Is Canada's government, or its weak economy, responsible for low drug prices?

Seeing Through the Snow

By John R. Graham

The Fraser Institute

ESS RATTRAY HAD HEARD ABOUT the low prices. A friend in Seattle told her how to buy what she needed cheaply. She flew from New York to Montreal, and headed to a store downtown. When she got there, the woman at the counter was on the phone speaking to a buyer from Boston who wanted to know what was in stock. The store had what Bess wanted, and sold it to her for half its American price. Bess walked out with a pair of sky-blue Celine jeans. As reported in last November's issue of Vogue, she also bought furs, pants, and shoes at discounts of about 50 percent.

In recent elections, American politicians did not campaign against price-gouging clothing manufacturers. They also did not attack higher American prices for software, automobiles, or any one of the thousands of goods and services that are significantly cheaper in Canada. However, with an eye to the seniors' vote, they honed in on prescription drugs and criticized drug manufacturers for charging different prices in different markets.

THE PMPRB

CONVENTIONAL WISDOM MAINTAINS THAT PHARmaceutical prices in Canada are low because of government price controls. Canada's Patented Medicine Prices Review Board (PMPRB) is a federal, quasi-judicial body that regulates introductory prices of newly patented drugs and price increases of extant patented drugs. The PMPRB does not purchase drugs; rather, it determines the maximum prices that manufacturers can charge for patented drugs, thereby preventing market participants from negotiating a price. Furthermore, the PMPRB controls only the price at which the manufacturer sells, not the wholesale price, retail price, pharmacist's dispensary fee, or any other distribution cost.

The PMPRB classifies patented drugs into three categories: Category 1 (line extension) usually contains drugs

John R. Graham is a senior analyst and acting director of the Pharmaceutical Policy Research Centre at the Fraser Institute in Vancouver, Canada. He can be contacted by E-mail at johng@fraserinstitute.ca.

that are a new strength of an existing drug. Category 2 (breakthrough) drugs provide a substantial improvement over predecessors. Category 3 (me-too) drugs provide moderate, little, or no improvement over existing medicines. With reference to these three categories, the PMPRB uses the following guidelines to set maximum prices:

- 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 patented drugs and those that bring a substantial improvement are limited to the median of prices charged for the same drug in France, Britain, Germany, Italy, Sweden, Switzerland, and the United States.
- The price of a patented drug cannot exceed the highest price of the same medicine sold in the above seven countries.
- Price increases for existing patented medicines are limited to changes in the Consumer Price Index.

During the five years from 1994 through 1998, drug manufacturers introduced 408 newly patented human drugs in Canada. Of those, the PMPRB classified 213 (52 percent) as line extensions, 171 (42 percent) as me-too drugs, and 24 (six percent) as breakthroughs. Thus, the Board prohibited 94 percent of new drugs from entering the market at a higher price than existing drugs.

GENERIC DRUG PRICES

ON THE FACE OF IT, THESE STRICT REGULATIONS appear to have served their purpose well. As calculated by the PMPRB, the ratio of Canadian prescription drug prices to international prices has decreased every year from 1991 to 1998, and increased only marginally in 1999. In 1998, the PMPRB's price indices showed that patented drug prices in America were 62 percent higher than in Canada, whereas in 1987 — the year in which the PMPRB was founded — the difference was

36 percent. However, as Patricia Danzon explained in a previous issue of Regulation (Vol. 23, No. 1), it is not easy to measure price differences of prescription drugs across borders.

The PMPRB's Patented Medicine Prices Index may be the most accurate current estimate of the price differences of patented medicines between Canada and the United States. But because regulatory approval is so slow in Canada, innovative and highly priced drugs may be included in the U.S. price index before they are included in Canada's. In the United States, many of these drugs are priced well above existing drugs, but they nevertheless earn significant market share. Recent examples include such drugs as Viagra and the pain relievers Celebrex and Vioxx.

Furthermore, most studies of prescription drug price differences refer only to patented drugs, not non-patented branded drugs or generic drugs. This is a significant failing because generics comprise 47 percent of the U.S. prescription drug market by volume and 40 percent of all prescriptions written in Canada. In order to draw a more complete picture of prescription drug costs, we should investigate the prices of generic drugs and off-patent branded drugs.

A colleague and I at the Fraser Institute compared American and Canadian wholesale and retail drug prices for the sixty most prescribed drugs in the United States. Two drugs were more expensive in Canada at the wholesale level and seven at the retail level. These drugs were all generics. In fact, we found that the average retail price for generics was higher in Canada than in the United States, while branded drugs were significantly cheaper in Canada.

WHY ARE SOME CANADIAN **PRICES LOWER?**

WHEN PMPRB WAS ESTABLISHED IN 1987, its measurements showed U.S. manufacturers' prices for patented drugs were 36 percent higher than Canadian prices. Now, the price difference has widened to 60 percent. What has caused this 24-percent improvement in Canada's favor over eleven years?

The Role of Income Figure 1 displays drug prices and per capita income for Canada and eight other countries. The figure presents the ratio of each country's patented drug price index and Gross Domestic Product (GDP) per capita to Canada's (multiplied by 100). Differences in incomes across countries explain much of the variation in patented drug prices, and changes in relative incomes across time are consistent with changes to relative prescription drug prices.

Since the founding of the PMPRB in 1987, the median Canadian price for patented drugs has declined relative to other developed countries, but Canada's Gross Domestic Product (GDP) per capita (which reflects individual income) has also declined relative to those

countries. For example, in 1987 GDP per capita in the United States was 20 percent greater than Canada, at nominal market exchange rates. In 1998, it was 46 percent greater; the gap widened by 26 percentage points.

Figure 2 reports the changes in GDP per capita and drug prices for seven countries relative to Canada from 1987 to 1998. Each of these countries enjoyed superior growth rates relative to Canada over this period. They also experienced greater increases in patented pharmaceutical prices than Canada. Because prescription drugs are normal goods, this observation indicates that the relative decline in Canada's living standards has been a factor leading to relatively low price increases for patented drugs versus other countries.

The decline of Canada's standard of living versus the United States corresponds with the deviation from purchasing power parity of the Canada/U.S. exchange rate. The real price level of U.S. GDP in 1998 was 25 percent higher than in Canada. In 1987, the difference was only six percent. This 19-percent widening of the gap between Canadian and American aggregate price levels explains all but five percent of the increase in the pharmaceutical price difference between the two countries. Simply put, Canadians get a 25-percent discount on total purchases, including drugs, as compared to the United States. This gap has widened consistently since 1992.

Marginal Cost Versus Total Cost An increasing number of goods and services in the "New Economy" are based on intellectual property. Much of the total cost of producing such prod-

> ucts is incurred before they are packaged and sold; they are incurred in research and development, and are sunk before the manufacturer receives any revenue.

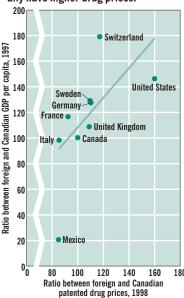
> The costs of research are joint costs; that is, they cannot be rationally attributed to specific units of output. However, consumers worldwide must share these costs for the market to be viable. In this type of industrial environment, manufacturing and distribution costs are a relatively minor proportion of total costs, but manufacturers must levy prices such that they can recover the sunk research and development costs as well. To do so, manufacturers will charge different prices to different consumers. When segmenting markets by country, they often use measures of national income to set prices. This means that wealthier countries will pay more.

> As we have seen, Canadians' incomes increasingly trail those of Americans. Canada's poor productivity drives this poor economic performance, and has had significant consequences for Canadians' standard of living. For example, Canadian businesses have difficulty purchasing relatively expensive machinery and equip-

Figure 1

Ratio of Income and Drug Prices between Foreign **Nations and Canada**

Countries with higher incomes generally have higher drug prices.



Mexican drug ratio reflects 1997 figure. Drug price informa Tion Courtesy of Canada's Patented Medicine Prices Review Board. GDP information courtesy of the United Nations' Organization for Economic Cooperation and Development.

ment from the more productive United States. These goods have high marginal manufacturing costs, making it difficult for producers to price differentiate in order to keep selling into the poorer country; they will lose money on each item they produce and sell there.

In contrast, manufacturers of goods with large fixed costs (like investment in research) and low marginal costs can respond to income differences across countries by increasing price differences across countries. We expect to observe such price differences between Canada and the United States for all goods and services for which marginal production costs are negligible.

For example, U.S. consumers can purchase Intuit's Quicken Basic 2000, a popular personal financial planning software package, from the company's Web site for \$34.95. However, the Canadian version, purchased from the company's Canadian Web site, costs \$20 (U.S.). AOL charges \$21.95 for unlimited monthly Internet access in the United States, but its Canadian subsidiary charges less than \$16 (U.S.) for the same service. The American customers of Intuit and AOL pay premiums of 70 percent and 40 percent respectively. The price differences are not the result of differing marginal costs to supply the two markets. Likewise, the differences are not the result of a Canadian "Patented Software Prices Review Board," which, of course, does not exist.

The Role of Litigation However, software and Internet service have proportionally lower marginal costs of manufacturing and distribution than prescription drugs. For prescription drugs, these costs comprise about 30 percent of the price. Therefore, we should not expect the pharmaceutical price difference to be so great; something else is increasing the difference.

The United States has a more litigious society than Canada. Because of this, we should expect that American pharmaceutical prices would be higher, reflecting the increased costs of legal liability. Economist Richard Manning, in a 1997 academic article, argued that the higher cost of legal liability protection in the United States accounted for one-third to one-half of that price difference. In Canadian courts, liability for personal injury is significantly less onerous than in the United States and Canadian judges rarely award large settlements.

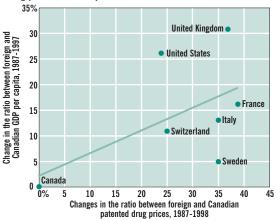
PRICES FOR DRUGS NOT **CONTROLLED BY THE PMPRB**

GIVEN THAT CANADA HAS NOT EXPERIENCED FREE market drug prices in decades, it is impossible to say what those drug prices would be if government were to remove its inter-

Figure 2

International Drug Prices and Incomes as Percent of Canada's, 1987-1998

Other nations have seen higher increases in income and drug prices, as compared to Canada.



vention in the market. The closest proxy for the price level of patented drugs in Canada is the price level of non-patented, single-source prescription drugs. These are branded drugs that were never patented, or whose patents have expired, and do not have generic substitutes.

Although such branded drugs require regulatory approval for their therapeutic benefits, their prices are not regulated by the PMPRB. In 1997, American prices for these drugs were 96 percent higher than Canadian prices. In contrast, the American price premium for patented drugs in 1998 was 60 percent. This means that the "Canadian discount" for branded drugs not regulated by

the PMPRB was far greater than the discount for those that were regulated!

On the other hand, generic drugs in Canada are more expensive than in the United States. Given lower incomes and less tort litigation in Canada, one would expect that Canadian generics would be significantly cheaper than American ones. The reason for this difference is that the U.S. generic market is more competitive than Canada's. In 1992, America had an average of 5.7 manufacturers of each therapeutic molecule, whereas Canada had only 2.02, (that is, one branded firm and one generic firm). Moreover, there is a great difference in the brand-name and generic market concentrations between the two countries. Of the ten top-selling pharmaceutical companies in Canada, only one is a generic manufacturer; the second largest generic ranks thirteenth. However, these two firms together had sales of \$568 million in 1998, fully 71 percent of the total generic market by revenue. In comparison, the top two brandname firms captured only 15 percent of the Canadian market for that sector, and it took sixteen companies to account for 71-percent market share. The Canadian brand-name market appears to be competitive, but the generic market is a duopoly with a competitive fringe.

Why is patented-drug competition more extensive than competition in the generic market in Canada? The two companies that dominate the Canadian generic industry grew rapidly during the period of compulsory licensing from 1969 to 1987. If a drug is patent-protected in Canada or the United States, the patent laws of both countries restrict generic companies from manufacturing and exporting a drug to a country where it is not patented. Because patents expire at different times in various countries, the export prohibition limits the ability of foreign generic manufacturers to compete in the Canadian marketplace.

What is more, Canada's price controls reduce the incentive for generic and branded-drug firms to compete on price. The PMPRB's deliberations are not generally open to

public scrutiny, and examples of introductory price setting are hard to find. There are, however, publicly available case studies for the hypertension medication Cozaar, the osteoporosis fighter Fosamax, and the cholesterol fighter Lipitor. Although the PMPRB does not regulate generic prices, it compares the prices of therapeutically equivalent generics to branded drugs.

Cozaar was the first of a new class of anti-hypertensives called angiotensin receptor antagonists. In order to set a price for Cozaar, the PMPRB had to compare Cozaar to members of another class of anti-hypertensives known as angiotensin-converting enzyme (ACE) inhibitors. The ACE inhibitor with the strongest market share is Vasotec, produced by Merck Frosst, the same maker as Cozaar.

Since Cozaar's launch, Health Canada has approved five other angiotensin receptor antagonists. Different companies produce each of these drugs, so five new competitors have entered the market. Although we do not know the marketing policy of Merck Frosst, we can see that PMPRB's guidelines unintentionally provide disincentive for the company to ever reduce its prices. First, in anticipation of the original launch of Cozaar, the company had incentive to keep the price of Vasotec high because the PMPRB would use Vasotec's price as a guideline for setting Cozaar's price. Second, anticipating the subsequent introduction of Cozaar's one-a-day 100mg dose, Merck Frosst would have been extremely reluctant to reduce the price of its original 25mg and 50mg doses for fear of spoiling the entry-price of the once-daily dosage. Furthermore, despite the introduction and potential entry of new competitors, Merck Frosst may resist future reductions in the price of either Vasotec or Cozaar because the firm must anticipate the effects of the PMPRB on the introductory price of future hypotensive drugs in its own development pipeline. Thus, the PMPRB's direct price controls inhibit price competition between drugs within a therapeutic class.

Even in therapeutic classes where many older, off-patent drugs compete against each other, the manufacturers of those drugs will tend not to reduce prices relative to each other. The PMPRB's price controls, by restricting brandname price competition, provide an umbrella under which generic substitutes can set relatively high prices. Almost by definition, generic drugs cost less than branded ones. Because Canada's drug-pricing regime discourages producers of branded drugs from ever lowering their prices, generic drugs can exercise price leadership with much less discounting than would occur in a free market for branded drugs, particularly given that two firms account for over two-thirds of the market.

CONCLUSIONS

THUS, WE CAN SEE THAT THERE ARE A NUMBER OF differences between the Canadian and U.S. pharmaceutical markets. Among the differences:

 The average price of goods and services in the United States is 25 percent higher than in Canada, due in large part to the significant decline in incomes in Canada relative to America.

- The types of products that drive this difference in prices are creations of intellectual property that have low marginal production costs. Manufacturers can earn marginal profits by charging low prices in those markets where consumers cannot pay prices high enough to cover the sunk costs of research and development.
- Canada's low branded-drug prices are chiefly the result of Canada's low standard of living relative to the United States and pharmaceutical companies' marketing response to Canada's declining incomes. This gap in both incomes and prices has increased over the past decade.
- Higher legal liability costs in the United States account for about one-third to one-half of the price difference for patented pharmaceuticals between Canada and America.
- The PMPRB does not keep prices low; rather, it keeps prices high because its guidelines discourage patented drug manufacturers from using price reductions as a competitive strategy. This allows generic companies to charge prices significantly higher than in a free market and insulates them from consequences of price competition between brand-name competitors.
- High U.S. drug prices result primarily from America's position as the world's most productive and wealthiest country. As long as the United States maintains this position, its drug prices (as well as the prices of other goods and services) will likely be higher than in other countries.
- American imitators of the PMPRB, such as the Maine Fair Drug Pricing Board, are unlikely to succeed in keeping prices low, but will have similar consequences as the Canadian PMPRB.

Given these differences, Americans should ask themselves if they can accept the trade-off of higher incomes and lower generic drug costs in exchange for higher, uncontrolled patented drug prices.

readings

- "Blame Canada," by Beth Rattray. Vogue, November 2000.
- "Making Sense of Drug Prices," by Patricia M. Danzon. Regulation, Vol. 23, No. 1 (2000).
- Public Policy Source Number 42, Prescription Drug Prices in Canada and the United States - Part 1: A Comparative Survey, by John R. Graham and Beverley A. Robson. Vancouver: The Fraser Institute, 2000.
- Public Policy Source Number 43, Prescription Drug Prices in Canada and the United States - Part 2: Why the Difference? by John R. Graham. Vancouver: The Fraser Institute, 2000.