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Prescription Drugs: The Surprising Way to Save

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It is estimated that as many as 10 million Americans are using the internet or actually making over-the-border trips to Canada or Mexico in order to purchase \$1.4 billion worth of pharmaceuticals from foreign suppliers.¹ With Medicaid pharmaceutical costs increasing an estimated 17% each year,² many state governments are following suit and exploring whether or not savings can be achieved by purchasing drugs from Canada or other foreign sources.

It should be noted that reimporting pharmaceutical products from foreign countries, as over a dozen states are considering, violates federal law. Currently, only manufacturers of the drugs are authorized to import their products from other countries for sale in the U.S. The federal Food and Drug Administration (FDA) warns that pharmaceutical quality from foreign sources cannot be assured. Despite questions of safety, proposals are surfacing in Congress to authorize pharmacists, wholesalers, and other qualified individuals to import prescription drugs into the United States from certain countries. However, drug companies strongly oppose liberating reimportation restrictions, resulting in one of the most heated political debates in the country.

As the country continues to search for ways to address the problem of pharmaceutical affordability, policymakers must determine if the savings from drug reimportation are a valid and sustainable answer to a burgeoning problem.

Why are Drug Costs Higher in the U.S.?

The United States does not impose government mandated price controls on pharmaceuticals. Price controls are a critical component of universal health care programs like the one found in Canada. In countries employing a price control strategy, the government serves as the primary bulk purchaser of pharmaceuticals for the entire country, imposing cost controls on drugs which distort the actual value of drugs being sold. Price controls are generally based on the manufacturing cost and may not allow for a recovery of other expenses, including research and development. In addition, almost every country in the world, except the U.S. and New Zealand, prohibits direct-to-consumer marketing.³ Therefore, American consumers' drug prices are unique because they include the costs of manufacturing, research and development, marketing, and the regulatory expenses for product approval. It is generally accepted that the entire world benefits from the pharmaceutical research and development paid for by American drug purchases, which the Tufts University Center for the Study of Drug Development estimates to be \$802 million (in year 2000 dollars) for each new prescription drug.⁴

¹ Shikha Dalmia, "Foreign Drugs Will Bring Liability Headaches for States," *Tech Central Station*, www.techcentralstation.com, 12/19/2003.

² Lydia Faulkner and Brendan Krause, "Issue Brief: State Actions to Control Health Care Costs," *National Governors Association*, November, 2003.

³ Elizabeth Wennar M.P.H., Ph.D., Statement to the Committee on House Energy and Commerce Subcommittee on Health, July 25, 2002.

⁴ Alex Adrianson, "Drug Reimportation Redux," *Consumers' Research Magazine*, August, 2003.

Some also question the use of retail pharmaceutical prices when making comparisons to other countries, as U.S. prices include wholesaler and pharmacist markups. These prices also do not reflect 8 to 10 percent discounts for managed care, Medicaid and other bulk purchasers in the U.S.⁵ In addition, price comparisons frequently ignore the fact that prices for generic drugs in the U.S. are almost always lower than in Canada and other countries. The under-reported and often significant savings available in the U.S. are demonstrated in Table 1.

Table 1: Sample Non-U.S. vs. U.S. Pharmacy Retail Prices

	Non-U.S. Pharmacy Low Price	U.S. Pharmacy Low Price	% Difference
Lipitor (Brand) Cholesterol Lowering Drug	\$159.33	\$271.68	56%
Celebrex (Brand) Arthritis Pain Relief	\$62.50	\$144.98	65%
Fosamax (Brand) Osteoporosis Treatment	\$49.38	\$67.99	33%
Fluoxetine (Generic) Antidepressant	\$49.78	\$13.19	89%
Albuterol (Generic) Antiasthmatic	\$12.11	\$8.59	57%
Acyclovir (Generic) AIDS treatment / Herpes	\$139.56	\$26.91	83%

Source: PharmacyChecker.com, February 2004. Prices based on normal strength and dosage and do not include shipping or other fees. Average shipping fees: U.S. - \$1.14, Canadian - \$13.74

It is important to note that pharmaceutical companies allow prices to reflect the purchasing ability of the consumers, which means prices are lower especially in poorer nations. For example, drug prices may be lower in Canada due in part to the currency being valued 22% less than the U.S. dollar.⁶ Americans obtaining drugs from foreign countries may also benefit from fluctuations in currency exchange rates. The 1990s decline in the Canadian dollar accounts for 19% of the 33% Canada-U.S. pharmaceutical price differential.⁷ However, while drugs may cost less in these countries, price comparisons to a country's per capita income suggests that drug price levels are slightly higher than in the U.S. A study by the University of Pennsylvania's Wharton School estimated drug prices in Canada are 4 percent higher than in the U.S., 25 percent higher in the United Kingdom, and 430 percent higher in Chile and Mexico when normalized for income.

Finally, Americans may pay higher prices for their drugs because of the cost of litigation. One study suggested that between 33% and 50% of U.S. and Canadian prescription drug price differences in 1990 were a result of legal liability protection in the U.S. This study pointed out that, unlike in the U.S., Canadian judges rarely awarded large liability settlements and their courts limited personal injury compensation to \$250,000.⁸

⁵ American Enterprise Institute, "The Price of Pharmaceuticals: International Comparisons and the Effects of Controls," December 2003, http://www.aei.org/events/filter_eventID.682/summary.asp.

⁶ Organisation for Economic Co-operation and Development, 2003 purchasing power parity estimates.

⁷ Patricia M. Danzon and Michael F. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," *Health Affairs Fact Sheet*, December 1, 2003.

⁸ Manning, Richard L., "Product Liability and Prescription Drug Prices in Canada and the U.S.," *Journal of Law and Economics* 40 (1997): 203-243.

Savings from Drug Reimportation?

Public officials and individual consumers are both seeking savings from drug reimportation. In order to aid individuals, some states created initiatives to direct residents or interested pharmacies to approved Canadian drug sources. Other states and local governments are seeking direct savings by purchasing less expensive drugs from Canada for employees, prison health care, Medicaid and other programs in need of pharmaceuticals. Drug reimportation is a violation of federal law, and the FDA and the Department of Health and Human Services (HHS) has threatened lawsuits and criminal action to stop the states' plans. Nevertheless, over a dozen states and several local governments continue to implement reimportation programs.

What are the actual savings that could be realized through drug reimportation? Illinois Governor Rod Blagojevich estimated \$91 million annually in state savings, Iowa's Governor Vilsack projects \$10 million, while Michigan's Governor Jennifer Granholm suggested tens of millions in Medicaid program savings by obtaining drugs from Canada. A growing number of local governments are seeking drug cost savings from Canada for employees and retirees, including Montgomery, Alabama and Boston, which hopes to save \$1 million.⁹ However, the insinuation by drug reimportation advocates that drug costs may be reduced by as much as 65% is grossly exaggerated. The Congressional Budget Office (CBO) estimates total prescription drug expenditures in the U.S. would be reduced by only 1% or \$40 billion over nine years (2004-2013). The reasons cited for diminished savings include:

1. **Discounts already provided** – Federal, state and other bulk pharmaceutical purchasers already receive among the lowest prices in the U.S. market;
2. **Foreign Supply** - Drug manufacturers may limit quantities shipped to countries to prevent U.S. drug reimports while foreign governments may restrict exports to assure their own country's pharmaceutical supplies;
3. **Price Increases** – Prices may be increased in other countries to compensate for losses in the U.S. due to reimportation. Transaction costs by importers would also increase the price;
4. **FDA Restrictions** – FDA requirements for relabeling, counterfeit-resistant packaging and production at FDA inspected facilities will add to the costs reimported drugs. Manufacturers may intentionally produce drugs that violate FDA requirements to prevent reimportation;
5. **Small Reimport Market Share** –The FDA estimates reimported prescription drugs could supply about 10% to 15% of the total U.S. market, further diminishing the opportunity for savings.¹⁰ For example, purchasing 10% of prescription drugs at prices discounted 25% is actually 2.5% of total drug expenditures.

While the CBO savings outlined in Table 2 should not be ignored, one should also recognize other forces which could reduce possible savings. The FDA believes initial increased enforcement efforts could cost \$100 million annually, eliminating over 25% of the estimated federal savings.¹¹ It should also be noted that generic pharmaceuticals are priced much lower in the U.S. than Canada, so savings can only be achieved from reimportation of brand name drugs. Generic drugs make up over 50% of the U.S. pharmaceutical market.

⁹ Julie Appleby, "More Cities, States, opt for Canadian Drugs; FDA might be forced to challenge each program," USA Today, December 23, 2003.

¹⁰ Congressional Budget Office Cost Estimate, "HR2427, The Pharmaceutical Market Access Act of 2003," November 19, 2003.

¹¹ Tom McGinnis, FDA Director of Pharmacy Affairs, "Ask the Experts: Drug Reimportation," Kaiser Family Foundation, 12/3/2003.

Table 2: Congressional Budget Office Estimated Drug Reimportation Savings	
National Savings	1% or \$40 billion over 2004-2013 period
Federal Savings	.5% or \$3.3 billion over 2004-2013 period
Federal Revenue Impact	\$1.5 billion increased federal revenues
State Medicaid Savings	\$240 million over 2004-2008 period

Source: CBO Cost Estimate, "HR2427, The Pharmaceutical Market Access Act of 2003," November 19, 2003

CBO estimates of state Medicaid savings of \$240 million over a four year period indicate many governors may have been overestimating the reduced costs they would obtain by reimporting prescription drugs.

Traditional retail purchasers likely have been able to realize savings when buying from foreign sources. However, upon implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, many seniors could realize significant savings through the subsidies and discounts provided by the new program. Medicare beneficiaries could save 10 to 25 percent off retail prices for most drugs and total prescription drug spending could be reduced by 20 percent by 2006.¹² Research by *PharmacyChecker.com*, which compares and evaluates prices between U.S. and Canadian online pharmacies, confirms the temporary Medicare discount cards will weaken the price competitiveness of Canadian pharmacies on several popular brand name drugs and that U.S. consumers may well be better off shopping for certain drugs at home.

Nevertheless, several states are creating websites and programs which allow residents to connect to Canadian pharmacies. Minnesota and Wisconsin have set up the state-sponsored websites that link potential prescription drug buyers to Canadian pharmacies offering low-cost prescriptions. The FDA sent Governor Pawlenty of Minnesota a strong warning, calling his state's Canadian reimportation program "unsafe, unsound and ill-considered." Despite the warning, both states have allowed their websites to continue operating. At press time, Illinois was pressing the FDA to allow for implementation of their state-sponsored reimportation program.

Extensive media attention has resulted in the incorrect assumption that all drugs are less expensive if obtained from Canada or other foreign sources. This phenomena is evidenced in a February 2004 Associated Press-Ipsos Poll which indicated nearly "two-thirds of those surveyed said the government should make it easier to buy cheaper drugs from Canada or other countries." The politicization of the issue and candidate' rhetoric will only further the public's erroneous belief that all prescription drugs are less expensive in Canada.

The Minnesota and Wisconsin websites linking people to Canadian pharmacies do include small sections informing consumers about less-expensive generic drugs from the U.S. Unfortunately no warnings are given to consumers at the time of their purchase that significant savings can be achieved by utilizing generic drug equivalents. As can be seen in Table 3, many prescription drug generics cost less at Walgreen's in the U.S. than purchasing the brand name drug from Canada through the State of Minnesota website. In the case of Fluoxetine, the generic to the antidepressant Prozac, thirty 10 mg. tablets from Walgreens retail for \$31.99 while it will cost

¹² Department of Health and Human Services, Public Affairs Office, "Beneficiary Savings Under the Medicare Prescription Drug Benefit," January 14, 2004.

\$41.10, plus \$14 in shipping, to order it from Canada through the Minnesota website. In cases like these, the state fails miserably in its goal to help people reduce the burden of prescription drug expenses.

Table 3: Comparison of Prescription Brand-Name Drug Prices from RxConnect Canada vs. Generic Equivalents in the U.S.

<u>Brand or Generic Drug from Canada</u>	<u>Price</u>	<u>Generic Equiv. from Walgreens in U.S.</u>	<u>Price</u>	<u>Difference</u>
Prozac (30 10mg Tabs) Antidepressant	\$68.34	Fluoxetine (30 10mg Tabs)	\$33.94	\$34.40
Zantac (60 150mg Tabs) Ulcer Treatment	\$91.95	Ranitidine (60 150mg Tabs)	\$44.94	\$47.01
Vasotec (60 10mg Tabs) High Blood Pressure	\$90.71	Enalapril (60 10mg Tabs)	\$33.94	\$56.77
Glucophage (100 500mg Caps) Diabetes	\$47.65	Metformin (100 500mg Caps)	\$41.94	\$5.71
Zestril (100 10mg Tabs) High Blood Pressure	\$89.65	Lisinopril (100 10mg Tabs)	\$60.74	\$28.91
Atenolol (60 50mg Tbs) High Blood Pressure	\$58.58	Atenolol (60 50mg Tbs)	\$17.34	\$41.24
Glyburide (100 5mg Tabs) Diabetes	\$32.43	Glyburide (100 5mg Tabs)	\$31.64	\$0.79

Note: Canadian drug prices obtained from State of Minnesota's RxConnect Online and <http://www.walgreens.com/library/finddrug/druginfosearch.jhtml> using comparable dosages. Prices include \$14.95 shipping from Canadian Pharmacy and \$1.95 from Walgreens.

The Risks from Drug Importation

If the savings are not as significant as expected, many policymakers must decide if the problems that stem from drug reimportation are worth it. Risks, like safety of the drug supply and liability concerns, are so significant that government leaders must not ignore them.

The illegality of reimportation means states risk enforcement actions against them, and **fiscal notes should be attached to enabling legislation or executive orders acknowledging potential legal exposure.** The FDA and HHS have taken a strong stance against allowing drug importation because the policy will make it considerably more difficult for them to guarantee the safety and efficacy of the nation's prescription drug supply. Such a policy could result in 15% of pharmaceuticals used in the U.S. supplied by sources not overseen by FDA, "opening the borders to products that may be counterfeit, superpotent, subpotent, contaminated, or inappropriate."¹³ While Canada's drug oversight system is well respected, Canadian officials indicate they will not monitor large shipments of pharmaceuticals to the U.S. originating from Canada or those that pass through from other countries.¹⁴ The FDA has reiterated that the minimal savings from drug reimportation is not worth the risk to the American public.

The potential for risk is compounded with the World Health Organization and the Pharmaceutical Research and Manufacturers' Association estimate that between 8 to 10 percent of

¹³ U.S. Dept. of Health and Human Services Response to Sen. James Jeffords on Drug Reimportation, July 9, 2001.

¹⁴ John Calfee, "Why Drugs from Canada Won't Cut Prices," *Consumers' Research Magazine*, Nov. 2002.

prescription drugs on the world market are counterfeit. According to FDA Commissioner Mark B. McClellan, there is a "significant and growing problem of counterfeit drugs." The FDA estimates that up to 40 percent of pharmaceuticals shipped from countries such as Argentina, Colombia, and Mexico may be counterfeit. It should also be noted over 40% of pharmaceuticals imported into Canada were not manufactured in the U.S. Prescription drugs Americans are purchasing from Canada may originate in countries like Bangladesh, China, Turkey, Saudi Arabia and the Philippines.¹⁵ Many of these countries have serious problems with counterfeit or unsafe drugs.

Other investigations have exposed the serious problems and questionable operations with internet prescription drug purchases. Advocates of drug reimportation should take note that Richard "Bo" Dietl, a former New York City police detective, conducted an investigation by making purchases from internet pharmacies. Many arrived with improper packaging from "unexpected countries" or came from operations run by disreputable individuals. He was able to find evidence of medications being shipped to U.S. online purchasers from Kashmir in the troubled border region of India and Pakistan. Dietl also placed online orders for 146 drugs without providing a written prescription and received more than 50. Even his children, ages nine and thirteen, were able to purchase weight-loss and antidepressant drugs over the internet. Finally, the drugs he received were tested and preliminary results showed contaminants.¹⁶

States are exposing themselves to potential liability if they distribute prescription drugs that do not meet FDA standards. Should any of these drugs cause injuries, states would have little legal cover because they knowingly allowed the distribution of pharmaceuticals with safety not ensured by the FDA. According to Victor E. Schwartz, a liability expert with Shook, Hardy & Bacon law firm in Washington D.C., "the liability lawsuits that states are exposing themselves to may end up costing -- not saving -- them money."¹⁷

Policy Alternatives to Pursuing Drug Importation

Lawmakers understandably are seeking policies designed to stem the tide of rising pharmaceutical costs. Action has already been taken by the federal government to make prescription drugs more affordable to senior citizens. Cards providing drug discounts will be issued in the summer of 2004 and the Medicare drug benefit will be fully implemented in 2006. The FDA has also revised patent rules to allow less expensive generic drugs to reach the market sooner. A task force created by Secretary of Health and Human Service Tommy G. Thompson could also develop a response to concerns about the impact and safety of imported drugs. Other possible federal actions include:

1. Revising the drug approval process to reduce the time and significant costs associated with the development and introduction of new pharmaceuticals.
2. Changing federal rules to enhance the ability of private health care providers to negotiate discounts with manufacturers.
3. Address the significant cost legal liability protection adds to the price of drugs in the U.S.
4. Enhance the system to protect Americans from unsafe imported prescription drugs.

¹⁵ Robert Goldberg, Remarks given to the National Symposium on Drug Importation, October 23, 2003.

¹⁶ Sarah Lueck, "Drug Industry Enlists Ex-Cop Lobbyist," *The Wall Street Journal*, October 22, 2003.

¹⁷ Shikha Dalmia, "Foreign Drugs Will Bring Liability Headaches for States," *Tech Central Station*, www.techcentralstation.com, 12/19/2003.

Instead of risking the use of pharmaceuticals from foreign sources, state and local governments may also save money on their own prescription drug costs by expanding upon use of pooled pharmaceutical purchasing to increase bargaining leverage with manufacturers. West Virginia saved 5% on drug expenses for state employees by forming a purchasing coalition with Maryland, Missouri, and New Mexico.¹⁸ States should also more aggressively utilize formularies, prior authorization, generic substitutions, step therapies and disease management strategies. Wisconsin, for example, saved 10% in certain drug categories and specifically \$1 million in its first year of using prior authorization for certain ulcer treatment drugs.¹⁹

Response to concerns over high pharmaceutical costs should not preclude lawmakers' responsibility to protect the public. In addition to the savings Medicare beneficiaries may realize, states can also consider the policies highlighted below:

Tax Policy & Health Savings Accounts – Tax policies may be modified to further assist individuals with prescription drug cost burdens. States can also update their tax codes to allow employers and individuals to benefit from Health Savings Accounts.

Alternative Drug Discount Programs – Some states have cooperated with pharmaceutical manufacturers to provide their own drug discount cards to eligible individuals, seniors and families. Ohio recently enhanced its discount card program which provides low-income enrollees with a 25%-40% savings on prescription drugs. States can also use their resources to direct people to the discount programs offered by most pharmaceutical manufacturers.

Drug Import Safety – As part of its role in consumer protection, states can play an important role in warning people about the risks associated with importing prescription drugs. States can also play a role in taking action against illegal drug import operations and procedures.

Website Improvements – The few states which operate websites linking consumers to Canadian pharmacies should provide better information about less expensive alternatives. States should also notify consumers that use of their website may result in higher costs than retail and online sources in the U.S., as evidenced with Minnesota's website. Further, information should be updated to reflect savings available from the federal Medicare discount program starting in summer 2004.

Conclusion

There is no doubt that escalating pharmaceutical costs are a problem for some Americans, leading many individuals, states and local governments to seek savings through lower prices from foreign sources. However, Congressional Budget Office estimates indicate actual savings from drug importation by government entities is minimal, and the practice is illegal and not without risk. Legal means of reducing prescription drugs costs are available, including the new Medicare prescription drug assistance program that will provide significant savings to seniors. Unfortunately, politicization of the issue has drowned out discussions about the serious risks involved in obtaining pharmaceuticals from foreign sources.

Are the risks of importing drugs from foreign suppliers worth the minimal savings? If policies promoting the use and importation of prescription drugs could mean almost 15% of

¹⁸ Christopher Rowland, "State Eyes Bulk Drug Purchasing Program," *The Boston Globe*, February 6, 2004.

¹⁹ Wisconsin Legislative Fiscal Bureau, "Prescription Drug Assistance Programs," Paper 482, June 4, 2001.

pharmaceuticals used in the U.S. would come from sources not overseen by the FDA and an increase in counterfeit, contaminated, or inappropriate products; the answer is no.

Most importantly, states should heed the advice of the FDA about the significant risks involved with drug importation and halt programs that advocate the illegal importation of foreign drugs. Government leaders are obligated to exercise leadership by informing the public about the significant risks associated with pharmaceutical imports. More importantly, with a little research, public officials can help their constituents access affordable and safe prescription drugs from reliable sources within the U.S.

About the Author:

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