Importing Prescription Drugs

Not only is the practice illegal, but it is unsafe

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BECAUSE there has been so much chatter about modifying restrictions on importing drugs so that we can obtain less costly drugs, physicians might be confused about the status of the law regarding importing drugs. But let there be no doubt, it is illegal for a physician to import prescription drugs for patient use-our federal laws do not permit it. There is no exception applicable to physicians importing drugs for use by their patient, whether the drugs come from Canada, Mexico or some other foreign venue.

Efforts to Modify Federal Laws

Federal statutes from the U.S. Federal Food, Drug and Cosmetic Act generally prohibit anyone except pharmaceutical manufacturers from importing prescription drugs into the U.S. Still, various attempts have been made to modify the federal law. Congress actually passed The Medicine Equity and Drug Safety Act of 2000 (commonly referred to as the "MEDS Act"), which would have allowed certain importation of drugs by pharmaceutical wholesalers and pharmacies if the Secretary of the U.S. Department of Health and Human Services concluded that the importation was safe and would result in significant cost reduction to the American consumer. However, the then Secretary of DHHS under the Clinton Administration, and the subsequent Secretary of DHHS under the Bush Administration, each concluded it was not possible for the FDA to guarantee the safety of imported drugs and that the factors involved would make it very unlikely the consumers would receive any significant cost benefits. As a result, the MEDS Act was rendered meaningless.

Congress also passed the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (commonly referred to as the "Medicare Modernization Act" or "MMA"). Portions of the MMA replaced the MEDS Act and would have allowed certain importation of drugs from Canada by pharmaceutical wholesalers and pharmacies, and certain importation by individuals for their own use. However, the MMA required the same conditions for implementation mandated under the MEDS Act-for example, that the Secretary of the DHHS must conclude that the importation was safe and would result in significant cost reductions for American consumers. The Secretary of the DHHS refused to make such determinations. As a result, the proposed importation rights under the MMA could not take effect and have also been rendered meaningless.

Personal Use Exemptions

Currently, there are certain limited exceptions that may apply for a person who imports drugs for his or her personal use. The primary policies behind what are loosely referred to as the "personal use exemptions" are: 1) to enable international travelers the ability to travel with a limited supply of prescription drugs for their own medical use during the course of their travel, and 2) to enable access to drugs not otherwise available in the U.S. for the treatment of serious illnesses such as HIV and cancer. The personal use exceptions were not intended for people to acquire cheaper drugs.

It is important to note that the personal use exceptions do not make the importation of the drugs "legal"—it is still illegal. Physicians might be surprised to learn how very limited the personal use exceptions are. For example, the personal use exceptions do not apply to physicians who seek to import drugs for use by their patients.

Reasons for Restrictions

Some concerns with importing prescription drugs from foreign countries are:

1 Patient safety. The FDA has strict regulatory control over the manufacture, packaging, labeling, storing, sale and distribution of drugs in the U.S., with its primary purpose being to protect consumers. The FDA does not generally have jurisdiction over foreign manufacturers and distributors and has determined that it cannot effectively ensure that foreign made and products are safe for U.S. consumers or that the drugs are effective. Most justifications for limiting the importation of drugs relate to patient safety concerns.

2 Counterfeit and adulterated drugs. In some countries, regulatory protections with drugs is lax and has resulted in an abundance of counterfeit, adulterated and ineffective drugs being put into the marketplace. Also, drugs thought to be manufactured in and/or distributed from one country, such as Canada, are often actually manufactured in or distributed from other countries. According to the World Health Organization, counterfeit medicines occur worldwide, in both developing and developed countries, and no country is immune to the problem. The WHO generally groups counterfeit drugs into four categories: products without active ingredients; products with inadequate quantities of active ingredients; products with incorrect active ingredients, and products with correct quantities of active ingredients but with the wrong name of manufacturer and/or country of manufacture indicated on the label. The WHO encourages all countries to combat the problem of counterfeit drugs by, for example, regulatory and enforcement measures, but also by improving the availability and affordability of medicines.

3 Purchase and use without medical care or supervision. Some drugs regulated as prescription drugs in the U.S. are sold over the counter in other countries and do not require a prescription. In the U.S., many drugs are limited to prescription use because they are either deemed unsafe without medical supervision or a medical diagnosis is required to ensure that the medication is appropriate for the patient's condition. There is real concern with patients obtaining and using drugs from foreign sources that may not be safe for their particular medical condition or that are unsafe to take without proper medical supervision (for example, for proper dosage or issues with side effects).

4 Strong lobbying by U.S. pharmaceutical companies. Pharmaceutical companies have strong incentive to lobby for maintaining strict importation laws. Limiting the U.S. market for drugs enables the companies to control the high prices they charge for drugs. Pharmaceutical companies insist they need to charge, at least initially, high prices for their drugs in order to finance the high cost of meeting FDA and other regulatory compliance, to finance the high cost of research and development, and to help cover their product liability risks. Arguably, permitting foreign companies to export drugs into the U.S., when they are not subject to comparable regulatory schemes and costs, enables foreign companies to potentially unfairly compete with U.S. companies. U.S. pharmaceutical companies are also concerned with protecting their patents and brands against counterfeiting.

Potential Penalties

Violating the federal laws can result in civil and criminal penalties. The penalties can include imprisonment, fines, or both. For example, a first offense involving importation of a drug without applicable FDA approval can result in imprisonment for not more than a year or a fine of not more than $1,000 or both. A second offense can result in imprisonment for not more than three years or a fine of not more than $10,000 or both. Those who aid and abet a criminal violation of the FFDCA, or conspire to violate the FDDCA, can also be found criminally liable and subject to penalty.

Violating the federal laws can also result in disciplinary action by the California Medical Board. For example, under Section 2238 of the California Business & Professions Code, a violation of any federal statute or federal regulation or any of the statues or regulations of the State of California regulating dangerous drugs or controlled substances constitutes unprofessional conduct. Physicians found guilty of unprofessional conduct can face an array of penalties, up to and including license revocation. Being subject to Medical Board discipline can also result in other professional consequences, such as difficulty in obtaining hospital privileges, exclusion from participation with managed care plans, exclusion from Medicare and Medi-Cal programs, loss of referrals within the medical community, and possible loss of DEA certification.

Liability Exposure

A physician importing drugs for use by his or her patients has other liability exposure. For example, if a patient has a bad reaction to an adulterated drug, who will be responsible? The patient may not have adequate recourse to the foreign manufacturer or distributor of the drug, leaving the U.S. physician as the only "deep pocket" for recourse. Claims against the physician might include, for example: 1) malpractice claims for failing to exercise appropriate levels of care by illegally importing the drug from a foreign source without adequate safety and quality assurances; and 2) product liability claims, since the physician would be within the chain of distribution in getting the drug to the patient. Product liability claims are generally strict liability claims, mandating payment of damages to the patient who only has to prove that the drug caused the patient harm (and not that the physician was in any way responsible for the adulteration of the drug). The physician may also find himself or herself inadequately insured for such claims, or may find the insurance carrier refusing to provide coverage for the claims on the basis that the physician's importation of the drug was illegal.

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Federal Preemption

A number of state and local governments have sought ways to circumvent these federal laws. Some state and local governments have actually initiated programs for assisting their government employees and retirees, and in some cases their citizens, in sourcing imported drugs, mainly from Canada. Such programs are contrary to the FFDCA. Generally, federal law trumps any conflicting state and local laws, pursuant to the Supremacy Clause of the U.S. Constitution. The federal government has the ability to challenge these state and local activities on the basis of preemption. Thus far, though, it does not appear the federal government has taken significant action to stop them.

In conclusion, in spite of what you may have heard or thought, it is illegal under federal laws for a physician to import prescription drugs for patient use. There are significant risks involved in violating those laws-mostly to the physician, but also to the patient. Don't do it!

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