



## Drugs from Canada

### EXECUTIVE DIRECTOR'S MESSAGE



By Bill Sandberg

**A number of patients are buying drugs from outside of the country. But the practice has not been specifically authorized and remains a gray area for prescribing physicians.**

There has been a good deal of news coverage of Medicare patients, and others on limited incomes or without health insurance, getting their prescription drugs from Canada. Controls there limit the costs of pharmaceuticals. Promotions on the Internet report savings on some medications as high as 80 percent, but 50 to 60 percent is most often quoted.

During the past year, SSVMS has received a number of calls from physicians asking about the legality of pharmaceuticals from Canada, and whether the practice places the physician in peril.

To research this issue, I spoke to the California Medical Association and the California Pharmacists Association. The CMA's On Call Document 0510 is an excellent review on general prescribing requirements. I also visited the Food and Drug Administration's website at [www.fda.gov](http://www.fda.gov). Finally, I conducted an online search through Google.com using the words, "Prescription Drugs from Canada," which returned 143,000 results.

### What Physicians Should Know

When you write a prescription, your patients are free to do whatever they want with it.

As a physician, you want to be certain your patients take the medications prescribed, that they report any side effects to you or the pharmacist, and that they keep needed follow-up appointments. Obviously, you must perform a good faith physical exam before prescribing any medication. These are standard practices that you should be especially vigilant about if your patient is getting medications outside of the United States.

Patients can fill prescriptions from Canada (or any other country) in several ways. They may mail or fax the prescription to a Canadian pharmacy; or they may travel to Canada. Other options can also be found on the Internet. The patient will be asked to fill out a health questionnaire that includes the name of the US physician responsible for the patient's ongoing care. Fees are charged for handling and shipping and for any prescriptions written by the Canadian physician. One physician told me he was asked to fax his written prescription directly to a Canadian physician. Patients often have multiple prescriptions filled.

Don't be surprised to get a call from a Canadian physician regarding your prescription. Canadian law requires that a Canadian physician review and write all prescriptions. So your prescription will be reviewed and re-written by a Canadian physician whom you do not know. It is suggested that you keep a copy of the prescription if your patient intends to have it filled in Canada and that you make your customary prescription notes in the patient's chart. Brand and generic names may differ in the US and Canada, so it is a good idea to have some way to check that patients have received the medication you prescribed.

(or an appropriate substitute), and in the correct dosages and frequency.

A 1998 amendment in FDA communication (HFC-170, 4/3/98) states that importing drugs that lack FDA approval, whether for personal use or otherwise, is a violation of the US Federal Food, Drug and Cosmetic Act. The FDA's concern is that imported drugs are not subject to the same strict oversight, evaluation and manufacturing standards as those produced in the US under FDA regulations.

The communication gives FDA personnel discretion to determine whether to take action against the importation of unapproved drugs. Specifically, it reads:

*"The General Guidance Sections states that the FDA should consider not taking enforcement actions against such importation when 1) the intended use [of the drug] is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; 2) there is no known commercialization or promotion to persons residing in the US by those involved in the distribution of the product at issue; 3) the product is considered not to represent an unreasonable risk; and 4) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 months supply) and provides the name and address of the doctor licensed in the US 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."*

At the FDA website, a page on "Buying On Line, Tips and Warnings for Consumers" warns, "Don't purchase from foreign Websites at this time because generally it will be illegal to import the drugs bought from these sites, the risks are greater, and there is very little the US government can do if you get ripped off."

Recently, legislation was proposed in Congress to expressly authorized importation of drugs, but failed to move. There have been reports of medications being seized and of US citizens receiving warning letters from the FDA, but I found no reports of arrests.

This is still uncharted territory. Besides a careful follow-up with patients who obtain medications from other countries, it would be advisable to note in your chart that you have discussed the problems mentioned here. Finally, it is probably not a good idea to encourage patients to go outside of the US for prescriptions.

I would appreciate hearing from physicians who have had personal experience with this subject.

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