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Rx for Canada:

Close the Internet Pharmacies

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In this issue...

Internet pharmacies are a threat to drug prices in Canada — both Canadian consumers and the drug companies can win by closing them down.

The Study in Brief

Canada's Internet pharmacies represent a threat to domestic drug supplies and prices, and the federal government should close the business.

Drug companies charge different prices to different buyers internationally and within the U.S. Uninsured buyers, and those in relatively small buyer groups in the U.S., pay among the highest prices in the world. Their purchases from Canadian Internet pharmacies have until now been relatively small in volume, but could grow much larger if the President signs legislation permitting retail pharmaceutical imports. Since the prices of some drugs are relatively low in Canada, legalization of imports would likely result in large increases in demand on Canadian suppliers.

Drug manufacturers do not want to cannibalize the profitable U.S. market by supplying low-priced imports from Canada, so they will press for higher prices in Canada. Since Canadian federal regulations prohibit them from increasing drug prices at a rate higher than inflation, the manufacturers' only method of protecting their American profits would be to restrict supply to Canada, which could lead to shortages and eventually to higher prices.

Because the cross-border trade remains mostly illegal and the volume small, Canada has not suffered a serious shortage of drugs or big price increases. This situation could quickly change if legislation is passed in Washington to legalize imports.

From Canada's perspective, it makes sense to act sooner rather than later. If the next President implements legislation to facilitate drug imports, it would look hostile on Canada's part to immediately prohibit drug exports.

Stopping exports soon would eliminate the prospect of shortages and price increases and is entirely advantageous for Canada. It would also be an act of moral leadership. Ottawa recently passed a bill allowing exports of generic drugs to developing countries that issued compulsory licenses for them. That bill required developing-country recipients to take "reasonable measures" to prevent re-exports of those drugs, so that Canadian manufacturers were not undercut by shipping low-price drugs to lower-income countries. Canada should lead by taking reasonable measures to prevent unauthorized exports of the drugs regulated by the Patented Medicines Prices Review Board.

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Internet pharmacies in Canada are enjoying a booming business selling prescription drugs to U.S. consumers, with sales estimated at as much as \$600 million (unless otherwise specified all figures are in Canadian dollars) in 2003, or approximately 3.8 percent of total retail drug sales (IMS Health Canada 2004). Do these sales threaten to increase Canadian drug prices, cause shortages, or solve the U.S. problem of high drug prices, as a number of commentators have suggested? If they are a threat to Canada, are there any desirable remedies? We conclude that the sales do constitute a danger and we recommend a protective policy for the federal government.

As we discuss in this paper, there are two barriers to a substantial increase in Internet pharmacy exports. The first barrier is that the drug companies actively monitor sales to eliminate supplies to pharmacies selling into the U.S. and the second is that the *U.S. Food and Drug Act* prohibits retail drug imports. There is now a fair probability that these laws will be modified to allow drug imports from some Canadian sources and if that happens, there is no certainty that the drug companies would be successful in preventing a substantial increase in retail drug exports. Should such exports increase, it seems likely that drug companies would seek — and perhaps be able to obtain — higher prices in Canada. Any increases in the price of drugs could have severe consequences on provincial health budgets where spending on pharmaceuticals already represents as much as 16 percent of total health expenditures, the second largest line item after spending on institutions.

One of the sticking points in the Internet pharmacy debate is the perception among the U.S. public and legislators that drug price controls in Canada account for the price differences between Canada and the U.S. As a result, U.S. politicians put strenuous pressure on Canada to eliminate drug price controls.¹ As we argue in this paper, eliminating Canadian price controls may not be a way out of this problem. On the contrary, the preponderance of evidence indicates that federal price controls, exercised through the Patented Medicines Prices Review Board (PMPRB), have relatively little impact on drug prices in Canada.

Because this finding implies that prices in the U.S. and Canada are essentially set by drug companies in response to demand conditions, including the leverage exercised by provincial drug plans, our analysis employs the standard economic framework of price discrimination (the situation when companies charge different prices to different buyers for the same type of good). This well-developed economic literature allows us to develop some helpful insights into reasons for and possible policy responses to Internet pharmacies.

We build on the standard analysis of price discrimination and parallel imports as presented in Maskus (2000), Malueg and Schwartz (1994) and Gallini and Hollis (1999). Parallel imports are imports of genuine products, produced under protection of trademark and made available for sale in the originating country, thus — potentially — violating the trademark, patent, or copyright held by a local

1 For example, Speaker of the House of Representatives Dennis Hastert recently complained that Canada's "price control regime is unfair to American consumers; Americans shouldn't be forced to subsidize the health care for the rest of the world." (Office of Speaker Dennis Hastert web site 2003).

company. This is exactly the situation of the Internet pharmacies. Typically, parallel imports arise when a company attempts to discriminate in pricing between markets.

Several papers have focused on drug imports. For example, Calfee (2003) examined the political economy of imports into the U.S. and argued that they will lead to “rapidly escalating pressure for pharmaceutical price controls” in the U.S., a direction that was totally rejected in the 2003 *Medicare Act* (Calfee 2003). Indeed, if anything, it seems to have led to escalating pressure from the U.S. for the elimination of any form of Canadian price controls. Arfwedson (2003) examined parallel trade in pharmaceuticals on a global scale and, while briefly discussing Canadian Internet pharmacies, chiefly explores the trade-off between preserving intellectual property rights and ensuring access to essential medicines in developing countries.

Our analysis, in contrast, focuses explicitly on Canadian policies and options. We offer a perspective highlighting the convergent interests of Canadians and of drug companies. We argue that the best policy for the Canadian government is to take steps to eliminate, or at least to reduce, Canada’s Internet pharmacy exports to the United States, a policy that exactly matches what the drug companies want. We also offer some cautions on the difficulty of constraining such exports.

There are two underlying reasons for the recent rise of Canada’s Internet pharmacies. For one thing, the cost of finding low-priced drugs in Canada and shipping them to the U.S. has fallen because of the Internet — which makes instant price comparisons possible — and improved express shipping. A cross-border trade in drugs has existed for a long time, fuelled by seniors willing to take a bus to Canada to buy cheap drugs, but it is the rise of the Internet and better shipping that has enabled drug exports to expand massively.

For another, the success of the Internet pharmacies depended on prices for some drugs in Canada being lower than the prices available to some consumers in the U.S. Not all drug prices need be lower in Canada to stimulate exports and indeed there are many products for which the price is lower in the United States. Overall, drug prices in Canada tend to be lower than in the U.S., but Danzon and Chao (2000), using 1992 data, find prices about the same when accounting for products available generically as well as branded products. Danzon and Furukawa (2003), using 1999 data, find prices for patented drugs in Canada to be on average about 36 percent below U.S. prices. (They say that lower relative Canadian prices are largely explained by depreciation of the Canadian dollar.) Naturally, however, exports to the U.S. have been of those drugs that are lower-priced in Canada.

It has been well documented that in the U.S., drug companies practice extensive price discrimination with uninsured consumers paying the most, large corporations and Health Maintenance Organizations (HMOs) paying somewhat less, and the federal government paying the least. The bulk of the Internet pharmacy exports from Canada have been to uninsured consumers who face high drug prices. Thus, all that is necessary for Internet pharmacies to have substantial cross-border sales is for at least *some* drugs to be priced substantially higher in the U.S. for at least *some* classes of consumers, a condition which is readily met because of the high prices faced by retail consumers in the U.S.

There is an additional wrinkle in appreciating why Canadian and U.S. drug prices differ. U.S. federal legislation requires pharmaceutical manufacturers to provide price discounts for certain types of government purchases. For example, a clause introduced under the *Omnibus Budget Reconciliation Act* (1990) gives “Most Favored Customer” status for all drug purchases under the Medicaid program. Scott-Morton (1997) has shown that this lessened market competition among both branded and generic companies leads to a 4 percent average increase in prices. Similarly, drug manufacturers are required to discount all drug purchases by the U.S. Department of Veterans Affairs.

The Big Picture

In the next section, we begin with a look at the current state of Canada's Internet pharmacy exports. We then briefly review the economics of price discrimination and parallel imports and offer some evidence on Canada's drug price controls, showing that for the most part they have little effect on prices. That enables us to argue that a standard analysis of price discrimination is appropriate. Then we discuss Canada's options and make some recommendations for responses.

The Facts

High drug prices have produced alluring incentives for U.S. consumers to look abroad to fill their prescriptions. For the United States overall, the U.S. Customs Service estimates that approximately 10 million citizens bring medications across land borders with Mexico and Canada each year. In addition, there are millions of shipments by mail from Internet pharmacies in Canada, as well as approximately two million packages of pharmaceuticals arriving annually by international mail from countries around the world (Flaherty and Gaul 2003). Most Internet pharmacy sales are made from Canada, rather than from other countries, such as Mexico, because Americans generally feel more comfortable with the quality standards in Canada.

IMS Health Canada estimates that in 2003, sales by Internet pharmacies to U.S. consumers were between \$566 million and \$605 million, more than double the level in the 2002. IMS estimates that, given U.S. retail prices for the products exported, their retail value to U.S. buyers — including foot-traffic, or consumers who personally cross the border to fill their prescriptions — was \$1.4 billion. This implies that the losses to drug companies may be as high as \$500 million, which explains why pharmaceutical companies are very concerned about Internet pharmacy exports. The number of Canadian pharmacies with an active online export business has risen to approximately 120 in 2003 from four in 1999, although only a handful of these have substantial sales.

Retail pharmacy imports to the U.S. are technically not permitted under Food and Drug Administration (FDA) regulations, except for small personal exemptions for travelers and for imports of certain drugs not available in the U.S. Although wholesalers and pharmacies in Canada fall outside the ambit of the FDA, drugs cannot be freely exported into the U.S, even if they have previously been imported

from there and are in fact identical to drugs sold legitimately in the U.S. However, Washington has not seriously tried to prevent actual shipments because that only penalizes the small number of consumers whose deliveries are blocked. The difficulty is compounded by the fact that when medications are intercepted, the consumers who ordered them are upset and complain to their politicians. Indeed, there has been a continuous flow of legislation in Congress — none so far successful — to legalize drug imports from Canada and elsewhere.

Patients' Safety

The main reason given by the FDA for not permitting retail drug imports into the U.S. is that they may jeopardize patients' safety. The principal problems are of two types. First, there are concerns about Internet pharmacies, whether they operate domestically or internationally. These pharmacies do not see their clients personally or ensure that faxed-in prescriptions are used only once. There is also concern about drugs being subject to unsuitable environmental conditions while in transit (for example, being subject to too much heat). These problems are relevant not only to international Internet pharmacies. Internet pharmacies also operate domestically in the U.S., and we do not believe that those in Canada deserve any extra concern in this regard.² Another safety concern is that counterfeit drugs — manufactured under unsanitary conditions and perhaps not containing the correct amount — if any — of the active ingredient, may be able to slip into the supply stream because of weak controls by a foreign country such as Canada. Clearly, then, before the U.S. government is willing to change its regulations to allow retail imports from Canada, it will have to at a minimum, provide a method of ensuring the safety and integrity of the supply network. At present, the FDA has not declared itself satisfied with the patchwork of oversight that would occur if Health Canada, the Canadian provinces, and provincial pharmacy associations were collectively responsible for safety in Canadian Internet pharmacies (FDA 2004).

There are two business models currently used in Canada for Internet drug exports. The most common one is for a pharmacy to hire physicians in Canada to co-prescribe the medication with a U.S. physician. The Canadian signature is a requirement for the pharmacist to fill the prescription. This approach has some drawbacks. The Canadian physician may be in breach of professional obligations. Most of the provincial Colleges of Physicians lay down strict rules requiring physicians to maintain extensive records and show evidence that they have full knowledge of the patient's conditions, including concomitant medications that they may be taking, before prescribing medicines to them. It is likely that these

2 Indeed, compared to U.S. Internet pharmacies serving their customers in the U.S., it is arguable that there is extra protection when the same customers go to a Canadian Internet pharmacy because in the latter case their prescription will be checked by a second Canadian physician who reviews the file and prescription of the patient's U.S. doctor, before co-signing the prescription. A recent report by the General Accounting Office showed that in some respects, Canadian Internet pharmacies had stricter standards than those in the United States, consistently requiring physician-written prescriptions before filling orders, and including appropriate labels, instructions, and warnings ("Few problems at Canadian Internet Pharmacies," *Washington Post*, June 17, 2004).

rules are being violated, at least in spirit if not in the letter of law, and could be enforced more rigorously by taking away prescribing privileges of the offending physicians (the federal government has encouraged the provincial physicians' colleges to be enforce such rules). The problem, however, lies in identifying physicians in breach of these standards. At the same time, the co-signing physician introduces extra costs, typically charging a fee of \$10 per prescription (Simon 2003). As well, the Canadian physicians who co-prescribe without seeing the patient may be unable to obtain liability insurance for this activity; the Canadian Medical Protective Association announced that as of February 2004, it will no longer extend assistance to physicians facing legal actions arising from co-signing prescriptions where the physician has no recognized doctor-patient relationship (Sproule 2004).

The threat of sanctions by professional associations and the absence of liability insurance have apparently not been frightening enough to prevent doctors from co-signing prescriptions. Provincial physicians associations appear to have pursued very few doctors who have co-signed prescriptions for Internet pharmacies. For example, in Manitoba, only one case is publicly listed of a physician who has been reprimanded for co-signing prescriptions (College of Physicians and Surgeons of Manitoba 2004). In that case, the College first warned the physician to stop this activity. When the physician continued co-signing, he was fined \$14,190, including costs, and received a reprimand. Based on a rate of \$10 for each of the 2,271 prescriptions he co-signed, it appears that he still made a profit even after accounting for the fine.

The alternative — and relatively rarely used — business model is to function only as an exporter of pharmaceuticals. Under this approach, the pharmacy is not accredited by its provincial pharmaceutical association, and does not use Canadian doctors to co-sign prescriptions. This solves some of the problems already mentioned, but is of questionable legality.³ The operation of such pharmacies has been defended under the Canadian *Food and Drugs Act*, Sec. 37, which explicitly exempts drugs not sold for consumption in Canada.⁴ Provincial governments appear to have been loathe to take action against these Internet pharmacies, as long as their activities are restricted to exporting.

Wisconsin's Example

Canadian Internet pharmacies can offer substantial savings to some American consumers, particularly those with chronic conditions — such as high blood pressure or high cholesterol — requiring regular, predictable doses of medicine over long periods. Newspapers have been filled with reports of consumers who claim to have saved hundreds of dollars through buying in Canada. The State of

3 For example, the Ontario Drug and Pharmacies Regulation Act requires all pharmacies to be accredited by the Council of the Ontario College of Pharmacists.

4 This section of the *Act* was intended to apply to drugs manufactured in Canada, but the Internet pharmacies have tried to use it to provide a legal defence for their activities. Health Canada has nevertheless attempted to inspect at least export-only pharmacies (Canadian Press 2004).

Wisconsin maintains a website that “gives our citizens the ability to buy certain prescriptions at significantly lower prices directly from Canadian pharmacies that our state has visited and found to be safe, reputable, and reliable.”⁵ The website contains ordering information and prices of drugs which cost less in Canada.

A quick comparison of the prices advertised there and on the official U.S. government’s Medicare website shows substantial differences between prices for many drugs. For example, a 100-pill supply of Mobic, used to relieve osteoarthritis in adults, costs us \$78.60 at a Canadian pharmacy shown on the Wisconsin government site, while it costs us \$243.68 at the lowest-priced Medicare drug card site.⁶ On average, Canadian prices for patented single-source drugs were 64 percent of U.S. prices in 1999, when weighted by consumption and adjusted for discounts (Danzon and Furukawa 2003); after adjusting for a 10 percent increase in the Canadian exchange rate since 1999, the average prices currently may be extrapolated to be around 75 percent of U.S. prices. However, exports are likely to be concentrated in individual drugs which are considerably cheaper in Canada than in the U.S., such as Mobic.

The price differentials may be due to a variety of factors. In the next section we consider why drug prices in Canada and the U.S. are so different.

Price Discrimination, Parallel Imports and Exclusive Territories

Price discrimination is said to exist when a firm charges different prices in different markets for substantially the same good.⁷

The Theory

We commonly see price discrimination by movie theatres, where children and seniors are charged lower prices for the same product. The reason for price differences of this sort is not any affection for children and seniors, but the realization that it is profitable to charge a lower price to them in order to sell more tickets. More generally, monopolists may wish to charge different prices in different markets if they have different characteristics. The monopoly price in each market will depend on the shape of the demand curve, as well as cost conditions.

In general, markets with low demand elasticity will have relatively higher prices. (In the movie example, children and seniors have high demand elasticity.) Typically, the monopoly price in poorer countries will be lower. Profitable price discrimination requires that a company have market power, or the ability to set prices to some extent, that it is able to distinguish between markets, and that

5 Available from: (<http://drugsavings.wi.gov/index.asp?locid=2>). According to the *Globe and Mail*, some 16 states and 22 municipalities have or are in the process of setting up similar websites (Zehr 2004).

6 Available from: (<http://www.medicare.gov/default.asp>). The price comparisons were made May 20, 2004.

7 Economists call this “third-degree” price discrimination.

arbitrage or resale between markets is limited. All of these conditions have historically characterized drug markets, which helps to explain some of the widely observed variation in international drug prices. Price discrimination does not imply cross-subsidization among different consumers, as long as consumers in all markets are paying at least marginal costs, a condition which certainly holds in developed country pharmaceutical markets.

One reason that we observe very different prices charged in different countries and to different types of buyers is buyer-power, which is the bargaining leverage of purchasers to extract price concessions from sellers. Individual consumers evidently have little buyer-power, while large-scale purchasers, such as provinces, may refuse to list drugs in their formularies unless they obtain price discounts. The exercise of buyer-power is closely related to the notion of demand elasticity: the exercise of buyer-power by large purchasers can be seen as being an indication that they have more elastic demand because they are better informed about possible substitutes.

International price discrimination tends to induce companies and consumers to engage in cross-border resale. While within countries there are few limits on resale, between countries such resale is described as a parallel import and in certain circumstances companies may be able to obtain government support to stop the cross-border trade. Companies often use intellectual property rights — patents, copyright, and trademarks — to eliminate parallel imports. This strategy can work when the patent or trademark in a country is owned by one company, and the goods imported from another country are deemed to be infringing the local patent or trademark. The ability of the patent holder to prevent trade depends on its treatment of international property rights (Maskus 2000). U.S. law historically has not allowed the use of intellectual property rights to prevent parallel imports when the intellectual property is owned by the same company or by affiliated companies in the exporting and importing country (Gallini and Hollis 1999).⁸ However, in a recent case (*Jazz Photo v. ITC*, 264 F.3d 1094, 2001), the Court of Appeals for the Federal Circuit has, at least partially, reversed this historic pattern. Thus, for pharmaceutical products not first sold in the U.S., patent infringement actions may be successful in stopping parallel imports into the U.S. (though, as we will illustrate, some proposed legislation eliminates the ability to use patent rights to stop parallel imports).

Are Price Controls Actually Setting Prices in Canada?

An important condition for the claim that there is price discrimination between Canada and the U.S. is that the drug companies are in a real sense setting prices in

⁸ A subtle irony here is that the reason that U.S. law permits parallel imports when the intellectual property rights are controlled by the same company is that the company in that case has a remedy, which is to charge the same price in both countries. This remedy is not readily available in the case of pharmaceuticals.

both countries. Drug prices face no explicit government price controls in the U.S. However, if the prices in Canada are controlled by government, then the claims that there is price discrimination may ring hollow. We therefore examine the importance of federal price controls in the following section.

Canadian Drug Pricing Practices

Are price controls on pharmaceuticals actually effective in Canada? Ottawa appears to have a somewhat contradictory attitude toward price controls. On the one hand, the federal government operates the Patented Medicine Prices Review Board (PMPRB) which, among its other functions, is widely characterized as a pharmaceutical price-control agency. On the other hand, Canada's ambassador to the U.S. claimed that the "price review regulations play a minor role" in determining drug prices (Kergin 2003). The PMPRB is apparently intended to curb "excessive" pricing only, and such pricing is found in a small number of drugs each year. This means that the average pricing of drugs in Canada is little affected by the price review process. The board has ordered or obtained a voluntary undertaking of a price reduction for only eight products in the last five years, although the threat of investigation by the PMPRB will presumably have been effective in pushing down prices for other products as well.⁹ A PMPRB restriction on the maximum rate of annual price increases has left drug companies unable to respond to parallel trade by raising prices domestically.

Various studies have confirmed that the effect of the PMPRB on prices may not be substantial. Anis and Wen (1998), using a study based on 1992 data, show that the PMPRB maximum allowable price thresholds appear not to be binding. Graham (2000) notes that historically drug companies have not taken full advantage of the PMPRB provisions that allow them to increase prices annually with the rate of inflation. The implication is that the preferred profit-maximizing price chosen by drug manufactures in Canada is often lower than the ceiling established by the PMPRB.

There is also evidence from other countries that pharmaceutical price controls are not a major determinant of average prices. Danzon and Furukawa (2003) examine prices of drugs in nine countries in 1999 and find that prices vary substantially across countries, but that, after correcting for discounts and rebates on U.S. drugs, average U.S. prices are not far out of line with those of major trading partners. In particular, they show that examining a basket of prices including generics tends to reduce the price differential, and that using purchasing power parity instead of nominal exchange rates makes the U.S. cheaper than most

⁹ Surprisingly, of those eight drugs, three are classified as "Orphan Drugs" under the U.S. *Orphan Drugs Act*, meaning that the U.S. government provided special incentives for their development because the markets were thought to be too small to support development on a commercial basis. The PMPRB's targeting of drugs financed in part under the Orphan Drug Act leaves Canada in the morally tenuous situation of imposing price controls on rare-disease drugs financed by the U.S. government, while U.S. consumers pay higher prices.

other countries. They also point out that the observable differences at nominal exchange rates seem to be well explained by income differences across countries.¹⁰

One reason that drug prices may be lower in Canada than in the U.S. could be bargaining power exercised by provincial formularies and other large purchasers. A provincial formulary listing is the key to successfully marketing a drug in each province because listing ensures that the provincial drug plan will cover the cost of the drug for eligible beneficiaries. In an effort to control the cost of insured drugs, most provinces require evidence of cost-effectiveness of new drug introductions. Anis et al. (2001) show that formularies are selective in the products they list, in part based on their evaluation of the cost-effectiveness of the product, and this, implies that the drug companies may be willing to offer their products at lower prices in order to obtain a listing (Borrell 2003).

Even if formularies do choose to list a product, they may assign limited-use designations to particularly expensive drugs. Such designations require extra paperwork for both doctors and pharmacies. As a result, drug manufacturers are somewhat constrained in their pricing if they wish to increase the chances of obtaining an early, unrestricted listing on provincial formularies. While direct bargaining between formularies and pharmaceutical companies over the price at which a drug will be listed is rarely observed, formularies may have passively exercised some discipline over pricing simply through their discretion over whether and how to list a new product.¹¹

So while there is a common perception that the cause of low prices in Canada is government regulation, the evidence appears to point instead to the low price in Canada being caused by profit-maximizing behavior on the part of the pharmaceutical manufacturers facing a population with lower incomes than in the U.S. and a system of health insurance that is looking for value for money.

Still, it is true that PMPRB reviews are binding on the prices of at least some drugs. And it is most likely the case that drug companies would like to increase Canadian prices to prevent export sales into the U.S. market. Normally, if the manufacturer of a product does not want to see parallel imports flowing from a low-priced country into a higher-priced one, the company has a remedy: either increase the price in the low-price country, or lower it in the higher-priced one. In the case of pharmaceuticals, increasing prices in Canada is not necessarily an available option because of PMPRB regulations. The alternative remedy of reducing prices in the U.S. is not reasonable because the U.S. market is both large and profitable. For example, pharmaceutical sales revenue at just one drugstore chain in the U.S., CVS Pharmacy Inc., is substantially greater than the entire retail drug market in Canada. We discuss the implications of these facts in the following section.

10 This claim is weakened by a glaring exception: The two lower-income countries in their study, Brazil and Mexico, had prices that were more or less in line with the average of the higher income countries.

11 It is true that price regulation and buyer-power may be very similar in their effect, particularly if the buyer represents a significant proportion of the market, as is the case with the Canadian provinces. The difference is that buyer-power typically reduces prices only for a given buyer and that price regulation is usually backed up with the threat of compulsory licensing, if the seller refuses to sell at the allowed price.

Internet Pharmacies: A Threat to Canadian Drug Prices

If large-scale drug exports were to occur, most likely drug prices would rise in Canada to U.S. retail levels, which would eat into provincial health care budgets and increase drug costs for most Canadians.

The Threat of a Huge Increase in Exports

U.S. retail prices may be lower or higher than Canadian prices for particular drugs, but on average, patented drugs are more expensive in the U.S. In 2002, total drug spending in Canada was around \$18.1 billion, with \$6.6 billion financed by the public sector (Canadian Institute for Health Information 2004). As a result, a price increase of, say, 15 percent on average, holding quantities constant, would cost Canada approximately \$2.7 billion, with \$1 billion coming from government. This would be an unambiguously bad outcome for Canada. Most likely, however, such an increase in prices would result in some decrease in the quantity purchased, probably leading to worse health conditions and substitution of other forms of medical care.

Because of the difference in prices for at least some drugs between Canada and the U.S., what prevents more and more drugs being exported? The quick answer is that there are two main obstacles to export growth. First, there are legal obstacles to imports in the U.S. that make it more expensive and less convenient to import retail drugs than it would be in the absence of the obstacles. Second, drug companies are restricting supply in Canada, and are trying to target pharmacies that are actively exporting into the U.S. We now evaluate just how much protection these obstacles to exports really offer.

Murky Federal Restraints

Currently, federal regulations make the import of pharmaceuticals from Internet pharmacies illegal, but the FDA policy results in “enforcement discretion” at U.S. Customs, which, in effect, allows most drugs through. The illegal status of drug imports from Canada leads many insurance plans — with or without co-pay requirements — to refuse to cover any drugs bought from Canadian Internet pharmacies, which severely limits the demand for Canadian drugs. As a result, most of the U.S. demand for drugs from Canada comes from consumers with no insurance at all, or from consumers with health benefits paid for by the few cities and states that offer coverage for purchases from Canada. If federal regulations were to change to allow imports from Canada, then demand for Canadian drugs would increase substantially. As we will discuss, there is a fair probability that such a change in federal regulations will occur within the next year or so.

The response of the state and federal governments in the United States to the growth in Internet pharmacy imports from Canada has been divided. Normally, with price discrimination between countries, it is in the interest of the country with the higher prices to encourage arbitrage — but in the case of pharmaceuticals, the manufacturers are also located in the high-price country. Thus the issue of whether to allow drug imports comes down to a trade-off. The

trade-off is between supporting the profitability of the pharmaceutical companies through enabling continued segmentation of markets and differential prices based on the profit-maximizing price for each market, and reducing prices for domestic consumers (while increasing them for foreign consumers). Different political groups have lined up in support of different positions. The Republicans have typically fought against importation, while the Democrats have tended to favor it. Meanwhile, governments of some states and cities — particularly those without a significant pharmaceutical industry — have been pushing actively for access to pharmaceuticals at Canadian prices.

The result of this split in interests is that the *Medicare Prescription Drug Improvement and Modernization Act* of 2003 was passed with a compromise on drug importation. The *Act* requires the Secretary of Health and Human Services to conduct a study of the desirability of drug imports, and then, if possible to write appropriate regulations ensuring safety, to allow importation of medicines from Canada only. This provision means that for the present there will be continuous obstacles to importing drugs, but that there is a fair probability of amendments to the laws regarding imports of drugs from Canada. The FDA has consistently argued that drugs imported from Canada cannot be assumed to be safe, even if they have been approved by Health Canada.¹² However, consumers, employers and city and state governments are exerting such pressure to obtain lower prices that the outcome of this debate in the U.S. is unpredictable. Tommy Thompson, the Secretary of the Department of Health and Human Services, recently predicted that drug re-importation “is coming”, adding that he would not advise the President to veto a bill allowing drug imports from Canada under certain conditions (*Boston Globe* 2004).

Two bills in the Senate to facilitate imports of drugs, especially from Canada, Dorgan/Snowe (S. 2328) and Gregg (S. 2493) have received bipartisan support. Both bills allow for imports of pharmaceutical products at retail and wholesale levels, giving some FDA oversight for safety. The Dorgan/Snowe bill is particularly strong because it also eliminates some other roadblocks to drug imports: It overrides the Jazz Photo decision, expressly noting that patentees in the U.S. will not have the right to block imports of legitimate, patented drugs that were first sold abroad and it prohibits manufacturers from discriminating in supply against companies that are exporting drugs into the U.S.¹³

Some state and city governments have already added coverage in their insurance plans for employees who buy prescription drugs from outside the United States, but so far they have not faced legal action. In addition, several states and cities have been investigating how drug importing would be most

12 The FDA has conducted a number of blitzes to determine what sort of medicines are being imported from Canada currently. The agency has discovered that there may be some safety problems, owing to the underground nature of the business. For example, they found that some lots of a given product had been recalled in Canada. The FDA suggested that U.S. buyers of the product might not have been informed of the recall by the Canadian Internet pharmacy (*FDA News* 2004).

13 There is some question as to the legal validity of the “forced trade” provisions of the Dorgan/Snowe bill, which do not allow drug manufacturers to discriminate in price or quantity when selling to companies that export products to the U.S. (Pilon 2004).

effective. The State of Illinois, which undertook a substantial study arguing that Canadian drug approval, safety and control standards were equivalent to those of the FDA, has been active in promoting drug imports (Kamath and McKibbin 2003). Similarly, the State of Wisconsin is actively promoting purchases from Canadian Internet pharmacies. The sustained pressure from states, cities, a large number of members of both houses of Congress, as well as such lobbying groups as the American Association of Retired Persons (AARP) make it likely that federal laws will be changed to allow retail drug imports from Canada.

The Rx&D Response

If retail drug imports become legal in the U.S., how will the pharmaceutical manufacturers, individually, and acting as a group through their industry associations, Research-Based Pharmaceutical Companies (Rx&D) and the Pharmaceutical Research and Manufacturers of America (PhRMA) react? They will have several options. They can attempt to set prices in Canada and the United States that will not lead to arbitrage — this implies prices becoming fairly similar. Alternatively, they can try to stop the cross-border shipments of drugs. A final approach is to tolerate the arbitrage while keeping prices different.

Harmonizing prices in Canada and the U.S. may seem to be the easiest choice for the drug companies because, as discussed, they charge many different prices in the United States, depending on local markets and the situation of buyers. As a result, any single price in Canada would not match with at least some of those prices. If the Canadian prices were set equal to those charged to the U.S. federal government, that would be exactly the same average relationship between prices as currently (Hollis 2004 forthcoming). Arbitrage would be prevented only if Canadian prices were similar to the retail price for uninsured United States residents. However, in that case, average U.S. prices would be much lower than Canadian prices, a situation that would not be desirable for the pharmaceutical companies. Recall that prices in the U.S. for uninsured consumers are set in order to maximize profits.¹⁴ Since Canadians have lower incomes and the bargaining process includes large buyers in Canada, it is likely that for most drugs, the profit-maximizing price in Canada will be below the profit-maximizing price for uninsured retail consumers in the U.S. (Danzon and Furukawa 2003).¹⁵ As discussed, it appears that the pharmaceutical companies are already charging near their profit-maximizing price in Canada, so raising prices to the highest U.S. levels would likely lead to a decrease in profits. In any case, in the short term PMPRB regulations prohibit substantial price increases, and even for new drugs it seems unlikely that the PMPRB would allow Canadian prices to be set at U.S. retail levels because that would make Canada the highest-priced jurisdiction in the world.

14 Possibly they are set above the profit-maximizing level because the government requires that purchases by the VA and affiliated organizations be 24 percent below the “average wholesale price”, which means that the optimal price for all other buyers will be pushed above the profit-maximizing price.

15 This is not necessarily the case in every circumstance, however. Consumers who are insured may be less price-sensitive than those who are not insured.

A second approach for Rx&D would be to leave prices as they are and try to minimize cross-border shipments of drugs. This would maintain the existing structure of price discrimination. There are a number of ways to lessen arbitrage, and it appears that Rx&D has engaged in all of them to varying extents. Among other things, it has threatened to supply only the amount normally required for Canadian demand, so that if substantial exports occur, there will be drug shortages in Canada.¹⁶ This strategy is probably not very relevant given the current level of Internet exports, though it could become binding if the volume of exports increases substantially. The public announcements of this policy can be seen as a way of indicating that if the Internet pharmacy export business is allowed to grow unchecked, there will be some consequences for Canada.

Pharmaceutical manufacturers have attempted to limit supply to individual wholesalers that supplied pharmacies engaging in cross-border sales. For example, in February 2004, Pfizer announced that it had stopped supplying two pharmacy wholesalers, based on concern that they were supplying Internet pharmacies (Agovino 2004). However, attempts to limit supply to Internet pharmacies are under attack in U.S. and Canadian courts. The State of Minnesota started an investigation of GlaxoSmithKline Inc. on the basis that the company's threats to limit supply to Canada because of Internet pharmacies might have violated state antitrust laws in Minnesota (State of Minnesota District Court 2003). A separate class-action lawsuit in the U.S. alleges that the big pharmaceutical companies conspired to eliminate cross-border sales through common means of restricting supply (Iverson et al. v. Pfizer et al. 2004). In Canada, four applications have been filed with the Competition Tribunal by pharmacies, alleging that several manufacturers' refusal to supply them constitutes a refusal to deal under S. 75 of the *Competition Act*. It appears that the manufacturers blacklisted these pharmacies because they were reselling some products to Internet pharmacies. The language of S. 75 leaves scope for the application because there is nothing in the *Act* that seems to contemplate cutting off supply to one retailer on the basis that it might resell products to a second one.¹⁷ If the applicants are successful at the Competition Tribunal, then the manufacturers will be unable to stop third-party supply of the Internet pharmacies.

The third approach that Rx&D could adopt is to ignore the arbitrage. This policy might be attractive if it were desirable to price discriminate between retail

16 Allowing supply shortages is a risky strategy for the pharmaceutical manufacturers, since the Patent Act allows the Canadian government to issue compulsory licenses in case of non-supply. However, the timetable required to show supply shortages, then obtain a compulsory license from the Commissioner of Patents, and then to obtain supply through a compulsory licensed generic manufacturer makes the threat of compulsory licensing irrelevant unless the supply shortage lasts a relatively long time.

17 The direct application to the Tribunal by the pharmacies is different from an unsuccessful attempt by Internet pharmacies to engage the Competition Bureau in 2003. The Bureau declined to support the Internet pharmacies, because: "The civil provisions of Canadian competition law pertaining to refusal to supply and market restrictions generally recognize that suppliers may set the terms and conditions of sales to businesses provided that they have reasonable business justification." (News release at <http://strategis.ic.gc.ca/epic/Internet/incb-bc.nsf/en/ct02528e.html>, last accessed June 8, 2004) S. 75 explicitly notes that the terms of trade mean "terms in respect of payment, units of purchase and reasonable technical and servicing provisions," which does not, on the face of it, seem to include terms restricting resale.

buyers in the U.S. based on their willingness to search out low prices. However, large-scale arbitrage would almost certainly result in substantial decreases in profits. Price discrimination based on willingness to buy drugs from Canada would likely be ineffectual at separating out consumers based on willingness to pay high prices, and most likely the drug companies would simply lose sales at high prices in order to gain the same sales at lower prices. Because of the relatively large size of the U.S. market compared to the Canadian market, this would not make sense.

This review of the possible approaches makes it clear that the second one — maintaining price discrimination while trying to minimize arbitrage — is the most attractive strategy for the pharmaceutical companies given the current volume of parallel trade.¹⁸ However, this strategy could become very costly for both pharmaceutical manufacturers and Canada if the volume of parallel imports were to increase substantially because of implementation of the Dorgan/Snowe bill. In that case, the limitations on supply threatened by Rx&D would likely become a reality, leading to supply shortages, which in turn could only be fixed by increasing prices beyond the limits currently imposed by the PMPRB. Possibly, Canadian buyers would have to purchase drugs from American or other foreign wholesalers to meet demand. There is, of course, only a *risk* that FDA regulations will be changed to allow cross-border retail drug imports; however, if this happens, it seems unrealistic to expect that the drug companies will be able to manage drug supplies in Canada to meet both existing Canadian demand and vastly increased demand from the U.S.

What Should Canada Do?

Canada now faces the possibility of threats to provincial health budgets and shortages of drugs, so it seems useful to consider the available responses. In such a situation, one of the issues to consider is whether to be pro-active and eliminate the prospect of a problem, or to wait until the problem arrives before reacting. We favor the former approach in this case, because drug shortages could arise quite quickly if drug exports were to increase rapidly, while legislative changes take time to enact. Drug shortages could have serious, indeed fatal, consequences for Canadians. Moreover, a Canadian government ban on Internet sales into the U.S. enacted immediately after the U.S. government permits imports from Canada could be perceived as unhelpful or even hostile, so that the possible responses in the future may be more constrained than actions taken now.

Individual provincial governments are not likely to take effective action concerning Internet pharmacy exports because they do not have the same interests. The provinces that have substantial Internet exports — especially Manitoba — may have an interest in sustaining the business, which brings both jobs and tax revenue. The Internet pharmacy business employs an estimated 1,500 people in Manitoba and generates direct tax revenue of approximately \$150 million (Redekop 2004). Provinces without Internet pharmacies, on the other hand,

¹⁸ In an unusual turn of events, the interests of generic companies are aligned with those of the innovator firms because generic companies in the U.S. are harmed by low-priced competition in the brand-name product coming from Canada.

may wish that the business were stopped, but cannot do anything about it. As a result, we believe that any response to the Internet pharmacy exports must be a federal one. Ottawa could:

- Eliminate the price review functions of the PMPRB in order to remove the rationale for action by the U.S.;
- Do nothing at all, or take minimal actions including the application of existing laws to control Internet pharmacies where there is any infraction, or,
- Amend legislation to stop Internet pharmacy exports.

Consider a situation where price regulation was eliminated altogether in Canada, and FDA rules changed to accommodate cross-border imports of drugs from Canada. Drug companies would likely increase their Canadian prices to minimize losses from resale into the high-priced U.S. market, and Canadian drug prices would more closely match U.S. retail prices. This would eliminate the prospect of shortages, though it would not be particularly good for Canadians. It would also not be the best outcome for drug companies, as noted, because U.S. retail prices are generally higher than the profit-maximizing prices for Canada.

The second approach, using existing laws to inhibit cross-border pharmacy sales appears to be the strategy taken until this point by the federal government. However, as discussed, this approach leaves Canada vulnerable to a change in U.S. regulations on pharmacy imports.¹⁹ The use of existing laws to prevent Internet pharmacy exports from Canada is a reasonable first step. But it does not appear to have been particularly effective. Despite various attempts to stem the Internet business through implementation of existing laws, the public letter from Assistant Deputy Minister of Health Diane Gorman to the provincial pharmacy associations and others dated Oct. 27, 2003, reveals that the federal government has basically no leverage to stop Internet pharmacy exports without a change in the *Food and Drugs Act*. Instead, the government has relied on the provincial governments and pharmacy associations to limit the economic viability of exporting. The federal government, in short, appears to lack the ability to limit the activities of Internet pharmacies unless it takes the more serious step of enacting restrictive legislation.

The third approach — taking substantial steps to eliminate retail pharmacy exports — is, we believe, the best choice for Canada. This would involve modifying the *Food and Drugs Act* to explicitly restrict retail pharmacies from shipping any product reviewable under PMPRB guidelines to customers outside of Canada.²⁰ It is not hard to justify such a restriction because the PMPRB regulations prohibit pharmaceutical manufacturers from reacting to the current problems of re-exportation into the U.S. by increasing their prices. While Internet pharmacy exports currently represent only a small fraction of total Canadian

19 Note that if the FDA never finds a means to assure the safety of Canadian drugs, then this strategy may be the best one, but it does depend for its optimality on U.S. legislative inaction.

20 It may be possible that the Minister of Health could eliminate retail drug exports through administrative or regulatory changes falling short of an amendment to the *Act*. However, such an approach would likely be subject to court challenges and seems to us a less desirable solution.

demand, if the American market ever becomes open to parallel imports from Canada, the demand from the U.S. could easily exceed total Canadian demand for at least some products. Unless the pharmaceutical companies were willing to accept relatively large decreases in profit from their U.S. market, it is likely that they would follow through on their threats to limit supply in Canada. This would inevitably lead to supply shortages and price increases in Canada. Blocking Internet exports is a way of preserving a system of price discrimination, which happens to be favorable to Canadians and to the drug manufacturers.

The federal government's inaction on Internet pharmacy exports is also puzzling when considered alongside the recent amendment of the *Patent Act* to allow exports of patented medicines under compulsory licenses to developing countries in cases of health emergencies. Those amendments reflect particular concern to avoid re-exportation of medicines that were originally shipped to a developing country. Specifically, Bill C-9 does not permit compulsory licensees to supply drugs to a country which has not implemented "reasonable measures" to prevent re-exportation of drugs supplied under the *Act*. The U.S. is in a somewhat comparable situation regarding re-export from Canada. It seems hypocritical — to say the least — for Ottawa to require developing countries to establish "reasonable measures" to prevent re-exportation while Canada has no measures at all to prevent re-exportation of drugs subject to price controls under the PMPRB.²¹

Conclusion

In this *Commentary*, we have argued that Canadian Internet pharmacies exist in large part because of the market structure of the pharmaceutical industry and not because of any Canadian prices or regulations. High retail pricing for drugs in the U.S. is a made-in-the-U.S. issue, and it is unlikely that relying on imports from Canada can solve it in the long run. On the contrary, forcing Canadians to increase their domestic prices will hurt Canadian consumers and decrease U.S. multinational drug companies' profits because they will be forced to raise prices beyond their profit-maximizing levels.

Some readers of an earlier draft of this paper objected to the idea that the Canadian government should act to solve a problem of the drug companies (which simply wish to engage in a system of price discrimination) or to legislate a solution to a U.S. political impasse. It is a fact that Canadian drug exports to the United States are not, in themselves, a Canadian problem. But if, as a problem for the U.S. and drug companies, they lead to price increases and drug shortages in Canada, then pharmaceutical exports to the U.S. become a Canadian problem.

In Canada, drugs are not like other goods: They are price-controlled, and large-scale exports of price-controlled drugs to the U.S. are not compatible with

21 The former FDA commissioner, Mark McClellan, pointed out that the Canadian government had not been altogether helpful in eliminating Internet exports: "To simply say it's not our problem, these are not the words of a helpful partner ... [W]hen it comes to the health and safety of the American public, we are reaching out to them in the spirit of cooperation, asking for their assistance" (Wagner 2004).

low prices in Canada or the price-control system. Canadians are not likely to be able to enjoy low drug prices in Canada and profit from large-scale exports of drugs to the U.S. at the same time; Ottawa must make a choice as to which is more desirable. Indeed, if government chooses to try to profit from re-exportation of drugs, Canadians are likely to find that domestic drug prices rise and export profits dry up.

It appears that there is a fair probability that Congress will pass laws, and the President sign them, allowing large-scale imports of drugs from Canada. Most serious would be the Dorgan/Snowe version of drug importation legislation. There is also a chance that the applications by four pharmacies before the Competition Tribunal will be successful, which would hamper any manufacturers' effort to control exports into the U.S. If either of these possibilities become reality, then the pharmaceutical companies will be facing increased arbitrage between Canada and their retail (and perhaps wholesale) consumers in the U.S; if both happen, there will be large-scale arbitrage. This would likely lead the companies to restrict supply to Canada — possibly leading to shortages — and to push for substantial price increases in Canada in order to protect profits in the U.S. If Canadian drug prices were increased to match U.S. retail prices, the total impact on the health budgets of the provinces would likely be a cost increase of at least 2 percent and there would be additional costs for consumers. The upside of continuing to supply U.S. consumers through Canadian pharmacies is, on the other hand, relatively small. To us, this shows that finding a solution to the threat posed by pharmacy exports should be a priority.²²

The effects of price increases would be pan-Canadian, rather than being restricted to those provinces where the Internet pharmacy trade operates. As a result, there is a case for prophylactic federal — not provincial — action to prevent price increases or drug shortages. One reasonable approach would be to amend the *Food and Drug Act* to specifically prohibit retail exports of any pharmaceutical subject to price review by the PMPRB. If the federal government does not act it could jeopardize both provincial health care budgets and the health of Canadians.

²² A task force in Health Canada is studying whether Internet exports threaten to cause shortages. (Zehr 2004).

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