

## PRESCRIPTION DRUG PRICES IN CANADA

The high cost of prescription drugs, combined with the lack of prescription drug coverage for many older Americans, has resulted in substantial interest in how other countries—particularly those neighboring the United States—attempt to restrain prescription drug prices. Reports often appear in the popular press about American consumers who go to Canada or Mexico to buy their prescription drugs at a fraction of what they would pay in U.S. pharmacies, even though doing so is illegal.<sup>1</sup>

The interest in international drug prices has moved into the legislative realm as well. In 2000, the U.S. Congress passed, and President Clinton signed, legislation that would allow drugs to be re-imported into the United States if the Secretary of the Department of Health and Human Services could certify that it could be done in a way that would not result in health risks and would result in significant reductions in drug costs. While this legislation has not been implemented, the U.S. Senate passed legislation in 2002 that would have permitted U.S. residents to import from Canada up to a 90-day supply of prescription drugs for personal use (this legislation did not become law because it was not passed by the House of Representatives).<sup>2</sup>

The interest in Canadian drug prices raises a number of important questions:

- To what extent are prescription drugs less expensive in Canada than in the United States?

- To what extent have lower prices mediated trends in prescription drug spending increases in Canada?
- What factors account for lower prescription drug prices in Canada?

Based on the most current published information,<sup>3</sup> this issue brief (1) compares and contrasts key characteristics of pharmaceutical markets and prescription drug coverage in Canada and the United States; (2) reviews evidence on the extent to which the price of a prescription drug purchased in Canada differs from the price of the same drug purchased in the United States; (3) discusses the key issues raised in critiques of U.S.-Canada prescription drug price comparisons; and (4) identifies the factors that may contribute to any real differences in the financial burden of prescription drugs for older consumers. The issue brief concludes with a short description of the most recent efforts in Canada to restrain pharmaceutical spending and a brief discussion of the implications of these findings for the United States.

**BACKGROUND**

Despite their geographic proximity, there are substantial differences between Canada and the United States in both the structure of the pharmaceutical industry and in the extent to which people have insurance coverage for prescription drugs. The commonality is that both countries, like other industrialized countries, are experiencing relatively high levels of growth in prescription drug spending; however, the rate of

growth is substantially lower in Canada than in the United States.

### **Structure of the Pharmaceutical Industry**

With just 2 percent of worldwide pharmaceutical sales, Canada accounts for a small share of worldwide pharmaceutical use.<sup>4</sup> Canada is also home to a relatively small research-based pharmaceutical industry, thereby making a small contribution to new drug development globally. Research-based drug manufacturers spent nearly 10 percent of their Canadian sales revenues on pharmaceutical research and development (R&D) in Canada in 2001—above the 6 percent level of the late 1980s but somewhat less than in the mid- to late 1990s. Canadian R&D spending reached its peak of 11.7 percent of Canadian sales in 1995.<sup>5</sup>

By contrast, the United States leads the world in both use of prescription drugs and development of new drug products. The United States is home to many of the world's top pharmaceutical manufacturers. Pharmaceutical R&D spending in the United States equaled about 18.0 percent of U.S. sales in 2001, a rate that is similar to recent years but below the peak of 20 percent reported for 1995–1998.<sup>6</sup>

Generic drugs are important in both countries. Generic drugs account for about 40 percent of prescriptions in Canada and about 45 percent of prescriptions in the United States. However, the generic industries in these countries are quite different from each other. Canada's generic drug industry accounts for about 14 percent of all revenues from Canadian drug firms,

compared to nearly 8.5 percent for the U.S. generic drug industry. In addition, the Canadian generic drug industry is less competitive; sales are dominated by five firms, and a smaller number of these are particularly dominant.<sup>7</sup> As a result of the small number of generic manufacturers, in Canada there are fewer of the competitive pressures that lead to declining generic drug prices in the United States.

### **Prescription Drug Coverage**

Most Americans know that Canada offers universal access to health insurance. The Canadian health insurance system, known as Medicare, provides universal coverage for acute care hospital and physician services. Financed by the federal and provincial governments, Canada's Medicare program is administered by the provinces.<sup>8</sup>

Less well known, however, is that Canada's Medicare *does not* provide coverage for outpatient prescription drugs. Still, despite the lack of coverage through a national system, most Canadians have some form of prescription drug coverage. However, the type of coverage that a person has is likely to be a function of age, income, province, and type of employment.<sup>9</sup> Public programs financed and administered by the provinces typically provide drug coverage for elderly, disabled, and low-income residents' coverage levels vary from province to province. Some provinces also offer coverage to the remaining population. The federal government offers coverage (through programs separate from Medicare) for small segments of the population, such as veterans and First

Nations and Inuit people.<sup>10</sup> Most other Canadians receive prescription drug coverage through their employers.

While this coverage structure does leave some gaps, those gaps are less substantial than in the United States. As an example, about 98 percent of Canadians age 65 and over have prescription drug coverage,<sup>11</sup> compared to about 60 percent of Medicare beneficiaries in the United States who have prescription drug coverage throughout the entire year.<sup>12</sup> Overall, public insurance plans in Canada pay for about 44 percent of total prescription drug spending; private plans cover 34 percent of spending; and the remaining 22 percent is paid out of pocket.<sup>13</sup>

#### *Publicly Funded Drug Coverage*

While publicly funded drug coverage pays for less than half of total prescription drug spending in Canada, it pays a substantial share of costs for older, disabled, and low-income Canadians. Every province offers some form of prescription drug coverage to persons age 65 and older. Some provinces (e.g., Ontario, British Columbia, and Alberta) offer relatively generous benefits and universal eligibility, and cover 70 to 85 percent of persons age 65 and over. Others have stricter eligibility requirements and/or require premiums (e.g., Newfoundland, New Brunswick, Nova Scotia, and Prince Edward Island); these provinces enroll as few as 35 percent of persons age 65 and over.<sup>14</sup>

Provinces use a variety of cost-sharing mechanisms to restrain public spending on prescription drugs. (See Figure 1 for a description of premiums and cost-

**Figure 1: Premiums and Cost-Sharing for Non-Low-Income Elderly in Provincial Drug Benefit Plans in Canada, 2003**

<b>ALBERTA</b>
<b>Coinsurance:</b> 30% (maximum C\$25 per drug)
<b>BRITISH COLUMBIA</b>
<b>Deductible:</b>
<ul style="list-style-type: none"> <li>• 1% of net income for persons with incomes C\$33,000-C\$50,000</li> <li>• 2% of net income for persons with incomes above C\$50,000</li> </ul>
<b>Coinsurance:</b> 25%, with income-related cap ranging between 1.25% and 3% of net income
<b>MANITOBA</b>
<b>Deductible:</b> 3.15% of adjusted income
<b>NEW BRUNSWICK</b>
<b>Premium:</b> C\$89 monthly
<b>Copayment:</b> C\$15
<b>NOVA SCOTIA</b>
<b>Premium:</b> Up to C\$336 annually, depending on income
<b>Coinsurance:</b> 33%, up to C\$350 per year
<b>ONTARIO</b>
<b>Deductible:</b> C\$100
<b>Coinsurance:</b> 100% of pharmacy dispensing fee, up to C\$6.11
<b>PRINCE EDWARD ISLAND</b>
<b>Coinsurance:</b> C\$10 plus pharmacy dispensing fee
<b>QUEBEC</b>
<b>Premium:</b> Up to C\$422 annually, depending on income
<b>Deductible:</b> C\$9.13 monthly
<b>Coinsurance:</b> 27.4%, up to C\$68.50 monthly
<b>SASKATCHEWAN</b>
<b>Deductible:</b> 3.4% of income
<b>Coinsurance:</b> Variable percentage, depending on income and total drug costs

Sources: Alberta Provincial website <http://www.health.gov.ab.ca/coverage/benefits/drugs/seniors.html>; British Columbia Ministry of Health Services, *PharmaCare* <http://www.healthservices.gov.bc.ca/pharme/plani/planiinfo.html>; Manitoba Provincial website <http://www.gov.mb.ca/health/pharmacare/estimator.html>; personal communication with New Brunswick Department of Health and Wellness, Prescription Drug Program, May 21, 2003; Nova Scotia Provincial website [http://www.gov.ns.ca/health/pharmacare/seniors\\_pharmacare\\_faqs.htm](http://www.gov.ns.ca/health/pharmacare/seniors_pharmacare_faqs.htm); Ontario Provincial website [http://www.health.gov.on.ca/english/public/program/drugs/drugs\\_mn.html](http://www.health.gov.on.ca/english/public/program/drugs/drugs_mn.html); personal communication with PEI Health and Social Services, Medical Programs Division; Quebec Provincial website <http://www.ramq.gouv.qc.ca/crc/eng/public/assmed/pers.shtml>; personal communication with Saskatchewan Department of Health, Drug Plan and Extended Benefits Branch, May 21, 2003.

sharing features that apply to non-low-income elderly.) Each province requires that patients pay for part of the cost of their drugs through deductibles and/or coinsurance or copayments.

For example, provincial drug plans cover all residents of Saskatchewan, British Columbia, and Manitoba, but residents pay a deductible that represents a flat percentage of income. All residents without private prescription drug coverage are covered under public drug plans in Quebec, but most residents pay a monthly deductible of a flat dollar amount.<sup>15</sup>

Coinsurance is more common than copayments and deductibles in provincial prescription drug plans, and ranges from 10 to 33 percent of the actual cost of the prescription drug.<sup>16</sup> Some provinces—even those that offer coverage without regard to income—impose income-related differences in cost-sharing.

Provincial programs are subject to frequent changes that can result in a substantial overhaul of the system. For example, in May 2003, British Columbia changed from a plan that paid almost all drug costs for elderly residents to one that now imposes income-related deductibles and more substantial coinsurance (25 percent up to an income-related cap on out-of-pocket payments).<sup>17</sup> Some of the savings from this policy change are to be used to provide coverage of nonelderly persons with catastrophic drug costs.<sup>18</sup>

#### *Privately Funded Drug Coverage*

Most Canadians who are not covered under a provincial plan receive prescription drug benefits through an

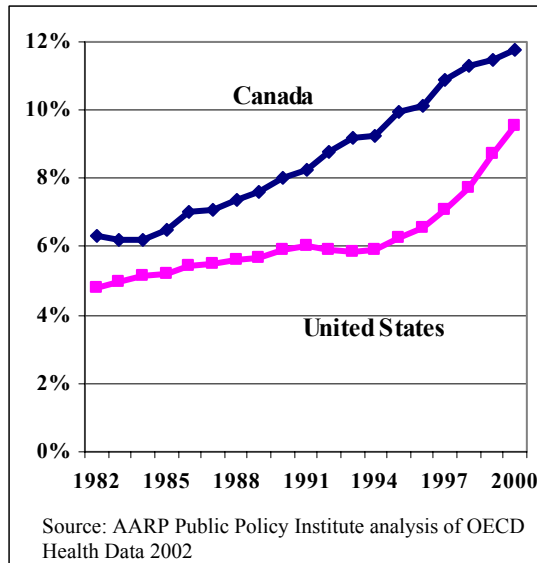
employer-sponsored plan. In 1999, about 62 percent of *all* Canadians had some form of private coverage for pharmaceuticals.<sup>19</sup> Most private drug plans use pharmacy benefit management procedures such as formularies, therapeutic substitution, and rebates (retroactive price reductions from drug manufacturers) to reduce costs. Formularies used by private drug plans often include all drugs approved by Health Canada, the federal agency responsible for health-related issues.<sup>20</sup>

It has been reported that 10 percent of Canadians with drug coverage are underinsured (i.e., patients are reimbursed less than 35 cents of every dollar they spend on prescription drugs).<sup>21</sup> Almost one-third of Canadians with inadequate drug coverage are between the ages of 55 and 64.<sup>22</sup> Furthermore, there is substantial geographic disparity in the existence and generosity of private coverage: provinces with a larger industrial base have more generous employer-sponsored programs than do less industrialized provinces.<sup>23</sup>

#### **Prescription Drug Spending**

Regardless of the reports of lower prescription drug prices, total prescription drug spending in Canada—as in the United States—accounts for an increasing share of national health care spending. Prescription drug expenditures as a share of national health spending doubled or nearly doubled in both countries between 1982 and 2000 (see Figure 2).<sup>24</sup> While Canadian drug spending rose more rapidly in the early part of this period, in recent years, prescription drug spending has been rising more rapidly in the United States.

**Figure 2: Trend in Prescription Drug Expenditures as a Percentage of Total Health Expenditures, 1982–2000**



Between 1990 and 2001, prescription drug spending in the United States grew by about 12 percent per year,<sup>25</sup> compared to an average of about 9 percent per year in Canada.<sup>26</sup>

### CANADA-U.S. PRICE COMPARISONS

Although there is general agreement that many prescription drugs cost less in Canada than in the United States, there is less agreement on the size of the difference. To a large extent, this lack of consensus stems from key differences among studies in the nature of the comparison of drug prices between countries. For example, different price comparisons measure a drug's price at different points in the distribution chain: some focus on retail prices; others look at prices charged by manufacturers.

Studies also differ with regard to which payer's price is being measured. In the United States, different payers pay different prices: cash-paying customers

typically pay the highest prices; insurers and managed care plans are able to negotiate discounts and manufacturer rebates; and government programs can get even deeper price reductions.<sup>27</sup> By contrast, in Canada, there is little variation in prices paid by different payers.<sup>28</sup>

Finally, studies differ in the sample of drugs being compared. Like the differences described above, this sampling difference might reflect different goals of the studies: one study might be designed to focus only on price differences among patented drugs; another might be interested only in price differences among drugs with high sales volumes; yet another might seek to provide a broad comparison of all commonly used drugs.

Also contributing to the lack of consensus about the magnitude of drug price differences between Canada and the United States are technical difficulties associated with developing an appropriate methodology for comparing prescription drug prices across countries. Among the issues that must be addressed in an international drug price comparison are (1) choosing an exchange rate that is not sensitive to day-to-day currency fluctuations but nevertheless captures the costs to citizens in one country of buying drugs in another country, and (2) choosing the appropriate weight to give to each drug's price difference in the process of calculating an aggregate (or average) price differential (i.e., choosing a price index).<sup>29</sup>

Partly as a result of these challenges, there are few studies in the past several

**Figure 3: Summary of Published Estimates of Canada-U.S. Drug Price Differences, 1990 to Present**

Source	Date of Comparison	Study Sample	Key Findings
<b>Differences in prices charged by drug manufacturers</b>			
Patented Medicine Prices Review Board (2001)	1987–2001	Patented drugs	<ul style="list-style-type: none"> <li>Prices charged by manufacturers were 69% higher in the U.S.</li> <li>Differential increased from 36% in 1987 to 60% in 2000.</li> </ul>
U.S. General Accounting Office (1992)	1991	121 frequently dispensed drugs sold in same strength and form in U.S. and Canada	<ul style="list-style-type: none"> <li>81% of drugs were more expensive in the U.S. than in Canada.</li> <li>Price differentials ranged from U.S. price of 44% below Canadian price to 967% above Canadian price.</li> <li>A market basket of all 121 drugs would cost 32% more in the U.S.</li> </ul>
Danzon and Kim (1998)	1992	Generic and brand-name cardiovascular drugs	<ul style="list-style-type: none"> <li>Estimated average price differentials were sensitive to the choice of a price index, ranging from 9.2% lower in Canada to 116.6% higher.</li> </ul>
Danzon (1996)	1992	Generic, brand-name, and over-the-counter drugs	<ul style="list-style-type: none"> <li>Estimated average price differentials were sensitive to the choice of a price index, ranging from 55% lower in Canada to 3% higher.</li> </ul>
<b>Differences in wholesale drug prices</b>			
Graham and Robson (2000)	1998	45 prescription drugs (brand-name and generic) with greatest volume of U.S. prescriptions between January and October 1998	<ul style="list-style-type: none"> <li>Canadian prices were 42% lower than U.S. prices.</li> <li>Only two drugs—both generic drugs—cost more in Canada than in the U.S.</li> </ul>
<b>Differences in retail drug prices</b>			
Graham and Robson (2000)	1998	45 prescription drugs (brand-name and generic) with greatest volume of U.S. prescriptions between January and October 1998. These were not necessarily the same drugs used in the wholesale price comparison. Prices were measured from a single retail outlet that sold prescription drugs in both the U.S. and Canada.	<ul style="list-style-type: none"> <li>Canadian prices were 28% lower than U.S. prices.</li> </ul>
Minority Staff, U.S. House of Representatives (1998)	1997	10 brand-name drugs with the highest annual sales to older Americans in 1997. Prices were obtained from 9 Maine pharmacies and 4 Canadian pharmacies.	<ul style="list-style-type: none"> <li>Average retail prices in Maine were 72% higher than comparable prices for comparable drugs.</li> <li>No price index was calculated.</li> </ul>
National Legislative Association on Prescription Drug Prices (2003)	March 2003	20 brand-name drugs. Prices were obtained from mail-order pharmacies in the U.S. and Canada.	<ul style="list-style-type: none"> <li>All drugs were more expensive in the U.S. than in Canada. Sixteen drugs were 30%–65% more expensive, and seven were 50%–65% more expensive.</li> </ul>

years from which to draw in an examination of drug price differentials (see Figure 3). For example, a 2000 report from the U.S. International Trade Commission identified only a handful of studies that compared Canadian and U.S. prescription drug prices.<sup>30</sup> Following are results of Canada-U.S. drug price comparisons for three different points in the distribution chain: prices charged by manufacturers, prices charged at the wholesale level, and retail drug prices.

### **Differences in Prices Charged by Drug Manufacturers**

Some Canada-U.S. drug price comparisons focus only on the prices charged by drug manufacturers. While this measure does not capture the entire cost of a drug, the manufacturer price component accounts for an average of 75 percent of a prescription drug's price in the United States.<sup>31</sup> For the most part, studies show that manufacturer prices tend to be higher in the United States, although some drugs—particularly generic drugs—may cost more in Canada. At least one study contends that the price comparison is extremely sensitive to methodological decisions, such as how price differentials between countries are averaged (i.e., the choice of a price index).

- The Patented Medicine Prices Review Board (PMPRB), the Canadian agency charged with “ensuring that prices charged by manufacturers of patented medicines are not excessive,” reported that manufacturers’ prices for patented drugs were 69 percent higher in the United States than in Canada in 2001.<sup>32</sup> Furthermore, the PMPRB found that this difference

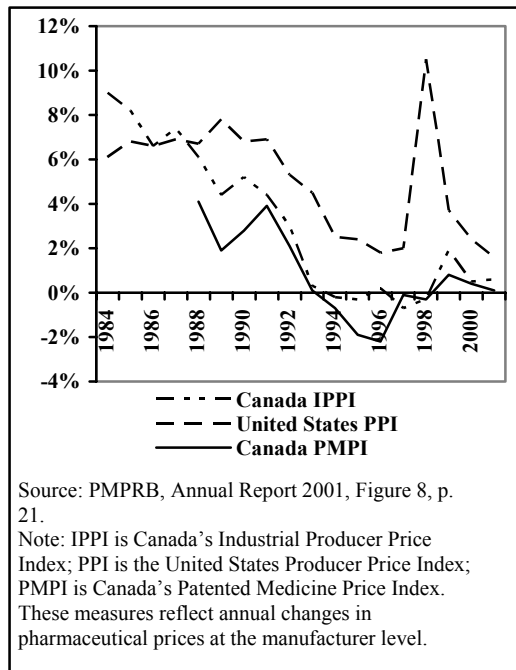
increased over time, from a differential as low as 36 percent in 1987, the year the PMPRB was established, to a 60 percent price differential in 2000.<sup>33</sup> The PMPRB’s measure of manufacturer prices in the United States does not capture price reductions given to private third-party payers, as they are based on confidential agreements between payers and drug manufacturers, but it does reflect price reductions given to federal purchasers such as the Department of Veterans Affairs.

- The U.S. General Accounting Office (GAO) reported estimates in 1992 that are consistent with the most recent PMPRB findings cited above. GAO compared May 1991 manufacturer prices of 121 frequently dispensed prescription drugs that were sold in the same strength and form in both the United States and Canada. These prices reflected charges to cash-paying customers and therefore did not capture any discounts or rebates received by private or public institutional purchasers.

GAO reported that 81 percent of the 121 drugs were more expensive in the United States than in Canada. U.S. prices ranged from 44 percent lower to 967 percent higher than the Canadian price. GAO did not calculate a price index because it was not able to acquire data on sales volume. However, it reported that a market basket containing one prescription of each of the drugs would have cost 32 percent more in the United States than in Canada.<sup>34</sup>

- The PMPRB also reported that recent manufacturers' prices for pharmaceuticals were rising more slowly in Canada than in the United States. Canadian pharmaceutical prices rose faster than U.S. pharmaceutical prices prior to the 1987 establishment of the PMPRB, but, after a period of sharp decline in inflation rates, rose at near-zero rates or actually declined each year between 1992 and 2001. By contrast, the pharmaceutical Producer Price Index (PPI) for the United States has varied considerably over the same years but has exceeded the Canadian growth rate—often by substantial amounts—every year since 1988 (see Figure 4).<sup>35</sup>

**Figure 4: Annual Percent Change in Pharmaceutical Price Indices, Canada and the United States, 1984–2001**



- Danzon and Kim (1998) reported price comparisons that differed substantially from the above

findings, although their analysis was limited to a single therapeutic category. They compared 1992 manufacturer prices of a broad sample of generic and brand-name cardiovascular drugs in several countries, including Canada and the United States.

Their primary finding was that estimated price differentials were sensitive to the choice of methodology in calculating a price index. Danzon and Kim reported that estimated price differentials for the drugs in their sample in Canada ranged from 9.2 percent lower in Canada than in the United States to 116.6 percent higher, depending on the price index used. This analysis included a large number of generic drugs, for which the U.S.-Canada price ratio tends to be lower.<sup>36</sup>

Danzon (1996) reported similar findings for a sample of drugs that included all therapeutic categories. The estimated price differentials ranged from 55 percent lower in Canada to 3 percent higher in Canada.<sup>37</sup>

### Differences in Wholesale Prices

- Graham and Robson (2000) examined U.S.-Canada price differences for 45 prescription drugs accounting for the greatest volume of U.S. prescriptions between January and October 1998. Their analysis included both brand-name and generic drugs. They found that wholesale prices—the prices charged to retailers—were 42 percent lower in Canada than in the United States. This is



equivalent to saying that U.S. wholesale prices were an average of 72 percent higher than Canadian wholesale prices. Only two of the drugs studied cost more in Canada than in the United States; both were generic drugs.<sup>38</sup>

### Differences in Retail Prices

- In addition to their study of wholesale prices, Graham and Robson (2000) compared retail drug prices for 45 widely used prescription drugs. Because of issues in identifying comparable prices, this study included three drugs that were not part of the wholesale price comparison and excluded three that were part of the wholesale price comparison. Graham and Robson measured prices in a single retail outlet—Costco—that sold drugs in both countries. They found that prices were 28 percent lower in Canada than in the United States. This is equivalent to saying that U.S. retail prices were 39 percent higher than Canadian retail prices.<sup>39</sup>
- The Minority Staff of the U.S. House of Representatives also compared U.S. and Canadian retail prices, but for a far more limited sample of drugs. This study compared prices of the ten patented brand-name drugs that had the highest annual sales to older Americans in 1997. Prices were obtained from a survey of nine Maine pharmacies and four Canadian pharmacies. The study found that average retail prices in Maine were 72 percent higher than average prices in Canada for

comparable drugs.<sup>40</sup> The reported average did not weight prices by sales volume.

- The National Legislative Association on Prescription Drug Prices (NLARX) compared mail-order prices of 20 brand-name drugs that were widely used in the United States and Canada in March 2003. It found that the U.S. price was consistently higher than the Canadian price. Sixteen drugs were 30 to 65 percent more costly in the United States than in Canada, and seven drugs were 50 to 65 percent more costly in the United States.<sup>41</sup>

### Critiques of International Drug Price Comparisons

International drug price comparisons are subject to a number of methodological criticisms: (1) whether the prices account for discounts, rebates, or other factors that influence actual price paid; (2) whether the prices being compared are representative of drugs on the market in the countries being compared; and (3) whether the price differences are aggregated, or averaged, in such a way as to accurately represent each drug's relative importance in a particular market (i.e., choice of a price index for aggregating the comparison).<sup>42</sup>

In evaluating these critiques, it is important to consider how germane they are to the purpose of the study and the interpretation of results. Criticisms that are based on the methodology of an international price comparison often hinge on differences between authors/researchers and critics in the perceived purpose of the comparison.<sup>43</sup>

Reflecting actual transaction prices.

Some critiques of international drug price comparisons assert that the prices used in these studies overstate U.S. prices because they do not account fully or at all for discounts, rebates, and other factors that reduce prices paid by institutional purchasers. This criticism is most relevant when the comparison is explicitly intended to capture average manufacturer revenues from all market segments.

The methodological issue is relevant, for example, when the PMPRB considers an average U.S. manufacturer price as part of the determination of whether the Canadian price for a breakthrough drug is excessive. Indeed, the PMPRB recognizes the shortcoming of not capturing price reductions for large purchasers and, since 2000, has included prices available to U.S. government agencies through the Federal Supply Schedule as a proxy for other major U.S. purchasers. Actual discounts and rebates provided to private purchasers and state Medicaid programs are not publicly available.

The criticism about not accounting for discounts and rebates has also been leveled against the GAO study.<sup>44</sup> However, it may not be as relevant for studies such as GAO's or other studies that intentionally focus on prices charged to a particular market segment—in GAO's case, sales to cash-paying customers who do not have access to price reductions received by institutional buyers. If such studies had accounted for discounts and rebates given to institutional purchasers in the United States, they would have understated the transaction prices on

sales to the cash-paying segment of the market.

Representing each country's pharmaceutical market. Another methodological criticism regards whether the drugs in the price comparison are broadly representative of each country's pharmaceutical market. For example, Danzon and Kim contend that an accurate price comparison should not be limited to brand-name drugs but should include as broad a sample of drugs as possible; they have developed a technique to include many generic and over-the-counter medications that are not included in other studies. They contend that excluding generics and over-the-counter medications results in higher average U.S. drug prices, because such drugs—particularly generic drugs—often are less expensive in the United States than in Canada.

Again, the relevance of capturing as much of the market as possible depends on whether the purpose of the comparison is to contrast the average cost of *all* pharmaceutical therapies in different countries. It is not an appropriate approach when the study's purpose is to show differences in the cost of particular drugs (such as brand-name products) to consumers who are buying the same product in different countries.

For example, both GAO and Graham and Robson focused their analyses on prices that consumers pay for widely used drugs sold in both countries, not the average cost of pharmaceutical therapy in each country. The GAO study, which compared prices charged by the same manufacturers in the United States and Canada, focused on brand-name drugs

because generic drugs are often manufactured by different companies in different countries. The Hill Minority Staff and NLARX focused only on brand-name drugs with the highest sales volumes. The PMPRB examined only prices of patented drugs that are under its jurisdiction.

Calculating average price differences. A third methodological issue is whether average differences are based on a price index that weights each product by its relative importance in the market (i.e., volume of sales) or a straight average (i.e., each product is given equal weight in the calculation). If a price index is not used, then the results are subject to misinterpretation. Danzon and Kim show the sensitivity of the price index choice to the estimate of average price differentials.

For example, although the GAO did not report an “average” price differential for its Canada-U.S. price comparison, it did report an overall differential for a market basket composed of one prescription of each drug in its sample. However, referring to this figure as an average price difference without clarifying that the average is unweighted (which has happened) could mischaracterize price differences. Whether the overall differential is an overestimate or an underestimate of the actual average depends on the underlying weights, to which GAO did not have access. Similarly, the average cited by the House Minority Staff likely would have been different if weighted by the relative sales volume of each of the drugs in its comparison.

The choice of a price index is important when describing average pricing trends

in different countries. It becomes less important when the purpose is to describe the distribution of differences in prices of individual drugs. For example, a price index is not a particularly important measure for a study that is intended to show how many widely used drugs cost X percent more in country A than in country B. In such a case, a simple count of widely used drugs should be sufficient.

### **POSSIBLE EXPLANATIONS OF PRICE DIFFERENCES**

Prescription drug price differences between Canada and the United States can largely be attributed to two major differences between the U.S. and Canadian pharmaceutical markets. First, Canada’s federal PMPRB regulates the maximum prices that can be charged for patented drugs; no such regulations exist in the United States. Second, public and private third-party purchasers in Canada, particularly the provincial drug benefit plans, have adopted cost management approaches to try to induce price competition among therapeutically similar drugs. These may not be the only factors affecting prescription drug price differences. Some research has suggested that country differences in the standard of living and spending on direct-to-consumer drug advertising and medical liability may also contribute to price differences.

### **National Price Controls on Patented Drugs**

All patented prescription drugs sold in Canada are subject to a set of pricing guidelines established in law and administered by the PMPRB. The PMPRB is a quasi-judicial body that

regulates the price that a manufacturer can charge for any patented drug sold in Canada; it does so by determining maximum levels for introductory prices of new patented drugs and increases in the prices of extant drugs. The PMPRB's jurisdiction includes patented drugs sold by manufacturers to Canadian hospitals, wholesalers, retail pharmacies, and others.

The PMPRB was established in 1987 to complement and counter a change in Canadian law that strengthened patent protection on pharmaceutical products by providing greater market exclusivity. For the 18 years before the establishment of the PMPRB, patented pharmaceutical products sold in Canada had virtually no right of market exclusivity. During that period, Canadian public policy was to foster drug price competition by allowing generic manufacturers to obtain a license from the Commissioner of Patents to sell versions of patented drugs. Manufacturers that were selling generic versions of patented products were required to pay a royalty to the patent holder while the patent was in force; this royalty was viewed as nominal relative to revenues that the generic manufacturer would earn.

This market dynamic was dramatically altered when, in order to address concerns about discouraging pharmaceutical R&D in Canada, Parliament passed a law that introduced a seven- or ten-year period of market exclusivity during which generic drugs could not enter the market. (In return, Canadian drug manufacturers pledged to double the ratio of pharmaceutical R&D spending to sales in Canada over the period from 1987 to 1996. This ratio rose from 6.1 percent of sales in 1988 to

11.7 percent by 1995, but dropped to 9.9 percent in 2001.<sup>45</sup>) To address concerns among provincial health plans and private payers that market exclusivity would lead to substantial increases in prices for patented drugs, the law also established the PMPRB and gave it authority to take certain measures to keep patent drug prices from becoming "excessive."<sup>46</sup>

The PMPRB does not approve a drug's price before it is marketed in Canada. Rather, it reviews information that manufacturers are required to provide to it on prices and sales of the same medicines in other countries. Information on launch prices and sales of new patented medicines must be provided to the PMPRB within 60 days of the date of the first sale; thereafter, prices and sales figures must be provided twice annually. Prices must conform to the following guidelines:

1. Manufacturer prices for most new patented drugs are limited so that the cost of therapy using the new drug does not exceed the highest cost of therapy with existing drugs used to treat the same disease in Canada.
2. Manufacturer prices of breakthrough patented drugs and those that bring a substantial improvement are limited to the median of the prices charged for the same drug in other industrialized countries listed in the PMPRB's *Regulations* (France, Germany, Italy, Sweden, Switzerland, the United Kingdom, and the United States).

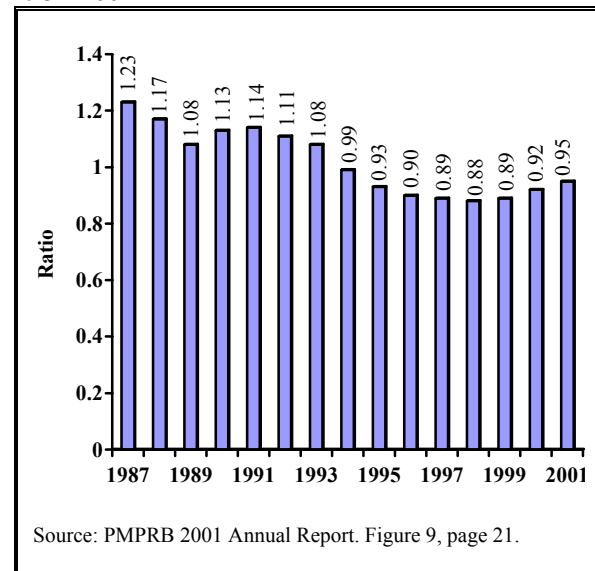
3. Manufacturer price increases for patented medicines after launch are limited to changes in the general Consumer Price Index (CPI).
4. Manufacturer prices of a patented drug in Canada may at no time exceed the highest price for the same drug in the countries listed in the *Regulations*.<sup>47</sup>

The PMPRB can investigate allegations of excessive pricing. It has significant power to take action against companies that do not comply with its guidelines. Specifically, the PMPRB can order patent holders to reduce the price and can take measures to offset any excess revenues the patent holders may have received, including requiring the manufacturer to relinquish double its excess revenues.<sup>48</sup> Excess revenues can be relinquished through monetary penalties or price reductions. Although the PMPRB monitors pharmaceutical industry R&D, it does not take the R&D investment into account when determining whether a manufacturer is charging a price that is out of compliance with its guidelines.<sup>49</sup>

Several measures suggest that the PMPRB has been effective at restraining prices of patented drugs relative to those in other countries. First, average annual price increases for patented drugs in Canada have fallen substantially during the time that the PMPRB has been operating, and increases have been at or around zero percent per year since 1992 (see Figure 4). Second, as shown in Figure 4, price increases for patented drugs in Canada have been far below those in the United States, where there is no drug price regulation. Finally,

Canadian prices for patented drugs have fallen substantially relative to prices in the PMPRB's comparator countries. Whereas Canadian drug prices were, on average, 123 percent of the median price of its seven comparator countries in 1987, this ratio has fallen to between 88 and 95 percent since 1995 (see Figure 5).

**Figure 5: Ratio of Canadian Prices to Median International Prices for Patented Drugs, 1987–2001**



Critics of drug price regulation have suggested that the PMPRB's pricing guidelines might set or keep prices higher than would a competitive market. The assertion is that the PMPRB's pricing guidelines may inhibit price competition between drugs within a therapeutic class.<sup>50</sup> This viewpoint assumes that health care and pharmaceutical markets operate according to competitive market theory. However, health care market analysts typically note that health markets generally, and pharmaceutical markets in particular, do not satisfy many conditions of competitive markets because costs are often paid by insurance, decisions about drug

treatments are made by physicians rather than by payers, and consumers lack information about the relative cost and effectiveness of therapeutic alternatives.

### **Cost Management Approaches of Public and Private Drug Benefit Plans**

In addition to the PMPRB's regulation of patented drug prices, third-party payers, particularly the provincial drug benefit plans, have applied cost management approaches that are intended to further restrain prescription drug costs. As large purchasers, these payers use cost management tools to enhance their ability to negotiate with drug manufacturers and pharmacies about the terms under which their plans will cover and reimburse drug products. The approaches they use can lead to patented drug prices that are *below* the maximum allowable prices set by the PMPRB and can promote the use of less costly versions of therapeutically similar drugs.<sup>51</sup> Many of these approaches are developed by the provincial drug plans; some private insurers simply adopt policies and prices negotiated by the provincial plans (unlike in the U.S. Medicaid program, net drug prices paid by the provincial plans are not considered to be proprietary and are, therefore, available to the public).

Among the tools used by these provincial drug benefit plans to reduce prices are the following:<sup>52</sup>

- **Use of price information to determine formulary inclusion.** Each province has a *formulary*, or list of drugs that are covered under its plan.<sup>53</sup> The drugs on the formulary vary among the provinces. A plan's ability to

exclude a drug from the formulary or to require prior authorization (the granting of special approval before a prescription will be reimbursed for a particular individual in a given situation) may give drug manufacturers incentives to set their prices at a level that makes it financially attractive for plans to include the products in their formularies.

- **Use of cost-effectiveness evaluation to determine formulary inclusion.** Ontario's drug benefit program applies pharmacoeconomic evidence of a drug's cost-effectiveness to determine its placement on the provincial formulary. Drug manufacturers seeking to have a product included on the provincial drug benefit formulary must complete a submission to the Ontario Ministry of Health and Long-Term Care that describes the drug's clinical effectiveness and cost-effectiveness. An independent Pharmacy and Therapeutics Committee of physicians and pharmacists reviews these submissions and makes recommendations about coverage.

On the basis of the committee's recommendation, the ministry determines that (1) the drug be reimbursed for all patients with no restrictions; (2) it should be reimbursed only for patients who meet certain clinical criteria; or (3) it should not be reimbursed without a special written request indicating why it is required for a particular patient.

Reasons for Ontario to impose restrictions on when a drug will be reimbursed include the following: its effectiveness relative to currently available therapies is small; it offers some marginal benefit relative to alternative treatments but at a much higher price; the manufacturer's data submission did not convincingly demonstrate its effectiveness; or it is cost-effective only in a subgroup of patients.<sup>54</sup>

- **Reference pricing.** British Columbia has implemented a “reference price” system to establish reimbursement rates for five therapeutic categories of drugs and their related conditions.<sup>55</sup> This approach, in effect, seeks to set up competitive pricing among therapeutically similar drugs.

As in Ontario, an independent committee of physicians and pharmacists reviews published evidence of the clinical effectiveness and cost-effectiveness of new drugs and uses this evidence to determine which drugs can be expected to have similar therapeutic effects. The province uses this information to set a reimbursement or reference price, as the lowest cost of therapeutically similar products. Enrollees who are prescribed a different product must pay the difference between the cost of the prescribed drug and the reference price for the class of drugs.

Studies of British Columbia's reference price system have found that it has resulted in substantial

cost savings. These studies have found no adverse quality impacts or financial barriers to access to appropriate drugs as a result of the system. One reason for this might be that, on behalf of their patients, physicians are allowed to ask for full reimbursement for a drug that exceeds the reference price if the reference drug is not medically appropriate.<sup>56</sup>

- **Provincial price regulation.** The province of Ontario, in addition to its use of pharmacoeconomic analysis to make coverage decisions, effectively regulates the prices that it will pay for prescription drugs on its formulary. Since 1994, Ontario has prohibited price increases for drugs on its formulary. In 1999, it started case-by-case negotiations with drug manufacturers to establish reimbursement prices of new brand-name drugs.<sup>57</sup>
- **Promoting generic substitution.** Most provincial drug benefit plans will pay only the cost of the lowest priced generic drug in cases where generic substitutes are available.<sup>58</sup>
- **Pharmacy reimbursement policies.** Provincial drug plans also establish the amount that pharmacies will be paid for each prescription dispensed. Various mechanisms exist, including actual acquisition cost, lowest cost alternative, maximum allowable cost, and best available price. Plans may also stipulate the pharmacists' dispensing fees that will be paid.

## Other Possible Causes for Price Differences

Several other reasons have been suggested as contributors to U.S.-Canada drug price differentials:

- **Differences in standards of living.** Danzon (1999) and Graham (2000) have suggested that Canada's relatively lower prices for patented drugs might be partly explained by lower income and declining gross domestic product per capita compared to the United States.<sup>59,60</sup> The theory is that, as a result of differences in the responsiveness of demand to product price in each country, the manufacturer can maximize its profits by engaging in "price discrimination"—that is, selling the product in different markets at different prices. According to this reasoning, the higher average income level in the United States may mean that Americans are less price sensitive than Canadians, thereby allowing pharmaceutical manufacturers to charge higher prices in the United States than they do in Canada.

This theory, however, is not consistent with the greater level of insurance coverage in Canada, particularly among elderly persons, who are most likely to need prescription drugs. The lack of insurance for prescription drugs among older U.S. residents is usually thought to make them *more* sensitive to prescription drug prices, despite higher relative incomes in the United States.

- **Direct-to-consumer advertising.** Canada does not allow direct-to-consumer (DTC) advertising of prescription medicines. By comparison, spending on DTC drug advertising in the United States has grown rapidly, from \$55.3 million in 1991 to \$2.8 billion in 2001. The top 50 drugs with the most DTC advertising spending in 2000 were responsible for nearly half of the \$20.8 billion increase in U.S. retail prescription drug spending from 1999 to 2000.<sup>61</sup> At a minimum, advertising affects total spending on prescription drugs by increasing consumers' demand. In addition, some believe that the cost of advertising contributes to the fixed costs that a business takes into consideration when establishing prices.

While there have been efforts to allow DTC drug advertising in Canada, the Minister of Health recently stated that the government has no intention of changing the current policy.<sup>62</sup> However, Canadians are increasingly exposed to cross-border advertising of prescription drugs, indirect and disease-oriented advertising originating in Canada, and drug ads on the Internet.

- **Cost of litigation.** One study suggested that one-third to one-half of any U.S.-Canada drug price differentials in 1990 were due to the higher cost of protection from legal liability in the United States.<sup>63</sup> This study noted that Canadian courts limited compensation for personal injury to C\$250,000 and



that Canadian judges rarely awarded large liability settlements.

## **CONTINUING EFFORTS TO RESTRAIN PRESCRIPTION DRUG SPENDING**

### **Moving Beyond Price Reduction in Canada**

Despite the general trend of having lower drug prices (at least for high-cost patented drugs that do not have generic substitutes), Canada—like the United States—is not free from the fiscal pressures of rising levels of pharmaceutical spending. As previously noted, expenditures on prescription drugs account for an increasing share of national health care spending. These costs threaten the ability of provincial and private benefit plans to continue providing benefits at current levels.

As a result of financial pressures, public policy discussions have moved beyond the issue of drug prices and traditional utilization management approaches (i.e., encouraging generic substitution; increasing cost sharing) to the broader issue of how to maximize value for pharmaceutical spending. Experts suggest that provinces must establish structures to ensure that a drug's price reflects its relative therapeutic value and that patients and physicians have both the *information* and *incentives* to balance benefits and actual costs.<sup>64</sup>

Ontario's use of pharmacoeconomic analysis to establish its formulary and British Columbia's reference price system represent two approaches for considering the therapeutic and economic value of drugs. In Ontario, a

drug must show clinical and economic value before being listed on the provincial formulary. In British Columbia, drugs that are determined to be of similar therapeutic value must compete on the basis of price. Two key features of both policies are that (1) clinical evaluations of the drugs are made by an independent panel of physicians and pharmacists and (2) physicians can obtain exceptions for patients for whom a formulary drug (in Ontario) or lower cost reference drug (in British Columbia) are not medically appropriate. Based on experience to date, Ontario and British Columbia appear to have slowed the growth in pharmaceutical spending without affecting access to medically appropriate drugs.

There has been debate in Canada about whether the federal government should take a more prominent role in helping to restrain prescription drug costs beyond price alone. The Commission on the Future of Health Care in Canada (also known as the Romanow Commission) recently proposed that the federal government assist provincial and private plans by establishing a national drug agency that would, among other functions, consolidate Health Canada's current drug approval process and the PMPRB's price regulation functions; extend price regulations to generic drugs; perform and disseminate cost-effectiveness analysis; and establish and manage a national drug formulary to ensure that decisions on formulary inclusion or exclusion are based on the best clinical, pharmacological, and economic evidence.<sup>65</sup>

As one step in this process, a nationwide, uniform process for

economic evaluations of prescription drugs was scheduled to begin early in 2003.<sup>66</sup> The federal government hopes to enhance the ability of provinces to apply pharmacoeconomic analysis in their benefit plans by developing a national database that will provide information on drug utilization patterns and the clinical results of different therapies.<sup>67</sup>

It is important to assess how these approaches affect access to necessary prescription drugs as well as incentives for pharmaceutical research and development. This tension between health and industrial policy is important in both Canada and the United States, where efforts to restrain prescription drug spending compete with a desire to maintain a vibrant industry that provides substantial health and economic benefits.<sup>68</sup> It is difficult to determine the extent to which R&D levels are attributable to cost control policies as compared to other factors that can affect pharmaceutical R&D, including the scientific and research infrastructure in a country, the size of the domestic market, and the speed of drug approval. Furthermore, cost control policies may have the positive effect of redistributing pharmaceutical R&D away from extensions of existing products and toward the development of products that can increase manufacturers' revenues under the new provincial payment policies—that is, products that offer substantial therapeutic advantages or are more cost-effective than existing products.

There has also been debate about the federal role in ensuring access to prescription drugs in Canada. The Romanow Commission voiced its concern about the disparities in drug

coverage across the country and the burden of high pharmaceutical costs on the small but significant share of Canadians who lack prescription drug coverage. It proposed that the federal government finance the costs of catastrophic prescription drugs in order to provide greater fiscal relief to provincial drug benefit plans and to reduce national disparities in drug coverage.<sup>69</sup>

### **Implications for the United States**

Interest in Canadian drug prices largely stems from the substantial differences that often exist between prices charged to cash-paying American consumers (i.e., those without drug coverage or with indemnity-type coverage for drugs) and prices charged for identical drugs in Canada. One reason that Americans—particularly older Americans, who are more likely to need prescription drugs—are relatively sensitive to differences in drug prices is that, unlike their Canadian counterparts, they are much more likely to lack drug coverage. Drug coverage—not lower prices—provides much of the financial relief for older Canadians, even as lower prices help to reduce the costs of coverage. However, rapidly rising drug expenditures are threatening the ability of public and private insurers in both countries to maintain their current benefit levels, and certainly contribute to the challenge of designing a financially sustainable drug benefit within the U.S. Medicare program.

Canada's success at restraining prices of patented drugs has helped to reduce spending levels but has not fully stemmed the rapid growth of prescription drug spending. While efforts in Canada have led to reductions

in the cost of individual products, these efforts have had a far smaller effect on spending increases associated with: higher per capita drug use; changes in the mix of drugs from less costly drugs to newer, more costly alternatives; and an aging population. In this respect, Canada is much like the United States.

The most important lessons of the Canadian experience for the United States may come less from its use of price regulations than from recent provincial and national efforts to apply clinical and economic evaluation to drug payment decisions. The approaches used in Ontario and British Columbia—in effect, establishing conditions for a more competitive pharmaceutical marketplace based on evaluations of quality and price—fit the American political context better than price controls. Indeed, to some extent, these policies are already being adopted in the United States. For example, Medicaid programs in several states, such as those in Maine and Michigan, are using evaluations of pharmacoeconomic data to determine placement on preferred drug lists. The Oregon Health Plan has established a reference price system similar to British Columbia's.

Whether these management systems will successfully restrain pharmaceutical spending in the United States without adversely affecting access or pharmaceutical R&D is yet to be seen. The early evidence from limited applications of these management systems suggests that they may be successful when implemented more broadly. They certainly warrant further assessment as Americans and their health insurers seek greater value for their pharmaceutical dollar.

David Gross, AARP Public Policy Institute, June 2003. The author acknowledges the valuable technical assistance provided by Judy Xu and Ryan Cool in the preparation of this Issue Brief.

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<sup>6</sup> Pharmaceutical Research and Manufacturers of America (PhRMA), *PhRMA Annual Membership Survey 2002*,

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