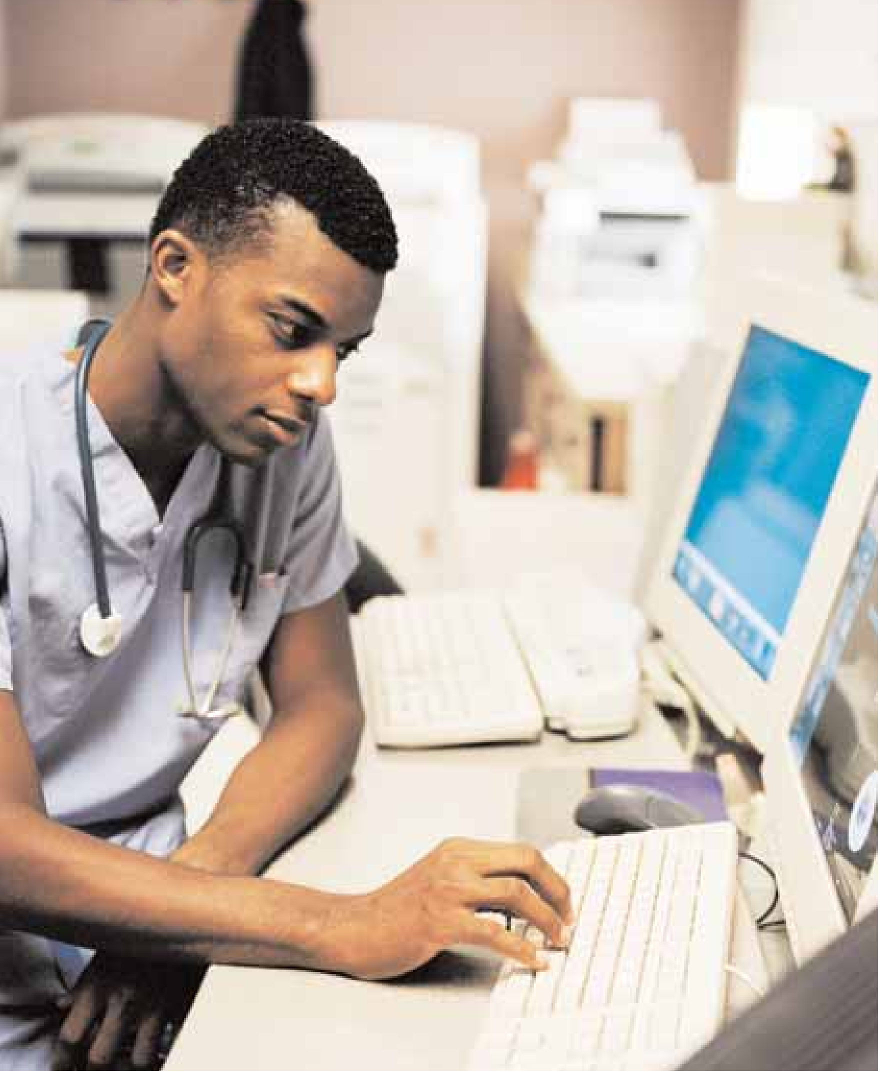

Prescription Drug Importation Gains Momentum

By Irakli Khodeli

Escalating prescription drug prices have prompted some state and local government officials to explore importing prescription drugs from Canada and Europe to save money. Officials in at least 13 states and seven municipalities have expressed interest in the idea or have acted to import less expensive Canadian medications for their public assistance and employee benefit programs.

Although state and local drug importation programs currently violate federal law, the federal government has not acted to halt existing programs. And federal policy on the subject may change in the near future. On May 5, 2004, U.S. Health and Human Services Secretary Tommy Thompson said he would ask President Bush to "not stand in the way" of importation legislation if it emerges from continuing Senate deliberations. Several bills are pending in Congress to permit drug imports from Canada and elsewhere. If a drug importation bill passes, more states and localities may pursue this option soon.

The primary reason for importing prescription drugs from foreign countries is to save money – for state and local governments, for individuals who receive health care through them, and for uninsured residents who may otherwise be unable to afford prescription drugs. State estimates of potential savings from drug importation programs include $90.7 million in total savings for Illinois, $10.4 million for Massachusetts and $1.6 million for New Hampshire. Since many brand name drugs are less expensive in Canada and elsewhere than in the United States, advocates claim that importing drugs or helping individuals access foreign supplies should be a legitimate strategy for coping with escalating prices.

Major Issues of Concern

Drug importation or re-importation (importing drugs that were originally manufactured in the United States for sale in a foreign country) poses several potential risks and unanswered questions:

- *Legality*—Although political pressure is building for a change in federal policy, importing most prescription drugs currently violates federal law, along with many state laws and regulations regarding pharmacy registration and licensing.
- *Safety*—Critics claim that importing prescription drugs heightens the risk to U.S. consumers because foreign drugs may not meet the U.S. Food and Drug Administration standards. Moreover, it heightens the possibility of counterfeit medications and other dangerous substances entering the U.S. market, increases the risk of unsupervised use of certain medications, and poses risks to consumers who receive drugs with labels in foreign languages.
- *Liability*—The question of who is liable for the safety of imported drugs remains unanswered. State and local governments that support importation may find themselves embroiled in litigation.
- *Feasibility*—Some analysts believe that importation programs are not feasible or sustainable in the long run. Proponents, they argue, underestimate the true costs and overestimate the amount of money state and local governments would actually save. In addition, some analysts question whether the supply of foreign drugs is adequate to meet U.S. demand—especially given drug manufacturers' recent

efforts to restrict supply to Canadian pharmacies that export drugs to the United States.

Policy Options

States that plan to pursue importation of foreign prescription drugs can take steps to enhance consumer safety, ensure the program's feasibility and minimize government liability. States can also amend their laws to allow legal operation of foreign drug stores on their territories.

Ensuring drug safety. States with proposed or existing drug importation programs have addressed safety concerns primarily by promoting quality assurance and by offering participants guidance and supervision by pharmacists. In order to promote quality assurance, states can specify the types of production facilities from which the imported drugs will originate, and inspect foreign pharmacies before offering their services to state residents. In addition to securing safe production facilities and transit routes, states can conduct random drug inspections once the medications arrive in the state. To promote regular contact between consumers and their pharmacists, Illinois' importation plan introduces the concept of a primary care pharmacist. Patients schedule regular visits with a druggist for consultation and guidance regarding the imported medications.

Addressing legal issues. While the federal regulatory changes that would allow state importation programs to operate legally are in the hands of Congress, states have the ability to make their pharmacy licensing and registration regulations more flexible to allow the legal importation of Canadian drugs under state laws. Currently, 42 states require nonresident pharmacies to register with or be licensed by a state board of pharmacy before they can ship prescription drugs to residents of that state. Only a few of these states have laws and regulations that are broad enough to allow for licensing foreign pharmacies.

In addition, in order to avoid violating U.S. patent protections on drugs that have expired patents abroad, states can exclude such drugs from importation programs.

Determining feasibility. Producing a valid, reliable and realistic estimate of how much money states can save by importing drugs is of paramount importance. States already enjoy substantial savings as a result of pooled purchasing and the various drug manufacturers' discount and rebate programs. If the true amount of potential savings is not substantially greater than the current discounts, the additional costs of monitoring for safety and ensuring against liability may render the logic of drug importation untenable.

States can take several steps to produce reliable estimates of financial savings: calculate savings based on participation rates that reflect the current mail-in participation rate of state beneficiaries, at least for the first year of the program; account for all additional costs associated with drug importation, including shipping, liability and implementing safety measures; and rely on the comparison of median drug prices in the United States and abroad to arrive at more accurate price differences.

Protecting against liability. Because determining liability is a very fact-specific inquiry, the absence of a legal precedent makes it difficult to evaluate the potential legal and financial liability for states that broker imported medications. Most state Web sites that link consumers to Canadian pharmacies include explicit disclaimers. Wisconsin, for example, warns patients that the state "makes no representation as to the legality of the importation or re-importation of pharmaceuticals from Canada, and it expressly disclaims any and all liability from such importation or re-importation or the use of any products so acquired." Similarly, many Canadian drug stores require people to sign waivers of the pharmacy's legal responsibility for the quality and effectiveness of the drugs sold.

Although such waivers may partially insulate participating governments from legal liability, they make consumer recourse difficult in cases of defective medication.

Continued growth in prescription drug spending and a growing number of uninsured citizens are challenging state and local governments to come up with effective solutions to rising prescription drug costs. Importing drugs from Canada and possibly from Europe is a trend that is rapidly gaining popularity among state and local officials. Before pursuing this option, however, state decision-makers should consider the legality, safety, liability and feasibility of importation programs to evaluate the potential risks and benefits.

TrendsAlert: Prescription Drug Importation explores the recent trends in state efforts to import medications, and provides an overview of related issues and policy options. The full report is available at *www.csg.org* (keyword: importation).

—Irakli Khodeli is a research assistant at The Council of State Governments.

State Drug Importation Programs

State	Stage	Estimated Annual Savings
Minnesota	Operating	$1.5 million
North Dakota	Operating	Not available
New Hampshire	Operating	$1.6 million
Rhode Island	Operating	Not available
Wisconsin	Operating	$70 million to $100 million
Connecticut	Planning	Not available
Illinois	Planning	$90.7 million
Iowa	Planning	Not available
Michigan	Planning	Not available
Massachusetts	Planning	$10.4 million
Ohio	Planning	Not available
Vermont	Planning	Not available
West Virginia	Planning	Not available