Protecting Patients from Dangerous, Misbranded, Adulterated, and/or Counterfeit Drugs

Background

- Prescription drug importation occurs when foreign pharmacies, traders or suppliers ship pharmaceuticals, which may or may not have been approved for use in foreign countries, into the United States for use by American consumers. Importation of prescription drugs is becoming a growing problem.

- Some practitioners see importation as a cost-saving alternative, because some prescription drugs are sold at lower prices in foreign countries due to artificial price controls in these other countries and because the foreign and unlicensed importers do not comply with FDA regulations. These practitioners can undercut companies selling legitimate drugs. The patients who visit these practitioners usually do not realize they are being treated with illegally-imported drugs, nor do they understand the risks associated with such treatment.

- The importation of prescription drugs raises significant concerns, however. This practice not only is illegal; it also poses health risks to consumers. Imported drugs are often counterfeit, do not contain the same active ingredients, and do not contain the same important instructions and warnings as their U.S. counterparts and/or may be compromised in some way (e.g., due to inadequate storage or shipping).

- On December 19, 2012, FDA issued a letter to more than 350 medical practices that they may have received unapproved medications from a foreign supplier, that may be counterfeit, contaminated, improperly stored and transported, ineffective and/or unsafe. FDA warned these medical practices to stop purchasing and administering unapproved drugs received from foreign suppliers because they were placing patients at risk and violating federal law.

Legal Concerns

- Virtually all prescription drugs imported into the United States from other countries violate both the Federal Food, Drug and Cosmetic Act (“FDCA”) and applicable state laws because they are unapproved drugs, labeled incorrectly, and/or are dispensed without a valid prescription.

- 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, packaging location, container/closure system, and appearance.

---

1 A copy of the letter, as well as a list of doctors/clinics that received the letter, is available at http://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm330610.htm#Text.
5 21 C.F.R. § 314.50.
• Importing a drug into the United States that is unapproved (or not intended) for U.S. sale and/or does not comply with the labeling requirements in the FDCA is prohibited. Import drugs that do not comply with the labeling requirements in the FDCA are also prohibited by most applicable state laws.

• Even if the manufacturer of drugs sold outside of the United States has FDA approval for the U.S. version of those drugs, the version produced for foreign markets usually will be misbranded if imported into the U.S. because it lacks information that is required by the FDA but is not required in the foreign country. Additionally, these drugs often are labeled in a language other than English, making it difficult or impossible for consumers to understand the risks associated with and instructions for use of those drugs. In addition to violating federal statutes, misbranded and mislabeled drugs violate most applicable state laws.

• Because many states have enacted their own version of the Food, Drug and Cosmetic Act, the provisions of which parallel the FDCA, the sale of imported drugs in most cases violates both federal and state law and is subject to action by both federal and state authorities.

• It is illegal for healthcare professionals who use imported drugs to file for reimbursement. These providers are subject to claims under the federal False Claims Act and similar false claims laws of many states. If patients are harmed by the use of illegally-imported drugs, these professionals also can face claims for medical malpractice and violations of consumer protection laws.

• Illegal importation also implicates the fair business practices acts of many states. Specifically, the sale of misbranded and mislabeled drugs likely would constitute an unfair and deceptive practice in the context of a consumer transaction in violation of state laws. Further, representing that the drug is of a particular standard, quality, or grade when it is not likely would violate many state laws.

  Health Concerns

• Drugs obtained from foreign sources, and which are represented as FDA-approved prescription drugs, are often of unknown origin and quality.

• In examining imported drugs sent through the mail, the FDA has identified counterfeit drugs, so-called “foreign versions” of FDA-approved drugs, improperly-labeled drugs, drugs that failed to meet special storage conditions, and drugs requiring physician monitoring that were being dispensed without a physician's involvement.

• When a drug is illegally imported, there is no guarantee as to the active ingredients in the drug or the potency of the drug. Imported drugs may contain too little active ingredient, in which case

---

6 See 21 U.S.C. §§ 331(a) and/or (d). For example, Amazon Medica claims to be importing into the United States versions of Botox approved for sale in the U.K. Also, only two versions of Juvederm® are approved for sale in the United States, yet other versions are often imported from other countries and sold to American consumers by doctors and unauthorized distributors. This activity is illegal under the FDCA. See 21 U.S.C. § 331(d); see also 21 U.S.C. §381(a).

7 21 U.S.C. §§ 352 or 353(b).

8 21 C.F.R. § 201.15(c).

Therapeutic effects will be minimized. Alternatively, these products may contain too much active ingredient, which can result in harm to consumers and negative interactions with other medications.

- Manufacturing, storage, packaging and transportation of illegally imported drugs are not regulated by the FDA. This can lead to degradation of the product and harm to consumers.

- Some imported medicines – even those that bear the name of a U.S.-approved product – may, in fact, be counterfeit versions that are unsafe or even completely ineffective.

- Some imported medicines and their ingredients, although legal in foreign countries, may not have been evaluated for safety and effectiveness in the United States. These products may be addictive or may contain other dangerous substances.

- Imported drugs may be labeled in languages that American consumers do not understand and may make medical claims or suggest specific uses that have not been adequately evaluated for safety and effectiveness by the FDA. Additionally, imported drugs may lack information about side effects caused by the medicine.