

US-Canada Rx price differential: A political scientist reviews policy gaps that are making US lawmakers nervous

By Jillian Clare Cohen, PhD



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The United States government has a new border threat to deal with: the infiltration of Canadian medicines into the US market.

During the past year, the phenomenon of American seniors and other consumers buying from Canadian Internet Pharmacy Services (IPS) has burgeoned from an industry concern into a major news item. The issue now is not just busloads of American seniors scooping up Canadian medications. US city and state governments are looking into Canadian suppliers for their drug benefit plans, raising the stakes exponentially. The US pharmaceutical market, valued at close to US\$200 billion, is potentially wide open for business from Canadian Internet pharmacies at Canadian prices.

The policy dilemma is as follows. On the one hand, US consumers are increasingly willing to breach federal legislation to access less expensive medications. Meanwhile the US research-based pharmaceutical industry — which has rarely lacked for significant influence in Washington — fears erosion of their US market. Caught in the middle are both Canadian IPS pharmacists and a US President whose job-performance review starts next spring. He and the US Congress know that health care was the decisive factor in the last congressional election for American seniors — an important electoral constituency — and that pharmaceutical coverage is at the top of the agenda.

Unregulated market

In Canada, we see a domino effect from US policies of omission:

- No price regulations
- No federal drug plan

About 35% of seniors under Medicare (and the disabled under Medicaid [see box p. 25]) lack drug benefits.¹ Additionally, the Congressional Budget Office projects that rising drug prices will continue to assume a large share of seniors' incomes. This office also projects an increase in drug spending (measured as a share of after-tax income) at 24.9% between 2000 and 2013 for

the population with the lowest income. In this context, scenarios arise of seniors taking half doses of needed medications — scenarios which will not help Republican congressmen and women come election time.

Many state initiatives to fill the gap, while promising, are not meeting the demand for widespread pharmaceutical coverage. This governmental failure has heavy repercussions politically. The House of Representatives, responding to the public will, recently passed a law that would legalize the reimportation of US-made pharmaceuticals from Canada and more than 20 other countries. The proposed legislation (which has not yet been approved in the Senate) is arguably an attempt to match law with reality, as the pharmacy of choice for a growing number of American consumers is in Canada.

**US seniors
put drug costs
at top of agenda
come election time**

Canada's low dollar a factor

In Canada the Patented Medicines Prices Review Board (PMPRB) and provincial and territorial governments regulate drug prices. This and the weaker Canadian dollar contribute to comparatively much lower prices in Canada — putting them more or less on par with those in other Western jurisdictions. (The PMPRB noted that in 2002, Canadian pharmaceutical prices were about 1% higher than median foreign prices.)

For many Americans, particularly seniors, buying pharmaceuticals from Canadian Internet pharmacies is a rational economic decision, despite US federal law that prohibits the practice. The law is open to interpretation. For example, it states “FDA personnel may use their discretion to allow entry of shipments of violative FDA-regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user.” Until recently, the FDA has tended to show benign disregard towards infractions.

The reimportation of pharmaceuticals is supported by many credible figures, such as the head of the powerful lobby group, American Associations of Retired Persons. William Novelli recently stated that while reimportation is not a policy solution, it may ease double-digit growth in prescription drug costs. Recent events (see p. 14) send a

Continued on p. 25

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US-Canada price differential *Cont'd from p. 23*

strong signal to the Bush administration that intense consumer pressure for a comprehensive prescription drug coverage program demands resolution. Otherwise, Internet pharmacy will continue. Meanwhile, access to medications will likely be one of the key issues for the Presidential primaries and House elections in 2004.

Responses to IPS

International pharmaceutical companies have all taken measures to respond to a perceived failure of governments to regulate Internet pharmacy purchases. Since January 2003, measures have included limiting supply of pharmaceuticals or stopping the sale of pharmaceutical products to Internet pharmacies.

The Canadian Pharmacists Association policy on IPS (Statement on International Prescription Services and Distance Provision of Pharmaceuticals) (www.pharmacists.ca) states that cross-border sales:

- Compromise the relationship between the patient and the health care professional
- Violate local (and international) laws
- Present a credible threat to drug supply
- Threaten Canadian drug prices

All of these reasons are sound and suggest that public policy reforms are needed in Canada as well as the US.

Cross-border drug shopping illuminates the need to regulate the "wild west" of the Internet. It starkly demonstrates that current drug legislation and regulations that govern this area are not sufficient. From the Canadian perspective, this phenomenon imperils the integrity of our health and pharmaceutical systems.

The Canadian Pharmacists Association emphasizes that the "...public

SORTING OUT MEDICAID AND MEDICARE

Medicare is a federal program providing health insurance for seniors (65+) and persons with disabilities. Medicare does not provide Rx drug benefits, so Medicaid is a key purchaser of drugs for low-income Medicare beneficiaries.

The Medicaid entitlement program for low-income persons is financed by state and federal governments. [Prescription drug spending totalled >\$21 billion in 2000 and 18% annual increases are cited. Prescription drug utilization and costs are highest among the elderly and disabled, who are allocated most of the program's budget.] State governments administer the program under federal guidelines. Outpatient prescription drug coverage is an optional benefit for all programs.

protection safety net can be bypassed with the purchase of pharmaceuticals through the Internet." We are finding, mainly in the United States, an intensification of the safety argument, from the FDA and others. The FDA points to the risk of counterfeit medications entering the US through IPS, although the problem to date is very small. Still, proponents of reimportation contend that the safety argument is not valid. "You can get sick on imported strawberries," a House Republican aide said.

The fallout has compelled the FDA to move towards the more rigorous enforcement of imported Canadian drugs. It is focusing on institutions, such as health maintenance organizations and Internet pharmacies (learning from the music industry that prosecuting individuals is not good for public relations). It also plans to revise its policies on Rx packaging

and distribution in response to concerns about counterfeit medications. However, the FDA has limited human resources to prevent the reimportation. The cold reality is that borders, no matter how tightly monitored, are porous.

Generics in the picture

The likelihood of better public coverage of drug costs remains a heavy political issue that will take time to work out. The challenge for the US government, the FDA, and drug companies is that now that American consumers are familiar with lower priced drugs, will demands for lower priced drug remain an issue until real change comes about?

Policy revisions, such as the faster approval of generic drugs to reduce drug expenditures, require less political deal-makings. Indeed, FDA recently passed a regulation that will make generic versions of select prescription drugs available more quickly. It is also reviewing its generic drug approval process to make generic drugs generally available faster. To address present concerns, institutions to govern Internet pharmaceutical purchases, such as the Internet Mail-Order Pharmacy Accreditation Commission, have emerged.

Finally, the purchase of Canadian drugs through the Internet by Americans will remain a twenty-first century phenomenon, unless the US changes its pharmaceutical policies and corrects both government and market failures. From the Canadian side, we must be mindful of the negative impact that cross-border purchases is having on our health system, and call for government action that protects its integrity. ■

1. Families USA, "Medicaid and Prescription Drugs" October 2002, www.familiesusa.org.

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