

Drug Importation: What's Legal, What's Safe?

APhA lays out the facts for pharmacists and their patients

by Susan C. Winckler, RPh, Esq.

Anyone who has opened a newspaper or an e-mail account recently has been accosted by offers of “cheap drugs” from other countries—and assurances that these “FDA-approved” drugs are available at the same quality for half the price. And for those who find the requirement of securing a prescription too much of a hassle, many of these solicitations offer a more convenient option: “no prescription needed.” Not surprisingly, many of these ads stimulate questions—questions that consumers bring to their pharmacists. With the quantity of information (and misinformation) in the marketplace, this article provides the facts.

Who may import medications into the United States?

No one may import a medication if the product is:

- a) an unapproved new drug,
- b) a misbranded drug (one that lacks FDA-mandated labeling or has been dispensed without a valid prescription), and
- c) an adulterated drug (one that was not manufactured under good manufacturing practices or is contaminated).¹

Because of the different standards for labeling in the world, very few products manufactured for foreign markets meet the requirements for FDA-approved labeling. For example, omeprazole is approved under the brand name Prilosec in the United States, but in Canada, omeprazole magnesium is approved under the brand name Losec. Such a difference in name may not yield a substantial difference in effect, but “Losec” was changed to “Prilosec” in the United States because of confusion between “Losec” and “Lasix”.² That confusion may be re-intro-

duced by different brand names in the global market.

What about re-importation, when a drug originally manufactured in the United States is sent abroad and then brought back into the United States?

Only the original manufacturer may import the product back into the United States.³ This restriction was added to the federal Food, Drug, and Cosmetic Act in 1988 through the Prescription Drug Marketing Act (PDMA). Prior to the passage of PDMA, drugs manufactured in this country could go to a foreign market and then be reimported into the U.S. Unfortunately, allowing this activity became a common way for adulterated and counterfeit drugs to be introduced into the United States drug distribution system. Not surprisingly, these drugs posed a public health problem because they

PSW Executive Vice President Chris Decker (at podium) and (l to r) PEB Chair Sue Sutter were joined by Cory Hoze of the U.S. Department of Health and Human Services and Tom McGinnis of the U.S. Food and Drug Administration at a November news conference in Madison.



PSW Responds to Governor Doyle's Drug Importation Plan; Calls for Injunctions Against Import Storefront Operations

The issue of importing medications from Canada has really heated up in the last few weeks. Recently, Chris Decker,

PSW's Executive Vice President, and Sue Sutter, Chair of Wisconsin Pharmacy Examining Board (PEB), were joined by Cory Hoze of the U.S. Department of Health and Human Services and Tom McGinnis of the U.S. Food and Drug Administration at a news conference in Madison Monday, November 3.



Local and state media covered the news conference on Canadian drug importation.

The purpose of the news conference was two fold:

- To educate the public and state policy makers on the inherent dangers of importing prescription medications from foreign sources and to point out that this practice violates federal law.
- To respond to an announcement by Governor Doyle that he and members of his administration were meeting with Canadian drug representatives to explore the feasibility of the State of Wisconsin buying drugs from Canada.

On Friday, November 7, the U.S. District Court for the Northern District of Oklahoma issued a preliminary injunction against Rx Depot, a storefront business similar to those operating in Wisconsin that facilitate the importation of prescription drugs. The court ordered Rx Depot to close all of its operations immediately. In light of that court order, PSW has called for the PEB and the Attorney

General to take similar action against all Canadian storefront operations in Wisconsin.

PSW has budgeted funds to have legal counsel review Wisconsin law on this issue. After this review is completed, the PSW board will be briefed and may consider whether legal action is warranted.

were found to lack active ingredients, contain unlabeled ingredients such as aspirin, lack adequate labeling, or were not approved drug products. For example, in 1985, over 2 million counterfeit tablets of Ovulen-21 from Panama were widely distributed throughout the United States. In the same year, a counterfeit version of the antibiotic Ceclor® found its way into the U.S. drug distribution from a foreign source.⁴

In 2000, Congress passed the Medicine Equity and Drug Safety Act which would permit wholesalers and pharmacists to re-import prescription medications manufactured in the United States and exported to certain foreign countries. The law, however, has yet to go into effect, because one provision of the law requires the Secretary of Health and Human Services to certify to Congress that implementing the law would pose no additional risk to public health and safety. Two HHS Secretaries have declined to make certification.

What about medications that are manufactured for the United States in foreign countries?


Some medications are manufactured for the U.S. market in foreign countries. The FDA has authority over these foreign manufacturing facilities through the new drug application process.⁵ The plants must comply with FDA current Good Manufacturing Practices, labeling requirements, and packaging and shipping requirements. These products are generally shipped directly from the foreign facility to the U.S. market for distribution.

Some of these ads say that it is illegal for individuals to import a 90-day supply of medications for their personal use. Is this correct?

No. To permit patients access to medications that are not available in the United States in certain limited situations, FDA established a policy that allows individuals to import medications. But this policy does not change the law, it simply outlines a situation where FDA will not enforce the prohibition against importation (where the Agency will exercise “enforcement discretion”). Under the policy, FDA may permit the importation of illegal medications when:

- a) the intended use of the drug is unap-
- proved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means;
- b) there is no known commercialization or promotion of the drug to persons residing in the United States;
- c) the product is considered not to represent an unreasonable risk; and
- d) the individual seeking to import the drug affirms in writing that it is for the patient’s own use (generally not more than a three-month supply), and provides either the name and address of the U.S. doctor responsible for his or her treatment with the product or provides evidence that the product is for the continuation of treatment begun in a foreign country.⁶

Obviously, the ads promoting importation violate one of the requirements of this policy—the ban on commercialization or promotion of the drugs. Also, the products promoted in these ads are often for foreign versions of products available in the United States—thus effective treatment is available in the United States.

 PSW HAS MORE ON IMPORTATION AT WWW.PSWI.ORG/GOVERNMENT/CANADA.HTM

But is there really a problem with these medications?

FDA recently surveyed the medications being shipped into the United States, and found that the vast majority of parcels (88%) contained unapproved drugs that could pose significant safety problems. These packages included drugs that are no longer available in the U.S. market for safety reasons, animal drugs sold to U.S. consumers for human use, drugs improperly packaged in sandwich bags or tissue paper, drugs without English labeling or proper instructions for use, and drugs requiring precise dosing and monitoring by a physician.

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Most consumers are interested in importing medications because the drugs are cheaper in other countries than in the United States. Why are some medications cheaper outside the United States?

Many other countries, including Canada and the countries of the European Union, negotiate with pharmaceutical manufacturers to establish a price for the products in their country. The lower prices, however, are usually only for brand-name medications. Many generic medications cost less in the United States than in other countries.⁷

What about the Medicare prescription drug benefit—will that make prescription drugs more affordable here in the United States?

The actual Medicare prescription drug benefit becomes available in January 2006. Between now and 2006, Medicare will be endorsing prescription drug discount cards that may provide consumers a lower price—but consumers should evaluate

these programs closely to determine if the benefits exceed those available from individual manufacturers, state-based assistance programs, and discounts offered by pharmacy providers. Low-income seniors can also qualify for \$600 to spend on prescription drugs through the discount card programs.

Beginning in 2006, Medicare beneficiaries should have a choice of at least two options for prescription drug coverage. Beneficiaries will pay an average of a \$35 monthly premium, a \$250 deductible, a 25% co-payment up to \$2,250, and catastrophic coverage when beneficiaries reach \$3,600 in out-of-pocket expenses (\$5,000 in drug spend). At the catastrophic level, beneficiaries will pay the greater of either \$2 for generics, \$5 for brands, or a 5% copay. Low-income beneficiaries may access the benefit at reduced or eliminated premiums, deductibles, co-pays, and gaps in coverage.⁸

What should I do when patients ask me for advice about the medications they've imported?

Understanding that, as pharmacists, we hold the well-being of the patient as the most important factor in our work, there are some potential liability concerns in providing professional advice in this situation. The patient has engaged in what is illegal activity, and pharmacists should avoid any situation where they are potentially facilitating this practice.

The situation presents clinical challenges as well. Foreign-versions of prescription medications may be different.

For example, the products may contain different active and inert ingredients, at different dosages, and in different dosage forms, depending on the country of origin. Also, the potential for the product to be fake or counterfeit is higher than domestically purchased medications.

Is it safer for consumers to use Web sites that are operated by pharmacies in Canada?

Legitimate pharmacy operators in Canada offer many of the same services as pharmacists in the United States. Unfortunately, there is emerging evidence that many of these operators are not actually practicing in Canada and/or are not dispensing Canadian medications. Because of the high trust Canada enjoys, some unscrupulous operators are posting the Canadian flag on their Web site and claiming to be in Canada, but the drug selling operation is actually operated in another country.

According to the FDA, when consumers order medications from outside the United States (e.g., Internet purchases, cross-border purchases), whether safe or unsafe, a portal of entry is created for counterfeit drugs into the U.S. distribution system. Counterfeiters can take advantage of this entryway by combining many small purchases from foreign countries into one and selling them to U.S. wholesalers or other unsuspecting enti-

ties. Due to the extensive resources involved in preventing small quantities of drugs from entering the United States, as the volume of unapproved drug imports increases, it is more difficult for FDA to use its existing resources to identify and stop unsafe importations.

What about these "storefront pharmacies" that are operating in my neighborhood? Is their business legal?

According to the Federal District Court in northern Oklahoma, no. On November 6, 2003, U.S. District Judge Claire

Eagen issued a preliminary injunction and ordered Rx Depot (a store-front "pharmacy" operator) to stop importing drugs, as well as to stop advertising any service that causes or facilitates prescription drug importation. Judge Eagen ruled that the firm had ten days to send a letter to its customers informing them that the company's business violated the law and that the safety and efficacy of

drug products obtained through the firm could not be assured.

Here's some history on that court case: On March 21, 2003, FDA and the Arkansas Board of Pharmacy issued a "warning letter" to a storefront operation known as Rx Depot. Rx Depot generally obtained drugs from Canada for U.S. consumers, exposing the public to the significant potential risks associated with imported prescription medications. Included in the letter were concerns that Rx Depot and similar companies have often incorrectly stated to consumers that FDA approves of their activities and that their prescription medications are "FDA approved." The Agency was concerned that this could lead consumers to the mistaken conclusion that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by FDA.

While Rx Depot responded to FDA's "warning letter," the Agency determined

that their response was inadequate. The U.S. Department of Justice and FDA filed an injunction on September 11, 2003, to stop Rx Depot from importing prescription drugs from Canada in violation of U.S. law. The Agency brought the suit because the storefront chain posed a risk to public health by importing unapproved prescription drugs and drugs that may only be imported by the U.S. manufacturer. These drugs pose a public health risk because they do not have the same assurance of safety and efficacy as drugs regulated by FDA

The District Court Judge concluded that operations such as Rx Depot expose the public to significant potential risks. FDA's decision to bring this action and the court's subsequent ruling sends a clear signal that FDA is committed to protecting the public health and challenging those who put profit before safety. This case also demonstrates FDA's commitment to protect the American public from illegal drugs that may be unsafe, ineffective or substandard.⁹

And FDA isn't the only regulator taking action. As of November 10, 2003, twenty-two states have taken, or are prepared to take, regulatory actions against storefront pharmacies that facilitate illegal imports of prescription drugs from Canada.¹⁰ ●

Susan C. Winckler is the Vice President of Policy and Communications and Staff Counsel for the American Pharmacists Association.

REFERENCES

1. 21 U.S.C. § 331.
2. "Making It Easier to Read Prescriptions", http://www.fda.gov/fdac/features/695_prescrip.html.
3. 21 USC § 381(d). "(d) Reimportation - Except as provided in paragraph (2) and section 384 of this title, no drug subject to section 353(b) of this title or composed wholly or partly of insulin 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. - The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.
4. FDA Counterfeit Drug Task Force Interim Report, Issued October 2003, p.11.
5. 21 USC § 355.
6. FDA Regulatory Procedures Manual, Chapter 9.
7. Transcript of Proceedings, US v. Rx Depot, Inc., Case No. 03-CV-0616-EA, (N.D. Okla.) October 8 & 9, 2003, p. 136.
8. Section 101, Subpart 2, Sec. 1860D-14, Premiums and cost-sharing subsidies for low-income individuals, page 107 of H.R. 1 Conference Report (108thCongress).
9. U.S. v. Rx Depot, Inc., 2003 WL 22519473, N.D.Okla., 2003. Injunction issued Nov. 6, 2003.
10. Testimony of John Nelson, FDA, before the Senate Commerce Committee, November 20, 2003.