

Who wants to be a millionaire? Canadian dot-com pharmacists, that's who.

By: Denis Morrice

These are boom times for Canadian pharmacies who sell prescription drugs to US consumers via the internet. Today, more than 100 on-line, big-box pharmacies efficiently process well over a million US prescriptions per year to the tune of two billion dollars in drug sales.

So what harm could there be in supplying poor and elderly patients with the low-cost prescription drugs they need — even if they're across the border in the US? Lots, it turns out. People are going to get hurt.

Consider the following:

- For the time being, cross-border sales of prescription drugs are illegal under US law.
- The pharmacists and doctors engaged in this practice are in breach of their strict codes of professional ethics.
- Inevitably, increasing American demand will outstrip Canadian supply, resulting in shortages of drugs for Canadians.
- Expect also sharp price increases for Canadian drugs as a result of a looming bilateral trade dispute on Canadian price-control practices.
- New drug launches may be compromised or postponed because the Canadian market is viewed as unfavorable by the US drug industry.
- Product safety may no longer be a given, as Canadian pharmacies scramble to fill their inventories from further and further abroad.
- The search for new sources of prescription drugs will leave Canada vulnerable to organized crime, which is behind a lucrative global trade in unsafe and counterfeit prescription drugs.
- Higher prices mean that provincial drug plans will limit patients' access to mainstream and innovative medications.

But to really understand the ramifications of cross-border sales of prescription drugs and how it's bad for your health, a crash course in this clash of business cultures is in order:

In the US, market forces dictate retail prices; whereas in Canada, prices are strictly controlled by our federal government's Patented Medicines Pricing Review Board. Not surprisingly, our American cousins don't appreciate that Canada's public-health system is a collective enterprise funded by taxpayers. When Canadians receive care they are receiving a dividend after investing a good chunk of their personal income via taxes year after year. The difference in price between the two countries for an equivalent product can range from 30 to 80 per cent. With the advent of e-commerce via the internet, Americans are able to purchase prescription drugs at Canadian retail prices from anywhere in the 50 states.

When American consumers place an order with a Canadian internet pharmacy, they must first sign a form that authorizes the pharmacy to act as an "agent and attorney" with the power to take all steps to obtain a prescription in Canada. Thus, the pharmacist acting as a proxy for the patient is protected from any liability, since only the laws of Canada and the province apply. Any unhappy consumers would, in effect, be forced to sue themselves in a foreign court.

To complete the transaction, a doctor must co-sign the American prescription or issue a new one. Typically, a medical questionnaire filled out by the American patient is the only information the doctor receives before approving the prescription. At no time is there any direct contact between the Canadian doctor and the US patient.

To meet accepted professional standards of care in Canada, a patient's physical evaluation, diagnosis and prescribed therapy should be based on an ongoing, in-clinic relationship with a qualified physician. Similarly, a patient's prescription history should be managed by a licensed

pharmacist who has developed a long-term over-the-counter relationship with the individual, especially these days when new drugs are coming onto the market every year.

Clinical profiles supplied by US patients, and a pharmacist acting as a patient proxy, are unacceptable substitutes for in-person consultations with physicians and pharmacists. The Royal College of Physician and Surgeons, the Canadian Medical Association, provincial and territorial medical-licensing bodies, and the Canadian Medical Protective Association (which provides malpractice and liability coverage for medical professionals) have all condemned co-signing American prescriptions. Likewise, the Canadian Pharmacists Association has added its disapproval, bluntly labelling the cross-border practice a breach of professional ethics. Moreover, the pharmacy regulatory bodies in Canada and the United States (NAPRA and NAPB) have issued a joint statement stressing the importance of compliance with federal, state and provincial regulations in both jurisdictions, as well as strongly promoting face-to-face relationships between pharmacists and patients. And not least, some 27 Canadian consumer and advocacy groups have joined the chorus of condemnation.

Surely all these well-respected organizations can't be wrong in their assessment that cross-border prescription-drug sales is bad medicine — bad for Americans, bad for Canadians, bad for people's health. So far, the cross-border internet pharmacies have turned a deaf ear to these complaints. They prefer to exploit a developing American consumer revolt against the world's highest prescription-drug prices. Make no mistake this is a practice fuelled by greed, pure and simple. Left unchecked, the cross-border traffic is destabilizing drug-prices and distribution in Canada, reducing access to medications for Canadian consumers, complicating immeasurably the already complex process of having new drugs approved in Canada, and seriously undermining the integrity of the pharmacy profession. Ultimately, on-line consumer convenience may replace the neighborhood pharmacy by a direct transaction between the doctor and the pharmaceutical manufacturer.

In the US, state legislatures and municipalities have been struggling for years to contain costs, using such strategies as generic substitutions, preferred-drug lists, evidence-based analysis of cost/benefit ratio, bulk-purchasing and rewarding changes in doctors' prescribing patterns. Expected relief through the newly approved federal Medicare plan has been short-circuited by provisions that discourage generic substitution, bulk buying and preferred lists. Many states and municipalities are beginning to see Canadian prices as their only alternative, even though they have no understanding how their actions will affect our public-health-care system. Indeed, 40 state representatives have introduced a bill before the US Congress to levy fines against pharmaceutical companies that prohibit their drugs from being shipped to American consumers from off-shore pharmacies.

Trouble is, the notion that the Canadian distribution chain can suddenly serve a population ten times larger without leading to shortages in Canada is grossly mistaken. For American institutional buyers, cross-border importation is simply bargain-hunting, and they really don't much care about its impact on Canadians. The United States claims half the global market for prescription medications, whereas Canada represents only a paltry two per cent. Cross-border retail sales from Canada through the internet currently total about \$1 billion for the *entire* United States. To put this in perspective, a mid-sized state such as Illinois spends about \$2 billion annually on prescription drugs. Imagine the increased pressure on Canadian supply as more and more state legislatures encourage their citizens to shop for bargains north of the border.

The effects of being sucked into this clash between state governments and the American pharmaceutical industry are already being felt here in Canada. A recent survey of non-internet pharmacies in Manitoba (the province with the largest volume of cross-border sales) found that more than 100 common prescription drugs were in short supply. These results are hardly surprising, given that Canada is a net importer of prescription drugs, half of which come from the US (about \$3.5 billion's worth). Lately, though, more and more imports are coming from off-shore — from countries that don't have equivalent safety controls, like Iran, Thailand and China, to

name only some. Thus, the chances for inferior quality drugs (or outright counterfeits) entering Canada's drug distribution chain are now much greater than before the cross-border sales phenomenon.

Naturally the pharmaceutical industry is taking measures of its own. After 10 years of price stability in Canada, some of the largest manufacturers have raised their bulk prices to wholesalers on commonly prescribed drugs by four per cent. It's a small hike — some expert observers say it was overdue — but significant as a precedent. Some companies have blacklisted cross-border internet pharmacies and their wholesale suppliers, refusing to fill their huge bulk orders. In response, blacklisted internet pharmacies are rewarding small community pharmacies across Canada with premiums of 10 to 20 per cent on the dollar to purchase their drug supply for them. Since these purchases are widespread and relatively small, drug companies are finding them difficult to trace. Like any bottom-line industry, US drug companies won't let two per cent of the world market (Canada) dictate to 50 per cent of the world market (the United States).

Bowing to the inevitable, the US Secretary of Health and Human Services, Tommy Thompson has signalled a change in policy that will open the door to legally importing prescription drugs into the United States. This may be a victory for the American consumer but not for Canada. Another report from the United States Trade Representative (USTR), released at the same time, takes direct aim at Canada's federal price controls as a trade issue.

The USTR report notes that the ability of innovative industries to continue to develop new products depends largely upon two factors: a strong and effective intellectual property system; and a regulatory regime that allows industry to market new products during the period of time when the exclusive intellectual property rights exist. The report goes on to outline these regulatory barriers as: non-transparent administrative regimes; decision-making that lacks a scientific basis; and cumbersome and lengthy drug listing and other administrative processes. Both Canada and Germany are cited as offenders.

This one-two punch almost certainly means that, while American consumers will get some price relief because of more open importing regulations, US trade representatives will use international dispute mechanisms to place unrelenting pressure on Canada to change the way it regulates domestic prescription-drug prices. Very likely the American campaign will try to set a global pricing regime that would see slightly lower prices in the US market but sharp increases in off-shore jurisdictions (namely Canada) in order to level the playing field.

Given the past history of previous trade disputes with the US, Canadians better brace themselves for much higher drug prices. And unlike the economic carnage falling out over the softwood lumber and mad cow disputes, it won't be producers who suffer. It will be Canadian consumers. Also, the price shock won't be a one-time event. We could very well have to get used to annual price hikes until there is a single global price for prescription drugs, which will be set by the US.

If this scenario unfolds, all those additional billions of dollars currently being invested by federal and provincial governments to shore up Canada's public-health system won't even begin to cover such increased drug costs. Could this be the proverbial straw that breaks Medicare's back?

Canadians can't afford to be complacent on this issue. This isn't a philosophical debate. We're all going to pay for a handful of Canadian internet profiteers' unmitigated greed, pay out of our pockets, and pay with our health. Make sure to contact your local federal MP to register your displeasure and demand action.