



## *InetCE*

Volume 8

2004

Number 2

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## May You Legally Import Medications for Personal Use?

*InetCE 221-146-04-071-H03*

**Laura A. Carpenter, J.D., R.Ph.**

Attorney at Law

Quarles & Brady Streich Lang, LLP

Phoenix, Arizona

**PLEASE NOTE:** The content of the article was current at the time it was written. The exam for this article is not valid for CE credit after March 1, 2007.

### GOAL

To educate pharmacists on 2003's legal, political, and professional issues arising when patients import medications from Canada, Mexico, and other countries. Because the political climate is constantly changing, this article will not address political developments after 2003. However, it will clearly explain the legal implications of importing medications into the U.S.

### LEARNING OBJECTIVES

1. Identify the economic and political reasons that U.S. citizens are seeking to import prescription medications from Canada and Mexico.
2. Explain the limited circumstances under which the U.S. Food and Drug Administration (FDA) allows licensed entities to import prescription medications.
3. Dispute the "common wisdom" advocated by new U.S. companies and foreign pharmacies that prescriptions may be legally imported for personal use.
4. Outline how various states are addressing the importation of drugs into their states.

**ABSTRACT:** This continuing pharmacy education article will discuss the legal, political, and professional issues arising when patients import medications from Canada, Mexico, and other countries. Particularly, it will point out the risks to pharmacies, physicians, and other people who assist patients in importing medications.

Although there are limited circumstances under which the FDA allows licensed entities to import prescription medications, there are numerous legal issues that make personal importation of prescriptions illegal. This article will discuss how the FDA, state boards of pharmacy, state boards of medicine, and state attorneys general are reacting to the recent surge of personal importation of prescription drugs.

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## MAY YOU LEGALLY IMPORT MEDICATIONS FOR PERSONAL USE?

### Political and Economic Background

Millions of Americans cannot afford to purchase their prescription medications—and hundreds of companies are promising to help obtain those medications “inexpensively” from Canada, Mexico, or other foreign countries.

It is clear, however, that such practices are illegal. William A. McConagh, Associate Chief Counsel to the FDA, recently explained, “Virtually all drugs imported into the U.S. by or for individual U.S. consumers violate the law.”<sup>1</sup>

Although many people are unable to afford prescription drugs, importing them from Canada or Mexico is not the answer. Because of the potential public health issues, the FDA is very concerned about the importation of prescription drugs. It has found that many drugs obtained from foreign sources that purport and appear to be the same as U.S.-approved prescription drugs are of unknown quality. As a result, the FDA cannot provide adequate assurance to the American public that the drug products delivered to consumers in the U.S. from foreign countries are the same as products approved by the FDA.

Shipping prescription drugs to consumers in the U.S. may also violate state law. Among other things, many U.S. states require that before a pharmacy may ship drugs to a consumer within that state, it must be registered with, or licensed by, that state.

From a legal standpoint, businesses and individuals who 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 (FDCA), FDA regulations, Customs laws, Drug Enforcement Agency (DEA) regulations, and various state laws. Practically speaking, it is extremely unlikely that a pharmacy could meet all of the applicable legal requirements. Until Congress or the FDA changes the law,

<sup>1</sup> William A. McConagh, Esq., American Pharmaceutical Association Annual Meeting Presentation, “Importation of Prescription Drugs,” March 29, 2003.

pharmacists and their patients should not import prescription medications.

### **Rising Prescription Costs and the Impact on Uninsured Americans**

During these difficult economic times, rising prescription costs become even more apparent than when most Americans are living an abundant life. This is especially true for America’s seniors, the unemployed, and under-insured individuals who often struggle to pay for medically necessary prescriptions.

A recent national survey of employers found that the average cost of private health insurance premiums climbed 12.7 percent between 2001 and 2002, driven by increases in prescription drug and hospital costs.<sup>2</sup> In response, fewer small businesses are offering health insurance to their workers—and even fewer are offering coverage for prescription drugs. A 2002 survey of employers found that in companies with fewer than 200 workers, health coverage fell from 67 percent in 2000 to 61 percent in 2002. As a result of employers dropping health coverage, the aging of America, and an increase in the number of unemployed, the total number of uninsured Americans rose from 39.8 million in 2000 to 41.2 million in 2001, according to the most recent findings from the U.S. Census Bureau.<sup>3</sup>

The average American spent \$449 out of pocket for drugs, or 0.9 percent of his or her income, in 2001. The average out-of-pocket spending in terms of dollars and the percentage of income clearly rises with age.

<sup>2</sup> Kaiser Family Foundation and Health Research and Education Trust, “Employer Health Benefits: 2002 Summary of Findings,” August 2002.

<sup>3</sup> Census Bureau Center on Budget and Policy Procedures, “The Number of Americans Without Health Insurance Rose in 2001 and Appears to be Continuing to Rise in 2002,” October 8, 2002.

Senior citizen out-of-pocket costs have been rising rapidly. In 2001, the average senior citizen spent \$884 out of pocket for drugs, or 3.2 percent of his or her income, compared with the average \$444 or 2.2 percent spent by seniors ten years earlier in 1991.<sup>4</sup>

As pharmacists are already aware, people without insurance generally pay more for their prescriptions than those with insurance. A study by the U.S. Department of Health and Human Services (HHS) found that in 1999, cash-paying patients paid nearly 15 percent more than customers with prescription drug insurance. For 25 percent of the most commonly prescribed drugs, this price difference was even greater—over 20 percent more for patients paying cash.

Finally, medication costs in the U.S. far outpace those in other countries, and even other industrialized countries like Canada. In many countries, this is because the government sets price controls on prescription medications, a measure our free-market Congress appears to shun.

### **Political Movements to Legalize Importation**

Congress has long attempted to expand the legalization of importing prescription drugs to allow people other than manufacturers to import them. In fact, in 2000, it passed the Medicine Equity and Drug Safety Act (MEDS). If it were in effect, MEDS would have allowed drug wholesalers and pharmacists to reimport prescription drugs from certain countries for sale to American consumers. Supporters of the law had hoped that lower drug pricing in other countries could be passed along to consumers. However, the MEDS law never became

<sup>4</sup> Centers for Medicare and Medicaid Services, HHS, “Health Care Industry Market Update: Pharmaceuticals,” January 10, 2003.

effective. It required the HHS Secretary to certify that the reimportation would “pose no additional risk to the public’s health and safety” and would “result in a significant reduction in the cost of covered products to the American consumer.”

HHS Secretary Tommy Thompson and former HHS Secretary Donna Shalala both declined to make such findings. “Once a FDA-approved prescription drug is exported for sale in another country, it is no longer subject to U.S. requirements and it can no longer be monitored by U.S. regulators.” Secretary Thompson wrote in a letter to Sen. James Jeffords (I-Vt.), one of MEDS’s sponsors, “In addition, it may not have the U.S.-approved labeling. Instead it may have labeling for the country to which it is exported.” As a result, Congress’ attempt to legalize this non-manufacturer importation never came to pass.

Congress is still attempting to legalize limited importation of drugs from Canada, Mexico, and other industrialized nations. One proposal would allow pharmacists and wholesalers to import drugs from Canada.<sup>5</sup> Pharmaceutical manufacturers and pharmacy regulators believe that such activities would put at risk the “closed” system currently guarded by federal and, to some extent, state authorities. Without jurisdiction over foreign sellers, they believe it is, and will continue to be, impossible to ensure the products being sent to the U.S. are FDA approved, safe, effective, and not adulterated, contaminated, or counterfeit.

Another proposal seeks to fine drug manufacturers for refusing to ship medications to Canadian pharmacies that dispense to U.S. patients.<sup>6</sup> This Bill arose

<sup>5</sup> S. 7, 108th Cong., 1st Sess. (2003).

<sup>6</sup> H.R. 847, 108th Cong., 1st Sess. (2003).

after certain U.S. manufacturers refused to sell their products to Canadian pharmacies that they suspected were shipping medications to U.S. residents. Again, pharmaceutical manufacturers, the FDA, and the National Association of Boards of Pharmacy (NABP) oppose this Bill, as it penalizes drug companies for complying with the laws and regulations of the U.S. NABP has stated that it believes that “existing laws and regulations prohibiting the importation of unapproved drugs must be obeyed and enforced or changed to incorporate these products and pharmacies into the federal and state regulatory system. Access to medication through illegal means does not resolve the problem of access but only increases the chances of U.S. patients being harmed by unregulated entities.”

A third proposal would disallow certain tax deductions and credits for pharmaceutical manufacturers that “discriminate” against Canadian pharmacies that sell prescription drugs to U.S. patients.<sup>7</sup>

In June 2003, the Senate voted to allow limited importation of drugs from Canada. The House passed a different import measure in July 2003. As with many highly debated issues, the Senate and House Bills are miles apart, and will require much negotiation. But, even if the Senate and House can agree to a compromise Bill, it is highly unlikely it will ever become effective, as the FDA has strongly signaled that it will again block the implementation of any new importation law. As a result, there currently are only very limited ways that anyone may legally import prescription drugs from Canada or any other country.

**Legal Ways to Import Prescription Drugs**  
From a legal standpoint, companies that are involved in shipping prescription drugs to

<sup>7</sup> S. 477, 108th Cong., 1st Sess. (2003).

U.S. consumers must take many steps to ensure compliance with all of the laws that apply. These include the FDCA, Customs law, DEA law, and state law. Practically speaking, it is extremely unlikely that any pharmacy or individual consumer could ensure that all of the applicable legal requirements are met.

The FDA only permits prescription drugs to be imported into the U.S. after the importer has filed an entry notice and paid all necessary entry bonds with the U.S. Customs Services.<sup>8</sup>

Further, only certain medications may be imported into the U.S. Specifically, to be imported into the U.S., a prescription drug must be:

- (1) Approved by the FDA in the dosage form that is sought to be imported; and
- (2) Manufactured outside the U.S. in a facility approved by the FDA to manufacture that product.

Even if the chemical compound and dosage form have been approved by the FDA, the drug may not be imported if it was manufactured in the U.S. (and then imported outside of the U.S. and seeking to be reimported) or if it was manufactured outside of the U.S. in a facility not approved by the FDA to manufacture that particular product.

<sup>8</sup> Food and Drug Administration, Office of Regulatory Affairs, “Import Program System Information,” March 17, 1999 ([http://www.fda.gov/ora/import/ora\\_import\\_system.html](http://www.fda.gov/ora/import/ora_import_system.html)). See also, Food and Drug Administration, Office of Regulatory Affairs, “Information on Importation of Drugs Prepared by the Division of Import Operations and Policy,” April 3, 1998 (<http://www.fda.gov/ora/import/pipinfo.htm>).

In addition, if the drug is a controlled substance, the importer must hold a DEA import permit and must have DEA approval to import each individual shipment of that drug. The FDA may refuse admission to any drug that “appears” to be unapproved. This is because the FDA cannot assure that such products were properly manufactured and are safe and effective.

If a prescription drug is approved and manufactured in the U.S. but later exported to a foreign country, the drug’s original manufacturer may only reimport it. The FDA believes that, generally, any other drugs are either unapproved, incorrectly labeled, or dispensed without a valid prescription. Thus, their shipment into the U.S. violates the FDCA.

### **The Personal Use “Exception”**

The FDA is very concerned about the importation of prescription drugs for public health. It has found that many drugs obtained from foreign sources that appear to be the same as U.S.-approved drugs are of unknown quality. Because the FDA cannot be sure that the drugs delivered to U.S. consumers from foreign countries are the same products approved by FDA, they do not allow “personal use” importations. However, in very limited circumstances they can turn a blind eye to certain importations.

In its online Frequently Asked Questions (FAQs),<sup>9</sup> the FDA states:

### **12. Can an American patient get a medication not approved in the U.S. from a foreign dispenser?**

As a general matter, it is illegal to import an unapproved drug into the U.S. However, under the FDA’s personal importation policy, the FDA has authorized its inspectors to use their enforcement

discretion to allow U.S. residents to import certain products under certain limited conditions. Under this policy, the FDA may allow a U.S. resident to bring into this country an unapproved drug for his or her personal use for a serious condition, if there has been no commercialization or promotion of the drug to U.S. residents.

### **13. Is it illegal for a foreign pharmacy to ship prescription medicines into the U.S.?**

It is illegal for anyone, including a foreign pharmacy, to ship prescription drugs that are not approved by the FDA into the U.S., even though the drug may be legal to sell in that pharmacy’s country. Under the scheme that Congress established to ensure that drugs are safe and effective, drugs are tested and test results are thoroughly reviewed by FDA scientists. U.S. law also requires that products approved for sale in the U.S. have their formulation approved by the FDA, be made in a plant registered with the FDA, and be produced under quality standards enforced by the FDA.

Prescription drugs available from a foreign pharmacy that are products that the FDA has not approved; products with similar, but not identical formulations as FDA-approved products; products not made under the quality standards required by U.S. law or labeled according to U.S. requirements; or products not stored or distributed under the quality conditions required in the U.S. cannot be legally sold in the U.S.

As these FAQs make clear, virtually all shipments of prescription drugs imported from a foreign pharmacy will run afoul of the FDCA, although it is a theoretical possibility that an occasional shipment will not do so. Put differently, to ensure compliance with the FDCA when they are involved in shipping prescription drugs to consumers in the U.S., businesses and

<sup>9</sup> <http://www.fda.gov/oc/buyonline/faqs.html#faqs12>

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 FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container/closure system, and appearance. They must also ensure that each drug meets all U.S. labeling requirements, including bearing the FDA-approved labeling. Pursuant to a valid prescription, a pharmacist must dispense the drug.

Canadian or other foreign versions of U.S.-approved drugs are generally considered unapproved in the U.S. because 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. Frequently, a firm that manufactures and sells drugs outside of the U.S. does not have FDA approval for those drugs. Moreover, even if the manufacturer has FDA approval for a drug, the version that it produces for foreign markets usually does not meet all of the requirements of U.S. approval and, thus, it is considered to be unapproved.

In very limited circumstances, the FDA may turn a blind eye and not prohibit certain personal use importations. This is similar to a highway patrol officer's ability to choose not to give you a speeding ticket if you are going 56 mph in a 55 mph speed zone. The FDA has published a Guidance identifying situations where it may consider refraining from taking legal action against an individual importing for "personal use." The Guidance clearly states, "***It is not a license for individuals to import for***

***personal use.***"<sup>10</sup> The Guidance makes it clear that it does not apply to the following bulleted statements:

- Drugs manufactured in the U.S. that have been imported to Canada are now being sought to be "reimported"
- Drugs manufactured for foreign use. Often these drugs have different names, shapes, colors, etc. Almost always, drugs manufactured for foreign sale have different labeling and package inserts, which have not been approved by the FDA.
- Drugs that are manufactured in an unapproved facility or a facility that is not approved by the FDA to manufacture that specific product
- Drugs not approved in the U.S. In addition to the obvious new drugs that have not yet been approved by the FDA, this would include products that are over-the-counter in another country, but require a prescription in the U.S.

The FDA has stated that it will not apply the "personal use" discretionary exemption if it appears that the products are intended for the commercial market, if the products pose an unreasonable health risk, or where there are fraudulent products.

The FDA may only ***consider allowing*** personal use importation when:

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<sup>10</sup> Food and Drug Administration, Office of Regulatory Affairs, Regulatory Procedures Manual, "Subchapter: Coverage of Personal Importations," [http://www.fda.gov/ora/compliance\\_ref/rpm\\_new2/ch9pers.html](http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html).

1. The intended use is unapproved and for a serious condition, and *effective treatment is not available domestically* either through commercial or clinical means.
2. 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.
3. The product does not represent an unreasonable risk.
4. The person seeking to import:
  - (a) Affirms in writing that the product is for his or her own personal use;
  - (b) Generally is not seeking to import greater than a three months' supply; and
  - (c) Provides the name and address of the doctor supervising his or her treatment with that product.

After reviewing these factors, it becomes clear that the FDA may “turn a blind eye” if the medication was prescribed by a U.S. physician. This is because Factor 1 does not allow medications to be imported when an effective treatment is available in the U.S. In other words, foreign made versions of drugs available in the U.S. are not covered by this policy (unless the person seeking their importation can establish that s/he needs the drugs to refill a prescription while s/he is traveling or that, otherwise, s/he needs the drugs while traveling).

As a result, the only ways to import prescription medications into the U.S. are:

- (1) By an approved import company, that is, a facility

that is located outside the U.S. and approved by the FDA to manufacture FDA-approved drugs of that specific product. In this case, the importer must file an entry notice (and pay any applicable entry bonds) with the U.S. Customs Services; or

- (2) Non-FDA-approved drug products that do not have similar FDA-approved products that are available in the U.S. Technically, these products still may not be imported. However, the FDA may exercise its discretion and not prosecute an individual who seeks to import these products if they are for his or her own “personal use.”

#### **Sanctions by the FDA**

If someone violates the FDCA or does not meet all of the requirements for “personal use,” there are many ways one may be found civilly or criminally guilty. A court can enjoin violations of the FDCA. A person who violates the FDCA can also be held criminally liable. Those who aid and abet a criminal violation of the FDCA, or conspire to violate the FDCA, can also be found criminally liable.

There have been several recent enforcement actions by the FDA in response to companies that assist people in importing medications from foreign countries. The most common action is to issue a “cease and desist letter,” sometimes also called a “cyberletter.” For example, a November 15, 2001, letter to CanadaRx warns that the marketing and sale of a drug product containing ciprofloxacin may be in violation

of 21 U.S.C. §§331(a), 331(d), and 355(a).<sup>11</sup> This is because “the ciprofloxacin offered for sale . . . does not meet the criteria in the FDA’s personal use policy, at least in part, because an approved version (Cipro®) is available in the U.S.”

The FDA could use such an enforcement action against a company advertising to assist people in importing drugs from foreign companies and against Canadian pharmacies that ship medications into the U.S. In addition, individuals have been sentenced to federal prison for operating businesses that assist people in obtaining mail-order prescriptions from foreign pharmacies.<sup>12</sup> In the Haas case, an individual who operated North American Pharmaceutical Services, Inc. (NAPS) was convicted of multiple conspiracy charges involving fraud and other illegal conduct relating to FDA regulations. He was also convicted of aiding and abetting others involved in the illegal conduct and introduction of misbranded drugs into the U.S. with the intent to defraud.

NAPS operated a mail-order business that advertised in the U.S. that it could supply pharmaceutical drugs at prices lower than average wholesale prices because of the “benefits of international trade.” To do this, NAPS helped people purchase drugs from a Mexican pharmacy and then NAPS transported the filled prescriptions into the U.S. Neither NAPS nor its customers declared the importation to customs. In short, NAPS had two different facilities, one

in San Antonio, Texas, and another in Nuevo Laredo, Mexico. Patients would mail prescriptions to NAPS’s San Antonio headquarters. NAPS employees would then transmit the prescriptions to the Mexican pharmacy where the prescriptions would be filled and mailed to the U.S. customer. Later, NAPS, instead of mailing the prescriptions over the international border, would have employees transport the final product across the border and then drop it into the mail once inside the U.S.

The Court found that although these medications could have been imported for “personal use” if they had been individually imported by the people, Haas’s activities constituted “commercial importation.” As a result, NAPS’s actions were found to violate the importing laws, and the FDA did not have discretion to turn its head under the “personal use” Guidance, leading to federal jail sentencing for Mr. Haas.

### **Board of Pharmacy Issues**

Currently, 44 states require non-resident pharmacies to be licensed or registered with the Board of Pharmacy before shipping or mailing prescription medications to patients in those states. (See Table 1, below.) For example, the NABP’s Model State Pharmacy Act, Section 501, provides that “Persons located outside this State that provide services to patients within this State shall be licensed by the Board of Pharmacy and shall annually renew their license with the Board.” As a result, Canadian pharmacies must be registered as non-resident pharmacies before shipping prescriptions into those 44 states.

<sup>11</sup> Food and Drug Administration letter to Target Zone dated Nov. 15, 2001 (<http://www.fda.gov/cder/warn/cyber/2001/ciproltr126.pdf>).

<sup>12</sup> United States v. Haas, 171 F.3d 259 (5<sup>th</sup> Cir. March 29, 1999) (<http://caselaw.lp.findlaw.com/scripts/getcase.pl?navby=5th&court=5th&no=97-41335>).

**Table 1**  
**State Boards of Pharmacy Requiring Non-Resident Pharmacy Licensure or Registration**

Alabama	Illinois	Missouri	Oregon
Alaska	Indiana	Montana	Rhode Island
Arizona	Iowa	Nebraska	South Carolina
Arkansas	Kansas	Nevada	South Dakota
California	Kentucky	New Hampshire	Tennessee
Colorado	Louisiana	New Mexico	Texas
Connecticut	Maine	New York	Utah
Delaware	Maryland	North Carolina	Virginia
Florida	Michigan	North Dakota	Washington
Hawaii	Minnesota	Ohio	West Virginia
Idaho	Mississippi	Oklahoma	Wyoming

Most state boards will only license pharmacies located in the U.S. However, an August 2002 survey of the state boards indicated that nine states' laws and regulations were broad enough to allow those state boards of pharmacy to register foreign pharmacies.<sup>13</sup> The dichotomy of providing legal recognition to an entity violating federal law has prevented any state from registering foreign pharmacies.<sup>14</sup> Additionally, the enforcement of a state action or the initiation of a mutual action by a foreign licensing body is virtually unheard of, making it difficult, if not impossible, for state actions to have any effect on foreign pharmacies.

In addition, most of these states also prohibit any advertising by a pharmacy not licensed by the Board. Therefore, an order sheet that lists a pharmacy's name or advertises the sale of prescription drugs may violate these

<sup>13</sup> National Association of Boards of Pharmacy, *Canadian Drug Imports to the United States*, 31 NABP Newsletter, 97 (2002).

<sup>14</sup> Although reports received by NABP on March 12, 2003, indicate that the Rhode Island legislature is considering such action, a move opposed by the Rhode Island Board of Pharmacy.

laws. Most of these statutes also prohibit any entity not licensed as a pharmacy from using words or symbols related to pharmacy. For example, Ohio prohibits the use of the words (or their equivalent)—pharmacy, drugs, drug store, pharmacist, druggist, pharmaceutical chemist, apothecary, drug sundries, and medicine.<sup>15</sup>

<sup>15</sup> Ohio Rev. Stat. §4729.36(A). Arizona similarly prohibits the use of such words. Ariz. Rev. Stat. § 32-196(B)(2) prohibits any business other than a pharmacy from offering drugs for sale at retail.

- A. It is unlawful for any person to manufacture, compound, sell, or dispense any drugs or to dispense or compound the prescription orders of a medical practitioner, unless he is a pharmacist, except as provided in 32-1921. This subsection does not prevent a pharmacy technician or support personnel from assisting in the dispensing of drugs if this is done pursuant to rules adopted by the Board and under the direct supervision of a licensed pharmacist.
- B. It is unlawful for any person, without placing a pharmacist in

Some states also prohibit a pharmacy from filling a prescription when the pharmacist knows or should know that a valid physician-patient relationship has not yet been formed. For example, California-licensed pharmacies, including non-resident pharmacies shipping medications to California residents, are prohibited from filling prescriptions that were “not issued pursuant to a good faith prior examination.”<sup>16</sup> While other states may not have a similar statute or regulation, those Boards may take the position that a non-resident pharmacy has pharmacists that are filling prescriptions that they know are not written pursuant to a good faith prior examination constitute negligent practice of pharmacy. Therefore, the Board of Pharmacy could seek an enforcement action against any persons related to such a venture.

Finally, boards of pharmacies may sanction entities and people who ship prescriptions into the state from a foreign country on the theory that those medications are either misbranded or adulterated. Medications are considered to be misbranded if they are

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active personal charge at each place of business, to:

1. Open, advertise, or conduct a pharmacy.
2. Stock, expose or offer drugs for sale at retail, except as otherwise specifically provided.
3. Use or exhibit the title “drugs,” “drugstore,” “drug shop,” “pharmacy,” “apothecary,” or any combination of such words or titles or any title, symbol, or description of like import or any other term designed to take its place.

<sup>16</sup> Cal. Bus. & Prof. Code §4067(a).

either (a) not approved in the U.S., (b) manufactured in a factory that is not approved by the FDA (even if the chemical product has been approved by the FDA), or (c) have been exported from the U.S. and are then reimported.

### **Board of Medicine Issues**

In addition to problems with Boards of Pharmacies, companies filling prescriptions in Canada may have problems with U.S. Boards of Medicine. Canadian physicians must write (or rewrite) the prescriptions for them to be filled at a Canadian pharmacy; Canadian pharmacies may only fill prescriptions written by Canadian-licensed prescribers. Most states consider a physician who is prescribing to patients to be “practicing medicine” in the state where the patient is located. As a result, the patient’s State Board of Medicine must license the Canadian physician in addition to the Province where the Canadian physician is physically located. If not licensed by the patient’s state, the Canadian physician may be convicted of unauthorized practice of medicine, and individuals who assist him in such action may be indicted for conspiracy.

Most states either have a statute, regulation, or policy statement that requires prescribers to have a valid physician-patient relationship before the physician prescribes medications. Generally, this means that the prescriber must obtain a history, complete a physical examination, and prescribe medications that have a logical connection to the patient’s physical complaint. As a result, a Canadian physician looking at a prescription written by a U.S. doctor and reviewing a patient’s attestation that s/he has received a physical examination does not meet these requirements. So, even if the Canadian physician were licensed both in Canada and in the state where the patient was located, most states would not allow him to prescribe without physically examining the patient.

As an example, Ohio law specifically prohibits physicians from prescribing medications unless they have personally examined the patient. “Except in institutional settings, on-call situations, cross coverage situations, situations involving new patients, protocol situations, and situations involving nurses practicing in accordance with standard care arrangements, a physician shall not prescribe, dispense, or otherwise provide or cause to be provided any dangerous drug that is not a controlled substance to a person who the physician has never personally physically examined and diagnosed. Except in accordance with the following requirements: (1) the physician is providing care in consultation with another physician who has an ongoing professional relationship with the patient and who has agreed to supervise the patient’s use of the drug or drugs to be provided; and (2) the physician’s care of the patient meets all applicable standards of care and all applicable statutory and regulatory requirements.”<sup>17</sup>

Another example can be found in Arizona, where it is considered to be “unprofessional conduct” for a physician to prescribe without physically examining the patient in most circumstances:

25. “Unprofessional conduct” includes the following, whether occurring in this state or elsewhere. . . .

(ss) Prescribing, dispensing or furnishing a prescription medication or a prescription-only device . . . to a person unless the licensee first conducts a physical examination of that person or has previously established a doctor-patient relationship. This subdivision does not apply to these statements below:

<sup>17</sup> Ohio Admin. Code §4731-11-09(B).

(i) A physician who provides temporary patient supervision on behalf of the patient’s regularly treating, licensed, health care professional

(ii) Emergency medical situations as defined in section 41-1831

(iii) Prescriptions written to prepare a patient for a medical examination<sup>18</sup>

Other states may sanction a prescriber even if there is not a specific law prohibiting prescribing without a physical examination. For example, the Illinois Department of Professional Regulation has relied upon its Board of Medicine’s professional conduct rules. These rules require the Board to sanction a physician for a breach in the physician’s responsibility to a patient or for engaging in activities unreasonably likely to cause harm to any member of the public, including failure to physically examine a patient before prescribing.<sup>19</sup>

#### **State Consumer Protection Law**

States have also begun to prosecute pharmacies, physicians, and companies assisting individuals in obtaining medications from foreign countries through their state consumer protection laws. Under these laws, the states theorize that the perpetrators are using “unconscionable tactics” and false advertising. Some of the theories include the following statements: the foreign medications are not the same as the FDA-approved medications, which are available for sale in the U.S.; using statements or implying that importing is “legal”; implying that prescriptions written by a physician who has no relationship with the patient is sufficient; and promoting and

<sup>18</sup> Ariz. Rev. Stat. § 32-1401(25)(ss).

<sup>19</sup> Ill. Admin. Code tit. 68 §1285.240.

selling adulterated and misbranded drugs within the state will harm state residents.

### **Other General Criminal Laws That May be Implicated**

In addition to the regulatory actions that we have discussed above, indictments have been handed to individuals involved in assisting people obtain medications from foreign countries under the theories of conspiracy, mail fraud, wire fraud, and drug trafficking.

### **Canadian Law**

The American Pharmacists Association (APhA), the Canadian Pharmacists Association (CPhA), and over 40 other pharmacy associations and colleges of pharmacy have endorsed a landmark Cross-Border Communiqué between the U.S.-based NABP and Canadian National Association of Pharmacy Regulatory Authorities (NAPRA). The communiqué addresses the issue of illegal importation of prescription drugs from Canada into the U.S.

In the Communiqué, NABP and NAPRA agreed that the international movement of prescription drugs between Canada and the U.S. undermines the regulatory systems established in each country to protect consumers. Further, the groups pointed out that businesses, individuals, and organizations that facilitate prescription drug importation for U.S. consumers are encouraging the violation of federal and state laws in the U.S., which are designed to protect the health and safety of its citizens. They identified the negative implications for both patient safety and the practice of pharmacy on both sides of the border caused by the illegal importation of prescription drugs from Canada into the U.S.

NABP and NAPRA pledged “to work together to protect the citizens each are mandated to service and to promote

compliance with the federal, state, and provincial laws and standards of Canada and the U.S., to ensure patient safety and integrity of the prescription drug supply in their respective jurisdictions.”

“The U.S. and Canada each have regulatory systems in place to protect consumers,” stated John A. Gans, Pharm.D., Executive Vice President of APhA. “However, illegal importation undermines these regulatory systems. Most important is the severing of the bond between the individual patient and his or her pharmacist. The pharmacist, whether practicing in the U.S. or Canada, is responsible for the patient’s medication management. Medications are powerful; that’s why they work. There can be adverse reactions between one prescription medication and another—as well as over-the-counter medications and dietary supplements. The patient’s physical condition; ability to effectively understand and comply with a medication regimen, level of physical activity, diet, and other lifestyle issues come into play.” Gans noted, “Patient safety is primary to pharmacists, and illegal importation that threatens that for patients must be addressed through active law enforcement.”

Jeff Poston, Executive Director of CPhA, stated, “We strongly share this concern. This is why Canadian pharmacists support the joint commitment of NAPRA and NABP to address this illegal practice by encouraging enforcement to ensure patient safety. Again, illegal importation severs the key pharmacist-patient relationship. Safe and effective medication management by pharmacists is enormously compromised when prescription drugs are treated as just another retail commodity, as opposed to the powerful medications they are. Patients may be dealing with multiple acute and chronic illnesses, as well as the lifestyle issues. Medications can alter the workings

of the body and the mind. It's quite different from simply shopping online for books or CDs.”

In addition to the negative implications to U.S. citizens, shipping drugs from Canada to the U.S. has negatively impacted Canadians. Several drug companies are refusing to sell their drugs to Canadian pharmacies that ship into the U.S. This has adversely affected certain cities' ability to supply Canadians with certain drugs.

### **Conclusion**

Although many companies advertise otherwise, pharmacies and individuals may not legally import prescription medications from foreign countries. True, the FDA may, in very limited circumstances, turn a blind eye to importations for “personal use,” but

even then, other regulatory concerns exist. State boards of pharmacy often require licensure in their state. State boards of medicine require physicians to be licensed and to physically examine the patients.

It appears that the only solution lies with the federal legislature. If Congress enacts a law that would protect Americans while allowing the import of less expensive foreign medications, the problem would be resolved. However, as all other tough issues, it appears that a resolution is a long way off. For now, pharmacists should advise their customers that importing prescription medications is illegal.