



February 12, 2003

Via Facsimile (504-524-4162)
and U.S. Mail

Robert P. Lombardi, Esq.
The Kullman Firm
P.O. Box 60118
New Orleans, LA 70160

Dear Mr. Lombardi:

I write in response to your letter to Mr. Harold Davis of this agency, dated November 8, 2002. In your letter, you state that your firm represents a number of sponsors and/or administrators of employer-sponsored health plans. You raise many questions about potential civil and criminal liability of various parties involved in importing prescription drugs from Canada.

For public health reasons, FDA is very concerned about the importation of prescription drugs from Canada. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.- approved prescription drugs have been of unknown quality. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA.

From a legal standpoint, businesses and individuals that are involved in shipping prescription drugs to consumers in the U.S. must take many steps to ensure compliance with the Federal Food, Drug, and Cosmetic Act (the Act). Practically speaking, it is extremely unlikely that a pharmacy could ensure that all of the applicable legal requirements are met.

If parties are involved in violations of the Act, there are many potential avenues of liability. A court can enjoin violations of the Act. A person who violates the Act can also be held criminally liable. Those who can be found civilly and criminally liable under the Act include all who cause a prohibited act. Those who aid and abet a criminal violation of the Act, or conspire to violate the Act, can also be found criminally liable.

FACTUAL SCENARIO

You ask us about the potential liability of various participants in the following factual scenario:

A health plan's sponsor amends a health plan to include coverage for prescription drugs purchased outside of the United States.

The health plan's administrator publicizes this change to plan members.

A health plan member in the United States obtains a valid prescription from a licensed U.S. physician and forwards the prescription to Expedite-Rx, a company that performs technological services for SPC Global Technologies, Ltd. ("SPC"), a claims processing company.

Expedite-Rx receives the prescription, performs certain data entry services and forwards the prescription, along with ancillary patient-protective information, to a licensed pharmacy in Canada.

In Canada, a Canadian doctor rewrites the prescription.

A Canadian pharmacy then fills the prescription and ships the drugs directly to the patient in the United States.

Neither the employer, SPC, nor Expedite-Rx handles the drugs.

Expedite-Rx consolidates the plan and patient co-pays and forwards the payment to the Canadian pharmacy.

The plan will not cover Cipro, "quack" drugs, or controlled substances from a source outside of the United States.

GENERAL LEGAL FRAMEWORK

The starting point for our analysis is the legal framework applicable to imports of prescription drugs from Canada.¹ First, as your letter notes, 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 United States (21 U.S.C. § 381(d)(1)). We believe that virtually all drugs imported to the U.S. from Canada by or for individual U.S. consumers also violate U.S. law for other reasons. Generally, 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. §

¹ We will limit our discussion to drugs imported from Canada because your request is so limited. The legal analysis is the same for drugs imported from any foreign country.

353(b)(1)). Thus, their shipment into the U.S. from Canada violates the Act. See, e.g., 21 U.S.C. 331(a), (d), (t).²

The reason that Canadian or other foreign versions of U.S.-approved drugs are generally considered unapproved in the U.S. is that FDA approvals are manufacturer-specific, product-specific, and include many requirements relating to the product, such as manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. Frequently, drugs sold outside of the U.S. are not manufactured by a firm that has FDA approval for that drug. Moreover, even if the manufacturer has FDA approval for a drug, the version produced for foreign markets usually does not meet all of the requirements of the U.S. approval, and thus it is considered to be unapproved. 21 U.S.C. § 355.

Virtually all shipments of prescription drugs imported from a Canadian pharmacy will run afoul of the Act, although it is a theoretical possibility that an occasional shipment will not do so. Put differently, in order to ensure compliance with the Act when they are 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 the FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. 21 C.F.R. § 314.50. They must also ensure that each drug meets all U.S. labeling requirements, including that it bears the FDA-approved labeling. 21 C.F.R. § 201.100(c)(2). The drug must also be dispensed by a pharmacist pursuant to a valid prescription. 21 U.S.C. § 353(b)(1).

Your letter mentions that 21 U.S.C. § 384 would allow drug wholesalers and pharmacists to import prescription drugs from certain countries under certain circumstances. As noted in your letter, however, that section is not in effect. That section would only become effective if the Secretary of Health and Human Services were to certify to Congress that the section's implementation will "pose no additional risk to the public's health and safety" and will "result in a significant reduction in the cost of covered products to the American consumer." 21 U.S.C. § 384(i). HHS Secretary Tommy Thompson and former HHS Secretary Donna Shalala both declined to make such findings.

FDA'S PERSONAL IMPORTATION POLICY

There has been some confusion about whether FDA's Personal Importation policy changes the law with respect to personal imports of pharmaceuticals. This confusion is reflected in your letter. The Personal Importation policy is used to guide the agency's enforcement discretion with respect to imports by individuals of drugs for their personal

² Shipping prescription drugs to consumers in the U.S. may also violate state law because, among other things, many U.S. states require that a pharmacy that ships drugs to a consumer within that state be registered with, or licensed by, the state. Obviously, we cannot analyze state law issues for you.

use. Under certain defined circumstances, as a matter of enforcement discretion, FDA allows consumers to import otherwise illegal drugs. Under this policy, FDA permits individuals and their physicians to bring into the United States small quantities of drugs 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 also 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. (Foreign versions are often what Canadian pharmacies offer to sell to U.S. consumers.) Moreover, the policy simply describes the agency's enforcement priorities. It does not change the law, and it does not give a license to persons to import or export illegal drugs into the United States. Although we must concede that FDA has not often prosecuted those importing illegal drugs into the United States from Canada, FDA reserves the right to do so in the appropriate circumstance.

POTENTIAL LIABILITY

As noted in your letter, there are many potential avenues of civil and criminal liability for parties involved in violations of the Act. A court can enjoin violations of the Act. 21 U.S.C. § 332. A person who violates the Act can also be held criminally liable. 21 U.S.C. § 333. A misdemeanor violation of the Act is a strict liability offense. See *United States v. Dotterweich*, 320 U.S. 277, 284 (1943); 21 U.S.C. § 333(a)(1). A violation that is committed with intent to defraud or mislead or after a prior conviction for violating the Act is a felony. 21 U.S.C. § 333(a)(2). Separately, it is a felony to knowingly import a drug in violation of the reimport prohibition. 21 U.S.C. §§ 333(b)(1)(A), 381(d)(1).

Those who can be found civilly and criminally liable include all who cause a prohibited act. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited"). Those who aid and abet a criminal violation of the Act, or conspire to violate the Act, can also be found criminally liable. 18 U.S.C. §§ 2, 371.

Beyond articulating these general principles, we are unable to advise you as to whether, in the factual scenario that you set forth in your letter, Expedite Rx, the plan sponsor, the plan administrator, the plan member, SPC, the Canadian pharmacy, or the Canadian doctor could be found liable under one or more of these avenues. We are reluctant to give an advisory opinion, especially because potential liability is a very fact-specific inquiry. However, any party participating in this kind of import plan does so at its own legal risk. Of course, if FDA were to take enforcement action in this scenario, our highest enforcement priority would not be actions against consumers.

CONCLUSION

I hope that the above discussion is helpful to you. From a public health standpoint, FDA is very concerned about the kind of scenario described in your letter. In our experience, many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs have been of unknown quality. FDA approves a drug based on scientific data submitted by the drug sponsor to demonstrate that the drug is safe and effective. We cannot provide adequate assurance to the American public that the drug products delivered to consumers in the United States from foreign countries are the same products approved by FDA.

Thank you for your interest in this matter. If you need additional information, please feel free to contact me.

Sincerely yours,

A handwritten signature in black ink, appearing to read "William K. Hubbard", written over a horizontal line.

William K. Hubbard
Associate Commissioner for Policy and Planning

Enclosures:
Personal Import Policy

SUBCHAPTER

COVERAGE OF PERSONAL IMPORTATIONS

PURPOSE

To provide guidance for the coverage of personal-use quantities of FDA-regulated imported products in baggage and mail and to gain the greatest degree of public protection with allocated resources.

BACKGROUND

Because the amount of merchandise imported into the United States in personal shipments is normally small, both in size and value, comprehensive coverage of these imports is normally not justified. This guidance clarifies how FDA may best protect consumers with a reasonable expenditure of resources.

There has always been a market in the United States for some foreign made products that are not available domestically. For example, individuals of differing ethnic backgrounds sometimes prefer products from their homeland or products labeled in their native language to products available in the United States. Other individuals seek medical treatments that are not available in this country. Drugs are sometimes mailed to this country in response to a prescription-like order to allow continuation of a therapy initiated abroad. With increasing international travel and world trade, we can anticipate that more people will purchase products abroad that may not be approved, may be health frauds or may be otherwise not legal for sale in the United States.

In addition, FDA must be alert to foreign and domestic businesses that promote or ship unapproved, fraudulent or otherwise illegal medical treatments into the United States or who encourage persons to order these products. Such treatments may be promoted to individuals who believe that treatments available abroad will be effective in the treatment of serious conditions such as AIDS or cancer. Because some countries do not regulate or restrict the exportation of products, people who mail order from these businesses may not be afforded the protection of either foreign or U.S. laws. In view of the potential scale of such operations, FDA has focused its enforcement resources more on products that are shipped commercially, including small shipments solicited by mail-order promotions, and less on those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from foreign medical facility where a person has undergone treatment.

PERSONAL BAGGAGE

FDA personnel are not to examine personal baggage. This responsibility rests with the U.S. Customs Service. It is expected that a Customs officer will notify their local FDA district office when he or she has detected a shipment of an FDA-regulated article intended for commercial distribution (see GENERAL GUIDANCE below) an article that FDA has specifically requested be detained, or an FDA regulated article that appears to represent a health fraud or an unknown risk to health.

When items in personal baggage are brought to FDA's attention, the district office should use its discretion, on a case-by-case basis, in accordance with the guidance provided under GENERAL GUIDANCE below, in deciding whether to request a sample, detain the article, or take other appropriate action.

MAIL SHIPMENTS

FDA personnel are responsible for monitoring mail importations. It is expected that a Customs officer from the Customs Mail Division will examine a parcel and will set it aside if it appears to contain a drug, biologic, or device, an article that FDA has specifically requested be held, or an FDA-regulated article that appears to represent a health fraud or unknown risk to health.

FDA should audit those parcels set aside by Customs in accordance with the guidance provided under GENERAL GUIDANCE below, using the following procedures:

Prepare a Collection Report for each parcel sampled. Generally, a physical sample is not required on mail importations because a documentary sample (for example, labeling, labels and inserts) will be sufficient for most regulatory purposes. If a physical sample is needed, collect only the minimum necessary for analysis by the laboratory. The remaining portion should not be removed from the custody of the Customs Mail Division.

Importations detained in accordance with this guidance should be held by Customs until they are either released or refused entry. Attached as guidance are two specimen letters that may be sent with the Notice of Detention and Hearing when a parcel is detained. (See Exhibit 9-3 for use in general mail importations and Exhibit 9-4 for use in unapproved drug or device mail importations).

On occasion, products detained by FDA will be mixed with non-FDA-regulated products. When we refuse admission of the FDA-regulated portion, any request for the release of the non-FDA-regulated portion should be referred to the Customs Mail Division with a Notice of Refusal of Admission covering the detained article. Final disposition of all merchandise, including the destruction of detained merchandise, is the responsibility of Customs.

GENERAL GUIDANCE

The statements in this chapter are intended only to provide operating guidance for FDA personnel and are not intended to create or confer any rights, privileges, or benefits on or for any private person.

FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. Even though all products that appear to be in violation of statutes administered by FDA are subject to refusal, FDA personnel may use their discretion to examine the background, risk, and purpose of the product before making a final decision. Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments.

Commercial or Promotional Shipments

Commercial and promotional shipments are not subject to this guidance. Whether or not a shipment is commercial or promotional may be determined by a number of factors including, for example, the type of product, accompanying literature, size, value, and/or destination of the shipment. FDA personnel may also consider whether an importation of drugs or medical devices is a commercial shipment by evaluating whether the article appears to have been purchased for personal use or whether the quantity suggests commercial distribution (i.e., the supply exceeds what one person might take in approximately three months). Commercial shipments generally include shipments other than those products that are personally carried, shipped by a personal non-commercial representative of a consignee, or shipped from a foreign medical facility where a person has undergone treatment.

Products Other than Drugs and Devices

Many products other than drugs, biologics, and devices that individuals seek to import in personal quantities do not pose a significant health risk although they appear to be violative and may be the subject of an import alert or automatic detention based on standards violations, filth, and/or labeling problems. When such items are brought to FDA's attention by Customs, it may be appropriate for FDA personnel to use their discretion to "Release with Comment" and advise the importer of the agency's concerns. FDA personnel should be alert to and should detain those products that do pose a significant health risk.

Drugs, Biologics, and Devices

When personal shipments of drugs and devices that appear violative are brought to FDA's attention by Customs, FDA personnel will use their discretion to decide on a case by case basis whether to detain, refuse, or allow entry of the product. Generally, drugs and devices subject to Import Alerts are not amenable to this guidance. Devices to be used by practitioners for treating patients should not be viewed as personal importations subject to this chapter. Drugs subject to Drug Enforcement Agency (DEA) jurisdiction should be returned to Customs for handling.

In deciding whether to exercise discretion to allow personal shipments of drugs or devices, FDA personnel may consider a more permissive policy in the following situations:

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to represent a significant health risk; or
2. when a) the intended use is unapproved 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 to persons residing in the U.S. by those involved in the distribution of the product at issue; c) the product is considered not to represent an unreasonable risk; and d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

If there are any questions about the application of these factors to any product, the product should be detained and FDA personnel should consult with the appropriate headquarters office.

When a shipment is not refused entry, FDA personnel may consider issuing a "Release with Comment" and, as appropriate, advise the recipient that 1) the drug (or device) that has been obtained for personal use appears to be unapproved in the United States; 2) the drug (or device) should be used under medical supervision; 3) FDA may detain future shipments of this product; and 4) the patient's physician should consider for example, enrolling the patient in an Investigational study or applying for Investigation New Drug (IND), Compassionate IND, or Treatment IND exemption.

IMPORT ALERTS

FDA personnel should recommend to the Division of Import Operations and Policy (HFC-170) the issuance of an import alert if they encounter:

1. personal importation of products that represent either a direct or indirect health risk; or
2. the promotion of unapproved foreign products for mail order shipment; or repeated importation of products that represent fraud*.

*(See Compliance Policy Guides Manual, Section 120.500, "Health Fraud - Factors in Considering Regulatory Action" (CPG 7150.10))