Prescription Drug Importation Programs

Information Relevant to the State of Connecticut

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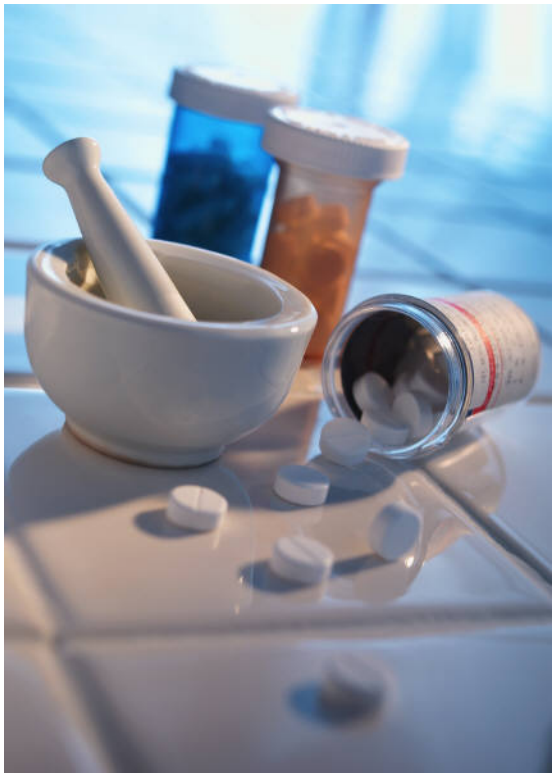

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Executive Summary

Introduction

The State of Connecticut Prescription Drug Importation Advisory Committee commissioned a report that reviews the processes that states and municipalities undertook in developing prescription drug importation programs. The Committee requested that the report focus on the safety, equivalence, and efficacy of imported medications and the legal issues surrounding government-sponsored personal importation of prescription drugs. The economic effects of prescription drug importation programs were also to be considered.

Through a contract with the State Department of Public Health, The University of Connecticut Health Center, in consultation with the UConn School of Law and UConn School of Pharmacy, investigated several existing prescription drug importation programs. Special attention was placed on the I-SaveRx program in Illinois, Vermont's participation in I-SaveRx, the MinnesotaRxConnect program in Minnesota, and the Springfield Meds program in Springfield, Massachusetts.

Background

Since 2003, several states and cities in the United States have developed and implemented programs to assist their residents import prescription drugs from other countries. The primary motivating factor for governments to take this action is economic; importation programs accessed by government employees and other covered populations are believed to reduce government expenditures on prescription drugs, while programs open to all residents are designed to provide individual economic relief, especially for those who lack prescription drug insurance coverage.

As part of the developmental stage of most importation programs, government employees from sponsor states and cities investigated several issues related to the safety of foreign drugs, legal issues associated with sponsorship of a program, and economic effects of potential programs. Should a state or local government consider pursuing drug importation subsequent to those already in existence, it would be prudent to review the results of examinations conducted by existing programs related to drug safety, legal issues, and economic effects. These are reviewed in summary below.

Safety, Equivalence, and Efficacy of Imported Prescription Drugs

The FDA has consistently stated its opposition to drug importation because it cannot ensure the safety, equivalence, and efficacy of imported medicines. Importation programs have used several strategies to make judgments about these issues. Some of the strategies used include comparing FDA and foreign country drug regulations and standards; investigating drug distribution, warehousing, and storage systems; comparing state pharmaceutical regulations and pharmacy standards to their foreign equivalents; inspecting foreign pharmacies, pharmaceutical wholesalers, and manufacturers; and investigating educational requirements and professional regulation of licensed pharmacists. At least one program planned, but has not yet implemented a testing program, where samples of medications imported through the program would be tested by pharmaceutical professionals for such things as the presence and potency of the active ingredient and makeup of inert ingredients.

All of the government sponsored programs analyzed have implemented several of the same basic safety measures, including:

- Exclusion of medications not suitable for shipping because they require special handling such as refrigeration.
- Exclusion of narcotics and controlled substances because of safety issues, potential for abuse, legal, and regulatory concerns.
- Exclusion of medications likely to be required right away, such as antibiotics for an infection, because of the time required to purchase them abroad.
- Allowing program pharmacies to fill only refill prescriptions for drugs prescribed to treat a chronic condition. The drug must have been initially filled at a US pharmacy and taken and tolerated by the patient for a minimum of 30 days.
- Requiring new customers to complete a health history questionnaire prior to issuance of the first prescription.

While none of these safeguards could be considered to completely ensure the safety of foreign drugs accessed through these programs, it would seem that government sponsored importation programs provide a measure of safety that is not available to individuals who acquire foreign medications independently, especially through Internet pharmacies.

Legal Issues of Government Sponsored Prescription Drug Importation

A prescription drug importation program contravenes current federal food and drug law and potentially exposes participants to enforcement actions on the part of the FDA. In the face of FDA warnings, several states have halted efforts to enable their residents to purchase prescription drugs from foreign pharmacies. Others have proceeded with existing programs despite their apparent illegality. Individual consumers importing drugs for personal use seem to face little danger under applicable federal law, although shipments of drugs do get seized at US borders with some regularity.

When contemplating an importation program, Connecticut will need to revisit certain existing state laws regarding pharmacy practices and the distribution of prescription drugs. Additionally, Connecticut opens itself up to potential tort liability, although other states have taken measures to reduce this liability and their efficacy remains untested. Connecticut consumers will retain most if not all of their existing rights of redress, although importation programs impose extensive waiver requirements that are similarly untested.

Economic Effects of Prescription Drug Importation

Development of an independent prescription drug importation program would require a significant investment in time and money for personnel to design the program and travel abroad to research foreign countries' pharmaceutical and regulatory systems, and inspect pharmacies, wholesalers, and manufacturers. Developing an independent program would provide few added economic benefits compared to joining an existing program. Joining an existing program may be more economically feasible initially, but this strategy relies heavily on the state that developed the program to maintain the program, in effect delegating the monitoring and oversight to the originating entity. Additionally, this arrangement would likely allow the sponsoring state to easily end the relationship, which would result in a return to a lack of access to a channel of foreign drugs for Connecticut residents provided by inspected pharmacies.

Cost savings to individuals are dependent on the specific medications needed and the level of discount offered through importation programs versus other available programs. Cost savings to the state for state employees, retirees, and other covered populations are dependent on enrollment and usage. Fluctuations in currency exchange rates can also impact the degree of savings to individuals

and governments as well. Enrollment and accompanying cost savings in several existing programs have not met projections. There are several other factors that might limit enrollment and cost savings of any drug importation program in Connecticut. It is a relatively small state in terms of population, and the population is relatively well covered by health insurance. The major incentive for participation in most state and municipal programs involves elimination of co-payments, which may not be sufficient in Connecticut since by union contract the co-pays for our state employees and retirees are relatively low.

An importation program in any form in Connecticut could still economically benefit persons who are uninsured or underinsured. In most cases, retail drug prices through importation programs are less than through comparable domestic mail-order pharmacies. For the fifty most prescribed drugs in Connecticut, 72 percent are available at lower prices through I-SaveRx and 76 percent are available at lower prices through MinnesotaRxConnect. Savings of over 25 percent are available through I-SaveRx for twenty-two of the fifty most prescribed drugs in Connecticut; savings of over 25 percent are available through MinnesotaRxConnect for twenty-five of the fifty most prescribed drugs in Connecticut. Downstream economic consequences are speculative (e.g., the impact on local pharmacies due to reduced volume).

Additional issues

Recently, the Attorneys General of Nevada and Texas, respectively, halted state importation programs and a Washington DC law authorizing importation did not receive the necessary approval from Congress. In January 2006, the Governor of California urged lawmakers to ease federal restrictions on purchasing prescription drugs outside the United States. The Governor himself has vetoed four bills that would have allowed prescription drug importation from Canada because it is illegal under current federal law.

Recent newspaper reports assert that federal enforcement officials seized drugs shipments imported from Canadian pharmacies at increased rates during January 2006, which prompted two members of the US House of Representatives to send a letter to the FDA and US Customs and Border Protection demanding an explanation.

One of the reasons that state governments sponsor drug importation programs is to help senior citizens acquire the drugs they need to maintain their health at more affordable prices. The federal government addressed the need for prescription drug coverage for Medicare enrollees through Medicare Part D. There are conflicting reports about the savings available through Medicare Part D versus purchasing Canadian drugs, however it has been reported that Canadian internet pharmacies have seen up to a 30 per cent reduction in cross border sales. It still may be too early to judge with certainty the impact that Medicare Part D will have drug importation programs.

Another option for those with inadequate or no insurance is the purchase of pharmaceuticals from safety net providers such as Federally Qualified Health Centers. Such entities are able to purchase and provide for their patients medications at a price established in concert with the Federal 340B drug program which is much lower than medications purchased through traditional sources such as local retail or mail order pharmacies.

For those not eligible for Medicare Part D or a pharmaceutical company assistance plan and without prescription drug insurance coverage or access to a safety net provider, importation could continue to be the most affordable option, and state involvement may increase the safety of foreign drugs that are currently being accessed independently.

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