

LEGAL ISSUES RELATED TO IMPORTATION OF MEDICATIONS FROM CANADA

A recent issue of significance in the area of healthcare involves the importation/re-importation of medications by U.S. consumers from foreign sources, particularly Canada. For public health reasons, the Food and Drug Administration (FDA) remains concerned about this practice because it cannot ensure the safety of drugs purchased from foreign sources. Although the drugs obtained from outside U.S. borders either purport to be or appear to be the same as U.S. - approved prescription drugs, the FDA cannot guarantee to the American public that such drugs are the same as products approved by the FDA.

In addition to these safety concerns, it is important to note that it is illegal, under the Federal Food, Drug, and Cosmetic (FD&C) Act, to import unapproved, misbranded, and adulterated medications into the U.S., including foreign versions of U.S.-approved medications. It is also illegal for anyone other than the drug manufacturer to re-import a prescription drug that was originally manufactured in the U.S.

This issue can have legal ramifications for health care providers and pharmacists who become involved in the process of obtaining medications for consumers from Canada or other foreign sources. Businesses and individuals involved in the shipping of prescription medications to consumers in the U.S. must take a number of steps to ensure compliance with the FD&C. If parties are involved in violations of the Act, there are various avenues of potential liability. A court can enjoin violations of the Act, and a person who violates the Act can be held criminally liable. All those who cause a prohibited act under the

FD&C can be held civilly and criminally liable, and those who "aid & abet" a criminal violation, or "conspire" to violate the FD&C, can also be held criminally liable.

The general legal framework applicable to importation of prescription drugs from foreign sources is that, even if a prescription drug is approved in the U.S., if the drug is also originally manufactured in the U.S., it is a violation of the Act for anyone other than the U.S. manufacturer to import the drug into the U.S. See 21 U.S.C. §381(d)(1). The FDA's position (Office of Regulatory Affairs Imports) has been that all drugs imported to the U.S. from Canada by or for individual U.S. consumers violate U.S. law for other reasons. Such drugs are unapproved (21 U.S.C. §355), labeled incorrectly (21 U.S.C. §353(b)(2)), and/or dispensed without a valid prescription (21 U.S.C. §353(b)(1)). Their shipment into the U.S. from Canada therefore violates the FD&C. See, e.g. 21 U.S.C. 331(a)(d),(t). Thus, in order to ensure compliance with the Act when involved in shipping prescription drugs to consumers in the U.S., businesses and individuals must ensure, among other things, that they only sell FDA - approved drugs that are made outside of the U.S. and that comply with FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. See 21 CFR 314.50.

There has been some confusion as to whether the FDA's Personal Importation policy changes the law with respect to personal imports of pharmaceuticals. Under defined circumstances, as a matter of enforce-

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ment discretion, the FDA allows individuals and their physicians to bring into the U.S. small quantities of medications sold abroad for a patient's treatment of a "serious condition" for which effective treatment may not be available domestically. This approach has been applied to products that do not present an unreasonable risk and for which there is no known commercialization and promotion to persons residing in the U.S. A patient seeking to import such a product must provide the name of the licensed physician in the U.S. responsible for his or her treatment with the unapproved drug product. See FDA Regulatory Procedures Manual, Chapter 9 Subchapter: Coverage of Personal Importations. However, this policy is not intended to allow importation of foreign versions of drugs that are approved in the U.S., particularly when the foreign versions of such drugs are being "commercialized" to U.S. citizens.¹

In conclusion, although the FDA has been reluctant to give an advisory opinion on these issues because potential liability is a fact-specific inquiry, the FDA has advised that any party participating in a plan of importation of prescription drugs from a foreign source does so "at its own legal risk." The FDA has also indicated that its highest enforcement priority would not be actions against U.S. consumers.



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¹ The above FDA prohibitions against Canadian imports/re-imports are applicable to prescription drugs as opposed to medical devices, which are controlled by distinct FDA regulation and are arguably not subject to the *per se* prohibitions discussed above.

DID YOU KNOW?

- that the Centers for Medicare and Medicaid Services (CMS) will now accept public comments on proposed or final regulations, as well as other documents soliciting public comments, electronically via the internet? The website is www.regulations.gov.
- that Local Medical Review Policies (LMRP), which provides Medicare coverage determinations for various states or regions, are being renamed Local Coverage Determinations (LCD)?
- that starting in 2005, Medicare intends to provide coverage of certain cardiovascular screening tests and certain diabetes screening tests?

Please call if you need further information.

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