

TRANSSHIPMENT OF DRUGS THROUGH CANADA

OVERVIEW: Some believe that limiting importation of foreign prescription drugs to only those imported from Canada will ensure it is safe. In practice, however, drugs “from Canada” could originate from any country in the world, and merely be shipped to the U.S. through Canada. Canadian law permits the “transshipment” of drugs from any country – including those in the third world -- into Canada and then into the U.S. As the HHS Task Force on Prescription Drug Importation found, “most countries impose a lesser level of regulation on products that are merely transshipped through their country.”¹ Allowing the importation of drugs from Canada into the U.S. could make Canada the gateway for counterfeit drugs to enter our prescription drug supply.

Between 2007 and 2015, there was a significant increase in Canadian imports of pharmaceuticals from countries such as China, Mexico, and Russia, according to Industry Canada, a department of the Canadian federal government. Many of these countries have documented counterfeiting problems and none have in place a Mutual Recognition Agreement (MRA) with Canada to facilitate reliance on their regulatory system governing prescription medicines.

Canadian Imports of Pharmaceutical Products (\$US), by Country, Year			
Country	2007	2015	% Change 2007-2015
China	\$55,035,695	\$109,350,860	99%
Brazil	\$5,096,458	\$118,945,205	2,234%
Pakistan	\$53,729	\$343,684	540%
Mexico	\$33,318,127	\$57,732,059	73%
Russia	\$1,891	\$57,541	2,943%
Colombia	\$1,628,126	\$3,038,211	87%

Source: Industry Canada, Trade Data Online, <https://www.ic.gc.ca/>, (accessed: January 23, 2017)

THE CANADIAN GOVERNMENT IS ON RECORD SAYING THAT WHILE IT REGULATES DRUGS MANUFACTURED FOR ITS CITIZENS, IT CANNOT BE EXPECTED TO ENSURE THE SAFETY OF MEDICINES THAT ARE SHIPPED THROUGH CANADA FOR EXPORT TO THE U.S.

As reported in the December 2004 Surgeon General’s Task Force report, a letter from Diane C. Gorman, Assistant Deputy Minister of Health Canada to U.S. Surgeon General Richard H. Carmona stated that “Health Canada does not assure that products being sold to U.S. citizens are safe, effective, and of high quality, and does not intend to do so in the future.”² Further, according to Gorman, “The Government of Canada has never stated that it would be responsible for the safety and quality of prescription drugs exported from Canada into the United States, or any other country for that matter.”³

FDA HAS STATED THAT CANADA WOULD BECOME A TRANSSHIPMENT POINT FOR DANGEROUS DRUGS IF IMPORTATION WERE ALLOWED

Former FDA Senior Associate Commissioner William Hubbard testified that importation would make Canada a transshipment point for dangerous drugs: “Throwing the door open to drugs purchased by individuals directly from Canadian sellers will encourage unscrupulous individuals to devise schemes using Canada as a transshipment point for dangerous products from all points around the globe.”⁴

¹ HHS Task Force on Drug Importation, Report on Prescription Drug Importation, at 60 (Dec. 2004).

² HHS Task Force Report citing Letter from Diane C. Gorman, Assistant Deputy Minister, Health Canada, to Richard H. Carmona, U.S. Surgeon General, pg. 60-61. June 1, 2004.

³ Letter to The Washington Post, Diane Gorman, Assistant Deputy Minister, Health Canada, May 9, 2003.

⁴ Statement of William K. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, FDA, before the Senate Special Committee on Aging, July 9, 2002

FDA INVESTIGATION FINDS DRUGS BEING PROMOTED AS “CANADIAN” CAME FROM 27 OTHER COUNTRIES AROUND THE GLOBE

A December 2005 FDA investigation found that 85 percent of the drugs being promoted as "Canadian" actually came from 27 other countries around the globe, including India, Costa Rica and Vanuatu. In response to the investigation, Andrew C. von Eschenbach, then the FDA's acting commissioner said, "These results make clear there are Internet sites that claim to be Canadian that in fact are peddling drugs of dubious origin, safety and efficacy." ⁵

CANADIAN INTERNET PHARMACIES' LONG HISTORY OF FILLING PRESCRIPTIONS FROM OVERSEAS

While many U.S. consumers ordering prescription medicines from Canada assume those medicines are coming from Canada, the heads of major Canadian Internet pharmacies confirmed long ago this is often not the case. As long ago as 2005, Daren Jorgenson, founder of Winnipeg-based Canadameds.com, confirmed "We're filling 50 percent of our prescriptions [from international pharmacies]." Jorgenson's website boasted, "Not just from Canada any more! Choose your country and your savings."⁶ The president and owner of CanadaRx.net also confirmed that his medicines were not coming from only Canada. According to Harvey Organ, "I can get drugs from all over the world."⁷

TRANSSHIPMENT OF DRUGS HAS CONTRIBUTED TO RISE IN COUNTERFEIT DRUG TRADE

A 2007 *New York Times*⁸ investigation highlighted the manufacture and transport of counterfeit drugs through countries and free trade zones with lax regulatory regimes. The *New York Times* article examined the supply chain of a Canadian internet pharmacy through six countries— a practice commonly referred to as transshipment. While this internet pharmacy has since closed down, the *New York Times* investigation further confirms what some Canadian pharmacies have publicly been saying for some time that they are not sourcing a good majority of their drugs from Canada anymore. Investigators believe the counterfeit drugs that were sold to online customers were manufactured in China, and then went onto Hong Kong, the U.A.E., Bahamas, and then a final stop to U.K., where U.K. postage would be affixed so as to disguise the source of the medicine, and then mailed to patients in the U.S. Passage through countries such as the UK was done to lend credibility to the medicine, according to the article. Similarly, Ilisa Bernstein, Director of Pharmacy Affairs at the FDA notes, such complex routes and "free trade zones allow counterfeiters to evade the laws of the country because often times the regulations are lax."

TRANSSHIPMENT OF COUNTERFEITS CONTINUES TODAY, A BIGGER PROBLEM THAN EVER

While the above examples are old, the problem has not gone away. Most recently, a 2015 federal indictment charged a major Canadian online pharmacy and a number of other related entities and people with conspiring to smuggle mislabeled and unapproved prescription drugs into the United States.⁹ The indictment alleges that \$78 million worth of medications were shipped to the U.S. by CanadaDrugs.com, some of which were counterfeit version of medicines meant to treat cancer.¹⁰ A former executive at PharmacyChecker.com, which bills itself as the only independent source for the safety verification of online pharmacies, was named in the indictment and accused of allegedly participating in the conspiracy to distribute non-FDA approved and counterfeit cancer medications to U.S. doctors' offices.¹¹ The distribution of the fake medicine was widespread – FDA sent warning letters to "over 100 doctors in 28 states."¹²

5 FDA News, "FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate From Other Countries," December 16, 2005 <<http://www.fda.gov/bbs/topics/NEWS/2005/NEW01277.html>>

6 Leonard Zehr, "Internet pharmacies aim overseas," *Globe and Mail*: February 6, 2005 .

7 Christopher Rowland, "Drugs from Anywhere; As Importation Networks Spread, Concerns for Consumer Safety Grow," *The Boston Globe*, December 16, 2004.

8 Walt Bogdanich, "Free Trade Zones Ease Passage of Counterfeit Drugs," *The New York Times*, December 17, 2007.

9 Dan Mangan, "Canada pharmacy charged in \$78M drug export scheme," *CNBC.com*, August 19, 2015.

¹⁰ Mangan *op cit*.

¹¹ S. Imber, "PharmacyChecker Executive Indicted in CanadaDrugs Fake Cancer Drug Scam," *The Partnership for SafeMedicines.org*, August 21, 2015, <http://www.safemedicines.org/2015/08/pharmacychecker-executive-indicted-in-canadadrugs-fake-cancer-drug-scam-8-24-15.html>.

¹² S. Imber, "PharmacyChecker Executive Indicted in CanadaDrugs Fake Cancer Drug Scam," *The Partnership for SafeMedicines.org*, August 21, 2015, <http://www.safemedicines.org/2015/08/pharmacychecker-executive-indicted-in-canadadrugs-fake-cancer-drug-scam-8-24-15.html>.