *Building on Values: The Future of Health Care in Canada – Final Report*, supra, note 13 at 203.

[19] Ibid at 202.

[20] "Runaway cost of drugs" probed. Canadian Press, 18 June 2003; see also the materials released by the National Union of Public and General Employees (NUPGE), and the supporting statutory declaration filed with the complaint, in the "Medicare Watch" section of the NUPGE website at www.nupge.ca.

[21] Federal/Provincial/Territorial Pharmaceutical Issues Committee (Task Force on Pharmaceutical Prices). *Drug Prices and Cost Drivers, 1990-97*.

[22] R Pear. Drug companies increase spending to lobby Congress and governments. *New York Times*, 1 June 2003: 33; A Cassels. Don't gamble with our drug prices. *Globe and Mail*, 23 June 2003: A13.

[23] *PhRMA Special 301 Final Submission*, 20 February 2001 (see section on Canada at 92-99) (available via www.phrma.org/international).

[24] Eg, S Stewart. Drug firm caps supply to Canada: AstraZeneca aims to curb shoppers. *Globe and Mail*, 22 April 2003: B3; L Zehr. US drug boycott threat called "ridiculous." *Globe and Mail*, 8 August 2003: B1; B Cusack, S Stinson. US drug firms set to boycott Canada. *National Post*, 7 August 2003: A1-A2; T Cohen. Internet drug firms ailing. *Globe and Mail*, 2 September 2003: B12; Lilly limits drugs sent to Canada. *Globe and Mail*, 20 October 2003: B3; T Blackwell. Fears of internet sales delay release of HIV drug in Canada: "Tip of iceberg." *National Post*, 4 November 2003: A1; Gilead Sciences refuses to sell antiretroviral drug tenofovir to Canada at reduced cost because of reimportation concerns. *Kaiser Daily HIV/AIDS Report*, 5 November 2003.

[25] B Tobin. Drug-pricing issue lurking in the weeds. *Globe and Mail*, 17 June 2003: A17; B McKenna. US prescription drug sector needs dose of medicine. *Globe and Mail*, 4 July 2003: B5; JC Cohen, A Cassels. Canada: get ready to defend affordable drugs. *Globe and Mail*, 26 August 2003: A17; T Blackwell. FDA enlists Ottawa in war on internet pharmacists. *National Post*, 30 October 2003: A5; A Cassels. Is big pharma pulling Canada's chain? *Globe and Mail*, 30 October 2003: A17; B McKenna. Canadian drugs not prescription for US health ills. *Globe and Mail*, 7 November 2003: B8; Brand-name drug companies hike prices. *CBC.ca*, 3 November 2003; G Ryerson-Cruz. Manley firm on drug price caps. *Globe and Mail*, 26 November 2003: B7. For a broader discussion about goals of US patented pharmaceutical industry in relation to Canadian healthcare policy as it affects pharmaceuticals, see: Cassels, supra, note 22, and D Saunders. Drug imports from Canada spark US policy crisis. *Globe and Mail*, 1 November 2003: A4.

[26] If such action were to be taken, it would highlight even further the importance of Canada, as a sovereign nation with an obligation to protect the health of its residents, having at its disposal policy tools such as compulsory licensing, to remedy the patent holder's "failure to work" its patent in Canada by allowing others, such as generic drug manufacturers, to make the medicine available for sale in Canada. Such measures would be compliant with Canada's obligations under international treaties on intellectual property.

[27] Public Citizen. *The Other Drug War 2003*. Washington, 23 June 2003, available via: www.citizen.org.

[28] G McGregor. Take two patents … and call me next year: the never-ending war to redraw Canada's arcane drug patent laws. *Ottawa Citizen*, 20 January 2002: C3; C Clark, S McCarthy. Drug-company donations to Manley spark controversy. *Globe and Mail*, 14 May 2003.

[29] HC Eastman, as quoted in: Historical perspective – reflecting on the last 15 years. *PMPRB NEWSletter,* January 2002; 6(1): 3-4 at 3. For a general overview of the regulatory environment of the pharmaceutical market in Canada, consisting of federal and provincial elements, see: R Corvari, D King, M Sanidas. Canada: Pharmaceutical pricing and reimbursement. Country profile prepared for: London School of Economics. *Worldwide survey on pharmaceutical pricing and reimbursement structures*. Research Study Commissioned by European Commission, Directorate General (Enterprise) and the G10 Medicines: High Level Group on Innovation and the Provision of Medicines, 2001 (available via: http://pharmacos.eudra.org). (The first author is a senior staff member of the Patented Medicine Prices Review Board.)

[30] The Canadian Institute for Health Information (CIHI) confirmed, in its 2002 report, that the increase in drug expenditure per capita was "largely due" to the increased utilization and introduction of new drugs: *Drug Expenditure in Canada, 1985-2001*. Ottawa: CIHI, April 2002 (available via www.cihi.ca). The majority of new drugs being marketed offer little or marginal therapeutic improvement over existing medicines, but are sold at much higher prices (particularly where a new drug may be under patent and the pre-existing drug may be off patent, and therefore faces competition from generics, or is about to go off patent and face such competition). This shift to new products, displacing existing products, was noted by then Minister of Health, the Hon David Dingwall, in his brief, *Drug Costs in Canada*, infra, note 41, submitted to the House of Commons Standing Committee on Industry in March 1997 as part of a legislatively mandated

review of the Patent Act. The Federal/Provincial/Territorial Pharmaceutical Issues Committee has also highlighted how the use of new drugs contributes to increasing expenditures by public health insurance plans, and hence the significance of controlling the introductory prices of these medicines: "PMPRB's review of introductory prices of new patented drugs are particularly important. About 80 new patented drug products come on the market every year. In 1997, newer drugs, on the Canadian market for five years or less, accounted for over half of the sales of patented drugs": F/P/T Committee, supra, note 21. Similar data have been reported by Green Shield Canada, the only national not-for-profit provider of healthcare benefits in Canada. Analysis of its data on drug claim costs over the 1997-2001 period, which complements three previous studies dating back to Patent Act changes in 1987, indicates that patented-drug costs represent an increasing proportion of the total drug costs claimed by its subscribers, rising to 65.1 percent of total cost in 2001, compared to 52.5 percent in 1997 and 44.0 percent in 1993: Green Shield Canada. Analysis of Drug Claim Costs 1997-2001. Toronto: Green Shield, 2003. See also: Green Shield Canada. Submission to the Commission on the Future of Health Care in Canada, 1 August 2001 (available via www.greenshield.ca); J Lexchin. Prescribing and drug costs in the Province of Ontario. *International Journal of Health* Services 1992; 22(3): 471-487.

Competition in the marketplace puts downward pressure on pharmaceutical prices. Therefore, the regulatory environment that hinders or facilitates generic competitors entering the market has an effect on drug prices. In Canada, marketing approval by the federal government for generic medicines is tied to allegations by patent-holding companies of patent infringement. Under the Patent Act, the federal Cabinet has the authority to issue regulations regarding patent infringement: RSC 1985, c P-4, s 55.2. Under the Patented Medicines (Notice of Compliance) Regulations (SOR/93-133), a simple allegation by a patent-holding company of potential patent infringement is sufficient to obtain an automatic injunction, preventing the federal government from approving a generic drug as safe and effective and authorizing its sale in Canada, for up to 24 months. This preferential status for patent-holding pharmaceutical companies, with its inducement to "evergreening" of patents to block market entry by generic competitors, is the subject of ongoing debate and efforts at reform, including hearings in early June 2003 by a House of Commons committee. (For details of the Committee hearings, see the Committee's webpage on the website of the Parliament of Canada, available via www.parl.gc.ca.) The Romanow Commission on the Future of Health Care in Canada recommended a review of this issue with a view to streamlining the approval of generic drugs: Commission Report, supra, note 13 at 209.

[31] In Canada, the federal Food and Drugs Act prohibits advertising any drug to the general public as a treatment, preventative, or cure for any of the diseases listed in a schedule to the Act, and prohibits any sale or advertising of a drug in a manner that is "false, misleading or deceptive": RSC 1985, c F-27, ss 3, 9. Under the Act (s 30), the federal Cabinet has authority to make regulations regarding the advertising of drugs. Regulations currently in force in Canada limit advertising of *prescription* drugs to the general public to identifying only name, price, and quantity (Food and Drugs Act Regulations, CRC c 870, s C.01.044). This framework is supplemented by "guidelines" issued by Health Canada (Therapeutic Products Directorate) to govern advertising of drugs to healthcare professionals and advertising of non-prescription drugs to consumers. Concerns persist regarding the effectiveness of this current regulatory framework and inadequate enforcement in the face of violations: see, eg, Canadian Treatment Advocates Council. Position Paper on Direct to Consumer Advertising (DTCA) of Prescription Medications, 30 November 1999 (available via www.ctac.ca). See also: DM Gardner et al. Direct-to-consumer prescription drug advertising in Canada: permission by default? *Canadian Medical Association Journal* 2003; 169: 425-27. Recent research indicates that more direct-to-consumer advertising leads to more requests for advertised medicines and more prescriptions, even where physicians are ambivalent about prescribing the treatment; the consequence is increased spending on pharmaceuticals without any clear evidence of corresponding therapeutic benefit or cost-effective use of healthcare dollars. For example, see: B Mintzes et al. How does direct-to-consumer advertising (DTCA) affect prescribing? A survey in primary care environments with and without legal DTCA. *Canadian Medical Association Journal* 2003; 169: 405.

[32] For example, a 1998 study estimated that, across the country, the average discount in price associated with purchasing a generic versus an originator drug was about 50 percent: NERA. Policy Relating to Generic Medicines in the OECD. National Economic Research Associates, London, 1998, cited in: Corvari et al, supra, note 29 at 15. For more discussion, see: AH Anis. Substitution laws, insurance coverage, and generic drug use. *Medical Care* 1994; 32(3): 240-256.

[33] F/P/T Committee, supra, note 21 at 13-14, citing data from Brogan Consulting Inc, Merck Frosst Canada Inc. *Handbook on Private Drug Plans.* 1993-1996, at 49.

[34] A Blomqvist, J Xu. *Pharmacare in Canada: Issues and Options.* Prepared for Health Canada, 2001 (available via: www.hc-sc.gc.ca).

[35] *Understanding Canada's Health Care Costs – Interim Report of Provincial and Territorial Ministers of Health*, June 2000.

[36] OECD Report on Pharmaceutical Expenditure [summary]. *PMPRB NEWSletter* July 2002; 6(3): 3-4 at 4.

[37] PMPRB Symposium 2002 – Highlights, supra, note 17. Those countries are: Germany, France, Italy, Sweden, Switzerland, the United Kingdom, and the United States.

[38] Supra, note 36.

[39] PMPRB Symposium 2002 – Highlights, supra, note 17. For a review of some different approaches to cost containment, including through different forms of price controls, see: K Bloor, A Maynard, N Freemantle. Lessons from international experience in controlling pharmaceutical expenditure: II. regulating industry. *British Medical Journal* 1996; 313: 33-35.

[40] S Jacobzone. Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals. Labour Market and Social Policy – Occasional Papers No 40. Paris: OECD, 2000 (available via www.olis.oecd.org). For a fairly comprehensive, recent review of pharmaceutical pricing and reimbursement schemes in 28 OECD member countries, see: London School of Economics. *Worldwide survey on pharmaceutical pricing and reimbursement structure*s, supra, note 29.

[41] DE Angus, HM Karpetz. Pharmaceutical policies in Canada: issues and challenges. *Pharmacoeconomics* 1998; 14(Suppl 1): 81-96 at 82. See also Hon. David Dingwall, Minister of Health. Drug Costs in Canada. Submitted to the House of Commons Standing Committee on Industry for the Review of the *Patent Act Amendment Act, 1992.* Ottawa: Health Canada, March 1997, at 12 and discussion at 12-19.

[42] Blomqvist & Xu, supra, note 34 [emphasis added]; F/P/T Committee, supra, note 21 at 6-7 (and source of Figure 1: Drug Expenditures by Type of Drugs and Sector, Canada, 1997).

[43] Reproduced from: Federal/Provincial/Territorial Pharmaceutical Issues Committee (Task Force on Pharmaceutical Prices), ibid at 7.

[44] Canadian Institute for Health Information. Total Drug Expenditure by Type, Canada, 1985-2002 (available via www.cihi.ca under "Statistics by Topic – Drugs," accessed 30 June 2003).

[45] J Lexchin. Intellectual Property Rights and the Canadian Pharmaceutical Marketplace: Where Do We Go From Here? Ottawa: Canadian Centre for Policy Alternatives, June 2003, at 8-9, available via www.policyalternatives.ca.

[46] The data that follow here are taken from: (1) Canadian Institute for Health Information. *Health Care in Canada 2003*. Ottawa: CIHI, 2003; and (2) Canadian Institute for Health Information. *National Health Expenditure Trends, 1975-2002*. Ottawa: CIHI, December 2002. For a summary of key findings of this latter report, see both the CIHI summaries available on its website, and PMPRB. National Health Expenditure Trends. *PMPRB NEWSletter* January 2003; 7(1): 7. The findings in the December 2002 report revise some earlier estimates found in: Canadian Institute for Health Information, supra, note 30. All figures in this paper are in Canadian dollars unless otherwise indicated.

[47] Medically necessary drugs dispensed in hospitals are covered by public health insurance systems in provinces and territories, as required by the Canada Health Act, in order to be eligible to receive funding from the federal government; these are included in hospital spending in CIHI's estimates.

[48] Rx&D, Canada's Research-Based Pharmaceutical Companies, make the case for the therapeutic and economic benefits of new prescription medicines. *Improving Health Through Innovation: A New Deal for Canadians*, September 2002 (available via www.canadapharma.org).

[49] F/P/T Committee, supra, note 21 at 8-10 (and source of Figure 4: Pharmaceutical Market in Canada, 1997). For another detailed overview of the Canadian industry, see: Industry Canada. *The Biopharmaceutical Industry: Overview, Prospects and Competitiveness Challenges*. Ottawa: Industry Canada, 2001 (available at http://strategis.ic.gc.ca/SSG/bo01879e.html).

[50] Ibid at 10.

[51] Industry Canada. *Sector competitiveness frameworks. Pharmaceutical industry: part 1 – overview and prospect*. Ottawa: Industry Canada, 1997, cited in: J Lexchin, supra, note 45.

[52] PMPRB Symposium 2002 – Highlights, supra, note 17 [emphasis added].

[53] Reproduced from Elgie, supra, note 2 at 3.

[54] Reproduced from R Elgie. The PMPRB: Latest Developments. Notes for an address to Pharmaceutical Pricing & Reimbursement Conference, Toronto, 29 October 2002, at 3.

[55] PMPRB. *2002 Annual Report*, at 18.

[56] Ibid.

[57] Ibid, citing data from IMS Health.

[58] J Lexchin. After compulsory licensing: coming issues in Canadian pharmaceutical policy and politics. *Health Policy* 1997; 40: 69-80 at 76-77, with reference to: J Lexchin. Who needs faster drug approval times in Canada: the public or the industry? *International Journal of Health Services* 1999; 24: 253-264; H Grabowski, J Vernon. A new look at the returns and risks to pharmaceutical R and D. *Management Science* 1990; 36: 804-821; JA DiMasi et al. Cost of innovation in the pharmaceutical industry. *Journal of Health Economics* 1991; 10: 107-142. Note that the analysis by DiMasi et al did not factor in tax savings obtained by writing off 40 percent of R&D expenses.

[59] Lexchin notes that that it is often claimed that standard accounting practices overstate profits in the pharmaceutical industry. However, even when this is taken into account, the industry is still among the most profitable in the US. See: US Congress, Office of Technology Assessment. *Pharmaceutical R&D: costs, risks and rewards*. OTA-H-522. Washington, DC: Government Printing Office, February 1993 (available in archive of OTA publications via www.wws.princeton.edu/~ota/.)

[60] L Lauzon, M Hasbani. Analyse socio-économique de l'industrie pharmaceutique brevetée pour la période 1991-2000. Montréal: Université du Québec à Montréal (Chaire d'études socio-économiques de l'UQAM sur l'industrie pharmaceutique), April 2002 (available via www.unites.uqam.ca/cese, under "Santé").

[61] See: A Gambardella et al. Global Competitiveness in Pharmaceuticals: A European Perspective. Report prepared for the Directorate General Enterprise of the European Commission, November 2000, at 78. The US employs price controls in relation to its Medicaid program and the Federal Supply Schedule; Germany does not control prices, but limits overall expenditures.

[62] S Jacobzone, supra, note 40 at 33. For a fairly comprehensive, recent review of pharmaceutical pricing and reimbursement schemes in 28 OECD member countries, see: London School of Economics. *Worldwide survey on pharmaceutical pricing and reimbursement structures*, supra, note 29.

[63] For some discussion of policy initiatives in the US to introduce price controls, see: P Ohlilger. Price control legislation: the newest trend in controlling pharmaceutical costs. *Drug Benefit Trends* 2000; 12(7): 15-16. For an analysis of "government use" compulsory licensing provisions in US patent law that could be used to enforce reasonable pharmaceutical prices for drugs developed with federal subsidy, see: PS Arno, MH Davis. Why don't we enforce existing drug price controls? The unrecognized and unenforced reasonable pricing requirements imposed upon patents deriving in whole or in part from federally-funded research. *Tulane Law Review* 2001; 75(3): 631. In April 2000, Maine became the first US state to pass legislation to establish a pricing board and use the government's purchasing power to extract lower drug prices from manufacturers. The US patent-holding pharmaceutical industry association, PhRMA, obtained an interim injunction preventing Maine from implementing the legislation, but in May 2003 the US Supreme Court overturned the injunction and allowed the state to proceed pending the outcome of further litigation challenging its validity: *Pharmaceutical Research and Manufacturers of America* v *Walsh*, decided 19 May 2003, available at www.supremecourtus.gov/opinions/02pdf/01-188.pdf.

[64] Dingwall, supra, note 41 at 13; S Burshtein. Sublicense or supply agreement? Supreme Court of Canada interpretation benefits generic pharmaceutical industry. *Food and Drug Law Journal* 1999; 54: 73 at 74.

[65] For a succinct historical review of federal legislative measures to control the prices of patented medicines in Canada, see the judgment of Robertson JA in *ICN Pharmaceuticals, Inc* v *Canada (Staff of the Patented Medicine Prices Review Board)*, [1997] 1 FC 32 (CA). For a more detailed analysis, see: J Horton. Pharmaceuticals, patents and Bill C-91. *Canadian Intellectual Property Review* 1993; 10: 145-158; DJ French. Patent law reform in Canada. *Canadian Intellectual Property Review* 1987; 4: 337; RW Marusyk, M Swain. Price control of patented medicines in Canada. *Canadian Intellectual Property Review* (1993); 10: 159-174; JH Reichman, C Hasenzahl. Non-voluntary Licensing of Patented Inventions: The Canadian Experience. Paper prepared for the UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, October 2002 (at www.ictsd.org/iprsonline/unctadictsd/docs/reichman_hasenzahl_Canada.pdf).

[66] Patent Act, SC 1923, c 23, s 17.

[67] Ibid, s 41(4) (added by 1969 amendments).

[68] Ibid.

[69] *Hoffmann-LaRoche Ltd* v *LD Craig Ltd, Bell-Craig Pharmaceuticals Division* (1965), 46 CPR 32, [1965] 2 Ex CR 266 (Exchequer Court of Canada).

[70] *Hoffman-LaRoche Ltd* v *LD Craig Ltd, Bell-Craig Pharmaceuticals Division*, [1966] SCR 313, (1966), 48 CPR 137, at CPR 144 (Supreme Court of Canada).

[71] Only 22 compulsory licences were granted between the introduction of these measures in 1923 and the major amendments to the Patent Act in 1969 extending the scope of compulsory licensing: J Horton, supra, note 65 at 146.

[72] Restrictive Trade Practices Commission. *Report on the Manufacture, Distribution and Sale of Drugs*. Ottawa: Queen's Printer, 1963, cited by J Lexchin. Globalization, Trade Deals and Drugs. Briefing Paper Series: Trade and Investment (Vol 2, No 8). Ottawa: Canadian Centre for Policy Alternatives, November 2001, and E Hill, J Steinberg. Bill C-22 and compulsory licensing of pharmaceutical patents. *Patent and Trademark Institute of Canada Review* 1987; 4: 44 at 45.

[73] *Report by the Royal Commission on Health Services: Recommendations with Respect to Drugs* (the Hall Commission). Ottawa: Queen's Printer, 1964; Canada, House of Commons. Second (Final) *Report of the Special Committee of the House of Commons on Drug Costs and Prices* (the Harley Committee). Ottawa: Queen's Printer, 1967.

[74] Act to Amend the Patent Act, the Trade Marks Act and the Food and Drugs Act, SC 1968-69, c 49.

[75] *ICN Pharmaceuticals, Inc*, supra, note 65, citing the following instances of such judicial interpretation: *Wellcome Foundation Ltd* v *Apotex Inc* (1991), 39 CPR (3d) 289 (FCTD); *Parke, Davis & Co* v *Fine Chemicals of Canada Ltd*, [1959] SCR 219; *Merck & Co Inc* v *S&U Chemicals Ltd* (1971), 65 CPR 99 (Ex Ct).

[76] Hill & Steinberg, supra, note 72 at 45.

[77] *Manitoba Society of Seniors Inc* v *Canada (Attorney-General)* (1991), 77 DLR (4^{th}) 485 (Manitoba Court of Queen's Bench), affirmed 96 DLR (4^{th}) 606 (Manitoba Court of Appeal).

[78] *Smith, Kline & French Laboratories* v *Attorney General of Canada*, (1985), 7 CPR (3d) 145, [1986] 1 FC 274 (Federal Court, Trial Division), affirmed (1986), 12 CPR (3d) 85, [1987] 2 FC 359 (Federal Court of Appeal), leave to appeal denied SCC Bulletin 1987, at 566, [1987] SCCA No 72 (Supreme Court of Canada) (QL); *American Home Products Corporation* v *Commissioner of Patents and ICN Canada Ltd* (1983), 71 CPR (2d) 9 (Federal Court of Appeal); *Lilly* v *S&U Chemicals Ltd* (1973), 9 CPR (2d) 17; *American Home Products Corp* v *Commissioner of Patents* (1970), 62 CPR 155 (Ontario Court of Appeal). For a review of numerous cases regarding Canada's provisions on compulsory licensing up to 1985 (shortly before substantial amendments in 1987, followed by further major amendments in 1992), see *Pfizer Inc* v *Genpharm Inc et al* (1985), 8 CPR (3d) 68 (Federal Court, Trial Division).

[79] K Murphy. Pharmaceutical compulsory licensing. *Patent and Trademark Institute of Canada Review* 1987; 3: 11 at 12. See, eg, *Hoffmann-La Roche Ltd,* supra, note 70, approving the royalty fixed by the Commissioner of Patents at 15 percent of the patent-holding company's net selling price of the bulk active material (as opposed to 15 percent of net selling price of the patented drug in dosage form).

[80] See the commentary in Murphy, ibid, at 12, 14. See also: P Gorecki, I Henderson. Compulsory patent licensing of drugs in Canada. *Canadian Public Policy* 1981; 7: 559; PLC Torremans. Compulsory licensing of pharmaceutical products in Canada. *International Review of Industrial Property and Copyright Law*1996; 27: 316.

[81] *Hoffman-LaRoche* v *Frank W Horner* (1970), 61 CPR 243 (Exchequer Court of Canada).

[82] Murphy, supra, note 79 at 12. Murphy provides a review of case law relating to compulsory licensing under Canada's post-1969 Patent Act. The four percent royalty figure has indeed been standard in Canadian compulsory licensing cases, although there have been some exceptions. See also: Hill & Steinberg, supra, note 72 at 45.

[83] Reichman & Hasenzahl, supra, note 65 at 37, citing *Imperial Chemical Industries PLC Ltd* v *Novopharm Ltd*, (1991), 35 CPR (3d) 137 at 139-40 (Federal Court of Appeal); *Novopharm Ltd* v *Eli Lilly & Co* (1992), 42 CPR (3d) 27 (Commissioner of Patents); *Delmar Chemicals Inc* v *Merck & Co* (1992), 42 CPR (3d) 135 (Commissioner of Patents).

[84] C Harrison. Protection of pharmcaeuticals as foreign policy: the Canada–US Trade Agreement and Bill C-22 versus the North American Free Trade Agreement and Bill C-91. *North Carolina Journal of International Law and Commercial Regulation* 2001; 26: 457 at 511.

[85] Lexchin, supra, note 58 at 76, with reference to J Lexchin. Who needs faster drug approval times in Canada: the public or the industry? *International Journal of Health Services* 1999; 24: 253-264.

[86] *Report of the Royal Commission on the Pharmaceutical Industry*. Ottawa: Supply and Services Canada, 1985 (Eastman Commission). The Commission was chaired by Dr Harry Eastman, who subsequently served as the first Chair of the Patented Medicine Prices Review Board established in 1987 by amendments to the Patent Act.

[87] Ibid, Summary, at 7.

[88] An Act to amend the Patent Act and to provide for certain matters in relation thereto, SC 1987, c 41.

[89] R Marusyk. The beginning of the end of compulsory licensing in Canada. *Biotechnology Law Report* 1992; 11: 671.

[90] Supra, note 88, ss 39.11, 39.12, 39.14.

[91] Ibid, s 39.16.

[92] Patent Act, RSC 1985, c P-4, s 39.15(3) [inserted as amendment by SC 1987, c 41 (Bill C-22)].

[93] Eg, *Novopharm Ltd* v *GD Searle & Co* (1991), 40 CPR 3d 56 , where the court said: "The possible effects of the grant of a licence on the patentee's Canadian operations cannot outweigh the clear objective of the compulsory licence provision in the Act to reduce the price of drugs by introducing the element of competition."

[94] Eg, *Novopharm Ltd* v *Janssen Pharmaceuticals NV* (1992), 41 CPR (3d) 384 at 387-89; *Novopharm Ltd* v *Yamanouchi Pharmaceuticals Co* (1989), 27 CPR (3d) 249 at 253.

[95] Lexchin, supra, note 72 at 3, citing: D Crane. Drug bill concessions seem tied to trade talks. *Toronto Star*, 7 December 1986: B1; R Howard. MPs say Tories made deal on drug bill. *Globe and Mail*, 16 October 1987: A13 (emphasis in original).

[96] Lexchin, supra, note 72 at 2-3. For additional details of the US negotiating posture and tactics on the question of pharmaceutical patents, see Harrison, supra, note 84 at 508-520; and S Chase. 1985 memos show US ire at patent law. *Globe and Mail*, 16 December 2002: A4.

[97] Harrison, supra, note 84 at 501, citing authorities.

[98] J Hore. Pharmaceuticals, patents and Bill C-91: the historical perspective. *Canadian Intellectual Property Review* 1993, 10: 145 at 147, citing: SP Battram, WL Webster. The Canada/United States Free Trade Agreement. *Canadian Intellectual Property Review* 1988; 4: 267 at 271.

[99] This figure is that calculated for 1995 by IMS, a private company that is the leading worldwide provider of market data in the health-care and pharmaceutical industries, and cited in Government of Canada. *Review of the Patent Act Amendment Act, 1992* (Bill C-91). Ottawa: Industry Canada, 1997, at 11.

[100] T Walkom. Patent drug review a bitter pill for critics. *Toronto Star*, 27 April 1997: F4.

[101] Patent Act Amendment Act, 1992, SC 1993, c 2.

[102] *Apotex* v *Canada*, [1994] 1 FC 742 at 754(CA).

[103] Patent Act Amendment Act, supra, note 101, ss 19-19.2.

[104] Most of the conditions circumscribing government use are required by the North American Free Trade Agreement (NAFTA, Article 1709) and the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS, Article 31). However, in some respects the government-use provisions in Canada's Patent Act are actually more restricted than is required by either of these agreements – for example, the Patent Act does not facilitate, to the full extent permitted by NAFTA and TRIPS, government use of a patented invention to remedy "anti-competitive" practices by a patent holder.

These provisions were at issue in October 2001 when, as a result of concerns about possible bioterrorism using anthrax, the federal Minister of Health initially disregarded the Canadian patent on the antibiotic drug ciprofloxacin, held by the multinational drug company Bayer, by agreeing to purchase a generic version from Apotex, a Canadian generic drug manufacturer. The government did not take the necessary steps required under s 19 of the Patent Act to obtain a compulsory licence on the medicine, and ultimately reversed course. Consequently, the applicability of s 19 was not tested in this case.

[105] Patent Act, supra, note 30, ss 65-71. For a discussion of cases interpreting the "patent abuse" provisions, see Reichman & Hasenzahl, supra, note 65 at 20-24 (available at www.ictsd.org/iprsonline/unctadictsd/docs/reichman_hasenzahl_Canada.pdf).

[106] Patent Act, supra, note 30, s 65(2)(c).

[107] Ibid, s 65(2)(d)-(f).

[108] Ibid, s 65(1).

[109] Ibid, s 66(1)(a).

[110] Competition Act, RSC 1985, c 34, s 32(2)(c).

[111] Reichman & Hasenzahl, supra, note 65 at 26 (see 26-32 for the full discussion).

[112] Torremans, supra, note 80 at 322, cited in Reichman & Hasenzahl, ibid.

[113] M Halewood. Regulating patent holders: local working requirements and compulsory licences at international law. *Osgoode Hall Law Journal* 1997; 35(2): 243-287; A Rotstein. Intellectual property and the Canada–US free trade agreements: the case of pharmaceuticals. *Intellectual Property Journal* 1993; 8: 121.

[114] Harrison, supra, note 84 at 524-525.

[115] See NAFTA, Articles 1704 and 1709; TRIPS, Article 31. For an analysis of options open to Canada to reintroduce compulsory licensing, see J Dillon. On Feeding Sharks: Patent Protection, Compulsory Licensing, and International Trade Law. Study prepared for the Canadian Health Coalition, 4 March 1997 (available via www.healthcoalition.ca) and accompanying opinion from a leading Canadian

expert on international trade law, Barry Appleton, LLB, LLM, of Appleton & Associates, 4 March 1997.

[116] WT/MIN(01)/DEC/2, available via the WTO website at www.wto.org.

[117] Walkom, supra, note 100, cited in P Carter. Federal regulation of pharmaceuticals in the United States and Canada. *Loyola of Los Angeles International and Comparative Law Journal* 1999; 21(2): 215 at 245.

[118] Government of Canada, supra, note 99 at i, 2. Interestingly, the document admits elsewhere that compulsory licensing is permitted "in very limited circumstances" under NAFTA and TRIPS: at 9. But the government continued to repeat as of 1999 that compulsory licensing was eliminated "to be consistent with the NAFTA and the trade-related intellectual property rights agreements of the WTO": Industry Canada. Sector Competitiveness Framework Series: Pharmaceutical Industry ("Key Points about this Industry – North America Context"), 10 May 1999 (at http://strategis.ic.gc.ca/SSG/ph01428e.html#2.2). This document provides considerable detail about the pharmaceutical market and industry in Canada.

[119] Government of Canada. Government Response to the Report of the Standing Committee on Foreign Affairs and International Trade – "The Free Trade Area of the Americas: Towards a Hemispheric Agreement in the Canadian Interest," Recommendation 27 (Intellectual Property), 15 March 2000, available at: http://www.dfait-maeci.gc.ca/tna-nac/FTAAreport-full-en.asp#9.

[120] Department of Foreign Affairs and International Trade. Free Trade Area of the Americas (FTAA): Summary of Canada's Position – Intellectual Property Rights. Ottawa: DFAIT, 2001, at www.dfait-maeci.gc.ca/tna-nac/IP-summary-e.asp.

[121] Meeting between representatives of the Global Treatment Access Group (GTAG) and Catherine Dickson, Director, Information and Technology Trade Policy Division, Department of Foreign Affairs and International Trade, 9 May 2002; notes on file.

[122] *Canada – Patent Protection of Pharmaceutical Products*, Panel Report, WT/DS114/R (17 March 2000) [the "Generic Medicines" case], available via WTO document search facility at www.wto.org. For a critique of the panel's flawed reasoning in relation to the stockpiling exception, see R Howse. The Canadian Generic Medicines Panel: a dangerous precedent in dangerous times. *Journal of World Intellectual Property* 2000; 3(4): 493-507.

[123] Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 [as later amended by SOR/98-166, SOR/99-379] (NOC Regulations).

[124] *Apotex Inc* v *Canada (Attorney General)*, [1997] 1 FC 518 (Trial Division), at para 7, affirmed [2000] 4 FC 264 (Court of Appeal), leave to appeal denied [2000] SCCA No 379 (Supreme Court of Canada).

[125] Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, SOR/98-166.

[126] For a more detailed description of the NOC Regulations, see E Hore. Are the Patented Medicines (Notice of Compliance) Regulations Working? Presentation at conference on Drug Patents: New Developments, New Strategies, 4-5 March 2002, Toronto (Insight Information Co); E Hore. The Notice of Compliance Regulations under the Patent Act: the first two years. *Canadian Intellectual Property Review* 1995; 12: 207-221; PR Wilcox, DC Ripley. The Patented Medicines (Notice of Compliance) Regulations. *Canadian Intellectual Property Review* 2000; 16: 429-448; A Nador. Comparing Canadian Notice of Compliance (NOC) Regulations for Patented Medicines with Corresponding United States and European Union Provisions. Presentation at conference on Drug Patents: New Developments, New Strategies, 4-5 March 2002, Toronto (Insight Information Co).

[127] *Merck Frosst* v *Canada (Minister of National Health and Welfare)*, [1998] 2 SCR 193, 80 CPR (3d) 368 at 384.

[128] *Apotex Inc* v *Canada*, supra, note 124.

[129] *Merck* v *Minister of National Health* (1994), 55 CPR (3d) 302 (Federal Court of Appeal), at 304.

[130] E Hore. A comparison of United States and Canadian laws as they affect generic pharmaceutical market entry. *Food and Drug Law Journal* 2000; 55: 373-388; and see also regular updates, news articles, and documents posted on the website of the Consumer Project on Technology at www.cptech.org/ip/health/generic/hw.html.

[131] The proceedings of the Committee hearings can be found on the Committee's webpage via the website of the Parliament of Canada at www.parl.gc.ca.

[132] The PMPRB's Compendium of Guidelines, Policies and Practices can be found on its website at www.pmprb-cepmb.gc.ca.

[133] Patent Act, supra, note 30 at ss 91(1), 92. The Minister is not required to create an advisory panel to provide recommendations on appointments.

[134] Ibid at s 91(2).

[135] PMPRB. *2002 Annual Report*, supra, note 55.

[136] In practice, this information has generally been combined in a single annual report. Annual reports of the PMPRB are public documents, submitted to Parliament, and as far back as 1989 may be found online at www.pmprb-cepmb.gc.ca.

[137] Patent Act, supra, note 30 at s 89.

[138] Patented Medicines Regulations, 1994, SOR/94-688 at ss 5-6.

[139] Ibid at s 5(1).

[140] Ibid at s 5(4)(c).

[141] Ibid at s 6.

[142] Patent Act, supra, note 30 at s 90.

[143] Information provided by W Critchley, Executive Director, Patented Medicine Prices Review Board, comments dated 7 August 2003.

[144] *ICN Pharmaceuticals, Inc*, supra, note 65, at para 12 (Federal Court of Appeal), citing a Government of Canada news release (NR-10770/92-21, at 1).

[145] Reproduced from F/P/T Committee, supra, note 21 at 14. More recently, the PMPRB has indicated that manufacturers' factory-gate prices account for approximately 65 percent of the final price of a drug to the purchaser: Historical perspective – reflecting on the last 15 years. *PMPRB NEWSletter*, supra, note 29 at 4.

[146] Patent Act, supra, note 30 at s 82.

[147] Ibid at s 80; Patented Medicines Regulations, supra, note 138 at s 4.

[148] Patented Medicines Regulations, ibid at s 4(1)(g) and Schedule I.

[149] Filing Requirements: A Reminder. *PMPRB NEWSletter* April 2002; 6(2): 6-7.

[150] Patent Act, supra, note 30 at s 96.

[151] Ibid at s 76.1.

[152] Ibid at s 76.1(4).

[153] Ibid at s 83(6).

[154] Ibid at s 86(1).

[155] Ibid at s 86(2).

[156] Ibid at s 96(2)(b).

[157] Information provided by W Critchley, Executive Director, PMPRB, comments dated 7 August 2003.

[158] Patent Act, supra, note 30 at s 83(1). Some have questioned whether the PMPRB's price control powers fall within the constitutional competence of the federal Parliament: Marusyk & Swain, supra, note 65. Such a challenge, brought before the amendments to the Patent Act through Bill C-91 in 1993, had been previously rejected: *Manitoba Seniors Society Inc* v *Canada,* supra, note 77. Marusyk and Swain argue, however, that the reasoning in the decision is suspect because of its characterization of the PMPRB's powers (as they existed at the time) as correcting patent abuse rather than amounting to price regulation. They argue that, particularly since the 1993 amendments abolishing a special regime for compulsory licensing of pharmaceutical patents, this reasoning may no longer be persuasive. Subsequently, however, the Federal Court of Appeal in 1997 expressly reaffirmed Parliament's jurisdiction to legislate with respect to patents, citing the *Manitoba Seniors Society* decision: *ICN Pharmaceuticals, Inc,* supra, note 65 at para 55.

[159] If the Board, "having regard to the extent and duration of the sales of the medicine at an excessive price," finds that the company "has engaged in a policy of selling the medicine at an excessive price," it may order any of these things, but increase the offset amount to twice the amount of excess revenues obtained by the company from its deliberate conduct of over-pricing: Patent Act, supra, note 30 at s 83(4).

[160] Ibid at s 99(1).

[161] Ibid at s 84(1).

[162] Ibid at s 84(3).

[163] Ibid at s 76.1(2).

[164] Ibid at s 76.1(4).

[165] W Critchley. Drug Patents and Drug Prices: The Role of the PMPRB. Notes for an address to Insight Conference: Drug Patents – News Developments, New Strategies, Toronto, 4 March 2002, at 10 (available via www.pmprb-cepmb.gc.ca).

[166] CIHI, supra, note 30.

[167] Patent Act, supra, note 30 at s 65.

[168] Ibid at s 85(1).

[169] Ibid at s 85(2).

[170] Ibid at s 85(3). This power has not yet been exercised by the PMPRB.

[171] H Eastman [PMPRB Chairperson]. Pharmaceutical price review in Canada. *Pharmacoeconomics* 1998; 5(4): 278-285, cited in W Critchley. Current Issues in Price Controls for Patented Drugs. Notes for an address to Insight Conference – Drug Patents, Toronto, 28 March 2003, at 8.

[172] Critchley, ibid at 10.

[173] Patent Act, supra, note 30 at s 96(4).

[174] The Excessive Price Guidelines can be found at www.pmprb-cepmb.gc.ca. See also note 132.

[175] PMPRB, Excessive Price Guidelines, ibid, para 2.1.

[176] PMPRB, *2002 Annual Report*, supra, note 55 at 10.

[177] F/P/T Committee, supra, note 21 at 10-11, 22.

[178] PMPRB, *2002 Annual Report*, supra, note 55 at 14.

[179] Lexchin, supra, note 45 at 2.

[180] Ibid at 13. Lexchin notes even less encouraging findings from research done in France by the drug bulletin *Prescrire*: "Ever since 1981 *Prescrire* has been assessing the value of new drugs and new indications for older drugs on the French market. Over a 21 year period it has looked at 2693 drugs. A mere 7 have been rated as a major therapeutic innovation in an area where previously no treatment was available and another 73 were considered products that were important therapeutic innovations but with certain limitations. By far, the majority (1780) were categorized as a superfluous new product that did not add to the clinical possibilities offered by previously avail-

able products."

[181] Excessive Price Guidelines, supra, note 174 at para 8.3 and Schedule 1.

[182] Ibid at para 8.3.

[183] Ibid, Schedule 2.

[184] F/P/T Committee, supra, note 21 at 25.

[185] PMPRB's Research Agenda 2003-2006. *PMPRB NEWSletter*, January 2003; 7(1): 5.

[186] Excessive Price Guidelines, supra, note 174 at paras 8.5-8.6.

[187] PMPRB. *Trends in Patented Drug Prices.* PMPRB Study Series No S-9811, September 1998.

[188] F/P/T Committee, note 21 at 28. Another alternative would be to use the lowest, rather than the median, international price in this two-pronged test. This was among the suggestions received by the PMPRB's Working Group on Price Review Issues: Price Guidelines for Category 3 Drugs: Part 1 (Annex 1: Preliminary Outline of Issues), September 1998, at 2.

[189] PMPRB. *2002 Annual Report*, supra, note 55 at 33.

[190] PMPRB. Report of the Working Group on Price Review Issues to the Patented Medicine Prices Review Board on the Price Guidelines for Category 3 Drugs: Part II. October 2002, at 6.

[191] *PMPRB NEWSletter* January 2003; 7(1): 3.

[192] Excessive Price Guidelines, supra, note 174 at paras 9.1-9.2 and Schedule 4.

[193] Angus & Karpetz, supra, note 41 at 89 [emphasis added], with reference to SG Morgan. Issues for Canadian pharmaceutical policy. *Canada Health Action: Building on the Legacy*, Vol 4: Striking a Balance; Health Care Systems in Canada and Elsewhere. Ottawa: Health Canada, 1998.

[194] Patent Act, supra, note 30 at s 85(1)(d).

[195] Excessive Price Guidelines, supra, note 174, Schedule 4.

[196] Ibid, Schedule 3, para 2.1.

[197] See supra, note 193.

[198] J Berger. Choking on the Bitter Pill: Canada's Approach to Patents, Prices and Profits. Paper prepared at University of Toronto, Faculty of Law, 2001, at 23 (note omitted) (on file).

[199] PMPRB. *Road Map for the Next Decade: Report on the PMPRB's Public Consultations.* Ottawa: PMPRB, September 1998, at 1, 2.

[200] F/P/T Committee, supra, note 21 at 29-30. For the "recent analysis" comparing R&D expenditures to sales referred to in this passage, see PMPRB (1997) Study Series S-9709, A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries.

[201] Lexchin, supra, note 58 at 74, with references to K Balasubramaniam. Retail drug prices in the Asia-Pacific region. HAI News No 86, December 1995, supplemental tables (re: Consumers International survey), and Green Shield Canada. A Report on Drug Costs. Toronto, October 1994 (re: rise in Ontario prescription costs).

[202] J Lexchin. Putting a price on drugs. *Canadian Medical Association Journal* 1997; 157: 869.

[203] Critchley, supra, note 171 at 10.

[204] PMPRB, *2002 Annual Report*, supra, note 55 at 23.

[205] Ibid at 27. For the full study, see PMPRB. *Study Series S-0217: A Comparison of Pharmaceutical Research and Development Spending in Canada and Selected Countries 2002.* Ottawa: PMPRB, 2002 (available via www.pmprb-cepmb.gc.ca).

[206] It should be noted that Canada's drug review process continues to be slower than many other similarly situated industrialized countries. This likely has a negative effect on R&D spending in Canada, and also means Canada delays in setting a price on a new medicine until the price is already established in many of the comparator countries used by the PMPRB for regulating prices in Canada. This increases the impact, for better or for worse, of other countries' price-control schemes (where they exist) on Canadian prices.

[207] Supra, note 205.

[208] Ibid.

[209] PMPRB. *2001 Annual Report*, at 27.

[210] PMPRB. *2002 Annual Report*, supra, note 55 at 31.

[211] Conference Board of Canada. *Rating R&D Tax Incentives*. Ottawa: The Board, 2000. This study updates a review of R&D tax incentives among OECD countries first published in 1997: J Warda. *R&D Tax Incentives in OECD Countries: How Canada Compares*. Ottawa: Conference Board of Canada, 1997.

[212] Conference Board of Canada. News release: Canada tops global standings for R&D tax system, 12 January 2000.

[213] See Patent Act, supra, note 30 at s 85(3) regarding the Board's consideration of research costs pertaining to a medicine.

[214] PMPRB's Research Agenda, supra, note 185.

[215] G Hillson. The high cost of survival. *Living +*, July/August 1999: 21-23 at 21.

[216] Letter to LY Reinhard, Director – Compliance and Enforcement, PMPRB, from Louise Binder, CTAC Co-Chair, dated 22 July 1999 (on file).

[217] BC Centre for Excellence in HIV/AIDS. High price of Sustiva means limited access. *Living +*, July/August 1999: 22-23.

[218] A McIlroy. Canadian firm gouging patients, AIDS group says. *Globe and Mail*, 9 July 1999: A7.

[219] Reports on new patented drugs – Sustiva. *PMPRB NEWSletter* July 2002; 6(3): 4-6.

[220] Hillson, supra, note 215 at 22.

[221] Supra, note 216.

[222] Reports on new patented drugs: Ziagen. *PMPRB NEWSletter* July 2002; 6(3): 6-8.

[223] Letters to G Tognet, Director – Compliance and Enforcement Branch, PMPRB, from Glen Hillson, Vice-Chair, Canadian Treatment Action Council, dated 18 January 2002 (on file).

[224] L Binder. Drug Pricing in Canada. Presentation at Canadian Association for HIV Research Conference, May 1999, Victoria, British Columbia.

[225] G Hillson. Canadian treatment activists win important battle in the war against high drug prices; PWAs from across Canada target pharmaceutical manufacturers and price regulators. Update for the CTAC Committee for Fair Drug Prices, 1999; see also G Hillson. And they said it couldn't be done: CTAC wins pivotal battle in the war against high drug prices. *CTAC Newsletter*, September 1999: 4.

[226] Comments from L Binder, Chair, Canadian Treatment Action Council, 12 August 2003.

[227] F/P/T Committee, supra, note 21 at 56.

[228] Historical perspective. *PMPRB NEWSletter*, supra, note 29.

[229] In any event, this accounts for an increasingly insignificant number of drugs, given the abolition of the special pharmaceutical compulsory licensing regime in 1993.

[230] Patent Act, supra, note 30 at s 79(2).

[231] *ICN Pharmaceuticals, Inc*, supra, note 65 at para 46.

[232] *In the matter of Hoescht Marion Roussel Canada Inc and the medicine Nicoderm*, Decision of the Board, PMPRB-99-D6-Nicoderm, 8 August 2000.

[233] *Glaxo Group Ltd* v *Novopharm Ltd*, [1999] FCJ No 799 (Federal Court of Appeal) (QL).

[234] Critchley, supra, note 171.

[235] W Critchley. Controlling Drug Prices in Canada: Current Issues. Notes for an address to Canada's Pharmaceutical Industry Congress, Toronto, 21 November 2000, at 8.

[236] *In the matter of Hoechst Marion Roussel Canada Inc and the medicine Nicoderm*, supra, note 232 at 22.

[237] Patent Act, supra, note 30 at s 79(1).

[238] Ibid at s 55(2).

[239] *In the matter of Hoechst Marion Roussel Canada Inc and the medicine Nicoderm*, supra, note 232.

[240] Ibid.

[241] *Re Genentech Canada Inc* (1992), 44 CPR (3d) 316 at 328-9 (PMPRB).

[242] *Genentech Inc* v *Patented Medicine Prices Review Board* (1992), 44 CPR (3d) 335 (Federal Court Trial Division).

[243] Marusyk & Swain, supra, note 65 at 166.

[244] Critchley, supra, note 171 at 13.

[245] Ibid.

[246] Angus & Karpetz, supra, note 41 at 89 (references omitted).

[247] F/P/T Committee, supra, note 21 at 30.

[248] PMPRB, *2002 Annual Report*, supra, note 55 at 18.

[249] Ibid.

[250] Elgie, supra, note 2 at 10.

[251] National Forum on Health, supra, note 14.

[252] House of Commons, Standing Committee on Industry. Review of Section 14 of the Patent Act Amendment Act, 1992. Fifth Report of the Standing Committee on Industry, April 1997.

[253] Dingwall, *Drug Costs in Canada*, supra, note 41 at 17.

[254] *Road Map,* supra, note 199.

[255] Critchley, supra, note 165 at 5.

[256] F/P/T Committee, supra, note 21 at 30, 33.

[257] Elgie, supra, note 2 at 10. The PMPRB's 2002 Annual Report also indicates that, when the US was removed from the comparison, Canadian prices of non-patented single source drugs were 75 percent higher than the median price of the six European countries remaining in the basket: *2002 Annual Report*, supra, note 55 at 28. For the full study, see PMPRB. *Top Selling Non-Patented Single Source Drug Products: International Price Comparison, 1998-1999*. Ottawa: PMPRB, 2002 (available via www.pmprb-cepmb.gc.ca).

[258] Dingwall, *Drug Costs in Canada*, supra, note 41 at 17, citing Industry Canada, unpublished analysis, 1996; IMS Canada, "Canadian CompuScript," June 1996. As of 2003, the Canadian General Pharmaceutical Association (representing generic drug manufacturers)

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[259] Canadian General Pharmaceutical Association. The Canadian Generic Market – 12 months ending December 2002 (available at www.cdma-acfpp.org/en/resource_trends.html).

[260] F/P/T Committee, supra, note 21 at 35.

[261] Ibid at 38.

[262] Critchley, supra, note 171 at 8.

[263] PMPRB. A Study of the Prices of the Top Selling Multiple Source Medicines in Canada. Ottawa: PMPRB, November 2002. For a short summary of key findings of this study, see PMPRB. PMPRB study for the Federal/Provincial/Territorial Working Group on Drug Prices. *PMPRB NEWSletter* July 2003; 7(3): 4.

[264] Romanow, supra, note 13 at 203.

[265] NDMAC. Industry Profile: Canada's Self-Care Products Industry, at www.ndmac.ca/industry/F-profil.html (accessed 2 July 2003).

[266] About NDMAC, see www.ndmac.ca/about/index.html, accessed 2 July 2003. It should be noted that the membership of NDMAC includes at least a dozen pharmaceutical companies that focus on the manufacture of patented medicines (including prescription medicines), and some of the largest multinational patent-based companies, such as Abbott Laboratories, AstraZeneca, Bayer, GlaxoSmithKline, Merck Frosst, Pfizer, Procter & Gamble, and Hoffman-LaRoche.

[267] NDMAC. Nonprescription drugs and the *Patent Act*. Brief submitted to the Parliamentary Committee on Industry, 27 March 1997 (available at www.ndmac.ca/publicat/c91brief.htm); NDMAC. *Response to the Patented Medicine Prices Review Board November 1997 Discussion Paper: Examining the Role, Function and Methods of the Patented Medicine Prices Review Board*, March 1998 (available via www.ndmac.ca); NDMAC. A Submission on the Future of Health Care in Canada. Submission to the Commission on the Future of Health Care in Canada, 18 January 2002 (available at www.ndmac.ca/publicat/romanow.html).

[268] NDMAC, *Response*, supra, note 267.

[269] Ibid at 15-17.

[270] European Commission, Enterprise Directorate-General and G10 Medicines High Level Group on Innovation and Provision of Medicines. *Consultation Paper* (2001) (available via http://pharmacos.eudra.org), at 4.

[271] In practice, this information has generally been combined in a single annual report. Annual reports of the PMPRB are public documents. Those submitted to Parliament as far back as 1989 may be found online at www.pmprb-cepmb.gc.ca.

[272] Patent Act, supra, note 30, ss 89, 100.

[273] Jacobzone, supra, note 40 at 36.

[274] G Velásquez, Y Madrid, JD Quick. *Health reform and drug financing: Selected topics*. Health Economics and Drugs, DAP Series No 6. Geneva: World Health Organization (Action Programme on Essential Drugs), 1998 at 27 (available via www.who.int), reference omitted.

[275] Historical Perspective, *PMPRB NEWSletter*, supra, note 29 at 4.

[276] PMPRB, *2002 Annual Report*, supra, note 55 at 8. Lexchin notes that whether this trend is due to regulation via the PMPRB is unknown because pre-1987 trends are unknown; if Canadian prices were stable or increasing relative to those in Europe prior to 1987, the subsequent moderation in Canadian prices may be attributable to PMPRB regulation, but if Canadian prices were already declining relative to those in Europe, the impact of PMPRB regulation is less ascertainable: Lexchin, 16 July 2003, comments on file.

[277] Eg, S Morgan. 'Ideal Regulation' of Drug Prices – What Role for the Regulator? Draft paper, 25 March 1998, on file, at 15.

[278] The PMPRB has indicated that a study of the 1990-97 period found that "spending on new drugs accounts for a significant proportion of total expenditures in the jurisdictions studied. [In addition, a]pproximately 30% of spending in 1999-2000 represented spending on new drugs that had been added to the formulary within the previous five years": Elgie, supra, note 54 at 9.

[279] Lexchin, supra, note 58 at 74, with reference to Green Shield Canada, Report, supra, note 201.

[280] Dingwall, *Drug Costs in Canada*, supra, note 41 at 16 [emphasis added]. Note that the effect reported by the Minister is a "decline in the rate of increase" in the prices of "all drugs." This success in moderating increases in patented drug prices is important, but as data presented earlier on continuously rising drug *spending* show us, additional policy measures are needed to ultimately control costs – such as addressing shifts in use to newer, more expensive drugs when this may not be accompanied by significant therapeutic improvement.

[281] PMPRB, *2002 Annual Report*, supra, note 55 at 21. The PMPI is an index created by the PMPRB to monitor trends in manufacturers' prices of patented drugs, and measures average year-over-year changes in the transaction prices of patented drug products sold in Canada based on the price and sales information reported by patentees. For a detailed explanation, see PMPRB. A description of the Laspeyres methodology used to construct the Patented Medicine Price Index (PMPI), March 1997, revised June 2000.

[282] Patented Medicines Regulations, supra, note 138 at ss 5-6.

[283] Ibid at s 5(1).

[284] Ibid at s 5(4)(c).

[285] Ibid at s 6.

[286] Filing Requirements, *PMPRB NEWSletter*, supra, note 149.

[287] Patent Act, supra, note 30 at s 90.

[288] Lexchin, supra, note 45 at 1, 9-10.

[289] Ibid at 9. For the source of more detailed data on this point, see: PMPRB, Study Series S-0217, supra, note 205.

[290] PMPRB, *2002 Annual Report*, supra, note 55 at 10, 30.

[291] Ibid at 30-31. Lexchin notes that the PMPRB figures only report R&D spending by patentees, meaning that R&D spending by companies who do not yet have any patented medicines on the Canadian market (such as some smaller biotechnology companies) are not reflected in these figures: Lexchin, 16 July 2003, comments on file.

[292] For data, see PMPRB, Study Series S-0217, supra, note 205.

[293] PMPRB, *2002 Annual Report*, supra, note 55, Glossary at 44.

[294] PMPRB, 2001 *Annual Report* – Highlights. *PMPRB NEWSletter* July 2002; 6(3): 2.

[295] Lexchin, supra, note 45.

[296] PMPRB, *2002 Annual Report*, supra, note 55 at 8.

[297] House of Commons Standing Committee, supra, note 252, Recommendation 5.

[298] For an extended discussion of the failure to adequately research medicines for neglected diseases, see: Médecins Sans Frontières. *Fatal Imbalance: The Crisis in Research and Development for Drugs for Neglected Diseases*. Geneva: MSF and Drugs for Neglected Diseases Working Group, September 2001 (available via www.msf.ca).

[299] US Congress, Senate Special Committee on Aging, 103d Congress. Earning a Failing Grade: A Report Card on 1992 Drug Manufacturer Price Inflation. Comm. Print, 1993, at 1-2.

[300] Kaiser Family Foundation. *Prescription Drug Trends: A Chartbook Update*. KFF, November 2001, at 13 (and see Exhibit 31) (available at www.kff.org/content/2001/3112/RxChartbook.pdf).

[301] Consumer Project on Technology. Pharmaceutical company expenses: cost of sales, marketing, R&D compared, 19 April 2000 (available at www.cptech.org/ip/health/econ/allocation.html). Only two companies out of the 19 (neither of whom are major companies in the industry) spent more on R&D in 1999 than on marketing and administration; for three others, data on marketing and administration were not available.

[302] AIDS Action. *Silence = $*. Washington, DC: AIDS Action, released 20 July 1999.

[303] Lauzon & Hasbani, supra, note 60.

[304] PH Stone. PhRMA fights back. *National Journal*, 21 July 2001, at 2314.

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[306] S Ruttan. Sugar-coated pills: Canada's multibillion-dollar drug industry lavishes expensive perks on doctors to build sales – but there are growing signs of resistance in the medical community. *Edmonton Journal*, 5 October 2003.

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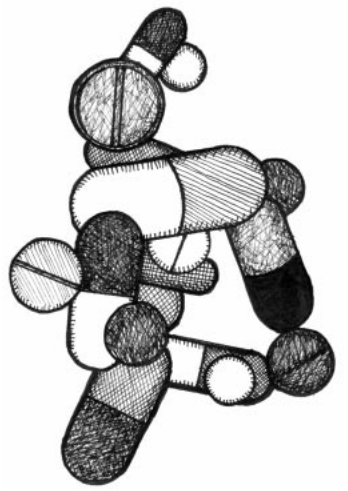

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