

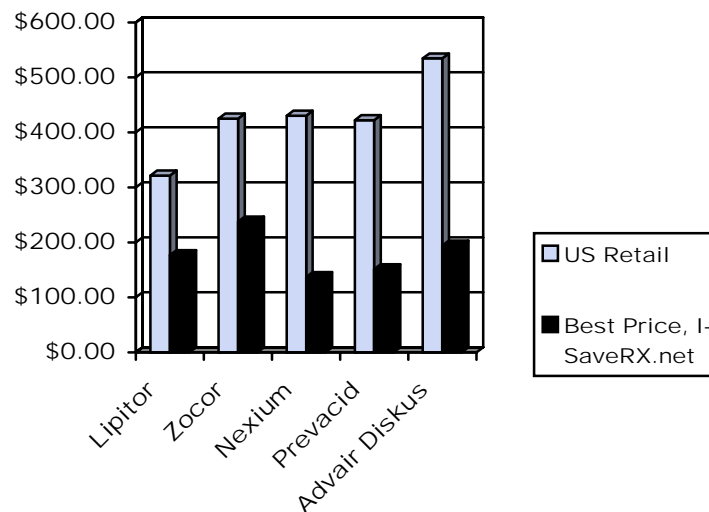
Current Trade Policy May Jeopardize Pharmaceutical Importation

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Pharmaceutical companies sell medicines at different prices in different countries and Americans pay more for medicines than any other people in the world. Thus, individuals and state governments have found they can save large amounts of money on drug spending by purchasing from Canada and other countries. Unfortunately, federal trade agreements threaten their ability to continue to do so.

The I-Save-Rx program provides an example of the possible savings. I-Save-Rx started in Illinois and expanded to four other states. It allows consumers to buy their prescriptions at the best price available in pharmacies in Canada, England, Australia and New Zealand. The graph below compares US retail prices and I-Save Rx prices for the five top-selling drugs in the US.¹ The average potential savings here on a three month supply of these drugs is 56%.



Similar savings potential has been found in other studies of international pricing by the pharmaceutical industry. The U.S. Department of Commerce estimated last year that drug prices in Canada and Europe are, on average, only 50-60 percent of the U.S. price.² States taking advantage of these programs have saved considerable sums of money on drug purchases. Illinois has estimated that it could save over one billion a year if its I-Save-Rx program becomes widely used.

¹ All prices are for a three month supply in November, 2006. The US retail prices were those found at www.cvs.com, the I-Save-Rx prices were the lowest price for a three month supply found on the program's website. Drugs in the sample were rated the top-five selling drugs in the US by IMS-Health.

² <http://www.ita.doc.gov/td/chemicals/drugpricingstudy.pdf>

Domestic Legal Issues

Despite its popularity and wide use, reimportation is technically illegal. Article 381(d) of the Federal Food, Drugs and Cosmetics Act reads “no drug... which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.”³ In practice, the Food and Drug Administration grants an exception for personal use that applies to individuals importing enough of their prescription(s) to last for 90 days or less. Most significantly, it has not interfered with shipments from internet pharmacies.⁴

The Customs and Border Patrol began a systematic campaign in November 2005 to confiscate all shipments from Canadian pharmacies being sent to Americans. They claim to have seized and destroyed more than 40,000 orders. Their seizure policy ended in October 2006, however, when Congress passed a provision in the Appropriations for the Homeland Security Appropriations Act prohibiting customs officers from preventing people from transporting up to 90 days worth of medicine for their personal use.

In recent years there have been numerous federal legislative efforts to legalize reimportation. Reimportation bills have passed both Houses of Congress by large margins, but have not been signed by either President Clinton or Bush. Both administrations opposed allowing imports of drugs from Canada and other developed countries, and Secretaries of the Department of Health and Human Services have been vocal opponents of the practice. This year, The Pharmaceutical Market Access and Drug Safety Act, S. 242 and H.R. 380, have been introduced, and are widely expected to pass.

Trade Agreements, Reimportation, and Exhaustion

Since most brand name drugs are patented products, trade rules on intellectual property apply. The resale of patented products by people or businesses which have purchased the product from the patentee is governed by “exhaustion” rules. A country’s law may or may not provide that once a patent holder has sold the product covered by the patent, the patent right has been “exhausted” or used up, and the patentee no longer has the ability to stop the sale or distribution of its invention. Under such a set of rules, once a drug manufacturer sells a drug to a retailer, it has no say over where or to whom that manufacturer resells the drug.

The World Trade Organization rules do not expressly permit or forbid reimportation. Article Six of the Agreement on Trade Related Aspects of Intellectual Property Rights (commonly referred to as the TRIPS Agreement) says “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” This means a patent right may be “exhausted,” or used up once a patented good has been sold by the legitimate patent holder. Different countries have different rules concerning exhaustion, but today’s multilateral trade agreements do not address the issue at all.

Some of the bilateral free trade agreements that the United States has entered into give companies the power to prevent reimportation through contracts. The US-Australia FTA, for example, reads, “the exclusive right of the patent owner to prevent importation of a patented product... shall not be limited by the sale or distribution of that product outside its territory,” provided the patentee has contractually restricted reimportation of the product. The Free Trade Agreements with Singapore and Morocco include similar language.

³ 21 USC section 301

⁴ <http://www.mondaq.com/article.asp?articleid=43750>

To date, no patent holding companies have attempted to use these provisions in the FTAs to block pharmaceutical reimports, but Americans are buying drugs from abroad (and the I-Save Rx program specifically buys drugs from Australia) so the potential for a legal challenge exists.

Federal Reimportation Bill May Violate FTAs

This year's reimportation bills may violate these commitments made by the US Trade Representative. S. 242, The Pharmaceutical Market Access and Drug Safety Act lists Australia as a country from which Americans can import drugs from the retail market, and it specifically says that "It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention ... that was first sold abroad by or under authority of the owner or licensee of such patent."⁵

Congressional Attempts to Reign In USTR

More recent free trade agreements do not include similar provisions designed to block reimports. This is due to an amendment inserted into the 2005 USTR appropriations by Rep. Northup that forbids trade negotiators from using its funds to negotiate language in trade agreements identical to the language in FTAs with Australia, Singapore and Morocco. A few months later, Sen. Debbie Stabenow amended the corresponding Senate appropriations bill with the same language. However, the appropriations bill will expire at the end of the Fiscal Year. Rep. Northup lost reelection in 2006, so if similar language will be reintroduced, another congressional sponsor must be found.

Conclusion

Reimportation yields considerable savings for individuals and state government programs, but legal issues may endanger the practice. It is still a violation of the Food Drugs and Cosmetics Act for anyone other than the manufacturer to import pharmaceuticals into the U.S. Congress has tried to address this matter, but no law has been passed. International trade agreements on intellectual property may also endanger the practice of reimportation. The WTO does not affect the practice, but more recent bilateral trade agreements include provisions to block imports of branded medicine.

Rules on Reimportation in Trade Agreements

WTO Agreement on Trade Related Aspects of Intellectual Property Rights

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

US-Australia Free Trade Agreement

Article 17.9

4. Each Party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.

Exhaustion Language in Current Reimportation Legislation

It shall not be an act of infringement to use, offer to sell, or sell within the United States or to import into the United States any patented invention under Section 804 of the Federal Food, Drugs and Cosmetic Act that was first sold abroad by or under authority of the owner or licensee of such patent."

www.pijip.org

⁵ S.242 The Pharmaceutical Market Access and Drug Safety Act, Sec. 4 (d)(1)(B)