AIMS

commentary

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Alice in Borderland

Why Canadians Cannot Afford to be Complacent About American Drug Re-importation

By Brian Ferguson

he idea that Americans should be able to buy their prescription drugs in Canada, either in person or, more importantly, over the Internet, has been gaining favour with US politicians for some months now. It's to the point where a number of states have either passed, or are considering passing, legislation that they believe will make this kind of cross-border shopping legal. Most of the attention paid to the issue has been from the American perspective and has dealt with American issues, such as the US federal government's role in foreign trade and the efforts of the Food and Drug Administration's (FDA) refusal to permit the sale of Canadian drugs in the US market, a refusal that appears to make the states' legislation moot. (The FDA appears, at this writing, not to intend to permit the importation of flu vaccine from Canada, despite the critical shortage of vaccine in the US.) Canadians have tended to sit back smugly and see the debate as one more piece of evidence of Canadian superiority when it comes to health-related



matters. There are, however, important implications for Canadians in this debate, and important reasons why we might want to take an active part in it. At the risk of giving away the punch line, if re-importation ever becomes law in the US, American prices will not fall, while in Canada we will either find drug prices rising to US levels, or supplies being restricted and shortages developing.

Low Canadian drug prices

The conventional wisdom is that prices of prescription drugs are much lower in Canada than in the US. The consensus is that there exists a whole pile of studies showing exactly the same thing - that prescription drugs are cheaper here - and that this is a result of the efforts of the Patented Medicines Price

Summary

Differences in the prices of prescription drugs between Canada and the US have been a hot topic in the news in recent months, even intruding into the American presidential election. Part of the reason for the difference is simply the exchange rate, and the most likely explanation for the remainder is the fact that Canada and the US are separate markets.

It's not uncommon for the same good to be priced differently in different markets: prices tend to be lower in lower-income countries, for example, and Canadian incomes are lower then American incomes.

Maintaining the price difference requires that the market separation be maintained, and until now the American Food and Drug Administration has done Canadians the favour of keeping the two markets separate by preventing Americans from reimporting drugs from Canada.

If, as many states are demanding, reimportation becomes legal, Canadian consumers of prescription drugs are not going to be happy with the outcome.

The most likely outcome is that our market will be swallowed by theirs. When that happens, one of two outcomes will follow: either Canadian drug prices will rise to US levels or, if the Canadian government manages to prevent that, American pharmaceutical companies will restrict their shipments to Canada. In that case, each pill re-imported into the US will be a pill that is not available for Canadian consumers. In either case, we lose.

Review Board's (PMPRB) efforts to protect us from price gouging by multinational (primarily these days American) drug companies. We have been told of organized convoys of Americans, primarily elderly, coming to Canada to buy their drugs at a fraction of the price they pay in the US. And, given this background, we fully understand why Americans would want to open the border to drugs from Canada and tend to assume that the refusal of the US government - primarily through the agency of the FDA - to do so reflects the degree to which D.C. is in the pockets of the multinational

drug companies - of big pharma.

Unfortunately, this story has a lot of holes in it. By taking it for granted, we could suddenly find ourselves faced with much higher prices forprescriptiondrugs here in Canada.

Interestingly enough, there are no reports of American "medical tourists" having to wait weeks to see Canadian doctors

It is true that individual Americans have been buying prescription drugs in Canada, although it isn't clear how widespread this is. There has been enough of it going on for some Canadian doctors to profit from it - seeing American patients and writing them the prescriptions they need to buy their drugs. (And some Canadian doctors have found themselves in trouble with their professional bodies recently for countersigning prescriptions for US patients whom they had not seen.) Some newspaper reports suggest that some Canadian MDs have established clinics devoted exclusively to seeing American medical tourists. Again, there isn't a lot of data, but newspaper reports suggest that those GPs are taking advantage of the fact that services provided to US medical tourists are not insured services so far as provincial Medicare plans are concerned, and are charging their US patients about twice what Medicare would pay for a similar visit by a Canadian. Interestingly enough, there are no reports of American patients having to wait weeks to see Canadian doctors.

It's also true that Americans have been buying drugs over the Internet that purport, and in some cases actually do, come from Canada. There are certainly enterprising Canadian Internet pharmacies that fill prescriptions from Americans, shipping the drugs to US addresses.

American authorities have cracked down on a number of these operations, closing several down, and the FDA has warned about lack of quality assurance on drugs imported from Canada: the FDA can't certify the safety of those drugs and so won't approve them for sale in the US. The FDA's position has been the subject of considerable ridicule. How can it claim that drugs from Canada are unsafe? But there is merit to its position, a point to which we'll return.

The truth about "low" Canadian prices

There are, however, problems with the standard story. Some are technical: most of the reports of drug price differences are based

on newspaper reports or a couple of not-very-well designed surveys. Most importantly, those studies haven't always compared like-with-like in physical terms: haven't always ensured that things such as dosage were identical in the comparisons being used. More than that, they haven't ensured that they were comparing like-with-like in purchasing terms.

In making drug price comparisons, it's important to allow for the fact that the actual price paid by consumers is not, in many cases, set by the manufacturers but rather is a combination of the manufacturer's price, and wholesale and drug store retail markup. In making international price comparisons, we have to decide whether we should be looking at the producer's price, the wholesale price or the retail price. This sounds trivially obvious - we want to compare costs to consumers, so we should be looking at the consumer price - but it's not that simple. The two components of the consumer's price - the wholesale price and the retailer's markup - are affected by completely different factors. If we want to look at the behaviour of big pharma in different countries' markets, we should be looking at the wholesale, or producer's price. Again, we shall return to this point in more detail below, but for the moment, consider one simple factor.

The price those American medical tourists pay for prescription drugs in Canada is in Canadian dollars, since they walk into Canadian drug stores and buy them at the same counter as do Canadians. Unless they choose to identify themselves, it's not easy for pharmacists to distinguish them from Canadian customers, and it wouldn't matter much if they could.

But while the price those tourists pay over the counter is in Canadian dollars, the price that matters to them is the US dollar price. What they are comparing, when they make the decision to come to Canada to get their drugs, is the number of US dollars they'll have to spend to buy medication here versus the number they'll have to give up to get them in the US. Depending on where they live, that could include a significant element of transportation costs. Further, when we read those US newspaper stories about Americans coming to Canada, the drug price differences are reported in US dollars or, if the Canadian dollar price is given, are also converted to US dollars at the going exchange rate. Whether it's actually worth buying drugs in Canada will depend very much on that exchange rate. When the US dollar was worth roughly \$1.50 Canadian - or the Canadian dollar was worth approximately US\$0.67 - drugs costing C\$100 cost only US\$66.67. Once the loonie rose to roughly US\$0.80, though, or, looking at it the other way, the US dollar fell to C\$1.25, those same Canadian drugs, which still cost C\$100, now cost US\$80. That's a 20% increase in price, which is a pretty hefty inflation rate by any standards, especially for a good whose Canadian price hasn't risen. Unfortunately, lack of detailed data on drug sales to Americans means that we don't have a good idea of how the rise in the loonie affected the Canada/US difference in drug prices, or how it affected American medical tourism.

Patricia Danzon of the Wharton School at the University of Pennsylvania has conducted what is probably the most painstaking exercise in comparing like-with-like (2003), looking at manufacturer-level prices, allowing for exchange rate effects, and

taking account of the differing availability of generic substitutes in different countries. She says that, while there does seem to be a genuine Canada/US difference in drug prices, it's a lot smaller than most studies suggest. Danzon concludes that when you compare like-with-like, the price difference drops to approximately 33%, and that when you net out exchange rate differences, Canadian prices are only 14% lower than US prices.

What you might term the "real" price difference between Canada and the US, then, was only about 14%. Basically, when the Canadian dollar is cheap, so are Canadian drugs, at least as far as US consumers are concerned, and American pharmaceutical tourists have benefited from the fact that the Canadian dollar has been undervalued for the past several years. (Interestingly enough, despite everything we hear about the US being the most expensive country to be sick in, Danzon reported that Japanese drug prices were higher than US prices.)

Still the question remains as to why there should be any difference at all, and what would happen if Americans were free to buy all the drugs they wanted from Canada.

Most Canadians assume that drug prices in Canada are kept down by price control rules administered by the PMPRB. The Board certainly does negotiate with producers as to the prices at which they can introduce new drugs into the Canadian market and does limit the rate of future increase in the prices of those drugs to the general inflation rate. However, the PMPRB's guidelines for setting the initial price are pretty flexible, and we don't actually have good evidence on what prices the drug companies would set if they were free to set their own initial prices.

The power of drug companies

The general assumption is that in the absence of regulation, the drug companies would charge the same price in Canada as they do in the US, but there are reasons to be cautious in reaching that conclusion. The most important reason is that drug companies have market power. A drug company, once given a patent over a drug by a country, has the monopoly right to sell that drug in that country for a certain number of years. That's not as absolute a protection as it might sound: the company has a monopoly over a particular drug but not over the treatment of a particular condition. If another company can find an alternative drug that will treat the same condition, and if the drug is sufficiently different in composition to the drug of the first company, then the second company is free to patent its own treatment and enter the market in competition with the first company. Critics of the pharmaceutical industry refer to this as "me too" drug making and criticize it as a waste of resources, but the empirical evidence is that competition has the same effect in the pharmaceutical market as it has in any other market: it holds down drug prices.

Still, patent protection does give drug companies some degree of monopoly power in individual countries, and that monopoly power means that drug companies can engage in what the marketing literature calls pricing-to-market. A very common phenomenon, that simply means setting the product price in a particular market in terms of demand-and-supply conditions in that market. The economics literature calls it price discrimination, meaning charging different

prices for the same commodity in different markets.

A firm that is in a position to price-to-market can calculate, for each market, the price that will yield it the highest profit in that market. The result is that prices for identical products, produced by identical firms, will differ across markets. This isn't restricted to

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the pharmaceutical Recently sector. Apple Computer's iTunes service has been under attack in the UK for charging customers 79p for downloading music track, while customers in France and Germany pay the Euro equivalent of 67p. The Consumers' Association of the UK charged that this was anti-competitive and "another example of the rip-off culture

that the British people are often victims of." Apple said, though not in so many words, that all it was doing was pricing to market. "The underlying economic model in each country has an impact on how we price our track downloads," an Apple spokeswoman told BBC News Online. Because of differences in local market conditions, Apple was able to charge a higher price in the UK than in France and Germany.

The key condition for pricing-to-market to work is that re-sale between markets must not be possible. In other words, it must not be possible for a consumer to buy in the lower-priced market and resell to a consumer in the higher-priced market. If that could happen, a firm would effectively find itself in competition with itself, as consumers in the lower-priced market bought its product in bulk and re-sold it in the higher-priced market at a price above what they paid for the good but below what the original supplier was charging. Effective market separation is key to the functioning of price discrimination.

Price discrimination is not an unusual or improper practice, and no one has ever been known to object when it leads to their paying a lower price for some product than is charged in other markets. One of the results of the adoption of a common currency on continental Europe has been to reveal just how much the prices of such things as cars differed across national borders, differences that were to some degree concealed from the ordinary consumer when spotting them involved doing calculations in multiple currencies. Indeed, the price of cars differs between Canada and the US, with cars being cheaper in Canada, despite the absence of a Car Price Review Board in Canada. At one point, auto manufacturers were worried about the flow of cars from Canada into the US, but the appreciation of the loonie seems to have shrunk that re-sale market.

The importance of separate markets

s long as suppliers can keep markets separate, then, they can charge different prices in different markets. Up until now, FDA regulations have maintained a strict separation between the Canadian and American markets for prescription drugs. The FDA has a mandate to ensure the safety of the American drug supply, and has, not surprisingly, nightmares about another thalidomide episode. It is cautious to excess, probably retarding Americans' access to beneficial drugs, and it attempts to keep the seal on the US border absolutely airtight.

This strict separation of markets means that, even though the same companies are supplying both Canadian and US markets, and even though (and this is an important point) drugs sold in Canada come from the same factories (mainly in Puerto Rico, in fact) as those sold

in the US, drug companies would have the capacity to charge different prices in Canada and the US even in the absence of the PMPRB. The obvious question, then, assuming no government intervention and prices set strictly by profitmaximizing drug

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companies, is whether prices would be higher or lower in Canada than in the US? On balance, the answer is almost certainly lower.

There are a couple of factors at play. One of the biggest factors leading to differences in prices between markets is income differences. Canada's GDP per capita is less than the US'. In 2002, US GDP per capita was approximately US\$36,000, while Canada's, calculated according to the prevailing exchange rate, was US\$23,000. The loonie was undervalued at the time, though, meaning that that US\$23,000 underestimates the Canadian standard of living: when you compare the purchasing power of Canada's GDP per capita with that of the US, Canada's average real income comes out at approximately US\$30,400. While not as much less as the exchange rate conversion suggested, Canadian real income was still less than American, by roughly 16%. We would expect, therefore, that under price discrimination, pharmaceutical prices would also be lower in Canada. Indeed, in the article cited above, after having adjusted for differences in the cost of living across countries (a procedure that tends to increase the real incomes of poorer countries relative to pure exchange rate-based comparisons of incomes, since poorer countries tend to have lower prices), Patricia Danzon found that differences in drug prices followed differences in incomes very closely.

Price discrimination doesn't need to involve international trade. Even within the United States different purchasers are charged different prices; one of the problems with international comparisons is that they typically don't take into account who is paying for the drugs, meaning that they don't take proper account of discounts from list prices. And within the US, price differences also apply at the retail level. In fact, as a recent article in *US News & World Report* found, there can be dramatic differences between the price charged for the same drug by different drug stores in the same American city. When you get into all of the fine details, it really doesn't make much sense to talk about "the" Canadian or American price of a drug, although we will continue to do so in a loose way.

How litigation influences drug pricing

There's another factor worth considering here. We tend to talk A about drug prices being lower in Canada than in the US and look for explanations of that fact, but we could also turn the question around and ask why drug prices are higher in the US: what factors specific to the US would be driving prices up? One answer that has been given to that question is the American legal system. Canadians know the US is a litigious society - just see the cases referred to on OverLawyered.com. This is the country, after all, where a jury awarded millions in damages to a woman who sued McDonalds after she scalded herself by opening a cup of McDonald's coffee while driving. And Senator John Edwards, who is, at this writing, the Democratic vice-presidential candidate, made his millions by suing doctors for not having performed enough C-sections. Edwards' specialty was representing the families of children born with brain damage against their obstetricians, arguing against all medical evidence that, had they only been delivered by C-section, the children would have been born healthy. The epidemiological evidence is generally taken as indicating that there are, in fact, too many C-sections performed in the US as it is. (The ingenuity of trial lawyers is quite remarkable. In at least two cases where the companies being sued over alleged defects in medical products that they manufactured were driven into bankruptcy by legal costs, the lawyers then tried to go after the companies that had made the materials that the now-defunct outfits had used in manufacturing their products. Fortunately in most cases that ploy was too much, even for US courts.)

The pharmaceutical sector is not immune to the disease of lawsuits. The American supply of standard childhood vaccines is in a precarious state since lawsuits drove most of the suppliers of those vaccines out of business. Economist Richard Manning, in an article published in *The Journal of Law and Economics* in 1997, looked at the contribution of litigation reserves to differences in the prices of specific drugs between Canada and the US. He concluded that overall, half of the differences in the prices of the drugs that he looked at between the two countries could be attributed to the need to build up a litigation insurance fund in the US.

Basically, despite all of the claims made for the effectiveness of PMPRB, we don't have good estimates of the extent of price differences between countries or of the causes of the differences that do exist. We can, however, suggest some possible consequences for Canada if large-scale re-importation of drugs into the US became a fact.

From the US and back again

The key here is the word re-importation. Despite all of the talk in ▲ the US about "Canadian drugs," most of our prescription drugs are imported from US sources of supply. It is certainly not the case that there is a Canadian drug industry manufacturing all of those drugs here and sitting on enough excess capacity to satisfy the US market as well as our own. The fact that most of our drugs are manufactured in the same factories as those bought by Americans has been the basis of much criticism of the FDA's refusal to permit large-scale purchasing of drugs from Canadian Internet sites. The FDA has said that it can't certify the safety of those drugs and has been ridiculed on the grounds that they do come from the same factories as drugs sold in the US. The FDA's point, however, is quite valid: it cannot certify that drugs bought from Internet sites that purport to be selling "Canadian" drugs were actually made in those factories. The FDA's concern is that the drugs that American consumers are buying in the belief that they are re-imports from Canada are actually copies made

in countries whose quality control falls short of FDA standards. The FDA would, in all likelihood, insist that re-importation be done through no more than a handful of registered suppliers.

Re-importation would mean a number of things.

The FDA's point is quite valid: it cannot certify that drugs bought on Internet sites that purport to be selling "Canadian" drugs were actually made in factories in the US

First, and most obvious, it would mean that market separation would no longer apply. There are two cases to consider: when prices are established by market forces; and when PMPRB regulations limit prices. When prices are set strictly by market forces, with no constraint from regulation, any price difference between Canada and the US would be because charging different prices in different countries increased firms' profits. Once the border was effectively eliminated so far as prescription drugs were concerned, drug companies would have to treat the continent as a single market. Failure to do so, meaning continuing to charge a lower price in Canada than in the US, would lead to precisely what is happening now, but on a much larger scale. Re-sellers could buy drugs in Canada and export them to the US, charging a price somewhere between the current Canadian and American prices. This would, of course, not be acceptable to the drug companies, which would respond by raising the price they charged on all of their products shipped into Canada. The result would be virtually no change in the price charged in the US, but a significant increase in the price charged in Canada. So if the price differential between the two countries, whatever it actually is, is strictly market determined, large-scale re-importation from Canada to the US would simply raise the price of prescription drugs to Canadian consumers.

The other case, which most people assume applies, is the one

where Canadian prices are limited by PMPRB regulations. Here, a number of possible outcomes exist. Since the FDA would presumably still be responsible for certifying the safety of all drugs sold in the US - otherwise elimination of the Canadian border would amount to permitting free entry to the US of drugs produced anywhere in the world, with no guarantee that they were made properly - one possible outcome would be for American authorities to charge a licence fee for re-importers, to cover certification of their product. Since being licensed to re-import drugs into the US would also expose Canadian firms to American lawsuits, we could expect those firms to have to buy litigation insurance, the cost of which would be passed on to their customers (simply meeting FDA standards does not protect drug companies from lawsuits). Add the retail markup that would be charged to American customers (and let's face it, why exactly do those American states believe that Canadian price controls will apply in the US?) and you eliminate any price difference pretty quickly.

Another possibility, which some have threatened, would be that the multinational drug companies stop supplying the Canadian market altogether. That would actually be a fairly unlikely case. The threat, presumably, would be that because they have Canadian patents on their drugs they could stop supplying the Canadian market and no other supplier could enter to fill the gap. In fact, most countries' patent laws have historically included the restriction that a patent is valid only if the patent holder makes reasonable efforts to supply that country's market in a timely manner. This kind of provision prevents a company from patenting a drug in a country it doesn't currently plan to sell the drug in, solely to deny that country to other suppliers. Even if that provision is not in a country's current patent law it would not be difficult to insert it. Withholding a drug from the Canadian market because it might be re-exported to the US would probably result in the patent on that drug being voided and Canadian generic firms being licensed to produce the drug for sale in Canada.

There are all kinds of factors at play here. The Clinton health reform plan included a reference pricing system, comparing US prices with international ones, along the lines of Canada's current system. If such a system were to be brought on nationally in the US, or if large states started using such a system for their state drug plans, firms might well drag out the process of obtaining Health Canada approval for selling their drugs in Canada as long as they could. So long as they were jumping through the regulatory hoops, it would be hard to argue that their patents should be voided.

Other, likelier scenarios

There are more likely scenarios: one would have the drug companies simply restricting their total supplies to Canada to a quantity just sufficient to supply the Canadian market. If Canadian retailers chose instead to sell their stock into the US, it would be Canadian customers who suffered. Since, in this case, the Canadian market was being supplied in a timely manner, it seems unlikely that any challenge to the drug companies patents would get very far. Alternatively, they could engage in a form of two-part pricing, raising the price they charged purchasers in Canada on any units sold above

the quantity required to satisfy the Canadian market, on the grounds that the excess was being exported back into the US.

While the details of what would follow from elimination of the border, so far as prescription drugs are concerned, remain to be sorted out, we can predict the general shape of things to come. Most importantly, it will not have much long-term effect on drug prices in the US. Even if the drug companies themselves were to take no action at all, which is highly unlikely, the quantity of drugs that could flow in from Canada would be tiny relative to the US market. In 2002, according to data from the OECD, Americans spent roughly US\$162 billion on prescription drugs, while Canadians spent roughly US\$9 billion. In the late 1990s, the US, according to data in a report from the American International Trade Commission, made up approximately

40% of the world market while Canada accounted for roughly 2%.

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would be too small to have a significant effect on total supply, and therefore too small to have much effect on US price. Rather than driving the price down in the US, it is more likely that re-importers would settle for charging a price just slightly below current American prices. In Canada, the effect would be either to drive Canadian prices up to US levels, or, if the government insisted on keeping Canadian prices down, restricted access to drugs, as US suppliers would be in no hurry to fill the gaps in Canadian supply caused when drugs that they had shipped into Canada were exported back into the US.

We could run through a whole range of possible outcomes, but the one thing they all have in common is the potential to create a lot of trouble in the Canadian market for pharmaceuticals. Admittedly, the Canadian government doesn't seem concerned. At this writing, the federal minister of health, Ujjal Dosanjh, has, according to the CBC, said that while the issue of re-importation has an impact on Canada, the country's drug supply is "safe at this point."

Considering that no change has yet been made to US law or FDA regulations, this statement is both tautological and empty, and quite remarkable in view of the concerns being expressed about possible threats to Canadians' access to this year's flu vaccine. Critical vaccine shortages in the US, resulting from the refusal of British authorities to permit export of flu vaccine made by a company part of whose product was found to be contaminated, are prompting Americans to come north for their flu shots. In response, the president of the Canadian Medical Association has urged Canadian doctors not to used provincially purchased vaccine to give shots to Americans, and in Ontario, "the medical officer of health for Windsor-Essex County

said people seeking flu shots would be asked for 'reasonable' proof that they reside in the province' (Branswell, 2004).

It would be more reassuring if Dosanjh had assured us that there would be no threat to Canada's drug supply even after the next president is inaugurated, regardless of who it might be. The federal minister's attitude reminds one of the man who fell off a cliff and kept yelling that he was fine - until he hit the ground.

Perhaps inevitably, the whole re-importation issue is rather more complicated than most of the media coverage suggests. We will go into more detail with regard to these issues in an AIMS paper to be released shortly. The message here, though, is that if the Americans go ahead with re-importation, the most likely outcome is no improvement in their situation and a worsening of ours.

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