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**BEFORE THE**

**COMMERCE, SCIENCE, AND TRANSPORTATION SUBCOMMITTEE ON  
CONSUMER AFFAIRS, FOREIGN COMMERCE AND TOURISM**

**UNITED STATES SENATE**

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**Mr. Chairman and Members of the Subcommittee:**

**On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA), I want to thank you for providing the opportunity to testify on pharmaceutical price differences between the United States and Canada.**

**As part of the Medicare reform debate, the cost of some drugs for American seniors and price differences between Canada and the U.S. have attracted the attention of U.S. legislators and the media. Before I address these two topics, however, I think it is important to briefly discuss in a general way the Canadian health-care system. Members of Congress should be aware of the Canadian experience with health-care cost-containment policies for pharmaceuticals and other health-care services when considering changes to the U.S. health-care system.**

**The unintended, adverse consequences of government-driven cost-containment policies on access to appropriate medical and pharmaceutical care are not widely known. However, the results of such government intervention have been widely felt by patients. With respect to pharmaceuticals, cost-containment and price-control mechanisms have led to less choice and delays in access to the newest and most innovative medicines. In addition, these policies have also led**

to increases in other forms of more costly health care, such as hospitalization.

### Canadian Health-Care System

Health care in Canada is administered through the Ministry of Health in each of the Canadian provinces and territories. The Canadian system is primarily publicly financed through taxes collected at the federal and provincial levels to provide coverage for hospital and physician services. Although often portrayed as “comprehensive coverage,” Canadian health care is not truly comprehensive in that provinces are obligated to finance only “medically necessary” hospital and physician services. Since neither the federal government nor any of the provinces has defined “medically necessary,” this term has often been inconsistently interpreted.

An outpatient pharmaceutical benefit is also not nationally mandated. All provinces do provide coverage for seniors and low-income residents and four provinces have instituted universal coverage for all age groups and utilize cost-sharing arrangements such as significant co-payments and/or deductibles.<sup>1</sup> The majority of provinces, including Ontario, provide drug coverage only for seniors and low-income residents. Therefore, 56 percent of Canadians live without universal prescription-drug coverage. These individuals often receive pharmaceutical coverage through employers, unions, or private insurers.

In order to control rising health-care costs, Canada over time has implemented a number of cost-containment measures. Unlike the U.S., which has a market-based system, the Canadian system has controlled costs by relying on government financing and price-control mechanisms.

In response to dwindling federal funds, provinces have cut spending on health-care services through de-listing or de-insuring ancillary services, like home health care, and increasing cost-sharing for pharmaceutical services. Although successful in reducing the rate of increase in health-care costs, the impact on patients has not been positive. For example, according to the Fraser Institute, a leading Canadian think tank, over 200,000 Canadians are waiting for surgical procedures.<sup>2</sup> In 1998, the average Canadian patient needing care waited:

- 13.3 weeks for treatment from a specialist (6 weeks to see a specialist, and nearly 7.3 more weeks to receive treatment);
- 11.4 weeks for an MRI scan;

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<sup>1</sup> The Canadian Pharmacists Association, *Provincial Drug Benefit Programs*, 1999, (21<sup>st</sup> Edition).

<sup>2</sup> Michael Walker and Martin Zelder, Critical Issues Bulletin: Waiting Your Turn, The Fraser Institute (Vancouver), 1999.

- 25.4 weeks for orthopedic surgery, and
- About twice as long as is considered “clinically reasonable” for radiation for cancer and internal medicine.<sup>3</sup>

A December 1999 *Washington Post* article described the Canadian health system as “on the critical list, overwhelmed, and under attack.” For example, “[In] Ontario, the waiting list for MRIs is so long that one Ontario resident booked himself into a private veterinary clinic that happened to have one of the machines, listing himself as ‘Fido.’”<sup>4</sup> Wait times for prostate cancer patients became so long that a patient group actually formed the Society of those Awaiting Cancer Therapy, according to the *Wall Street Journal*.

Clearly, public dissatisfaction with health-care services in Canada is high and on the rise. Recent polls show that 78 percent of Canadians now say that their health care system is in crisis.<sup>5</sup> In a poll taken in December 1999 by Ekos Research Associates, 93 percent of the 3,000 Canadians interviewed reported that improving health care should be the federal government’s top priority.

### Drug Pricing in Canada

In sharp contrast to the U.S. where pharmaceutical prices are largely determined by market forces, drug pricing in Canada is regulated by two separate governmental bodies. Canada’s Patented Medicine Prices Review Board (PMPRB) is a federal government board that sets the maximum prices for innovative, patented medicines in Canada.

Prior to product launch, a manufacturer can either have discussion with pricing-board officials and submit cost-benefit information used to assist the company in determining its price, or make a formal request for an Advanced Ruling Certificate (ARC) for pricing, which occurs only rarely.

If a manufacturer has not received pre-approval for a price for a new product from the PMPRB, the price charged by the manufacturer must be submitted to the Canadian government pricing board within 60 days after introduction so that it can rule whether the manufacturer price is excessive. If the price of the medicine is deemed excessive by the Canadian government pricing board, manufacturers have two options:

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<sup>3</sup> Id.

<sup>4</sup> S. Pearlstein, “Health Care on the Critical List: Canada’s Public System is Overwhelmed, and Under Attack,” *The Washington Post*, December 18, 1999, p. A20.

<sup>5</sup> Angus Reid Group, Inc., February 2000.

- **Make a Voluntary Compliance Undertaking (VCU)**. A VCU is an agreement by the manufacturer with the PMPRB to reimburse the government for the difference between the price it had been charging and the price set by the PMPRB, and to accept the maximum price set by the pricing board rather than take the dispute further. This, however, does not mean that a manufacturer agrees that the price it established was excessive.
- **Appeal for Consideration**. If no agreement on a maximum price is reached with an appeal, the manufacturer can either agree to reduce the price and reimburse the government for differential revenues or it can appeal in the courts.

Ultimately, if there is no agreement on the maximum price a manufacturer can charge for a product, the Canadian government can:

- Impose a fine on the manufacturer equal to twice the amount of difference between the price actually charged and the government-controlled price;
- Annul the manufacturer's patent, and
- License the product to another pharmaceutical manufacturer.

In addition, if the government believes that a manufacturer knowingly sets the price of a product in excess of the Canadian government pricing board's maximum price, the manufacturer can be charged with a criminal offense. Not only must the price differential be reimbursed, but monetary penalties and jail terms are possible.

Maximum prices are determined by the Canadian government pricing board. The PMPRB uses several "tests" in controlling the prices of innovative medicines:

- The Reasonable Relationship Test is designed to ensure that the prices of different dosages or formulations of the same medicine are reasonably related.
- The Therapeutic Class Comparison Test compares the new medicine to other medicines in the same therapeutic class and sold in the same markets to ensure that prices are reasonably related.
- The International Price Comparison Test compares the average transaction price in Canada with prices in other price-controlled countries.
- The CPI Adjusted Price measures changes in the price of a medicine over time. It is designed to ensure that the price does not rise more quickly than CPI.

The Canadian government pricing board also establishes classes of new patented medicines for which price reviews are conducted.

Once the maximum price has been set by the PMPRB, the second tier of price regulation occurs at the provincial level. Provincial governments have separate health-care systems and drug-benefit programs that further restrict access to both care and drugs.

For example, Ontario, the province with the largest number of beneficiaries in its health-care system, has historically had one of the most restrictive formularies in Canada. From 1990 to 1997, Ontario only gave 35 new, innovative medicines full listings. From December 1996 to November 1997, this low rate of listing continued – Ontario gave full formulary listings to only 13 of the 80 innovative medicines introduced in Canada.

This double layer of price controls, along with restrictive provincial formularies, makes it difficult for Canadians to have access to and coverage for new, innovative, life-saving medicines.

#### How Canada's Drug Pricing System Affects Public Health

Cost-containment mechanisms have had a negative effect on access to pharmaceuticals and overall public health. For example, 27 percent of the physicians in British Columbia reported that they had to admit patients to the emergency room or the hospital as a result of mandated medicine switching.<sup>6</sup> Confusion or uncertainty by cardiovascular or hypertension patients due to mandated medicine switching was reported by 68 percent of doctors, while 60 percent observed worsening or accelerating symptoms.<sup>7</sup> British Columbia doctors reported similar problems, with the end result being an increase in patients who stopped taking their medications, which led to increased emergency-room visits.<sup>8</sup>

As compared to the U.S., Canadians experience longer delays in both access to and reimbursement for new pharmaceuticals due to:

- Delays in market approval dates.
- Delays in coverage until formulary decisions are made.

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<sup>6</sup> Dr. Bill McArthur, Think Tank Warns Clintonization is Candianization of Health Care, The Fraser Institute, January 27, 2000.

<sup>7</sup> Id.

<sup>8</sup> Id.

- Restrictions in product reimbursement because of restrictive formularies, reference-pricing schemes, and patient cost-sharing.<sup>9</sup>

### **Delays in Market Approval Dates**

Although regulatory review times for new products have decreased over the past several years, the Canadian regulatory process has consistently taken 1.5 times as long as the U.S. system for drug review and approval.<sup>10</sup> For example, in 1998 the FDA approved new drugs in an average of 365 days, while the Canadian Therapeutic Products Programme (TPP) took an average of 570 days.<sup>11</sup>

### **Postponing Coverage Until Formulary Decisions are Made**

The delays continue at the provincial level where various government “gatekeepers” review the “therapeutic value” of prescription drugs before they are included in the formulary. In the U.S., most health plans will cover new products either with no restrictions or through prior authorization until a formulary decision is made. In Canada, new products are not publicly reimbursed until formulary listing has been completed. Formulary access rates at six months post-product approval in Canada ranged from 51 percent in Quebec to less than 10 percent in Alberta, British Columbia, and Ontario. Eighteen months following new product approval, formulary access rates in Ontario, the province containing almost 40 percent of Canada’s population, were still only 23 percent.

### **Restriction in Product Reimbursement**

Canadian provinces limit product reimbursement based on formulary restrictions, referenced-based pricing, and patient cost-sharing. Although these cost-containment mechanisms have lowered utilization of prescription drugs by seniors and low-income adults, emergency-room visits and the use of other medical services increased.

For example, in the first 10 months following increased patient cost sharing in Quebec, savings of \$17 million (Canadian dollars) were achieved for income security recipients who regularly took drugs for chronic diseases. However, due to the new cost-sharing structure, recipients financed one-third of the savings. Drug savings were all offset by a \$4.1 million increase in other health-care expenditures.<sup>12</sup> In another example, British Columbia will only reimburse for two

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<sup>9</sup> The Lewin Group, The Impact of the Canadian System on Access to New Medical Technology Including Prescription Drugs, March 7, 2000.

<sup>10</sup> Id.

<sup>11</sup> Id.

<sup>12</sup> Id.

arthritic drugs as first-line therapy. Three commonly-used anti-arthritic drugs in the U.S. are not covered under any circumstances.

### U.S.- Canadian Price Differences

Many have asked why drug prices are sometimes higher in the U.S. than in Canada. The answer is based on many variables. However, the main reason is that in the U.S. each individual company is generally able to price its own medications based on normal market factors, such as supply, demand, quality, value, and cost-effectiveness.

The prices set for medicines reflect the cost of drug development, not only for drugs that make it to the market, but also for those that do not. In 2001 alone, the pharmaceutical industry is expected to invest \$30.5 billion in drug research and development. Estimates by the Boston Consulting Group indicate that the pre-tax cost of developing a medicine introduced in 1990 was \$500 million.<sup>13</sup> And just because a drug makes it to market does not mean it is a commercial success. A 1994 study conducted by economists at Duke University found that only three out of every 10 drug products, or new chemical entities, introduced from 1980 to 1984 had returns higher than average after-tax R&D costs.<sup>14</sup>

The prices also need to generate revenues that meet investors' expectations to continue to attract private investment. Investors seek to be compensated for their investment commensurate with risk; drug discovery and development are high-risk and require substantial funds over many years before medicines may reach the market.

In Canada, each company is denied the freedom to set prices for its own innovative prescription medicines. Prices are controlled by the Canadian government. The only choice a manufacturer has is to sell at the price set by the Canadian government – or not to sell its product. If a manufacturer opts not to sell its product, the government is allowed to authorize a Canadian company to copy and sell the drug, even without the patent holder's permission. In other words, if a manufacturer does not sell at a price Canada allows, the government effectively expropriates the value of the patent; the patent holder receives only royalties, which historically have been only 4-5 percent.

**Outside the United States, most countries choose to interfere in the market**

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<sup>13</sup> The Boston Consulting Group analysis based on J.A. DiMasi et al. (1991) as quoted by the Office of Technology Assessment in *Pharmaceutical R&D: Costs, Risks, and Rewards*, February 1993.

<sup>14</sup> Henry J. Grabowski and John M. Vernon, "Returns to R&D on New Drug Introductions in the 1980's," *Journal of Health Economics* 13 (1994) 338-406.

and set limits or controls on pharmaceutical prices, particularly for new, innovative products, to control health-care expenditures. Unfortunately, these practices have not worked. As a part of Canada's total health-care spending in 2000, total expenditures on drugs at the retail level, excluding drugs prescribed for use in hospital settings, have increased faster than other major components of health care, and reached a forecast level of 15.5 percent of total health-care expenditures.<sup>15</sup> In contrast, in the United States, outpatient prescription drugs as a percentage of U.S. National Health Expenditures was estimated to be 8.6 percent for 2000.<sup>16</sup>

In addition to the use by Canada of price controls on prescription drugs, there are other reasons why prices for prescription drugs differ in the U.S. and Canada. Prices vary from country to country for a host of reasons, including living standards, income differences, willingness to pay, differences in medical practice, product volume, exchange rates, the level of competitive medical service or product prices, patent term and expiration dates, the length of time and costs of drug-marketing approval, as well as government-imposed reimbursement and price controls.

Another common reason that price differences exist between the U.S. and Canada and the U.S. is product liability. Questions of whether to sue, the nature of the forum, the level of proof needed to prevail, the nature or size of the case, and the level of damages awarded often make product-liability cases in the U.S. more costly to pharmaceutical manufacturers than in other countries, particularly in Canada.

A study released in December 2000 by the U.S. International Trade Office (ITC) explored foreign markets and U.S. prices, pharmaceutical development and approval processes in various countries, and how prices are established within countries. The report also considered how to measure the differences in prices between countries and concluded, "A single, definitive, unbiased measure of comprehensive price differences does not exist."<sup>17</sup>

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<sup>15</sup> See the *National Health Expenditure Trends, 1975-2000*, published by the Canadian Institute for Health Information (CIHI), 2000.

<sup>16</sup> Health Care Financing Administration, OACT, 2001.

<sup>17</sup> "Pricing of Prescription Drugs," United States International Trade Commission, Investigation No. 332-419, Publication 3333, December 2000.

### **Most Cross-National Price Comparisons are Flawed**

Recently, snapshot cross-border comparisons of pharmaceutical prices have gained great popularity as “demonstrating” that prices charged in the U.S. are higher than those charged abroad. Like any still frame out of a movie, these snapshots often mislead and fail to tell the whole story.

The ITC report examined several studies relating to pricing and determined that there are methodological flaws with each. Sample selection issues biased comparisons and “severely limit the generality of the conclusions of this research.” The report also identifies the replacement cost benefit that pharmaceuticals can play in overall health care, stating, “At times, pharmaceutical products are used instead of costlier options such as hospitalizations.”<sup>18</sup>

Virtually all of the cross-border “studies” comparing drug prices have been flawed by faulty methodology. Professor Patricia Danzon of the Wharton School, and Fredrik Andersson and colleagues at the Battelle Medical Technology and Policy Research Center, have published extensively on the shortcomings of different approaches for comparing drug prices internationally. They conclude that international price comparisons are misleading and generally based on flawed methodologies, and suggest that public policy is all too often influenced by price studies without an understanding of their technical limitations.<sup>19</sup>

One of the most common flaws of many price comparisons is comparing manufacturers’ list prices for drugs in the U.S. with list prices in other countries. This practice leads to erroneous conclusions because the actual transaction price in the U.S. is often significantly lower than the list price, unlike in many other countries.

Another common flaw is that price comparisons are also typically made on the basis of simple averages of the top-selling drugs in a given country for which matching products are available in other countries. This often results in the use of extremely small samples. The studies also typically make no attempt to include the most frequently used drugs in comparison countries, nor do they attempt to weigh the prices based on the consumption of drugs in countries examined.

Yet another flaw in many comparisons is that the sampled drugs are not always directly comparable. Differences in package size, dosage forms,

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<sup>18</sup> Id.

<sup>19</sup> See e.g. Danzon, P., Pharmaceutical Price Regulation: National Policies versus Global Interests, (AEI Press: Washington, DC, 1997).

strengths, indications, and dispensing methods need to be taken into account, but rarely are. In short, apples-to-apples comparisons are rare, so reported results must be viewed with care.

Converting foreign prices to local prices for comparison purposes produces another type of error, given that changes in exchange rates over time create considerable variability in price relationships.

This problem is further exacerbated by foreign government price setting. When faced with a devaluation, U.S. exporters of most products try to raise their price in local currency to keep constant in U.S. dollars. This is evident to anyone visiting a local bookstore. A \$25 book in the U.S. is actually priced on the jacket at Canadian \$33. Newspapers costing \$1.50 in the U.S. are listed at Canadian \$2. But with pharmaceuticals, the price ceiling imposed in Canada by the PMPRB – totally disconnected from exchange rates – has no mechanism that allows U.S. exporters of medicines to adjust their prices in Canada due to exchange-rate fluctuations.

Many studies have focused on the final prices to patients or third parties rather than revenue received by the manufacturers. However, in most countries, pharmaceutical wholesalers and retail pharmacies are reimbursed at fixed percentage mark-ups over the ex-manufacturer price. The margins are set by law and differ substantially from one country to another. Many countries also impose a value-added tax. Even if a manufacturer were to set a uniform wholesale price in all industrialized countries, the final retail price to consumers would vary by as much as 90 percent due to these mark-ups. If a manufacturer sold a product for \$1.00 in North American and European markets, the final price to a consumer would range from a low of \$1.14 in the UK to a high of \$2.08 in Finland. The U.S. price would be \$1.43. Only the UK and Sweden would have a consumer price lower than that available to U.S. consumers.

There are numerous ways in which “simple” cross-border comparisons result in inaccurate conclusions. While these problems may be well known in academia, they are often missing from the public debate. On top of all of the technical problems discussed above, it is also important to remember that for U.S., non-government purchases, market forces set the price. In other countries, like Canada, governments, directly or indirectly, set the price and no government bureaucracy has ever been able to mimic a market-based price for a large number of products on a sustainable basis.

### **Many Products, Not Just Prescription Drugs, Are Less Expensive in Canada**

Many products, not just prescription medicines, are generally less expensive in Canada than in the United States. **This is because the Canadian government imposes price controls and unnecessary regulations on many industries.** The Canadian government runs marketing boards for most industries. The boards operate within a specific province or throughout the entire country. For example, one such board is the Wheat Board. As Chairman Dorgan is keenly aware, the Wheat Board in Canada monitors and sets prices on the sale of wheat in Canada. Therefore, the cost of wheat products, such as bread, are directly related to the price dictated by the Wheat Board.

### **Reimportation of Pharmaceutical Products into the U.S.**

Although some seniors in the U.S. are traveling to countries like Canada or using foreign-based web sites in search of less expensive pharmaceuticals, they may be putting their health at risk by doing so. Government investigation into the reimportation of pharmaceuticals has shown that it opens our nation's borders to counterfeit medicines and places vulnerable populations at risk. Reimportation proposals are a distraction to the real solution – a Medicare prescription drug benefit.

### **Conclusion**

In conclusion, although pharmaceutical prices in Canada are sometimes less than what they are in the U.S., it is important to remember why this is so. As discussed above, there are many reasons for price differences between countries. But the primary reason is government-mandated price controls. In Canada, this has meant limited choice and access to the newest and most innovative medicines. It has also meant lengthy delays for other health-care treatments and less access to medical technology. So although government-imposed price controls can appear as an attractive choice, they hurt the very people they are designed to help – patients.

We should learn from Canada's mistakes – not import them. Nor should we make the mistake of adopting a risky and dangerous reimportation scheme instead of addressing the underlying problem by reforming the Medicare program, including enacting a prescription-drug benefit.

That concludes my formal presentation. I will be pleased to answer any questions that the Chairman or Members of the Subcommittee may have.