

# CAPSULES

A Risk Management Publication from Cooperative of American Physicians, Inc.

## IMPORTATION BY PHYSICIANS/PATIENTS OF FOREIGN DRUGS AND MEDICAL DEVICES: WHAT'S WRONG WITH SAVING MONEY?

by Dan Groszkruger, JD, MPH  
Consulting Editor



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Many prescription drugs and medical devices appear to be available from foreign countries, at prices significantly lower than in the U.S.—especially, from Canada and Mexico. Doctors ask: Why shouldn't my patients be able to buy their drugs from foreign sources, directly or over the Internet? Why shouldn't physicians take advantage of big price breaks offered by foreign vendors of drugs and medical devices?

The simple answer is: **You may not, because it's illegal.**

But a more detailed answer requires a review of some history, appreciation for the role of politics, and a healthy dose of common sense.

Consider the common sense angle first. What explains the significant difference in prices -- domestic compared to foreign sources? Can safe and effective drugs and devices be marketed in Canada or Mexico at much lower prices than those in the U.S.? Do pharmaceutical manufacturers and device-sellers care less about making a profit in Canada or Mexico? Probably not!

Prescription drugs from Canada are cheaper due to governmental price controls. Pharmaceutical companies

choose to market their drugs for less in Canada, or not at all. In Mexico, other factors may be at work. Mexican drug prices tend to vary, depending upon the product. The Mexican government warns U.S. tourists that they need a prescription from a Mexican doctor. But, many drugs seem to be available from Mexican pharmacies, or from other less reputable sources, either with or without a doctor's prescription.

Unquestionably, the prices of prescription drugs in the U.S. are affected by our

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degree of regulatory control. Physicians need not be reminded how aggressively the government attempts to control the distribution of certain classes of drugs. By comparison, regulation of prescription drugs in Mexico and in many other foreign countries is far less

stringent, or even non-existent. Concerns in the U.S. about the efficacy and safety of drugs go a long way to explain the drug price disparity.

So, regardless of the reason(s) for the price disparity in Canada and Mexico, why shouldn't both patients and physicians take advantage of the savings? The answer to this question should be evident based on a risk vs. benefit analysis.

Currently, the federal Food & Drug Administration (FDA) outlaws the

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importation of drugs from foreign countries that are manufactured in the U.S. and then sent abroad. The FDA cannot ensure the quality or safety of drugs that come into the U.S. without inspection. Since 1987, the Prescription Drug Marketing Act (PDMA) has banned importation of drugs from foreign countries. One exception is a true “re-importation” of a drug, conducted by the original manufacturer of that drug.

As a matter of enforcement discretion, the FDA has advised U.S. citizens that drugs obtained overseas are not legal, but has generally allowed returning U.S. citizens to bring in small quantities, for personal use. The FDA advises U.S. citizens to consult with their private physicians regarding the use of such drugs. But, obtaining foreign drugs by mail order, e.g., over the Internet, is still illegal. Nevertheless, confusion over the legality of buying prescription drugs over the Internet has persisted. Despite the legal problems, federal, state and local governments have adopted laws that encourage, and even attempt to legitimize the practice.

Politics has played a central role both in creating and perpetuating the confusion about importation of drugs. Both governmental and private organizations have proposed laws designed to legalize importation of drugs from foreign countries. It appears that legislators have sought to respond to mounting public pressure to make drugs more affordable. But, FDA approval is still required for all state and local laws that have been adopted to date. And, **the FDA has never lifted the ban on importation of drugs from foreign countries.**

Foreign producers of medical devices that are imported into the U.S. must comply with applicable U.S. regulations. The FDA does not recognize regulatory approvals from other countries. The rules applicable to medical devices and products that emit radiation are even more stringent. So, attempting to purchase medical devices from foreign sources is not advisable, regardless of the amount of potential cost savings.

In summary, the risks inherent in importation of drugs or devices from foreign countries appear to outweigh the potential benefits (i.e., cost savings). Physicians may risk doing irreparable damage to an otherwise defensible medical malpractice case by use of an un-approved drug or device. Physician-members are reminded that the MPT Agreement (Article VII, Section 5a, p. 31, No. 17) states that the use, administration or prescribing of any “non-approved drugs and devices” are excluded from coverage.

For more information, consult the HHS Task Force on Drug Importation Report (December 2004) at: <http://www.hhs.gov/importtaskforce/Report1220.pdf>.



**TRYING TO HELP  
TURNS OUT TO BE  
“NO FAVOR”**

by Gordon Ownby



If there is one impulse that seems to get physicians into trouble all too often, it is trying to “do the patient a favor.”

A 50-year-old cement worker suffered a terrible work accident when a 2,000-pound door fell on him, crushing his trunk and leg. The worker underwent an emergency splenectomy and external knee fixation before coming under the care of Dr. OS, an orthopedic surgeon assigned through Workers Compensation.

Dr. OS first evaluated the patient in May 2000. By June, however, the patient had significant complaints involving his external knee fixation and Dr. OS suspected a wound infection. Dr. OS applied a short leg cast and arranged for a psychological assessment, all without much improvement.

In early 2001, Dr. OS received approval to perform a total knee arthroplasty. Later, a culture tested positive for methicillin-resistant staph (MRSA). Dr. OS immediately called his infectious disease consultant, who prescribed Zyvox. The left knee arthroplasty was successful, with the wound healing well.

In early 2002, the patient asked Dr. OS to prescribe refills of the Zyvox. Evidently, the patient could save several thousand dollars on the medication with a prescription coming from his Workers Compensation physician.

Dr. OS failed to discuss the refills with the infectious disease physician. Rather, he took a bottle prescribed by the infectious disease physician, copied the dose and frequency for his own prescription, and approved three refills.

The patient, who was excellent historian, told Dr. OS that he needed to have blood work drawn while on the medication. Dr. OS complied, noting that the initial lab data after his prescription showed an elevated white blood cell count, low hemoglobin and low hematocrit. A month later, the labs were not much better. Dr. OS ordered over-the-counter iron supplements, told the patient to eat some red meat, and referred the gentleman to a hematologist. Apparently, Dr. OS did not link the patient’s anemia to the Zyvox.

Meanwhile, the patient reported to Dr. OS radiating back pain and vision problems. Soon, he began losing his vision. Zyvox had been linked in research to damage to the optic nerve. Dr. OS advised the patient to discontinue the Zyvox and to follow up with an internist, neurosurgeon, and ophthalmologist. Dr. OS continued as the patient’s Workers Compensation gatekeeper.

The patient received a large award from the Workers Compensation case and then pursued Dr. OS and the drug manufacturer for nerve and vision injuries. Dr. OS and the patient resolved the matter informally without going to trial.

A physician’s urge to be a patient’s advocate – especially after a devastating industrial accident – is quite understandable. But more often than not, the best thing for all involved is to remain within one’s own discipline and to rely on others for a patient’s specialized needs.

**CASE-OF-THE-MONTH**

is a regular feature of CAPSULES, the Bulletin, and the Members Only section of the CAP-MPT website [www.cap-mpt.com](http://www.cap-mpt.com)

Comments on Case of the Month may be sent to Gordon Ownby, CAP-MPT’s General Counsel, at [gownby@cap-mpt.com](mailto:gownby@cap-mpt.com).



## MAY PRESCRIPTIONS BE FAXED TO MEXICAN "FARMACIAS"?

by Dan Groszkruger, JD, MPH  
Consulting Editor  
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**Q.** Some patients have asked me to send drug prescriptions directly to Mexican pharmacies, or to other foreign sources, in order to save money. Is this O.K.?

**A.** No. U.S. prescriptions are not valid in Mexico or in other countries. And, the safety and efficacy of drugs obtained from foreign sources cannot be verified.

To save money, some patients will cross the border to purchase cheaper drugs in Mexico or elsewhere. Some patients have asked their U.S. physicians to fax prescriptions directly to Mexican "farmacias." But, will faxing a U.S. prescription really assist in buying and successfully transporting drugs from Mexico back across the border? Probably not!

U.S. prescriptions are invalid in Mexico or outside the U.S.. Some prescription drugs in the U.S. may be purchased "over-the-counter" in Tijuana. But, this does not ensure that the patient will be allowed to bring the drugs back across the border. The main value of a U.S. prescription may be to convince a Mexican doctor that the patient's U.S. physician already prescribed the drug, in order to obtain a Mexican prescription. Later, it may be helpful to persuade a U.S. Customs/DEA Officer to allow the patient to keep the drug upon re-entering the U.S. But, faxing a U.S. physician's prescription to a "farmacia" in Mexico does not serve either purpose.

The prescribing U.S. physician cannot know whether a drug from Mexico or from another foreign source is safe or effective. There is no recourse if drugs obtained from Mexico turn out to be worthless or harmful. CAP-MPT physician-members should warn patients about these risks. Serious safety concerns militate against obtaining drugs from foreign sources, no matter how much money may be saved.

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