

ILLEGAL DRUG IMPORTATION: FREQUENTLY ASKED QUESTIONS

Q: I've seen advertisements for pharmacies that sell cheap prescription drugs imported from Canada. Is that legal?

A: No. Federal law provides that only drug manufacturers may reimport their drugs from Canada.¹ In addition, the U.S. Food and Drug Administration recently wrote that “virtually all drugs imported to the U.S. from Canada by or for individual U.S. consumers also violate U.S. law” because “such drugs are unapproved ... labeled incorrectly ... and/or dispensed without a valid prescription....”²

Q: The importing pharmacies' websites say the FDA created a “personal use exception” that makes it legal for consumers to buy a 90-day supply of prescription drugs from foreign countries. Is that true?

A: No. These foreign pharmacies are misleading you; there is no “personal use exception.” The FDA has said it will not enforce the import prohibition when consumers with deadly diseases import drugs that are not available in the U.S. But this FDA enforcement guidance, entitled “Coverage of Personal Importations,” applies only in extremely limited circumstances where the imported drugs are not advertised in the U.S. and no treatment for the disease is available in the U.S. This enforcement guidance specifically states that it does not apply to international mail order shipments, such as those advertised by Internet pharmacies.³ Even the drug imports covered by this FDA enforcement guidance are illegal. The FDA has explained that “[e]ven if all of the factors noted in the guidance are present, the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized.”⁴

Q: Didn't Congress recently pass a law that legalizes importation of drugs from other countries?

A: That law never went into effect. The Medicine Equity and Drug Safety Act (known as the “MEDS Act”) would have allowed importation of prescription drugs only if the Secretary of the Department of Health and Human Services concluded that importation was safe. Both the present and former Secretaries of HHS – one a Republican and the other a Democrat – concluded that it was impossible to guarantee the safety of imported drugs. For that reason the MEDS Act never went into effect.⁵

Q: Why would the government want to prohibit importation of cheap drugs from Canada?

A: In a word, safety. Allowing foreign pharmacies to import drugs into the U.S. dramatically increases the risk of sneaking counterfeit, adulterated and misbranded drugs across the border. Internet pharmacies may advertise that their drugs come from Canada, but the truth is you really can't know whether those drugs are actually

counterfeits from Vietnam, China, India or some other third-world country. Congress and the FDA have established and maintained a drug safety net for consumers that is the best in the world, but that safety net is completely bypassed when drugs are imported through foreign pharmacies.

Q: Doesn't the government assure that these foreign pharmacies are as safe as my corner drug store?

A: No. Your state board of pharmacy licenses your local community pharmacies and pharmacists to be sure they provide safe and effective treatment and counseling in accordance with strict safety standards. But foreign pharmacies that import drugs are operating without a license from your state board of pharmacy. Those foreign pharmacies do not comply with your state's strict safety laws.

Q: Why do foreign pharmacies insist that I sign a long, confusing waiver form before I can purchase their foreign drugs?

A: The foreign pharmacies don't want to accept the same responsibilities as local community pharmacies, because they are vulnerable to serious liability. They know that what they are doing is unsafe and illegal, so they make you promise that you will never sue them if you are injured by their foreign drugs. They know their foreign drugs may be adulterated or subpotent, so they make you promise not to return their drugs for a refund. They also know the U.S. government may seize their illegal drug shipments at the border, so they force you to agree not to demand a refund if the drugs never arrive. The forms routinely make you waive many other rights, such as your right to privacy, your right to consult a qualified pharmacist, your right to child proof packaging, and any warranties that the drugs are safe and effective. Read the fine print and you will see how much you lose when you buy drugs from foreign pharmacies.

Q: Do I face any potential liability for importing drugs?

A: It's possible. Anyone can be fined or even imprisoned for violating the federal laws that prohibit drug importation. For example, anyone who violates the law against reimporting prescription drugs originally made in the U.S. can be fined up to \$250,000 and imprisoned up to ten years.⁶

¹ See 21 U.S.C. § 381(d)(1).

² See letter from FDA's William K. Hubbard to The Kullman Firm (Feb. 12, 2003), *available at* www.fda.gov/ora/import/kullman.htm (citing 21 U.S.C. §§ 331, 353, 355).

³ See FDA, "Coverage of Personal Importation," *available at* www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html.

⁴ See FDA Traveler Alert, *available at* www.fda.gov/ora/import/traveler_alert.htm.

⁵ See HHS, "Secretary Thompson Determines That Safety Problems Make Drug Reimportation Unfeasible" (July 10, 2001), *available at* www.os.dhhs.gov/news/press/2001pres/20010710.html.

⁶ See 21 U.S.C. §§ 331-33.