

# Prescription Drug Importation

## Trends *Alert*

Critical information for state decision-makers



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# **Prescription Drug Importation**

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The Council of  
State Governments

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## Executive Summary

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.<sup>1</sup> Several bills are pending in Congress to permit drug imports from Canada and elsewhere.<sup>2</sup> 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. 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.

However, 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.

In spite of the many gray areas and unanswered questions, several states have forged ahead with plans to import prescription drugs, while taking steps to enhance consumer safety, ensure the programs’ feasibility and minimize government liability. This *TrendsAlert* addresses these issues, describes the existing models for state and local government importation programs, and outlines steps states can take to realistically evaluate the potential risks and benefits of such programs.

## 1. Current Trends

By May 2004, officials in at least 13 states and seven municipalities had expressed a desire to broker various arrangements to import cheaper medications from Canada for state public assistance and employee benefit programs. In fact, New Hampshire, Minnesota, Wisconsin, Rhode Island and North Dakota have already launched state Web sites that help consumers order prescriptions online from approved Canadian pharmacies. The cities of Springfield, Mass.; Montgomery, Ala. and Burlington, Vt. also operate voluntary mail-in programs that supply municipal workers and retirees with prescription medications from Canada.

### Cost Savings of Prescription Drug Importation

Drug importation programs are designed to save money for three different types of payers:

- state or local governments that spend money on drugs for their employees and retirees, inmates at correctional facilities and various public assistance programs;
- people who receive some type of coverage under a state- or city-administered program (health benefits for public workers and retirees and beneficiaries of special assistance programs); and
- uninsured residents, who face the highest out-of-pocket expenses for medications.

#### *Cost Savings for States*

The main reason states are pursuing prescription drug importation is to save money. Most drug importation initiatives are designed to do this by controlling public spending in categories such as corrections health care, health care assistance for public employees and retirees and special prescription drug assistance programs. No state has yet attempted to apply the logic of drug importation to Medicaid, because state Medicaid programs already get large discounts for drugs they purchase in the United States.<sup>3</sup>

State and local leaders expect to save money by helping individuals access cheaper prescription drugs from foreign countries. Most state governments, for example, assist active and retired state employees with purchasing prescription drugs. If eligible beneficiaries switched from higher-priced pharmaceuticals available at U.S. pharmacies to cheaper drugs imported from abroad, state spending on pharmaceuticals could decrease.

However, estimates of just how much states and individual consumers could save are widely disputed. A report commissioned by Illinois Gov. Rod Blagojevich, for example, estimated that the state's proposed program to contract with Canadian and European clearinghouses would save \$90.7 million (\$56.5 million for the state and \$34.2 million for state employees and retirees). Critics, however, dispute the estimate, which presumes that 100 percent of the eligible state employees and retirees would participate. The program would waive co-payments for participants (\$14 a month per prescription and \$28 a month for prescriptions not listed in the state formulary), which proponents say would be a sufficiently powerful incentive for near-full participation.

Massachusetts spends \$187 million annually on 3.7 million prescriptions for its eligible beneficiaries, \$67 million of which goes to U.S.-based mail-order pharmacies.<sup>4</sup> Estimates based on price differences for the 28 most commonly prescribed medications and a current mail-order participation rate of 18 percent indicate that switching to a Canadian drug supply could result in \$12.3 million in gross savings.<sup>5</sup> Only a small portion of these savings, however, would remain with the state. Like Illinois and other states, the proposed program would waive co-payments as an incentive for customers to mail-order drugs from Canada. These waivers would save \$9 million for state workers and retirees who buy prescription drugs, but would also decrease potential savings to the state budget by the same amount.<sup>6</sup> The state would also lose \$1.9 million in rebates currently offered by U.S. drug manufacturers. After these deductions, savings to the state coffers would shrink to \$1.4 million.<sup>7</sup>

#### *Cost Savings for Individuals Participating in Government-Administered Programs*

As indicated above, a significant share of the savings from proposed importation arrangements would benefit government employees and retirees. The savings would come from co-payment waivers offered

by government plans as an incentive to participate. Illinois' plan, for instance, assumes that 38 percent of total savings will go to state employees and retirees, while the city of Springfield, Mass., estimates that 70 percent of total savings will go to municipal workers and retirees.<sup>8</sup>

### *Cost Savings for the Uninsured*

Another group that could benefit from drug importation is the uninsured. Regardless of race and ethnicity, about half of the U.S. working-age uninsured population with chronic conditions face financial barriers to accessing prescription drugs.<sup>9</sup> According to a recent survey, 27 percent of the uninsured reported not purchasing a needed prescription medication, compared to 10 percent of those with drug coverage.<sup>10</sup>

For millions of Americans who lack any kind of drug coverage and pay for their prescriptions out-of-pocket at the full retail price, the availability of cheaper products may open access to needed medication that they cannot afford under U.S. pricing.

### **Types of Importation Programs**

In order to take advantage of potential cost savings, states and localities have at least three options in designing drug importation programs:

- Government officials may act as brokers.
- Government officials may contract directly with drug suppliers.
- Government officials may set up a Web site to help residents find foreign pharmacies.

At the highest level of government involvement, a state or local government acts as a broker between foreign distributors and consumers. In this arrangement the state compiles a list of medications it deems most important to save money, negotiates with foreign wholesalers for the best price and imports the drugs to a central repository for distribution to local pharmacies. The advantage of this approach is the state's enhanced ability to monitor the safety of imported medications. For instance, the plan may include random testing of imported medications at state laboratories or universities. There are disadvantages as well, such as potentially greater legal liability and administrative costs than those associated with other types of drug importation programs.

Illinois' drug importation plan includes a central repository where state employees and retirees will be able to refill certain prescriptions with imported medications. To safeguard quality, the drugs will be randomly inspected by pharmacists at the University of Illinois to ensure against counterfeited or expired products. In addition, the plan provides beneficiaries with access to a local "primary care pharmacist" for consultations, and the state will waive participants' co-payments as an incentive to participate.

A second option is for the government to contract directly with foreign suppliers. The Springfield, Mass. city government, for example, has contracted with CanaRx Services Inc. to allow public employees, their dependents and city retirees to import long-term prescription medications via mail order from Canada. Beneficiaries send their prescriptions to the company, which fills them at participating Canadian pharmacies, sends the drugs directly to the buyers and bills the city. Like Illinois, the city is waiving co-payments to encourage participation.

A third option with less direct government involvement is the establishment of a state Web site to help consumers find safe and legitimate Canadian online pharmacies. This option may reduce the state's legal liability and eliminates administrative costs, but at the same time it increases the possibility of safety breaches, such as counterfeit, expired or diluted medications entering distribution channels. Five states – New Hampshire, Minnesota, Wisconsin, Rhode Island and North Dakota – already operate such Web sites. States pursuing this option offer financial incentives, such as co-payment waivers, to state beneficiaries for switching to Canadian online pharmacies for their prescription drug needs.

Minnesota, for example, established a Web site through which residents can buy prescription drugs from Canadian pharmacies at a state-negotiated price. The state chooses pharmacies that meet state safety standards, and consumers without access to a computer can order by phone.

**Table 1.1 State Drug Importation Plans and Programs**

| State         | Stage     | Description   | Estimated Annual Savings  |
|---------------|-----------|---|---|
| Minnesota     | Operating | State-run Web site lists Canadian pharmacies and provides order forms. More information at <a href="http://www.state.mn.us/cgi-bin/portal/mn/jsp/home.do?agency=Rx">www.state.mn.us/cgi-bin/portal/mn/jsp/home.do?agency=Rx</a>   | \$180 a year per drug for employees; \$1.5 million for the state                    |
| North Dakota  | Operating | State Web site provides a link to a pharmacy in Winnipeg, Manitoba.   | Not available   |
| New Hampshire | Operating | Stage I: State-sponsored Web site provides access to Canadian Internet pharmacies certified by the state as safe.   | Not available   |
|               | Planning  | Stage II: State will purchase Canadian drugs for the Department of Corrections, retired state workers and mental illness drugs for Medicaid patients. More information at <a href="http://nh.gov/governor/prescription/faq.html">nh.gov/governor/prescription/faq.html</a>  |   |
| Rhode Island  | Operating | State Web site provides a link to Wisconsin's Web site. More information at <a href="http://www.state.ri.us/rirx">www.state.ri.us/rirx</a>  | Not available   |
| Wisconsin     | Operating | State-supported Web site provides a link to Canadian pharmacies. State inspectors visited three Canadian pharmacies that are now listed on a state government Web site. The state's role is limited to facilitating Internet contact. More information at <a href="http://www.drugsavings.wi.gov">www.drugsavings.wi.gov</a> .  | \$70 million to \$140 million total savings.  |
| Connecticut   | Planning  | A pilot program would allow the state's ConnPace drug program for low-income elderly and disabled residents to purchase prescription drugs from Canadian pharmacies.  | Not available   |
| Illinois      | Planning  | State will contract with Canadian and European clearinghouses. State employees and retirees will be able to go to a central repository for refills on certain prescription medications approved by the state as safe for importation. Imported drugs will be randomly inspected by pharmacists at the University of Illinois at Chicago to ensure against counterfeited or expired products. Co-payment waivers will be offered for program participants, who will have access to local "primary care pharmacists" for consultations. | \$90.7 million total savings  |
| Iowa          | Planning  | State-supported Web site provides a link to Canadian pharmacies.  | Not available   |
| Michigan      | Planning  | State-supported Web site provides a link to Canadian pharmacies.  | Not available   |
| Massachusetts | Planning  | State-run pharmacy benefits manager will advise and guide residents in purchasing drugs from Canada, but will not serve as an intermediary.   | \$9 million savings for 250,000 employees and retirees; \$1.4 million for the state |
| Ohio          | Planning  | State-supported Web site provides a link to Canadian pharmacies.  | Not available   |
| Vermont       | Planning  | State-supported Web site provides link to Canadian pharmacies.  | Not available   |
| West Virginia | Planning  | State-supported Web site provides link to Canadian pharmacies.  | Not available   |

**Table 1.2 Local Drug Importation Plans and Programs**

| City                    | Stage     | Description  | Estimated Annual Savings |
|-------------------------|-----------|--|--------------------------|
| Burlington, Vt.         | Operating | BurlingtonMeds is an optional mail-order program designed for city employees and their dependents. Participants who order a three-month supply of medication from Canada receive co-payment waivers.   | \$100,000 to \$200,000   |
| Montgomery, Ala.        | Operating | A voluntary mail-order program to obtain Canadian drugs for city employees and retirees through a Texas-based company. Participation rate is between 7.5 percent and 10 percent.   | \$0.5 million            |
| Springfield, Mass.      | Operating | Springfield Meds contracts with CanaRx Services to allow public employees, their dependents and city retirees to import long-term "maintenance" prescription medications via mail order from Canada. Participants send their prescriptions to CanaRx, which fills them at participating pharmacies, sends the drugs directly to the buyers and bills the city. To encourage participation, there is no co-pay. Participation rate is approximately 15 percent. | \$2 million              |
| Boston, Mass.           | Planning  | Pilot program for city workers and retirees will begin July 2004.  | \$1 million              |
| Cambridge, Mass.        | Planning  | Pilot program for city workers and retirees.   | Not available            |
| Oak Creek, Wis.         | Planning  | Program for city employees and retirees.   | \$100,000                |
| Palm Beach County, Fla. | Planning  | Program for city workers and retirees.   | \$175,000                |

## 2. Issues Related to Drug Importation

When deciding whether or not to implement a prescription drug importation program, state decision-makers must weigh four major issues:

- *Legality* – possible repercussions of violating the existing regulations against drug importation;
- *Safety* – potential health risks to U.S. consumers associated with importing foreign medications;
- *Liability* – determining who is civilly, criminally and financially liable in importing drugs from abroad; and
- *Feasibility* – a need for accurate and evidence-based projections of net savings, as well as long-term sustainability of drug importation schemes

### Legality

The most striking issue related to state and local drug importation programs is the fact that they violate federal law. State and local initiatives to import prescription drugs from abroad raise three types of major legal issues:

- compliance with the existing federal regulations regarding drug importation;
- conformity with state pharmacy licensing regulations; and
- agreement with national and international patent laws.

### Federal Law

Current federal law regulating importation of pharmaceutical products – the Federal Food, Drug and Cosmetic Act – permits only the manufacturers to import drugs, including drugs originally produced in the United States and exported to a foreign country. The imported drugs must be produced by facilities that meet the Food and Drug Administration’s Good Manufacturing Practices.<sup>11</sup> The FDA is a federal agency in the Department of Health and Human Services that is charged with protecting public health through

approving safe products for the consumer market and preventing unsafe foreign products from entering the market.

Importation or re-importation of prescription drugs from foreign countries generally violates one or more provision of the Federal Food, Drug, and Cosmetic Act:

- *21 USC 355* – prohibits introducing non-FDA approved medications into interstate commerce, including foreign versions of U.S. approved drugs and U.S. manufactured drugs intended for foreign markets;
- *21 USC 353 (b) (2)* – prohibits dispensing a drug without proper labeling;
- *21 USC 331 (a), (d), (i)* – prohibits marketing misbranded, adulterated or counterfeit drugs; and
- *21 USC 381 (d) (1)* – prohibits re-importing drugs from foreign markets except for the drug manufacturer.<sup>12</sup>

Because the FDA must approve prescription drugs sold in the United States before they enter the market and most drugs from abroad generally do not meet this requirement, the FDA regards state and municipal importation plans as illegal. Federal authorities view states' attempts to import cheaper medication as a breach of the United States' "closed" production and distribution system.<sup>13</sup>

The FDA has threatened legal action against state and local governments involved in importing drugs.<sup>14</sup> However, federal agencies have so far refrained from actually prosecuting state officials for helping their residents obtain these medications. Instead, the FDA has met with state officials who are considering importation to warn them about safety concerns and legal liability. According to the FDA, the strategy has succeeded in Midwestern states such as Iowa, which have explored the option but have chosen not to pursue it.<sup>15</sup>

The FDA has not aggressively enforced the ban on prescription drug importation for two primary reasons. First, the customs and border inspectors who are on the front line of federal law enforcement are reluctant to deny elderly and needy Americans access to cheaper medications.<sup>16</sup> Second, top FDA officials contend that inspecting every package at the border and in the mail is impossible because of the sheer volume. The agency is already stretched thin in meeting anti-terrorism and homeland security objectives, leaving few human and technical resources for enforcing the ban on drug importation.<sup>17</sup>

Although the FDA has not acted against state and local officials, legal action has been brought against private storefront pharmacies in the United States that help residents fill their prescriptions from foreign sources. For example, a federal judge found the storefront operations of Oklahoma-based Rx Depot and Nevada-based Rx of Canada in direct violation of the Federal Food, Drug, and Cosmetic Act and barred the companies from importing prescription drugs for sale in the United States. These pharmacies had been sending the U.S. prescriptions and credit card information to a cooperating pharmacy in Canada. After a Canadian doctor rewrote the prescriptions, the pharmacy shipped the drugs directly to customers.<sup>18</sup>

The U.S. Congress has attempted to relax the FDA regulation on drug importation through legislation. The Medicine Equity and Drug Safety Act, enacted in 2000, and the Medicare Prescription Drug Improvement and Modernization Act of 2003 both allow prescription drugs manufactured in the United States and exported to certain foreign markets to be re-imported for sale in this country. Both pieces of legislation, however, include a provision stipulating that re-importation may occur only after the HHS secretary determines that an adequate level of safety can be ensured for U.S. consumers. Technically, therefore, the FDA could give states permission to import drugs. However, the HHS secretaries under both the Clinton and Bush administrations have refused requests to approve drug imports.

Congress is currently debating the legality of importing prescription drugs. A growing number of U.S. senators, including Arizona Sen. John McCain and Massachusetts Sen. Edward Kennedy, have expressed their support for importation and have urged Health and Human Services Secretary Tommy Thompson to give states legal permission to launch importation programs.<sup>19</sup> Minnesota's U.S. Rep. Gil Gutknecht is sponsoring legislation that would remove the FDA's veto power over importation of FDA-approved drugs from FDA-certified facilities in Canada, the European Union and seven other nations.<sup>20</sup>

Secretary Thompson recently appointed a 13-member federal task force, which is holding public hearings to gather testimony from consumers, pharmaceutical manufacturers, pharmacists, health care providers and other involved groups and to examine the feasibility and safety of drug importation.<sup>24</sup> In early May, Secretary Thompson conceded that passage of a congressional drug importation bill was inevitable – yet another indicator of growing public support and the political momentum for legalizing drug importation.<sup>25</sup> In another recent development, the two largest chain pharmacies in the United States, CVS and Walgreens, joined the ranks of importation advocates and urged the federal government to develop legal, safe channels for Americans to obtain imported pharmaceuticals.<sup>26</sup>

#### *State Law*

An increasing number of states favor the legalization of imported drugs and advocate the need for federal legislation. The attorneys general of 18 states – Arizona, California, Colorado, Connecticut, Illinois, Iowa, Maine, Maryland, Massachusetts, Mississippi, New Hampshire, New Mexico, New York, Ohio, Oregon, Rhode Island, Vermont and Wisconsin – recently sent a letter urging the Bush administration to support the state importation initiatives; several governors sent a similar letter to President Bush in early May.<sup>27</sup>

However, in addition to violating federal law, importation programs are likely to violate state pharmacy laws, which often parallel federal laws and require that drugs may only be dispensed by pharmacies licensed in that state.<sup>28</sup>

Currently, 43 states require non-resident pharmacies to register for a license with the state board of pharmacy if they ship prescription pharmaceuticals to state residents.<sup>29</sup> This ensures that in case of safety or other violations, state pharmacy boards can order violators to stop shipments into the state. Generally, the order to stop shipment is enforced by the board of pharmacy in the state where the violation occurred, or by mutual action with the board in the state where the pharmacy is based.

Because registering and licensing pharmacies that operate within a state's borders is vital to ensure quality care, the practice has withstood the advent of Internet prescribing and telemedicine. However, the fact that importing drugs violates federal law has prevented states from registering foreign pharmacies.<sup>30</sup> Consequently, pharmacies that assist individuals in obtaining foreign medications have been found in violation of state licensing laws.

By the end of 2003, 22 states had taken or were planning to take regulatory actions against storefront pharmacies that facilitate illegal imports of prescription drugs from Canada.<sup>31</sup> In Alabama and Oregon, for example, state courts have ordered the closing of storefront operations that imported Canadian medicine because they violated federal anti-importation laws and state regulations regarding pharmacy registration and licensing.<sup>32</sup> North Carolina and Oklahoma have been cracking down on companies that import medications from our northern neighbor. And New Jersey passed a law that prohibits mailing re-imported drugs into the state.<sup>33</sup>

#### *U.S. and International Patent Laws*

In addition to violating federal and state laws and regulations, importing prescription drugs from another country may also violate patent laws. Because patent laws are national, their expiration dates differ from

#### **Example 2.1 Loophole Allows Some Drug Importation**

The personal use exemption to the FDA ban on drug imports has become a commonly used loophole for individual U.S. residents to import drugs from abroad.

The exemption states that citizens with a valid U.S. prescription can import a 90-day supply of drugs not approved for sale in the United States for personal use only. The exemption is not intended to allow the importation of foreign versions of U.S.-approved drugs or import of foreign medicines for commercial usage.<sup>21</sup>

The rule, however, has opened the floodgates for drug imports: the FDA estimates that approximately 2 million parcels containing FDA-regulated products enter the United States every year through international mail, and 10 million U.S. citizens bring drugs across land borders each year.<sup>22</sup> Other sources estimate that approximately 70 Canadian pharmacies shipped almost \$500 million worth of medications into the United States in 2002.<sup>23</sup>

country to country. For example, European and Canadian patents for the drug Nolvadex® (tamoxifen) expired in the 1980s, but in the United States, the drug enjoyed patent protection until August 2002.<sup>34</sup> Importing a foreign generic equivalent of a drug that is still under patent protection in the United States violates U.S. patent laws.<sup>35</sup>

Not only are the durations of drug patents different in these countries, but they also have different mechanisms for introducing generic competition into their markets. American law stipulates that the manufacturer of a patented drug can prohibit its competitor from introducing a generic drug that violates the existing patents for 30 months. In Canada, the similar law delays the introduction of a generic competitor for only 24 months. In the United States, the first generic manufacturer that successfully challenges a drug patent is granted six months of exclusive manufacturing rights for the generic drug, but no equivalent regulation exists in Canada.<sup>36</sup> A large-scale drug importation program from Canada to the United States would likely negate the effects of these and many other national patent regulations, and would effectively import Canadian patent policy into the United States.

Violating patent protections might negatively affect drug manufacturers' confidence and reduce incentives for them to invest in research and development of new medications. A patent grants the innovator a temporary monopoly to charge more than the marginal cost for the new product, helping to recover the development costs and profit from the investment. Many economists are concerned that importing drugs from abroad will hinder the discovery of new life-saving treatments and therefore will have the effect of "killing the goose that lays the golden egg."<sup>37</sup>

### **Safety**

Concern for consumer safety is the most commonly cited reason for the FDA's refusal to allow importation of prescription medications across national borders. According to the FDA's associate commissioner for policy and planning, William Hubbard, in a system where international pharmaceutical trade outside the FDA-approved distribution channels evades the strict national regulatory mechanism, "buyer beware" is not only a bad health care practice, but also a misguided health care policy.<sup>38</sup>

Traditionally, the American system for manufacturing and distributing prescription drugs has been tightly regulated by federal laws and the FDA. Drugs are usually sold to one of the "Big Three" national wholesalers – Cardinal Health Inc., McKesson Corporation and AmerisourceBergen. These companies, in turn, sell directly to pharmacies, hospitals and doctors' offices. To protect the closed distribution system from safety breaches, federal law prohibits the importation of unapproved, misbranded or adulterated drugs, including foreign versions of FDA-approved medications and certain drugs purchased without a prescription. U.S. Customs officials can refuse to let a drug in if it has been produced and packaged in unsanitary conditions, is prohibited in its country of origin, or has been adulterated or mislabeled. To enforce these regulations,<sup>39</sup> the FDA has the authority to detain, collect and evaluate samples from suspicious shipments.

Recently, this distribution network has been compromised by an illegal drug market that takes advantage of Internet technology, global trade and drug price differences across national borders to amass large profits by selling counterfeit, expired and diluted medications. Millions of prescription drugs enter the United States not only from Canada, but also from Mexico, India, Nigeria and other countries with poor or nonexistent national regulatory mechanisms. U.S. Customs inspects fewer than 1 percent of an estimated 2 million packages containing medicine that are shipped into the country each year, primarily because it lacks the resources needed to intercept the illegal shipments.<sup>40</sup>

State health systems will face multiple safety issues if citizens switch to Canadian or other foreign pharmacies:

- *Quality Assurance* – Pharmaceutical factories in United States and FDA-approved facilities abroad manufacture drugs under quality assurance procedures that are verified to produce a safe and effective product. Medications not approved for sale in the United States are not produced under the same quality assurance procedures.

- *Counterfeit Medication* – Counterfeit medications ordered through bogus online pharmacies regularly enter the United States. Some of these drugs bear the name of common FDA-approved drugs. Counterfeit drugs are either totally ineffective or significantly diluted and may pose serious health risks to consumers.
- *Untested Substances* – Many drugs that are approved by foreign governments have not been evaluated for use in the United States and may contain addictive or otherwise dangerous substances.
- *Risks of Unsupervised Use* – The use of many medications requires close medical supervision. Medical evaluation is often necessary prior to starting a particular drug therapy and during treatment to make sure the dosage is effective and to monitor for dangerous side-effects. The traditional procedure of obtaining such drugs domestically encourages medical supervision, while importing the same drugs from abroad does not.
- *Labeling and Language Issues* – Drugs manufactured for non-English-speaking markets often have labels in foreign languages, effectively concealing the instructions for use and possible side effects from most American consumers.<sup>45</sup>

The FDA has documented cases in which unsuspecting U.S. consumers received counterfeit, expired, subpotent or superpotent medications from foreign sources. In such cases, the consumer who suffers an adverse reaction or other problems from taking a drug of dubious origin has little or no recourse, because the seller is either unknown or is beyond legal reach.<sup>46</sup>

### Liability

Some analysts and state officials are also concerned about state liability for brokering arrangements with Canadian suppliers and encouraging cross-border trade. The question of who is liable if imported drugs harm individual consumers remains unanswered.

Legally, entities involved in shipping prescription drugs to U.S. consumers are required to ensure compliance with the Federal Food, Drug, and Cosmetic Act. Among other requirements, the importing entity must ensure that:

- imported drugs are manufactured outside the United States and comply with FDA approval in all respects, including manufacturing location, formulation, source and specifications of active ingredients, processing methods, manufacturing controls, container and closure system, and appearance;
- imported drugs meet all U.S. labeling requirements; and
- imported drugs are dispensed by a licensed pharmacist on the basis of a valid prescription.<sup>47</sup>

Meeting these requirements may mean that importing some types of drugs costs more than state or municipal governments had anticipated and may eliminate any potential cost savings. In addition, drugs imported from Canada virtually never meet the criteria listed above, especially the labeling

### Example 2.2 Counterfeit Medications

The World Health Organization estimates that between 5 percent and 8 percent of world trade in pharmaceuticals is counterfeit. Many online pharmacies that claim to be Canadian actually operate from Mexico, China, India and other countries with lax regulatory environments.

The U.S. Customs Service estimates that 10 million American citizens bring medications into the country at land borders each year.<sup>41</sup> International mailings from countries such as Bulgaria, Thailand, India, South Africa and Nigeria bring in 2 million additional drug packages annually.<sup>42</sup>

During recent surveillance of several mail facilities, FDA officers discovered that 88 percent of parcels with medications contained unapproved drugs, including drugs that had been withdrawn from the U.S. market due to safety concerns, veterinary drugs sold illegally for human use, improperly packaged drugs, medications with no English language labels or instructions and drugs that require careful dosage and physician's monitoring.<sup>43</sup>

According to the FDA, reports of counterfeiting grew from an average of five cases per year in the 1990s to 20 cases per year since 2000.<sup>44</sup>

requirements.<sup>48</sup> A person or entity violating the existing act can be held criminally and civilly liable by a court. The FDA has said it will consider litigation against state and local authorities that promote importation if necessary to protect the public health. So far, the administration has refrained from launching legal proceedings against state governments because popular opinion strongly favors legalizing importation. Moreover, members of Congress have sent mixed messages to law enforcement agencies by voting on more than one occasion to legalize importation for personal use.<sup>49</sup>

In the current closed distribution system, manufacturers are liable for any harm that might result from prescription medications sold through licensed distribution channels. However, if a drug is intended to be sold in another country but a state or pharmacy diverts it back into the U.S. market, the burden of liability might shift to the importer if it fails to prove that a defect in the drug was the manufacturer's responsibility.<sup>50</sup>

According to some legal experts, states, cities and counties that support prescription drug importation run substantial financial risks of being embroiled in litigation and may be liable for damages. Even a single negative ruling against the state or local government may offset the potential savings from a drug importation plan.<sup>51</sup> For this reason, the Massachusetts commission that administers health insurance for state employees and retirees recommended that the potential savings of \$10.4 million a year would not be worth the liability risks of importing foreign medications.<sup>52</sup>

### **Feasibility**

Some analysts contend that proposed importation programs are not feasible or sustainable in the long run. Analysts question whether it is possible to save enough money to justify the start-up costs and risks involved. Critics give the following arguments:

- American consumers may not want to participate in drug importation programs.
- States underestimate the true costs of drug importation.
- The price differences between the United States and other countries are often exaggerated, especially for generic medications.
- Drug manufacturers can disrupt importation programs by limiting the Canadian drug supply.

### *Estimating Participation Rates*

Some analysts are concerned that the projected savings are unrealistic because they presume high consumer participation rates in the mail-order programs. The Illinois governor's report, for example, estimates about \$90.7 million in savings based on a 100 percent participation rate. The same report, however, admits that the current domestic mail-order participation rate is about 7 percent of eligible prescriptions.<sup>53</sup> A more conservative estimate of a 33 percent participation rate for Illinois would reduce savings to \$30 million.<sup>54</sup>

To calculate the potential savings, the Massachusetts commission that administers health insurance for state employees and retirees assumed an 18 percent participation rate, which matches the state's current mail-order purchase rate. The commission decided the estimated savings of \$10.4 million – \$1.4 million for the state and \$9 million for state workers and retirees – were not worth the liability risks and the disruption to existing insurance contracts.<sup>55</sup>

A relatively low participation rate in a state-supported Canadian mail-order program despite co-pay waivers may be attributable to a number of factors:

- general inconveniences associated with online shopping;
- time delays in getting the needed medications via mail;
- additional costs associated with mail-orders, such as shipping expenses;
- mixed messages coming from government regarding the safety, legality and feasibility of drug importation; and
- lack of information about the importation programs or lack of access to Internet.

On the other hand, some existing programs have generated savings, even with low participation rates. Springfield, Mass., for instance, has saved about \$2 million since launching its program last July, even

though only about 3,000 of 20,000, or 15 percent, of city employees, retirees and their dependents have taken advantage of cheaper Canadian mail-in drugs.<sup>56</sup> Advocates for importing drugs claim that the co-pay waivers that almost all importation proposals offer will encourage sufficiently high participation rates to make the programs feasible.

### *Estimating Costs*

Drug importation opponents claim that many of the state savings calculations are optimistic because they underestimate or overlook various costs associated with shipping, delivering medications across the border, ensuring safety, and bearing legal and financial liabilities. For example, according to the FDA, the Illinois estimate of \$90.7 million in savings does not account for costs associated with shipping, hiring state pharmacists to meet the safety needs and ensuring against liability.<sup>57</sup> Implementing the proposed primary care pharmacist concept to enhance safety, for instance, is estimated to cost \$3.3 million.<sup>58</sup> Including such necessary expenses in savings calculations is likely to result in a more realistic estimate, albeit a less optimistic one.

The estimates also fail to account for the additional inconvenience and financial risk consumers face when purchasing large packages that provide a long-term supply of drugs. In most cases, consumers will be unable to return their purchases if their prescriptions change for medical reasons.<sup>59</sup>

### *Estimating Price Differences*

In calculating potential savings, proponents of drug importation often tend to exaggerate the difference between U.S. and Canadian prices. For example, by comparing the cheapest Canadian pharmacy prices to the highest available U.S. prices for the same drug, state estimates often inflate the potential savings from importation.<sup>60</sup>

Similarly, some savings estimates are based on comparing a drug's manufacturer or wholesale price in Canada to its retail price in the United States. Since retail prices are higher than wholesale prices in both countries, comparing drugs in different stages of distribution results in estimates that do not reflect the real savings for U.S. consumers.<sup>61</sup>

Moreover, although brand name drugs are more expensive in the United States than in Canada, generic prescriptions tend to cost less in the United States. States implemented aggressive generic substitution programs in the 1990s, resulting in about a 42 percent average market share for generic drugs from 1996 to 2000.<sup>62</sup> The August 2003 changes to the FDA's generic drug approval process, which speed access to cheaper generic medications, promise billions of dollars in health care savings for consumers.<sup>63</sup> Future increases in the use of generic drugs over brand name equivalents may generate savings that equal or exceed the potential savings from importing drugs.

Finally, exchange rates have a tremendous influence on cost savings. Currently, the U.S. dollar maintains a strong position against the Canadian dollar and European currencies. However, changes in currency markets could suddenly eliminate much of the incentive for importation.

### *Estimating Foreign Supply*

Another issue that affects the feasibility of drug importation is the availability of drugs from Canada. With Canada's market less than 10 percent the size of the U.S. market, experts predict that importing drugs will negatively affect the Canadian pharmaceutical distribution system and exacerbate existing shortages in that country.<sup>64</sup> If importation becomes a commonly used method for supplying state programs with discounted pharmaceuticals, the current supply of Canadian drugs will not sustain the U.S. demand. According to some economists, U.S. drug manufacturers are unlikely to increase their shipments to Canada to make up for the extra drugs being re-imported back to the United States.<sup>65</sup>

In fact, major pharmaceuticals manufacturers have stepped up their efforts to limit drug re-importation by increasing prices in Canada and placing new sales restrictions on Canadian wholesalers.<sup>66</sup> Major U.S. drug manufacturers have increased prices of many of their Canadian products by between 4 percent and 8 percent since summer of 2003.<sup>67</sup> However, the drug companies' ability to raise the price of their

products in Canada is limited. Every six months, pharmaceutical companies are required to report price increases to Canada’s Patented Medicine Prices Review Board, which can roll back the increases if they exceed the country’s inflation rate.<sup>68</sup>

Drug manufacturers may prevent importation of cheaper medications into the United States by limiting supply and imposing strict conditions on pharmacy distributors in Canada. Some manufacturers have announced their intention to stop sales in the Canadian market altogether, unless Canadian prices are allowed to increase enough to decrease the flow of pharmaceuticals across the border. Under some companies’ new sales policies, wholesale drug distributors will be authorized to deal only with buyers that agree not to export the company’s products outside Canada.<sup>70</sup> Other companies require written assurances from Canadian pharmacies receiving their products that the medications will not be sold outside the country. In addition, major credit card companies have declared their readiness to stop serving Canadian pharmacies that participate in drug importation schemes.<sup>71</sup>

In a counter-move to the drug manufacturers’ restrictions on supplying the Canadian market, Illinois has dispatched a team of experts to Europe to study the possibilities of importing cheap medications from European countries.<sup>72</sup> However, in case of large-scale drug importation from other nations, the pharmaceutical industry is likely to impose the same limitations on the drug supply to those countries as well.

The restricted supply of U.S.-manufactured medications to the Canadian market raises concerns that Canadian pharmacies will turn to unreliable and unsafe foreign sources to meet the growing demand of U.S. importation programs.<sup>73</sup> In fact, some sources report that between 2002 and 2003, imports into Canada skyrocketed from countries such as Bangladesh (a 1,336 percent increase), China (a 439 percent increase), South Africa (a 389 percent increase), Saudi Arabia (a 90 percent increase) and Iran (a 65 percent increase).<sup>74</sup>

**Example 2.3 Congressional Budget Office’s Analysis of Drug Importation Savings**

The Congressional Budget Office (CBO) has analyzed the cost-saving potential of the re-importation provision in the Medicare prescription drug law (P.L. 108-173). The provision allows the Secretary of HHS to issue regulations permitting U.S. pharmacists and wholesalers to import prescription drugs from Canada. The Secretary must demonstrate that importation poses no additional risks to public’s health before issuing the regulations. The CBO concluded that the provision will not result in substantial savings for the federal government.

First, the office argues that manufacturers of brand name drugs are unlikely to increase their supply to Canada enough to permit a substantial volume of drugs to be imported into the United States.

Second, the U.S. market for prescription drugs is significantly larger than the Canadian market. If manufacturers’ attempts to limit the supply of drugs entering the U.S. from Canada failed, brand name drug prices in Canada would consequently rise much more than they would decline in the United States.<sup>69</sup>

**3. 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.

**Measures to Ensure Drug Safety**

States with proposed or existing drug importation programs have addressed safety concerns primarily by promoting quality assurance and by promoting pharmacist guidance and supervision for consumers.

*Promoting Quality Assurance*

In order to promote quality assurance, states can specify the types of production facilities from which the imported drugs will originate. Some proposed state legislation allows for importation only of medications

that are FDA-approved and manufactured in FDA-inspected facilities. Such a safety measure would also prevent importation of drugs approved in foreign countries but not evaluated for use in the United States that may contain addictive or otherwise hazardous substances.

However, many drugs manufactured in FDA-approved facilities for distribution in foreign markets do not meet all the FDA requirements for distribution in the United States. It is beyond the administration's means to track drugs in foreign markets once they leave the production facility and before they enter the U.S. market. Thus, there is little guarantee that the drugs entering the U.S. market that were originally manufactured for foreign distribution are in fact the ones approved by the agency and manufactured in the inspected facilities.<sup>75</sup> To avoid the risk of importing medications of dubious origins and transit routes, states can exclude any medication that was not manufactured in or has left the borders of the exporting country.

Some experts believe that an acceptable degree of safety can be assured if medicines are imported only from warehouses approved by the FDA or its Canadian counterpart, Health Canada, and ordered and sold by local pharmacists. Alternatively, an importation program can be arranged to allow purchases only from a Canadian pharmacy that requires a prescription from a U.S. doctor and can provide a copy of its pharmacy license upon request.<sup>76</sup>

A commonly proposed safety measure is to inspect foreign pharmacies before offering their services to state residents. Wisconsin officials, for example, inspected three Canadian pharmacies before posting their links on its Web site.<sup>77</sup> Similarly, the Minnesota Department of Human Services carefully reviews the Canadian pharmacies willing to negotiate additional price discounts with the state and places them on the Web site only after verifying their commitment to high safety standards.<sup>78</sup> As one of the safety precautions, the eligible pharmacy must be licensed by the Canadian province in which it operates.<sup>79</sup> Canadian pharmacies can verify that a customer lives in Minnesota and is eligible for the negotiated discount by using U.S. ZIP codes.<sup>80</sup> Controlled substances such as narcotics, drugs with special handling requirements and drugs needed immediately, such as antibiotics, are exempt from Minnesota's mail-order program.<sup>81</sup>

In addition to securing safe production facilities and transit routes, at least one state has proposed regular drug inspections once the medications arrive in the state. According to Gov. Rod Blagojevich's drug importation plan, some of the imported drugs will be randomly inspected by pharmacists at the University of Illinois lab facilities to screen for counterfeit, expired or improperly stored medications.<sup>82</sup> It should be noted that the plan also includes a central state repository where imported medications will be stored before being dispensed to consumers, making the random inspection of drugs possible. However, even if a state plan mandates that participating foreign pharmacies send medications directly to individuals, quality inspections can be conducted by randomly diverting the orders to a state laboratory.

Some of the regulatory challenges of ensuring safe drug importation are similar to the United States' attempts to keep counterfeit and low-quality medications from entering the domestic mail-order pharmacy systems. In 1999, the National Association of Boards of Pharmacy launched the Verified Internet Pharmacy Practice Sites (VIPPS™) program. The program issues a seal of approval indicating that an online pharmacy complies with state licensing and inspection requirements, along with other privacy and

### Example 3.1 Safety Features of Illinois' Proposal

Illinois Gov. Rod Blagojevich's plan to import cheaper Canadian prescription drugs for state employees and retirees includes various safety measures:

- Drugs that are likely to be spoiled in transit are not eligible.
- Canadian retailers receiving drug orders must only supply brand name drugs in packages that are warranted unopened from manufacturer to consumer.
- Drugs must be randomly tested by pharmacists at Illinois laboratories to ensure against counterfeit, expired or improperly stored medications.
- Illinois pharmacies serve as gatekeepers by ensuring that multiple prescriptions do not create a hazard of harmful interactions for patients.

safety criteria such as authentication of prescriptions. The program has helped the U.S. pharmacy industry protect consumers from rogue Internet drug stores that engage in illegal and unsafe practices.<sup>83</sup> Canada's National Association of Pharmacy Regulatory Authorities adopted a similar program. When designing their programs, states can incorporate the VIPPS online pharmacy certification system to exclude unauthorized distributors from supplying U.S. consumers.

Since importation programs often propose ordering drugs from non-English speaking countries, consumers may receive medications with labels and instructions in foreign languages. To avoid this problem, states can mandate certain labeling standards, such as that labels should be in English.

**Promoting Pharmacist Guidance and Supervision**

Some states propose innovative approaches to ensure that their residents receive proper guidance and supervision from a pharmacist in ordering and taking prescribed medications. Illinois' plan, for example, introduces the concept of primary care pharmacists as a safety component. Instead of visiting the druggist every time they need a prescription filled, beneficiaries will schedule regular visits. Pharmacists will consult with patients about their prescriptions to rule out dangerous drug combinations, detect unexpected or harmful side effects, and monitor the therapy's overall effectiveness. The pharmacists will be paid a flat fee for each prescription, which will cover the cost of the consultations.<sup>84</sup> Moreover, some experts contend that the primary care pharmacist concept will allow pharmacists to specialize in certain health areas, focusing on patients with asthma, diabetes, heart problems or other illnesses.<sup>85</sup>

| <b>Example 3.2 Safety Measures to Protect Mail-Order Drug Consumers</b>         |                         |
|---|-------------------------|
| <b>Type of Safety Measures</b>  | <b>States</b>           |
| Inspecting the participating Canadian pharmacies                                | Minn., N.H., Wis.       |
| Requiring drugs to be FDA-approved and manufactured in FDA-inspected facilities | Mass., Minn.            |
| Conducting random drug inspection in state laboratory                           | Ill.                    |
| Providing access to local pharmacists for consultation                          | Ill.                    |
| Providing safety information on the Web site                                    | Iowa, Minn., R.I., Wis. |

**Measures to Ensure Legality**

The recent legislative activity and increased lobbying by state officials have created a political atmosphere that is conducive to legalizing drug importation. The federal regulatory changes that would allow state importation programs to operate legally are in the hands of Congress. Apart from the congressional deliberations, however, states can change their pharmacy registration and licensing laws to allow the legal importation of Canadian drugs under state laws.

Currently, 42 states require non-resident pharmacies to register with or be licensed by a state board of pharmacy before they can ship prescription drugs to residents of that state.<sup>86</sup> In a 2002 survey of state boards of pharmacy, only nine states found their laws and regulations were broad enough to allow for licensing foreign pharmacies.<sup>87</sup> Only 8 percent of states responding to the survey indicated that they were planning to issue licenses to Canadian pharmacies.<sup>88</sup>

States can make their pharmacy licensing and registration laws more flexible to allow Canadian drug stores to register and operate legally under state law. This would enable states to monitor pharmacy practices, ensure high safety standards and revoke licenses in case of certain violations. For example, Rhode Island law requires all out-of-state pharmacies to register for a license with the state board of pharmacy before they can market drugs in the state. A bill passed by the Rhode Island House would expand the law to allow Canadian pharmacies to supply drugs to state residents after getting inspected and licensed by the state.<sup>89</sup> Similar policies of retailer-specific inspections and licensing are useful for importation programs because Canadian pharmacies are regulated by individual provinces, with no federal oversight that could ensure safety standards across the board.<sup>90</sup>

In order to avoid violating U.S. patent protections on drugs that have expired patents abroad, states can exclude such drugs from importation programs. Without this exclusion, if a patent has expired or is not honored in the exporting country the patent protection will also not be honored in the United States.

### **Measures to Ensure 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 the following 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.

In order to avoid exhausting the Canadian supply of pharmaceuticals, state officials can broaden the importation base to include other developed countries that offer cheaper prices but at the same time have well-established regulatory systems for ensuring safety. However, policy-makers should keep in mind the higher costs of shipping medicines from these countries.

### **Measures to Address Liability Concerns**

The absence of a legal precedent makes it difficult to evaluate the potential legal and financial liability for states that broker imported medications. Because determining liability is a very fact-specific inquiry, HHS has been reluctant to give an advisory opinion on the issue.<sup>91</sup>

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."<sup>92</sup>

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.<sup>93</sup> Although such waivers may partially insulate participating governments from legal liability, they make consumer recourse difficult in cases of defective medication.

### **Conclusion**

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, state decision-makers should consider the legality, safety, liability and feasibility of importation programs to evaluate the potential risks and benefits.

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