



The Facts about Drug Importation: Risks to consumers, states, and retirees

by Grace-Marie Turner and Conrad Meier

Imported drugs often unsafe

- The Food and Drug Administration examined mail shipments of imported drugs flowing through Miami, New York, San Francisco, and Carson, CA, to U.S. consumers in July and August, 2003. It found that the packages often contained dangerous, unapproved, or counterfeit drugs. In fact, 88% of the drugs examined did not meet FDA standards.[1]
- A second inspection blitz in November, 2003, at the Buffalo, Dallas, Chicago and Seattle mail facilities and the Memphis and Cincinnati courier hubs revealed similar problems: 1,728 unapproved drugs among the 1,982 parcels inspected. The unapproved drugs included “foreign versions” of FDA-approved drugs, recalled drugs, drugs requiring special storage conditions, drugs requiring close physician monitoring, and drugs containing addictive controlled substances.[2]
- Canada makes only a very small percentage of prescription medicines for internal use and gets the rest of its supply from around the world.[3]
- Shipments into Canada are increasing from countries with a history of counterfeit and unsafe drug production. There has been a 2,372% increase in imports from Iran and a 3,270% increase in imports from Brazil, for example.[4]
- Between 2002 and 2003, drug imports to Canada rose dramatically from other countries noted for their high rates of drug counterfeiting. (See table.) [5]
- When asked about the potential impact of U.S. pharmacies limiting shipments to Canadian pharmacies, a Canadian pharmacy owner and non-pharmacist told surveyors for the Minnesota Board of Pharmacy, “We won’t have any problem getting drugs. We have creative ways to get them.” [6]

Increase in Canadian Imports, 2002-2003

Bangladesh	1,336%
China	439%
South Africa	389%
Turkey	160%
Saudi Arabia	90%
Philippines	140%

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- Surgeon General Richard Carmona is very concerned about “the extremely robust counterfeiting system” for prescription drugs, adding that counterfeiting “would pose significant challenges to any importation plan that we may be considering in the future.” Dr. Carmona is the nation’s top doctor charged with guarding public health and also chairs the federal government’s task force on prescription drug importation.[7]

Warnings about Canadian drug imports

- Canadian health authorities have warned the U.S. that Health Canada will not take responsibility for the safety of drugs exported from Canada to the United States. [8]
- “If you think Internet drug sellers are safe because their Web sites display the Canadian flag, you’ve been fooled again,” says Lew Kontnik, co-author of the book *Counterfeiting Exposed*. “Canadian authorities do not inspect medicines that are transshipped through their country bound for U.S. consumers, which opens a huge loophole for counterfeiters to sell us fake medicines masquerading as Canadian prescription drugs.”[9]
- Former FDA Commissioner Mark McClellan warned that drug importation “creates a wide channel for large volumes of unapproved drugs and other products to enter the United States that are potentially injurious to public health and pose a threat to the security of our Nation’s drug supply.”[10]
- The Illinois Pharmacists Association spent more than \$50,000 on an advertising campaign that warned, “The medicine you buy from across the borders may be unsafe and ineffective.” This ad ran immediately after Gov. Rod Blagojevich (D-IL) announced his study of drug imports found that “Canada’s drug regulation and distribution system met American standards in every way.”[11]

Savings potential?

- The commission that administers health insurance for state employees and retirees found Massachusetts would save \$10.4 million a year by purchasing lower-cost prescription drugs from Canada. But the commission recommended against moving forward with the plan, saying the savings would shrink to \$1.4 million after waivers of co-payments to incentivize participation by employees and loss of drug company rebates. And, the commission said, even the \$1.4 million potential savings would not be worth the liability risks.[12]
- Canada spent a total of \$14.6 billion on prescription drugs in 2003 compared to more than \$160 billion in the U.S. With Canada’s market less than 10% the size of the U.S. market, it simply is not feasible to expect to run a significant part of the U.S. drug supply through Canada to have its price controls imposed, and then have the drugs shipped back to U.S.

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consumers. Any savings will quickly be consumed by middlemen and distributors.

- “It is likely that the intended cost-savings for consumers would be absorbed by fees charged by exporters, pharmacists, wholesalers, and testing labs,” according to FDA Commissioner Lester M. Crawford.[13]

Liability

- Borderless drug stores, including those in Canada, require people to sign waivers that hold harmless the seller from any legal responsibility for the quality or effectiveness of the drugs sold. And states that promote illegal drug importation programs, such as Minnesota and Wisconsin, say on their websites that they expressly disclaim “any and all liability from such importation or reimportation or the use of any products so acquired.” [14] The reason is obvious: There is no realistic way to verify the safety of these drugs imported through Canada and other countries.[15]
- “The bottom line is that [the state] will benefit by putting the drugs in the ‘stream of commerce’ and therefore must also bear the risk of loss if these drugs result in injuries.” The Illinois Supreme Court has recognized that “when a city creates a hazardous condition and someone is injured as a consequence, it must respond in damages, just as others are required to do.”[16]

Impact on investors

- Minnesota Secretary of State Mary Kiffmeyer voted against Governor Pawlenty’s resolution to sell off Pfizer shares in an attempt to pressure the drug company to lower prescription drug prices. Kiffmeyer said that although efforts to reduce prices for U.S. residents are “laudable,” the use of “funds that belong to state employees and retirees to pressure drug companies” is “not consistent with the board’s fiduciary duty.” [17]
- Daniel Clifton, executive director of the American Shareholders Association, a Washington, DC-based group created by Grover Norquist’s Americans for Tax Reform, said such a move would devalue the holdings of more than 10 percent of the state pension fund. “The [drug] cost issue has become a political football with no real solutions being provided,” said Clifton.[18]

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Notes

- [1] U.S. Food and Drug Administration. "FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments." FDA News Release. 29 September 2003. <http://www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html>
- [2] "Recent FDA/U.S. Customs Import Blitz Exams Continue to Reveal Potentially Dangerous Illegally Imported Drug Shipments." Food and Drug Administration News Release January 27, 2004. <http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html>
- [3] Robert Goldberg, Manhattan Institute, in *What's Wrong with Importing Drugs from Canada?*, edited by Joseph and Diane Bast, The Heartland Institute, 2003.
- [4] Nigel S.B. Rawson, Ph.D. "Rx: Canadian Drugs." Letter to the Editor. *New England Journal of Medicine*. 11 March 2004.
- [5] Ward Health Strategies Inc. "Price Controls, Importation and the Safety of the Drug Supply Chain." 20 October 2003. <http://www.wardhealth.com/index.php/article/articlestatic/58/1/5/>
- [6] Michele Mattila and Stuart Vandenberg in a December 24, 2003, State of Minnesota Office Memorandum detailing inspection report by the Minnesota Board of Pharmacy survey reviewing the practices of Canadian pharmacies.
- [7] "Challenges seen in safely importing drugs," Associated Press/*Miami Herald*, April 7, 2004.
- [8] Marc Kaufman. "FDA: Canadian Drug Position Misinterpreted." *The Washington Post*. 26 May 2003.
- [9] Genevieve Hernandez, Jennifer Topps, Partnership for Safe Medicines, April 1, 2004
- [10] Statement of administration policy. July 23, 2003.
- [11] *AARP Bulletin*, April 24, 2004. P. 24.
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- [13] July 17, 2002 letter from Lester M. Crawford, (then) Deputy FDA Commissioner to Senator Thad Cochran.
- [14] State of Wisconsin. Prescription Drug Resource Center. March 2, 2004. <http://drugsavings.wi.gov>
- [15] Conrad F. Meier, "Ill Wind from the North," *Health Care News*, May, 2004.
- [16] "Foreign Drugs Will Bring Liability Headaches for States," Shikha Dalmia, TechCentralStation, December 19, 2003.
- [17] *Minneapolis Star Tribune*, 3/4/2004
- [18] "Pfizer stands firm on opposition to imported drugs from Canada," Jim Suhr, Associated Press, April 23, 2004.

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