

Economic aspects of certain public policies concerning patented medicines

**Brief submitted by the MEI to the House of Commons Standing Committee on Health
in the context of its study on prescription drugs (October 2003)**

Introduction

Economics is the study of individual choices and their consequences. Among these choices, the pursuit of physical well-being through the use of modern medicines holds a high place in developed societies.

For this need to be met, consumers have an interest in the existence of a pharmaceutical industry that is as free, competitive and efficient as possible. Our analysis covers three areas where public policies influence industry performance and, at the end of the road, affect the opportunities available to consumers in making enlightened choices.

1. Shadows over the Canadian pharmaceutical industry

The situation of the Canadian pharmaceutical industry shows certain difficulties.

- The Patented Medicine Prices Review Board (PMPRB) has written that, by various measures, pharmaceutical R&D spending in Canada "lags the countries used for regulatory purposes, except for Italy."[\(1\)](#)
- Over the last few years, the worldwide research and development costs of pharmaceutical companies have risen more rapidly (14% per year) than their sales (7%).[\(2\)](#)
- As we shall see, public policies often deter patented drug producers, the most innovative of pharmaceutical companies.

This makes it easier to understand fears that Canada's and Quebec's pharmaceutical industry could follow what is happening to Europe's pharmaceutical industry, namely, being outclassed by the U.S. industry. This would bring no gains to consumers.

2. Price controls

2.1. *The role of prices*

Prices play a crucial role in the economy, as demonstrated by Friedrich Hayek, winner of the 1974 Nobel Prize in

economics.⁽³⁾ The efficiency of a market economy depends largely on the freedom of prices.

2.2. Canadian price controls on drugs

Since 1988, the federal government has controlled drug prices through the Patented Medicine Prices Review Board (PMPRB). The controls apply from the time of their launch, with a ceiling on price increases based on the consumer price index. Canada stands alone among major western countries in placing public controls on the prices of patented drugs that are not reimbursed by public health insurance plans as well as those that are.⁽⁴⁾

In addition, provincial governments control the marketing of patented medicines by deciding whether to include them on lists of reimbursed drugs. In Canada, nearly half of medical spending comes from provincial health insurance plans. Two provincial governments, those of Quebec and Ontario, have imposed price freezes for the last several years.

2.3. Their impact on prices

Since 1994, average Canadian prices for patented medicines have been 5% to 12% below median prices in Italy, France, Sweden, Germany, the United Kingdom, Switzerland and the United States. The only exception was in 2002, when Canadian prices were around average.⁽⁵⁾

We should note that price controls apply in all the countries concerned, with the sole exception of the United States. The U.S. is the country with the fewest government constraints on prices, even though the law provides special discounts for the federal government.⁽⁶⁾ The fact that Canadian prices are generally lower than international prices seems to indicate that controls are tighter here.

The prices of patented drugs in Canada average 40% less than U.S. prices, 6% less than Swiss prices and 4% less than British prices.⁽⁷⁾ Economists estimate that between one-third and one-half of the difference between Canadian and U.S. prices is due to lawsuits in the U.S.⁽⁸⁾ The rest of the difference can likely be attributed to the effects of price controls.

This is why the real prices of patented medicines have been falling in Canada over the last few years. Between 1998 and 2002, nominal prices of patented drugs rose by only 0.6% a year, compared to 1.9% for the prices of all medications and 2.5% for the consumer price index. This means real prices of patented drugs fell by 2% annually.

Everything seems to indicate that price controls on patented medicines in Canada have prevented prices from reaching market levels. This does not encourage Canadian producers to invest in the medications of the future.

3. The regulatory process for drug approval

3.1. Excessively long lead times

Health Canada's approval process for new drugs takes an average of 717 days, or nearly two years. This is almost twice as long as in the United States. It is also longer than in Japan, Australia, the European Union, France and the United Kingdom (the countries normally used in comparisons).⁽⁹⁾

To this delay in approval has to be added the time the provincial governments take to list these new drugs for health insurance purposes, varying from about 350 days in Quebec to more than 500 days in Manitoba. Moreover, depending on the province, only 38% to 59% of new medicines make it onto the lists.⁽¹⁰⁾

3.2. Consequences of delays in approval

3.2.1. For pharmaceutical companies

These delays in approval are very costly for patented medicine producers. A recent university research project estimated that development of a new drug takes an average of 12 years and costs an average of US\$800

million,⁽¹¹⁾ or about \$1.1 billion in Canadian funds. If we factor in a capital cost of 11%, what it costs the industry to remunerate its shareholders and lenders, each year of delay after a medication is fully developed costs more than C\$120 million for each product in the queue.

3.2.2. For the ill

For consumers in other words, the ill the cost can be calculated in added risk of illness or death. Research in the U.S. suggests that, over several decades, delays in FDA approval of drugs used elsewhere in the world has cost the lives of hundreds of thousands of Americans.⁽¹²⁾ It would seem that Canadians awaiting new treatments are penalized similarly.⁽¹³⁾

Delays in approval may have prevented catastrophes such as thalidomide (the approval process already existed in the U.S. in that era) but, according to an American expert, the FDA may have caused more deaths than it has prevented.⁽¹⁴⁾

4. Advertising aimed directly at consumers

4.1. Official objections to direct advertising

4.1.1. Non informative advertising

Opposition to direct advertising of medicines is usually justified by the fact that it does not contain information that is useful to consumers.

There are two responses to this objection. First, since consumers must decide on questions intimately linked to their personal well-being, and since they ultimately have to cover the costs (directly, or through insurance or taxes), it would be pertinent and useful to let consumers determine on their own whether the information is useful. Second, consumers whose opinion has been sought, as it was by the U.S. Food and Drug Administration (FDA), assert clearly that direct advertising of medicines is useful.⁽¹⁵⁾

4.1.2. Patient pressures

Another objection to direct advertising is that, to obtain an advertised drug, patients will exert detrimental pressure that their doctors cannot resist.⁽¹⁶⁾

This pronouncement is without empirical foundation. A majority of American doctors see mostly advantages in direct advertising. According to an FDA survey, 95% of American doctors believe direct advertising informs patients on treatment possibilities, and 79% agree that direct advertising brings their patients to consult them on potentially serious pathologies.⁽¹⁷⁾ In fact, 91% do not believe their patients have attempted to exert detrimental influence on their treatment. In any event, a high proportion of doctors do not issue the prescriptions suggested by their patients.

4.1.3. Patient-doctor relations

One related objection maintains that direct advertising risks bringing consumers to exert pressures on their doctors that would cause a deterioration in patient-doctor relations.

According to the FDA surveys, 84% of American doctors believe direct advertising facilitates discussions with their patients, and 82% do not believe it has harmed their relationship with them.⁽¹⁸⁾ In fact, 41% believe the relationship with their patients has been improved by it.

4.1.4. Overconsumption

There is nothing to indicate that direct advertising results in overconsumption either from a medical or an economic point of view. It is obviously incoherent to blame direct advertising for overconsumption of drugs while simultaneously favouring price controls that encourage overconsumption.

4.2. The advantages of direct advertising

To sum up, the economic analyses we consulted show that the information provided by direct advertising favours patient health. Those subject to it say they also use other sources of information. They often mention advertised medicines to their doctors and obtain prescriptions for these or other drugs. They frequently talk to their doctors about potential problems that have not yet arisen, they often obtain unexpected diagnoses, and they have an easier time remembering the dosage and renewal of their prescriptions.

In addition, it is likely that the ability to inform consumers directly encourages pharmaceutical companies to develop new medicines.⁽¹⁹⁾ It becomes less risky to develop a product knowing that it will be easier to make its existence known to consumers.

4.3. The real objections

If the scientific studies conducted on this topic are to be trusted, the advantage of direct advertising are so obvious that it must be paternalistic or corporatist interests that explain the fear of consumers having access to this additional source of information.

5. The new order

The impact of the Internet on public policies also has to be considered. A large number of pharmacies have cropped up on the Internet, about half of which may not have the required legal authorization and one-third of which do not require original prescriptions.⁽²⁰⁾ As can easily be verified on the Web, anybody at all can obtain popular prescription drugs. For example, a Google search for "celebrex purchase online Canada" provides many pages, with the first one giving access right off the bat to a number of Internet pharmacies.⁽²¹⁾

In an era of Internet pharmacies and widely accessible medical and pharmacological information, questions related to price controls, drug approval and consumer information take on a new dimension that has to enter into consideration. A legal market with poor information flow, where serious producers and recognized brand names face disadvantages, runs the risk of encouraging consumers to turn toward solutions that are riskier for their health.

6. Conclusions

To sum up, a number of public policies prevent consumer demand for medicines from being satisfied:

- It is likely that price controls on patented drugs over the last 15 years have had unfavourable effects on the pharmacological markets and, over time, on the health of Canadians.
- The slow pace of the approval process for new medications has caused the research and development costs of producers to rise and has likely harmed patients deprived of therapies they may have desired.
- The prohibition on direct advertising to consumers has given an information monopoly to doctors and has deprived patients of more complete information.

The Montreal Economic Institute is making no specific recommendations. This brief is intended solely to stir reflection among members of the Standing Committee on Health by offering an analysis of certain aspects of how the Canadian pharmaceutical industry is regulated, doing so in the light of economic teachings. We urge Committee members to examine the means they consider appropriate for the Canadian pharmaceutical industry, in the interest of consumers, to be as free, competitive and efficient as possible.

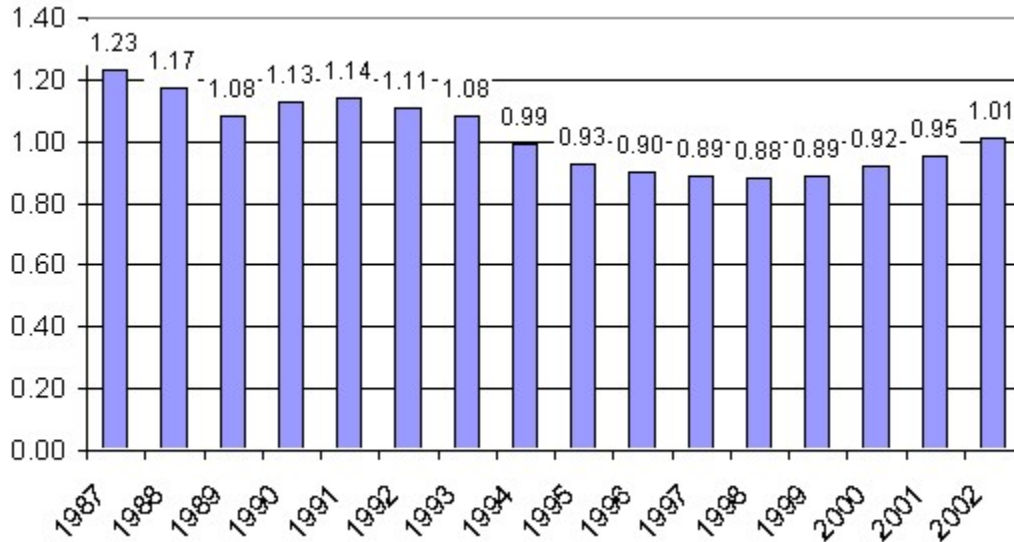
1. PMPRB (2003), p. 27. [>>](#)
2. SECOR (2003), p. 38. [>>](#)
3. Hayek (1945). [>>](#)
4. SECOR (2003), p. 78. [>>](#)
5. See Figure 1 in the appendices. [>>](#)
6. See Graham (2003), p. 9. [>>](#)
7. See Figure 2. The data come from the PMPRB. [>>](#)
8. Bandow (2003), p. 5. [>>](#)
9. SECOR (2003), p. 75, based on data from KPMG and from Ernst & Young. [>>](#)
10. SECOR (2003), p. 76. [>>](#)
11. DiMasi et al. (2003). Amounts are in 2002 dollars, and the estimate applies to drugs approved in the late 1990s. For a drug entering development now, the amount to be expected is closer to US\$1.9 billion (cf. *ibid.*, p. 181). [>>](#)
12. See Bandow (1997) and Goldberg (1995). Examples include the eight-year delay in the approval of beta blocking agents, falsely suspected of causing cancer, a delay that may have caused 119,000 patients to die. [>>](#)
13. An innovative idea worth exploring was suggested in the United States by Prof. Robert Goldberg, namely, that health authorities merely give a seal of approval but without preventing patients (and doctors) from using medications that are unapproved and clearly identified as such. This "opting out" formula is proposed in Goldberg (1995). [>>](#)
14. Dale Gierenger writes: "The benefits of FDA regulation relative to that in foreign countries could reasonably be put at some 5,000 casualties per decade or 10,000 per decade for worst-case scenarios. In comparison, it has been argued above that the cost of FDA delay can be estimated at anywhere from 21,000 to 120,000 lives per decade." (cited by Tabarrok [2000], p. 31). [>>](#)
15. See Aitkin (2003), who reports the results of the latest FDA survey FDA. [>>](#)
16. Gardner et al. (2003). [>>](#)
17. See Figure 3. [>>](#)
18. See Figure 3. [>>](#)
19. Calfee (2003), p. 118. [>>](#)
20. See Euromedia (2003) as well as http://www.pharmacychecker.com/news/news_040703.asp (page visited on October 13, 2003). [>>](#)
21. See Table 4. [>>](#)

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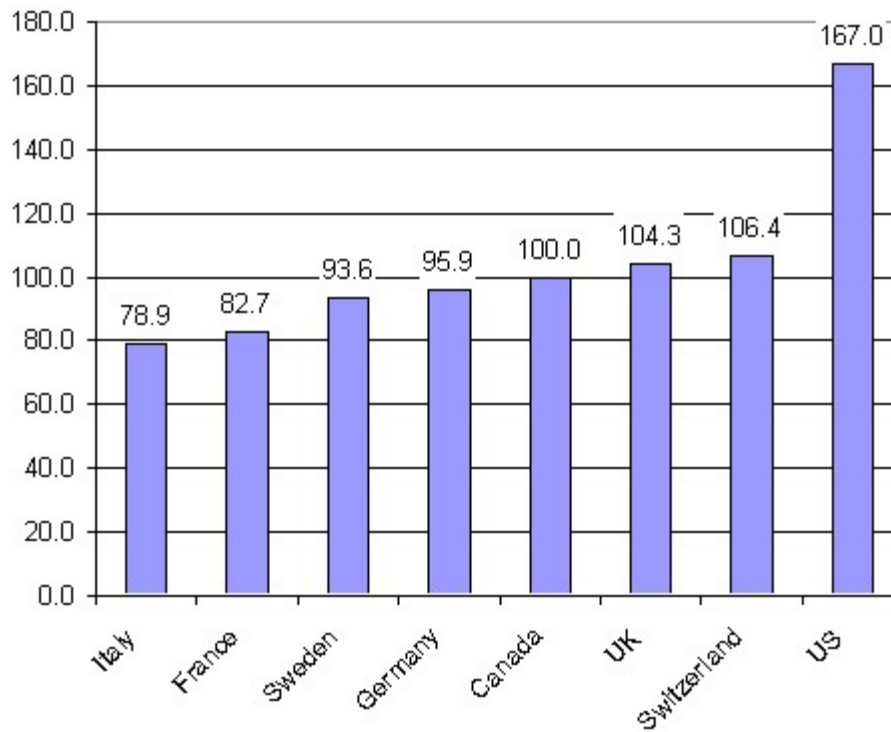
TABLES & FIGURES

Figure 1: Average Canadian price of patented medicines compared to median international prices



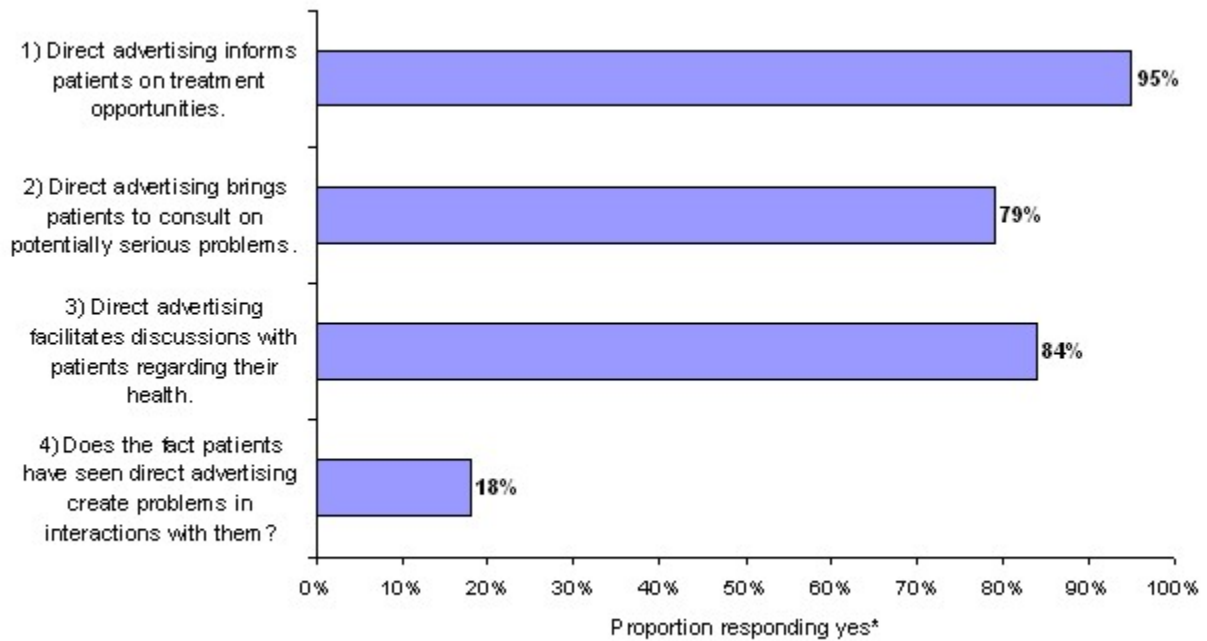
Source: PMPRB (2003), p. 23.

Figure 2: Average prices of patented medicines abroad as proportions of Canadian prices




Source: PMPRB (2003), p. 23.

Figure 3
Some responses of American doctors regarding the impact of direct advertising on their patients and on their relationships with their patients



* Statements 1, 2 and 3: proportion of doctors answering "a great deal," "somewhat" or "a little."
SOURCE: Aitkin and Swasy (2003), based on the FDA survey.

Table 4: Search for a popular medicine on Google (30/09/03)

 Recherche avancée | Préférences | Outils linguistiques | Conseils de recherche

celebrex purchase online canada | Recherche Google

Rechercher dans : Web Pages francophones Pages : Canada

Web | Images | Groupes | Répertoire | Actualités

Google a recherché **celebrex purchase online canada** sur le Web. 1 - 10 résultats, sur un total d'environ 88,800. Recherche effectuée en 0,17 secondes.

Celebrex - [Traduire cette page]
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buy-celebrex-purchase-vioxx-cheap-meridia-online.cheap-pharmacy-online.com/ - 10k - 28 Sep 2003 - En cache - Pages similaires

Celebrex Online Canada - [Traduire cette page]
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Et pourquoi pas votre propre message ?