

Canadian Pharmaceutical Drug Purchases

Issue

This White Paper examines the issue of prescription drug re-importation, with particular emphasis on Canada. This paper is intended to educate citizens on some of the legal, policy and political issues as they weigh the issue of purchasing prescription drugs from Canada. This White Paper does not recommend or condone purchasing drugs from Canada.

Background

Drug re-importation refers to the practice of re-importing prescription drugs (back) to the United States. These prescription drugs were originally manufactured in the U.S. and other nations and exported for sale in another country. Most often Americans re-import drugs for personal use by filling their prescriptions in Canadian pharmacies, either in person, or through mail order or Internet pharmacies.

Prescription drugs, primarily name brand medications, are often sold at lower prices outside of the United States. Canadian medicines have been price-controlled by the Patented Medicines Pricing Review Board (PMPRB) since 1987. In addition, differences in exchange rates and differences in product liability laws exist between the two countries.¹ Some Americans see re-importation as a way to potentially obtain access to other countries' lower drug prices. A growing number of Americans, particularly those who are uninsured or underinsured, are purchasing certain drugs from Canada through the Internet, at costs of up to 75 percent lower than in the United States.

Public sector entities have become particularly interested in reducing pharmaceutical costs, as many cities and states are trying to cope with sizeable budget shortfalls. Another factor that is creating havoc in municipal and state employee health programs is double digit inflation. At least five governors (Illinois, Iowa, Michigan, New Hampshire and Minnesota) are considering purchasing drugs from Canada for state employees and other state-covered populations, while the City of Springfield, Mass is already doing so. "It's a movement of the same intensity in certain sectors of society as the antiwar and civil rights movements," says Mike Hatch, Minnesota's attorney general.² Industry lobbyists estimate 25 states, and 15 localities are looking into the idea.

¹ Ward Health Strategies. The Economic and Policy Implications of Re-importation: A Canadian Perspective. Ontario, ON: 2003.

² BusinessWeek Online Nov. 17, 2003.

According to the new Medicare law, the U.S. Secretary of Health & Human Services must certify that importing such drugs is safe before it can be done legally. The current secretary has voiced his strong opposition to such a move, citing his inability to certify that imported drugs are safe. The FDA estimates that over two million shipments of prescription drugs crossed the border from Canada to the U.S. in 2003. While importing medicines is technically illegal, the FDA, until recently, has turned a blind eye on much of the border trade. As long as seniors on bus trips from northern states into Canada carry only enough drugs for personal use and provide documentation from their U.S. doctors, the FDA has allowed the shopping trips.

Many American seniors have turned to the Internet and mail order services to fill their prescriptions at Canadian prices. According to the Manitoba International Pharmacists Association, a regional association of online pharmacies, around 1 million U.S. residents obtain drugs they otherwise could not afford through Canadian online/mail-order pharmacies every year. Storefront operations are acting as middlemen between American customers and Canadian pharmacies. They have begun popping up in dozens of states in the U.S. These operations send consumers' U.S. prescriptions and credit card information to Canadian partners, who then obtain a duplicate prescription from a Canadian doctor, fill that prescription, and send the drugs directly to the U.S. customer.

Legal Background:

The State has been advised that re-importation of prescription drugs by any entity other than the drug's manufacturer is illegal. An exception is allowed if the drug is required for "emergency medical care," but otherwise importation is a violation of the Federal Food, Drug and Cosmetic Act. Further advice suggests it is also illegal to advertise or otherwise promote re-imported drugs.³ FDA enforcement guidelines⁴, however, do allow agents to exercise discretion for drugs imported for personal use. According to the guidelines, "FDA personnel may consider a more permissive policy in cases where an individual seeks to import no more than a three month supply of a product that does not appear to pose an unreasonable risk, if the individual affirms in writing that it is for personal use and provides the name and address of the U.S. doctor supervising their treatment." It is important to note that this is not a "legal" exception so much as it reflects the FDA's discretion not to prosecute these individuals. This policy could change at any time.

Advocacy groups cite these guidelines as proof that reimportation is legal. But in a February 2003 letter⁵ the FDA's Associate Commissioner, Thomas Hubbard, said the guidelines have been misinterpreted. They were meant to allow FDA agents discretion in allowing U.S. citizens access to medicines for serious conditions that were unavailable or hard to find in the states, not to allow international comparison price shopping. The FDA says that it's most concerned about the safety of the imported products. Drugs from

³ AARP. "Prescription Drug Re-Importation Question and Answer Sheet" 2004.

⁴ http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html

⁵ <http://www.fda.gov/ora/import/kullman.htm>

foreign pharmacies, which are not subject to the agency's jurisdiction, could be mislabeled, counterfeit or otherwise adulterated. Consumers buying those drugs would have no recourse if they suffered adverse effects.

The U.S. Food and Drug Administration (FDA) has warned that those who help U.S. residents purchase drugs from other countries or advocate such purchases may be violating civil and even criminal law. In 2003, in recognition of the increase in both Internet-based pharmacies selling drugs from abroad and organized busloads of older persons traveling to Canada to buy medicine, the FDA announced that it plans to enforce the law more rigorously. The FDA plans to bring civil or criminal charges against third party groups that help Americans import drugs from Canada.⁶ In early 2004, the Justice Department has been taking steps to close down the operations of the largest of the companies facilitating the importation of Canadian prescription drugs.

Political Context

A recent ABC News Poll shows strong support for importing pharmaceutical drugs among Americans.⁷ While only a minority of Americans (12%) has directly purchased pharmaceutical drugs from Canada or abroad, far more support the idea, when asked the following:

"Some people say it should be legal for Americans to buy prescription drugs from Canada, Europe, and other industrialized countries because they're less expensive. The U.S. Food and Drug Administration says it should be illegal because imported drugs may be less safe and effective. What do you think? Should it be legal or illegal for Americans to buy prescription drugs from Canada, Europe, and other industrialized countries?"

The results were fairly startling. 69% of respondents said that it should be legal, 28% illegal, and only 2% had no opinion. A CNN/*USA Today*/Gallup Poll from August 2003 had similar findings, with 71% of respondents favoring the legalization of importing pharmaceutical drugs. Clearly, prescription drug importation is a hot button political issue, particularly in the context of many people being unable to afford their prescriptions. Pew Research Polls reported that 35% of respondents have "Had great difficulty affording the cost of prescription drugs."⁸

A bipartisan group of senators on Capital Hill is pushing for enactment of freestanding drug import legislation because they remain doubtful about the prospects for a more comprehensive Medicare prescription drug bill. The legislation would allow imports of FDA-approved drugs from FDA-inspected plants in Canada and 25 major industrialized

⁶ The FDA's position presumably could lead some third parties to deny reimbursement for drugs purchased abroad. Otherwise, the FDA has allowed individuals to bring small amounts of medicine back into the country for personal use. How the FDA or a third party could distinguish between minor personal use and regularly making Canadian purchases to find bargains is unresolved.

⁷ ABC News/*Washington Post* Poll. Oct. 9-13, 2003. N=1,000 adults nationwide. MoE \pm 3 (total sample). Fieldwork by TNS Intersearch

⁸ Pew Research Center for the People & the Press survey conducted by Princeton Survey Research Associates. June 19-July 2, 2003. N=1,201 adults nationwide. MoE \pm 3.

nations.⁹ According to Minnesota's Governor Tim Pawlenty, "If you accept the premise [that] we're at a crisis point and on a trajectory that is not sustainable, somebody has to lead change. These proposals are not perfect and are not the long-term solution, but they do offer the potential for near-term relief and it puts pressure on federal officials to consider change." Minnesota intends to create an Internet site that lists Canadian firms that meet criteria for safety, reliability and credibility. The likelihood for a major confrontation between states and federal regulators is growing as is the likelihood of enforcement actions by state pharmacy boards.

Discussion

Are prescription drugs over-priced? Are the higher prices in the United States offset in other ways? Entwined in all this debate lies important disagreements about whether or not America gains from higher drug prices in the form of higher pharmaceutical research and development (R&D) spending. The Economist notes that Europe is not creating high skilled and high paying research and development jobs at the rate America is.¹⁰ Research-based drug manufacturers spent nearly 10 percent of their Canadian sales revenues on R&D. By contrast, the United States is home to many of the world's top pharmaceuticals manufacturers. Pharmaceutical R&D spending in the United States equaled about 18.0 percent of U.S. sales in 2001.¹¹ In addition, research shows that not all Canadian drugs are less expensive than the same drugs purchased in the United States. A 1991 Government Accounting Office (GAO) Report found that 81% of the 121 most frequently dispensed drugs sold in same strength and form in the U.S. and Canada were more expensive in the U.S. than in Canada. A 2001 PMPRB Review found that prices charged by manufacturers were 69% higher in the U.S. than in Canada, and that the differential increased from 36% in 1987 to 60% in 2000.¹²

The FDA has concerns about whether drugs coming into the country from abroad are safe, since there is no regulatory oversight of Canadian versions of drugs approved in the U.S. And, according to the FDA, it would cost hundreds of millions of dollars to set up a legal, safe program to import drugs from Canada. The FDA has repeatedly stated that it would not rely on Canadian approvals because the United States inspects drug manufacturers around the world, while Health Canada relies on inspections done by the drug maker's host country.

Storefront owners who act as third-party purchasers say the drugs come from licensed Canadian pharmacies and are safe. The Canadian government has also stated that it conducts regulatory reviews of drugs to ensure there is sufficient evidence of safety, efficacy and quality before they receive authorization to be sold in Canada. Furthermore,

⁹ Connolly, Ceci. "Analysis cites savings in importing prescription drugs from Canada." *The Washington Post*, October 27, 2003.

¹⁰ "The trouble with cheap drugs." *The Economist*. January 31, 2004.

¹¹ Pharmaceutical Research and Manufacturers of America (PhRMA), PhRMA Annual Membership Survey, 2002., <http://www.phrma.org/publications/publications/2002-11-08.612.pdf>. Accessed February 2, 2004.

¹² Gross, David. Prescription Drug Prices in Canada. AARP Issue Brief. Accessed February 2, 2004. <http://www.aarp.org/ppi>

Health Canada states that they also conduct surveillance and enforcement once the drug is on the market.¹³

Critics say the existing import ban is detrimental to U.S. consumers whose taxes financed research and development of drugs sold to Canadians at lower cost than in the U.S. market. There is no question that “if Congress gives the green light to imports, the impact on Big Pharma’s prices, and profits, could be huge.”¹⁴

The Federal Prescription Drug Marketing Act allows only the manufacturer to import, or re-import prescription drugs into the U.S. However, the FDA and U.S. Customs have not applied the importation ban to individuals bringing limited supplies of drugs for personal use across the border, including through mail order prescriptions. Pharmaceutical companies oppose efforts in Congress to relax the importation law, and one drug company has cut off sales to Canadian firms that resell drugs to Americans. A group of Web pharmacies reportedly has planned a lawsuit against the company, accusing it of anti-competitive practices. Senator Russ Feingold, D-Wisconsin, has introduced a bill that would deny tax breaks to pharmaceutical companies that block U.S. consumers' access to prescription drugs from Canada. Canada however, has little leverage on the world market, “with just two percent of worldwide pharmaceutical sales, Canada accounts for a small share of worldwide pharmaceutical sales.”¹⁵ The Canadian Government may move to tighten up on exports to avoid shortages for its own residents, which it has already experienced on a sporadic basis. Further, recent actions by Canadian insurers may result in Canadian Physicians invalidating their malpractice coverage for any actions associated with the with the reimportation process.

The most important lessons to be learned from the Canadian experience may come not from their use of price regulations but from their most recent provincial and national efforts to establish novel drug pricing strategies. Approaches used in Ontario and British Columbia, establish conditions for a more competitive pharmaceutical marketplace based on evaluations of quality and price. They may fit the American political context better than price controls or importation. Indeed, to some extent these policies are already being adopted in the United States. For example, Medicaid programs in several states, such as those in Maine and Michigan, are using evaluations of pharmaco-economic data to determine placement on preferred drug lists. The Oregon Health Plan has established a reference price system similar to British Columbia’s.¹⁶

Conclusion

Americans pay higher prices for their prescription drugs than the residents of any other country in the world. There is no question that this is an increasingly difficult burden for

¹³ Health Canada: <http://www.hc-sc.gc.ca/english/index.html>

¹⁴ Carey, John, Alexandra Starr and Amy Barrett. “Drugs, Why do Americans Pay More?” *BusinessWeek Online*. August 1, 2003.

¹⁵ Patented Medicine Prices Review Board (PMPRB), *Annual Report*, 2001 (Ottawa: PMPRB, 2002).

¹⁶ Gross, David. Prescription Drug Prices in Canada. AARP Issue Brief. Accessed February 2, 2004. <http://www.aarp.org/ppi>

our nation's aging population. Through cooperative government efforts, we drink imported fruit juice and eat imported meats with complete confidence. And we could likely do the same with prescription drugs. Governors and mayors across the country have come out in favor of buying cheap drugs from Canada, grabbing onto a popular issue. How states and cities develop these schemes is important because the efforts carry legal, health and political risks.¹⁷ Attorneys say the states could be liable even if they are not themselves importing the drugs. "The federal government can take the position that the state is facilitating an action that is illegal under federal law."¹⁸ The FDA says it will work with the Centers of Medicare and Medicaid Services to develop recommendations on how states can save money on U.S. drugs through options such as substitution of generics and group-purchase plans. However, it is unlikely that states will find an ally in the federal government to embark on trans-national ventures in the pharmaceutical drug business anytime soon. The legal risks being incurred by some cities and states are great, and no doubt reflect a level of desperation. It seems that the ultimate political goal is to push the federal government to address the issue of pharmaceutical pricing in a meaningful and rational way.

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17 The Wall Street Journal Online, Dec. 18, 2003.
<http://online.wsj.com/article/0,,SB1071694715171785100,00.html>
18 *ibid.*