Prescription Drug Importation Programs

Information Relevant to the State of Connecticut

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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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A. INTRODUCTION

In recent years, several states and local governments[1] have developed and sponsored prescription drug importation[2] programs that allow their residents access to less expensive prescription drugs than are available domestically. Prescription drug importation is of interest in Connecticut because of increasing prescription drug costs to the state for state-covered populations and to individuals and families that rely on prescription drugs to maintain and improve their health. This report investigates the processes that states and municipalities undertook in developing prescription drug importation programs and reviews their findings about the safety, equivalence, and efficacy of imported medications and the legal issues surrounding government-sponsored drug importation. The economic effects of prescription drug importation programs are also important to consider. This report was funded through a contract between the University of Connecticut and the State of Connecticut Department of Public Health.

The first prescription drug importation program sponsored by a government entity was the Springfield, Massachusetts program, which was launched in 2003 under the leadership of former Mayor Michael Albano. The Springfield program is available to city employees and other city-covered populations and was designed to reduce city government spending on prescription drugs. Following Springfield's lead, other local governments and several states have begun prescription drug importation programs. Municipal programs have generally remained exclusively for employee and other covered populations programs. Most state programs have been made available to all state residents, and have become especially important for state residents who have high drug costs and lack prescription drug insurance coverage.

While the City of Springfield is notable for starting the first prescription drug importation program, other jurisdictions have gone beyond Springfield in regard to the initial and ongoing investment in their programs. Perhaps the most prominent of the existing programs is I-SaveRx[3], the Illinois program developed under the leadership of Governor Rod Blagojevich. The geographic reach of I-SaveRx is one factor that sets it apart from other programs. Illinois officials have conducted site visits in and researched the drug safety and regulatory systems of Canada, the United Kingdom, Ireland, Belgium, France, Germany, the Netherlands, Australia, and New Zealand. Illinois officials have also looked into the possibility of importing from South Africa. I-SaveRx customers can currently order prescription refills from licensed, inspected pharmacies in Canada and the United Kingdom. These pharmacies purchase medications from retailers and wholesalers in Canada, the U.K., and Ireland. Within the borders of the United States and at the invitation of Governor Blagojevich, several other states have joined I-SaveRx, allowing their residents access to imported medications. As of December 31, 2005, Kansas, Missouri, Wisconsin, and Vermont had joined I-SaveRx.

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1 A partial listing of states and municipalities that facilitate the purchase of imported prescription drugs by their residents and or employees includes Illinois; Minnesota; North Dakota; New Hampshire; Rhode Island; Washington; Wisconsin; Boston, Massachusetts; Burlington, Vermont; Montgomery, Alabama; Montgomery County, Maryland; Portland, Maine; San Francisco, California; and Worcester, Massachusetts.

2 Except in the legal sections of this report where the terms may not be interchangeable, the term *importation* generally includes the "reimportation" of prescription drugs manufactured in the United States.

3 Throughout this report, the term "I-SaveRx" refers to the prescription drug importation program developed by the State of Illinois and its associated website addresses, which include www.i-saverx.net , www.i-saverx.com, and www.isaverx.net. The website www.isaverx.com is not associated with the Illinois program.

Another pioneer in prescription drug importation was the State of Minnesota, under the leadership of Governor Tim Pawlenty. The Minnesota program, MinnesotaRxConnect (for state residents) and Advantage-Meds (for state employees and their dependents) provides direct access to four Canadian pharmacies, which have been inspected by state officials, via a state sponsored website. Two of the four Canadian pharmacies in turn have contracted with pharmacies in the United Kingdom to also supply US residents with lower cost prescription drugs. Like the pharmacies in Canada, the pharmacies in the UK were inspected by Minnesota Department of Human Services personnel, including pharmacists.

UCHC research identified other prescription drug importation programs in various stages of development and implementation sponsored by cities, counties, and states throughout the country. While variations exist in the complexity and design of operational programs, they all seem to share at least two common attributes. All of the programs import from Canada and all programs have received letters from the FDA advising that the programs are illegal and that the FDA cannot ensure the safety of imported prescription drugs.

The three basic models of importation that have been considered by state and local governments include:

- Government officials act as wholesale importers.
- Government officials contract with a Canadian pharmacy benefits manager or other drug supplier.
- Government officials sponsor a website to link residents to foreign pharmacies.[4]

FDA enforcement efforts have deterred state and local governments from implementing wholesale prescription drug importation programs. Recent Canadian legislation also places limits on bulk exportation of pharmaceutical products.

The Springfield and Illinois programs are examples of programs designed to use the services of a contracted drug supplier. The most common program design facilitates access to foreign pharmacies through government sponsored websites (e.g., Minnesota, Wisconsin, and New Hampshire).

Generally, importation programs share a similar process for placing and filling an order:

1. Patient receives refill prescription from US doctor for treatment of a chronic condition (initial prescriptions must be filled domestically.)
2. US doctor or patient transmits prescription to approved foreign pharmacy or contracted pharmacy benefits manager (PBM).
3. Patient completes a health history form and transmits it to approved foreign pharmacy or PBM.

[4] Khodeli, Irakli. Prescription Drug Importation Trends Alert. The Council of State Governments. June 2004.

4. Physician licensed in country or province where pharmacy is located reviews health history and US prescription and re-writes prescription so that it may be legally filled in country or province where pharmacy is located.
5. Approved foreign pharmacy fills prescription and ships it to customer in the US.

Approved foreign pharmacies and PBMs also communicate by phone and e-mail contact with customers and US physicians to address any questions or problems that may arise during the process.

B. DESCRIPTIONS OF SELECTED EXISTING PROGRAMS

I-SaveRx—Illinois

Study

In response to rising costs of prescription drugs for state employees, dependents, and retirees the Governor of Illinois, Rod Blagojevich, issued an executive order[5] establishing a central purchasing, contract negotiation, and policy development program for prescription drugs. One of the primary duties of the Special Advocate for Prescription Drugs was to investigate the safety and effectiveness of prescription medications from Canada and determine if overall costs were lower for prescription drugs purchased from pharmacies in Canada. In general, pharmaceuticals purchased from Canadian sources are less expensive, because the Canadian government regulates drug prices and the United States does not. The Special Advocate submitted his initial findings to the Governor on October 27, 2003, in a report titled: *Report On Feasibility Of Employees And Retirees Safely And Effectively Purchasing Prescription Drugs From Canadian Pharmacies*. The report explored five issues: consumer safety, regulatory governance, program drugs (pharmaceuticals appropriate for coverage), projected cost savings, and policy and economic impact. The report's key findings were:

1) Prescription drugs can be safely purchased from Canada,
2) Pharmacy practice in the Canadian provinces investigated (Manitoba and Ontario) are equal or superior to pharmacy practice in Illinois,
3) A formal program to purchase prescription drugs from Canadian pharmacies would likely affect retail pharmacies in Illinois.

The report authors recommended that the State of Illinois contract with a non-domestic pharmacy benefits manager or similar entity, establish a primary care pharmacist model[6], and require employees and retirees to pay only the shipping cost for drugs obtained from Canadian

[5] State of Illinois Executive Department, Springfield, Illinois, 2003-15 Executive Order On Prescription Drugs.
[6] Kamath, Ram and McKibbin, Scott. *Report On Feasibility Of Employees And Retirees Safely And Effectively Purchasing Prescription Drugs From Canada*. Office of the Special Advocate for Prescription Drugs, State of Illinois Department of Central Management Services. October 2003. Appendix A-4 describes the Primary Care Pharmacist Model as recommended for the I-SaveRx program. The Primary Care Pharmacist would be a local pharmacist selected by the plan participant to respond to questions "such as the appropriateness of generics vs. brand, anticipated or possible complications, and review of potential drug interactions…" As of January 9, 2006, funding for implementation of these activities had not been made available.

sources (i.e., waive co-payments). Also recommended was an ingredient and quality assurance-testing program to ensure the quality of the drug supply.[7]

Following their research in Canada, Illinois officials investigated the potential for prescription drug importation from Europe, Australia, and New Zealand. In comparison to their Canadian study, which focused on a potential program for state employees and retirees, the European study focused on a potential program open to all residents of Illinois. On June 28, 2004, Illinois released a report entitled, *Can Illinois Residents and Businesses Safely and Effectively Purchase Prescription Drugs from Europe?* The Illinois team[8] met with representatives from governments and a range of pharmaceutical business entities in Belgium, France, Germany, Ireland, the Netherlands, and the United Kingdom. In each country they methodically assessed relevant aspects of the pharmaceutical industry, pharmacy practice, and regulatory structures and compared their findings to industry practice and regulatory structures in place in the United States. In all but one of the facilities assessed, the Illinois delegation determined that high quality standards were in place.

In addition to research for the purpose of personal importation, the Illinois delegation also investigated the feasibility of wholesale importation of European drugs for standard pharmacy distribution in Illinois. As compared to personal importation, wholesale importation would allow a wider variety of drug classes and would involve local pharmacies in the importation and prescription filling process.[9] Since the FDA has chosen to focus its law enforcement resources on wholesale importation rather than importation for personal use, Illinois has not moved forward with wholesale prescription drug importation. (This issue is described in further detail in the Legal Issues section of this report.)

Illinois released its report on prescription drug importation from Australia and New Zealand on June 30, 2005. Entitled *Australia and New Zealand: Recommended Expansion of the Illinois Personal Importation Program*, this report describes the findings of the Illinois research team regarding the safety, effectiveness, and affordability of prescription drugs in these countries. The research team included members from three State of Illinois departments. They followed the same procedures used in the European investigation and concluded that pharmaceuticals purchased from approved facilities in Australia and New Zealand were safe, effective, and more affordable than the equivalent product if purchased in the United States. However, due to the inability to clearly determine the legality in New Zealand of re-writing US prescriptions, the research team recommended that only over-the-counter medications available in New Zealand be

[7] Kamath, Ram and McKibbin, Scott. October 2003. The report recommended that the Illinois Department of Public Health and the University of Illinois Chicago College of Pharmacy "test drugs to ensure quality of both the domestic and non-domestic drug supply…" As of January 9, 2006, the process and methods for drug testing had not been finalized.

[8] Kamath, Ram and McKibbin, Scott. *Can Residents and Businesses Safely and Effectively Purchase Prescription Drugs from Europe?* Office of the Special Advocate for Prescription Drugs, State of Illinois. June 2004. Appendix 5 lists the members of the Illinois team, which included pharmacists, a physician, attorneys, doctorate-level scientists and a policy analyst employed at various departments of the State of Illinois including the Office of the Special Advocate for Prescription Drugs, the Department of Public Health, Department of Professional Regulations, Department of Human Services, the Governor's Chief Legal Counsel.

[9] Kamath, Ram and McKibbin, Scott. June 2004.

made available to I-SaveRx customers in the United States.[10] The report notes that several chronic care medications that require a prescription in the United States are available over-the-counter in New Zealand, such as Zyrtec, Allegra, and Flonase.

The primary reasons for expanding importation to countries beyond Canada are the threats from US pharmaceutical companies to limit shipments to Canadian wholesalers and pharmacies that conduct retail operations with customers in the United States[11] and from the Health Minister of Canada to suspend licenses of and malpractice insurance coverage for prescribers who re-write prescriptions for patients not seen in person. In Europe, Australia, and New Zealand these threats do not exist. Furthermore, some drugs may be equally safe and effective and also cheaper in Europe, Australia, and New Zealand than in Canada.

Implementation

In October 2004 (approximately one year after the Special Advocate presented its initial report to the Governor), the prescription drug importation program "I-SaveRx" was launched. While the initial research and planning focused on a program for state employees and retirees, when launched, I-SaveRx was made available to all residents in Illinois with no specific incentives directed at state covered populations. Illinois contracts with a Canadian pharmacy benefits manager, CanaRx Services, Inc., which provides a limited set of prescription drugs through a network of pharmacies inspected and approved by Illinois officials. Initially, program participants were able to refill prescriptions originally filled in the US through inspected pharmacies in Canada via a website or a toll-free phone number. At present, participants may refill prescriptions through pharmacies in the UK as well as Canada.

After the implementation of I-SaveRx, Governor Blagojevich sent a letter to the governors of every other state in the US inviting them work with Illinois to lower the costs of prescription drugs by joining I-SaveRx. As of December 2005, Kansas, Missouri, and Wisconsin have joined through the actions of their respective governors, and Vermont has joined through the actions of its legislature and governor.

Participating states have signed a Memorandum of Understanding with Illinois, which describes the relationship and sets parameters for participation, including program operation and oversight, marketing, press relations, liability and cancellation (See Appendix 1). States that join are encouraged to appoint two representatives to a Joint Work Group. Generally, one representative is a clinician and the other is a policy or program specialist. The Group meets on an as needed basis, generally at least twice a year. The Joint Work Group provides a venue for participating states to discuss concerns, questions, and suggestions for improvements.

Thus far, no custom drug formularies have been developed for particular states. Joint Work Group members have discussed removing or adding specific drugs to the available drug list. When a question arises regarding a specific drug, the group generally relies on the

[10] Kamath, Ram and McKibbin, Scott. *Australia and New Zealand: Recommended Expansion of the Illinois Personal Importation Program.* Office of the Special Advocate for Prescription Drugs, State of Illinois. June 2005.
[11] See "Pfizer to Restrict Drug Sales to US from Canada", Reuters, August 6, 2003; Congressional Research Service Report for Congress #RL32511, "Importing Prescription Drugs: Objectives, Options, and Outlook, August 4, 2004.

recommendations offered by members with clinical backgrounds and experience in prescribing or dispensing pharmaceutical products.

CanaRx, Inc., the pharmacy benefits management company for I-SaveRx, provides a number of services to Illinois and other participating states, including website management, pricing comparisons and savings guarantees, customer service, management of enrollment and patient health records, payment processing, communications with enrollees' prescribing physicians, drug utilization reports, monitoring shipping, outbound contacts for refills, reporting, and scheduled program reviews.

Illinois has taken an aggressive approach to marketing I-SaveRx. It has issued an RFP for marketing all of the state's health programs, including I-SaveRx. Some of the marketing strategies used thus far include direct mail, media releases, press conferences, and direct outreach to groups with disproportionately high numbers of uninsured people, such as the restaurant association. The Chief Medical Officer for the Illinois Department of Public Health serves on the advisory board of I-SaveRx and conducts outreach to physicians. When the program was launched, a letter was sent to all physicians in the state introducing the program. A dedicated toll-free phone number connects physicians to DPH personnel, who are prepared to answer questions about the program. Program administrators have given presentations about I-SaveRx at national meetings, including an AARP Global Aging Program and a conference for hospital discharge planners.

For the period from October 2004 to approximately June 30, 2005, "almost 61,000 interested citizens have requested an enrollment form…; 14,600 have completed the enrollment process; and over 10,000 orders have been placed through the program, each with an average savings of 25 to 50 percent."[12] As of January 16, 2006, over 18,300 total orders had been placed (includes orders from all participating states).[13]

Illinois claims that their research process prior to implementation of the program was "as comprehensive as possible" in the areas of consumer safety, regulatory governance, drugs suitable for inclusion in the program, projected cost savings, and policy and economic impact.[14] A review of the evidence used by Illinois and other states to substantiate the safety of the imported prescription drugs through state and local sponsored programs appears in the Safety, Equivalence, and Efficacy portion of this report. A review of the legal and regulatory issues related to prescription drug importation appears in the Legal section of this document and a review of the economic issues appears in the Economic section.

I-SaveRx—Vermont

Vermont is one of four states (Kansas, Missouri, Vermont, and Wisconsin) that joined Illinois' I-SaveRx program through the actions of their respective Governors and state legislatures. The Vermont governor signed a bill (S. 49) in 2005, which directed the state to join I-SaveRx.

[12] Kamath, Ram and McKibbin, Scott. June 2005.
[13] Personal communication, Cindy Laware, Deputy Commissioner for Human Services, State of Vermont. January 2006.
[14] Kamath, Ram and McKibbin, Scott. October 2003.

Vermont has also petitioned the FDA ("Citizen Petition" dated December 4, 2003) under the Federal Food Drug and Cosmetic Act (FFDCA) to waive or revoke the current FDA interpretation of the FFDCA that prohibits prescription drug importation by individual residents. Ultimately, the Citizen Petition was denied by the courts. Administrators in Vermont view their state's participation in I-SaveRx as a stop gap measure to help their residents access affordable prescription drugs in the short term. A unique aspect of the Vermont law is that health insurance or health benefits plans are required to provide coverage for drugs purchased through the program on the same terms and conditions as prescription drugs purchased in this country. This clause has not been tested or challenged in court as of January 23, 2006.[15]

Vermont and the other states that have joined I-SaveRx entered into an MOU with Illinois to join I-SaveRx. The MOU allows either party to cancel the agreement without cause or penalty. Illinois did not charge a fee to Vermont to join the program or for ongoing participation. Like Illinoisans, Vermonters access I-SaveRx through its website or toll-free phone number. An example MOU is provided in Appendix 1.

Participation figures demonstrate the limited impact of I-SaveRx in Vermont. During the first 12 months of Vermont's participation in I-SaveRx, 212 Vermonters enrolled and placed approximately 500 orders.[16] This limited participation could be explained by the relatively low number of uninsured Vermonters. According to Vermont's program administrator, several additional factors could be responsible for the limited participation. The state legislature did not provide any specific funding to market the program, thus marketing and outreach efforts have been minimal. Additional factors could include the relatively small number of available drugs (no generics, narcotics, or drugs not suitable for shipping), required consent forms, liability waivers, and shipping time requirements. Thus for Vermont, joining I-SaveRx has required a minimal investment by the state, but has had a limited impact.

Minnesota RxConnect and Advantage-Meds —Minnesota

Minnesota was one of the first states to enable its residents to order prescription drugs from Canadian pharmacies. Minnesota began developing a three-part plan in September 2003. The first two phases established web sites to provide information about various issues surrounding affordable prescription medicines and allowed state residents and employees to safely access prescription drugs from foreign pharmacies. Phase one was launched in January 2004. Titled "Minnesota RxConnect,"[17] it provides all state residents with access to prescription drugs from Canadian pharmacies through a website or a toll-free phone number. Phase two, "Advantage-Meds,"[18] followed in May 2004 and is available to state employees and their dependents. The third phase was intended to allow Minnesota to serve as a test state for the wholesale importation of prescription drugs from Canada and the United Kingdom by Minnesota pharmacies for distribution to individual customers. The required approval from the FDA has not been received.

[15] Personal communication, Mike McShane, Assistant Attorney General, State of Vermont. January 2006.
[16] Personal communication, Cindy Laware, January 2006.
[17] Available at http://www.minnesotarxconnect.com.
[18] Available at http://www.advantage-meds.state.mn.us/index.html

Minnesota is self-insured, so when an employee voluntarily participates in Advantage-Meds, co-payments are waived and the employee is not required to pay upfront and file for reimbursement; the State pays the Canadian pharmacies directly. The State contracts with administrative services only plans for claims processing and other administrative functions. The ASOs treat prescription drug claims from foreign pharmacies the same way they treat prescription drug claims from US pharmacies.

The Minnesota programs allow access to prescription drugs through four Canadian mail-order pharmacies. Each of these pharmacies was inspected and approved by a team that included pharmacists and health program administrators from the Minnesota Department of Human Services. Following threats from the pharmaceutical manufacturers to restrict supply to Canadian pharmacies that serve U.S. customers and threats from the Canadian Health Minister to outlaw the practice of re-writing prescriptions without seeing patients in person, two of the contracted Canadian pharmacies independently began negotiating with licensed pharmacies in the United Kingdom to fill certain prescriptions.

Additionally, at the direction of the Governor, the Minnesota Department of Human Services investigated the possibility of expanding the programs to include a European component. In March 2005, the department released its report on European importation of prescription drugs entitled, *Importation of Prescription Drugs from Europe: A Report to Commissioner Kevin Goodno*. This report describes background research and visits to facilities in the United Kingdom conducted by the employees of the Minnesota Department of Human Services. The report recommended that the state continue to work with the Canadian pharmacies and develop an option for the personal importation of medications from the UK.[19] Ultimately, the state expanded its importation programs to allow program participants to purchase prescription drugs from inspected UK pharmacies through the two Canadian pharmacies that developed the necessary business arrangements. Adding the UK as a source not only ensured drug availability, but also lowered costs for a substantial number of program drugs.

Between March 2004 and December 2005, MinnesotaRxConnect affiliated pharmacies filled over 17,929 prescriptions.[20] For the period between May 13, 2004 and December 31, 2005, the Advantage-Meds program enrolled 2,635 people, and 9,219 orders were placed.[21]

Springfield Meds—Springfield, Massachusetts

The City of Springfield program is noteworthy because it appears to have been the first prescription drug importation program operated by a governmental unit in the United States. Designed by the City's Employee Insurance Advisory Committee to reduce city expenditures on prescription drugs for city employees and their dependents, it is a voluntary program that went into effect on July 8, 2003. In essence, co-pays are waived if the insured selects a sanctioned Canadian pharmacy rather than a domestic pharmacy.

[19] Osberg, Brian and Wiberg, Cody. *Importation of Prescription Drugs from Europe: A Report to Commissioner Kevin Goodno.* Minnesota Department of Human Services. March 2005.
[20] Personal Communication, Richard Doering, Minnesota Department of Human Services. January 2006.
[21] Strebe, Paul. *Advantage-Meds Activity*. State of Minnesota. January 2006.

The Springfield program is accessed through a toll-free telephone number or a website.[22] Springfield contracts with CanaRx, Inc. for pharmacy benefits management services. A Canadian doctor reviews the Springfield patient's health information and prescription written by the patient's US physician. If the prescription receives the Canadian doctor's approval, one of nine contracted Canadian pharmacies fills the order and ships the medication directly to the consumer. The City of Springfield is self-insured, so when a city employee elects to use SpringfieldMeds CanaRx bills the City directly for the drugs shipped to the employee, and Springfield pays CanaRx. Springfield monitors the CanaRx drug prices it is charged to ensure adequate savings are being realized.

The Washington Post reported that 3,200 city employees and other city-covered populations used the program, and the city saved and estimated $2.5 million in prescription drug costs in its first year of operation.[23] Several other municipalities in Massachusetts have set up similar programs, including Boston, Cambridge, Newton, and several towns on Cape Cod.

RIMeds—Rhode Island

"RIMeds" was developed through the efforts of Rhode Island Secretary of State Matt Brown in response to concerns he received from residents about the increasing costs of prescription drugs. It is unusual in that it is an independent activity of the Secretary of State without authorization or approval from the Governor or State Legislature. The Canadian pharmacy benefits management company, CanaRx. Inc. was invited to Rhode Island by Secretary Brown to propose an importation program. CanaRx presented a program that was judged to have adequate drug safety measures by advisors to the Secretary of State. A dedicated website[24] and a toll-free phone number were set up for use by residents of Rhode Island.

Through RIMeds, Rhode Islanders may obtain drugs from Canada and the United Kingdom. According to the RIMeds website, the "CanaRx Pharmacy Network includes accredited Canadian pharmacies and State inspected International pharmacies" but does not identify the "State" or states that conducted the inspections. The website also states that "All medications dispensed through the CanaRx network of pharmacies are supplied through closely monitored government regulated distribution systems of the countries of origin, typically involving only a manufacturer, a wholesaler and a Pharmacy." Prescriptions are filled only for refill maintenance medications that have been taken by the patient for at least 30 days. Drugs available as generics in the United States are also available through RIMeds, but the website alerts potential customers that these drugs may be cheaper locally.

As of December 2005, approximately 100 people in Rhode Island had used program services.[25] The State of Rhode Island has not joined any existing program, because the Governor of Rhode Island currently opposes personal use prescription drug importation due to safety and legal concerns.

[22] Available at http://www.springfieldmeds.com.
[23] Connolly, Ceci. Drug Reimportation Plan Saves City $2.5 Million. Washington Post. July 15, 2004.
[24] Available at http://www.rimeds.com.
[25] Personal Communication, Paul Tencher, Office of the Secretary of State, State of Rhode Island. December 2005.

Independent of RIMeds, the Rhode Island legislature enacted a law in 2004 that authorizes the Rhode Island Department of Health to license Canadian pharmacies to import medications into Rhode Island. In a letter to the Attorney General of the State of Rhode Island, the FDA warned that the program presents safety risks to consumers and that it violates the FFDCA. According to the Rhode Island Secretary of State Press Secretary, no Canadian pharmacies had completed the licensing requirements as of December 2005.[26]

C. SAFETY, EQUIVALENCY, AND EFFICACY

Introduction

This section examines a number of areas related to the drug safety, efficacy and equivalency of drug importation programs. In addition, state regulatory issues are reviewed noting areas where present regulations may affect the importation of prescription medications.

The ordering of prescription drugs over the Internet by individual people is at best a risky proposition, as it is nearly impossible for individuals to verify the locations of Internet pharmacies and the sources and dependability of the medications supplied from such sources. The World Health Organization reports that it is estimated that more than 10% of the global medicines market is made up of counterfeit drugs and suggests that Internet-based sales of prescription drugs in industrialized countries are a major source of counterfeit medicines.[27] A June 2004 General Accounting Office (now known as the Government Accountability Office) report indicates both the ease with which one may order prescription drugs via Internet pharmacies located throughout the world (with or without a written prescription) and the range of safety, equivalency, and efficacy problems associated with drugs purchased from Internet pharmacies.[28] Some of the problems reported in the GAO report included improper handling (drugs requiring temperature control shipped in non-insulated envelopes), drugs shipped without dispensing pharmacy labels or warning information, receipt of counterfeit drugs, and not receiving drugs paid for. Another report from Department of Health and Human Services described the significant risks associated with the way individuals are currently importing drugs.[29] Establishing a network of pharmacies operating under similar standards and under the supervision of a central resource may overcome some of the problems described by the GAO, HHS, and others. However, a number of issues must be addressed in order to ensure safety, equivalency, and efficacy.

The government sponsored programs analyzed in this report have implemented several of the same basic safety measures, including:

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[26] Personal Communication, Paul Tencher, December 2005.
[27] Available at http://www.who.int/mediacentre/factsheets/fs275/en/print.html.
[28] United States General Accounting Office, *Internet Pharmacies: Some Pose Safety Risks for Consumers*, June 2004. Available at http://www.gao.gov/new.items/d04820.pdf. See Appendix 7 of this report for the Executive Summary of this GAO report.
[29] Health and Human Services Task Force, *Report on Prescription Drug Importation*, December 2004. Available at http://www.hhs.gov/importtaskforce/Report1220.pdf. See Appendix 8 of this report for the Executive Summary of this HHS Report.

- 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 as well as legal and regulatory concerns.
- Exclusion of medications used to treat acute illnesses, 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 used to treat chronic conditions. Each prescription must be filled initially 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.

Basic findings about drug safety, equivalency, and efficacy in Canada and Europe and safety measures implemented by existing programs.

Illinois

The I-SaveRx report on importing drugs from Canada discussed many issues regarding patient safety. The safety recommendations that were ultimately implemented include filling only refill prescriptions for customers who had been prescribed and tolerated a prescription drug for a minimum of one month; requiring patients to submit a medical history (see Appendix 6) that includes a list of all current prescription and over-the-counter medications and herbal, nutritional and vitamin supplements, operations, hospitalizations, present illness, and drug allergies; restricting available drugs to those required for a chronic condition, and requiring, wherever possible, pharmacies to fill and label prescription medication using "unit of use" packaging sealed and shipped directly from the manufacturer. The primary care pharmacist model, under which a patient's entire domestic and imported medication profile is monitored, and a drug testing quality assurance component were recommended, but have not been implemented to date.

The I-SaveRx team, which included pharmacists, a physician, and attorneys employed at several Illinois state agencies also investigated the Canadian regulatory system for pharmaceuticals and pharmacies. The team concluded that although not identical to the system in the US, both countries' methods of ensuring safety and efficacy of prescription drugs are effective.

In investigating the possibility of importing drugs from Europe, the Illinois team, which consisted of many of the same individuals as the Canadian investigation team, assessed and inspected pharmacy practices, pharmaceutical manufacturing, warehousing, storage, and distribution processes and compared these to Illinois standards. Where possible, the team also researched the regulatory processes and standards regarding the safety and efficacy of drugs, pharmacy practices, and drug dispensing. Unlike most prescription processing in the US, Canadian and European pharmacies often dispense medications in blister pack cards that are sealed in boxes by the manufacturer. In the opinion of the Illinois Special Advocate, this reduces the chances of processing vulnerability and counterfeiting.

Additionally, the Illinois team found that the European requirements for licensure as a pharmacist are substantially equivalent to Illinois standards; that storage conditions for prescription medications within the European pharmacies visited were similar to pharmacies in

Illinois, and that drug distribution streams in Europe (and Canada) generally involved fewer intermediate steps than in the United States. A possible exception involves the parallel importation of medications, which is common throughout the European Union. Under parallel importation medications are sold, shipped and transferred from a country with lower drug costs to those with higher costs. Many of the drugs that are parallel imported into the U.K. come from Greece, Italy, and Spain. The I-SaveRx program prohibits its contracted U.K. pharmacies from shipping parallel imported drugs to I-SaveRx customers unless the drugs are parallel imported from Ireland and were originally marketed for use in Ireland.

Minnesota

Minnesota set basic criteria, which Canadian pharmacies had to meet in order to participate in its program. For example, participating pharmacies had to be located in Canada, be licensed in accordance with Canadian laws, be willing to guarantee affordable prices, and be willing to allow Minnesota officials to visit their facilities. Minnesota state officials, including pharmacists, visited eight Canadian pharmacies and reviewed licensing requirements, safety protocols, order filling processes, and drug prices. Four Canadian pharmacies were selected for participation in the program. Selection of pharmacies was based largely on judgments by the Minnesota team about observed safety practices during site visits. Pharmacies selected for the program agreed to several additional safety measures, including:

- Maintenance of a Canadian license and assurance that employees have necessary Canadian licenses,
- Requiring a prescription from a US physician,
- Providing only prescription medications that are approved by Canada's Therapeutic Products Directorate for sale in Canada,
- Excluding medications for which no US FDA approved equivalent exists and medications that cannot be safely shipped.

The Minnesota programs added UK pharmacies as a source of prescription drugs in June 2005. Department of Human Services personnel, including a pharmacist, inspected UK pharmacies and wholesalers in March 2005, and conducted background research to learn about the pharmaceutical system in the UK. The UK pharmacies were associated with two of the Canadian pharmacies already participating in the Minnesota importation program. The decision to add the UK pharmacies to the program was based on the results of pharmacy inspections and research findings regarding the UK's prescription drug system and was conditioned on the UK pharmacies following the requirements imposed on the Canadian pharmacies participating in the program.

In contrast to I-SaveRx, the Minnesota program places no limitations on parallel imported medications. Medications from other European Union nations may to be dispensed by UK pharmacies at the discretion of the program participant.

Safety, Equivalency and Efficacy[30]

At present, medications sold and marketed in the United States are manufactured in plants under Federal Food and Drug Administration regulation, regardless of the country in which these drugs are manufactured. A number of drugs sold in the United States by drug manufacturers recognized as "American" are made in counties other than the United States. An estimated 44 percent of the medications consumed in Canada are manufactured in the US. The balance of medications sold in Canada comes from more than 80 other countries. The proportion of shipments from developing countries is increasing rapidly.[31]

In order to be sold legally in the United States drugs must be manufactured under FDA regulation and inspection. While it appears that Canada has similar regulatory oversight, a number of issues arise when the issue of importation is considered.

Drugs manufactured in the United States for shipment to other countries are not subject to the same FDA inspection and regulatory provisions as those made for consumption in the US. Drugs manufactured for export are the same chemical entities and are made in the same FDA inspected facilities. However, they are not subject to the same degree of regulatory review and oversight. This is not to say that Health Canada operates under lower standards; only that these medications are not necessarily made under FDA regulatory oversight. Health Canada is responsible for compliance monitoring and enforcement. The Health Products and Food Branch Inspectorate is primarily responsible for health product compliance monitoring activities such as industry inspection and product investigation. Health Canada focuses its activities on the products provided to the residents of Canada.

In addition, Health Canada has stated its intention to limit the scope of its inspection to drugs destined for US residents. This creates an area of potential vulnerability with regard to the quality of medications that may be used to fill prescriptions prepared outside the US for US residents. The Minnesota and Illinois plans attempt to safeguard against the potential lack of monitoring of drugs for export by requiring that the drugs exported by Canadian pharmacies be approved for consumption by Canadian citizens and, therefore, manufactured at facilities approved by Health Canada's Therapeutic Product Directorate.

In order to be FDA approved a medication must be manufactured under its specific regulatory oversight and must contain packaging and labeling specifically required for sale in the US. The FDA defines the "label" as the actual package label plus other materials such as the package insert. The FDA maintains specifications for information required on the label of each medication sold in the US. In addition the FDA requires a national drug code, lot number, and expiration date. Medications prepared in the US for export to other counties are packaged in such a way as to comply with the requirements of the importing countries, which commonly

[30] The following discussion focuses on some of the safety, equivalency, and efficacy issues that persist despite existing laws and regulations related to the safety of pharmaceuticals in foreign countries and additional safety measures put in place by existing programs. It is presented here to show the additional drug safety, equivalency, and efficacy issues that the State of Connecticut might need to address prior to initiating or joining an existing importation program.

[31] Available at http://www.pharmacytimes.com/ArticlePrinterFriendly.cfm?ID=1901.

require other information on the package label. Medications labeled for use in another country are not considered to be FDA approved.

Connecticut pharmacy regulations contain a number of provisions relevant to the importation of medications. Sec. 20-627 through 20-630 define a Nonresident Pharmacy and specifies the requirement for registration with the state of Connecticut for any pharmacy "which ships, mails or delivers, in any manner, legend devices or legend drugs… into this state pursuant to a prescription order." In essence these sections regulate the practice of pharmacy extended to patients in Connecticut from locations other than Connecticut. One requirement references the non resident pharmacy's license and requires a copy of a recent inspection report issued by the "state in which it is located." While clear in its intent, this regulation would create enforcement difficulties as State Drug Control would have limited jurisdiction and recourse to deal with a foreign pharmacy in the case of consumer complaint. In addition, Section 20-630 prohibits the advertisement of a nonresident pharmacy "likely to induce the members of the public in this state to use the pharmacy to dispense prescription orders," unless the registration requirements noted in 20-627 are met.

Some drugs marketed in other countries have different brand names than those used in the US. For example, on the I-SaveRx website the popular drug, Norvasc (US) is listed as being available from the United Kingdom under the brand name Istin. Similar differences were noted with some other popular brand names. In addition, some popular brand names used in the United States contain entirely different active ingredients in other countries. For example, US trade names such as Flomax and Dilacor are used for entirely different drugs in other countries.

In Europe the practice of parallel trading of pharmaceutical products is commonplace. Parallel trading involves the procurement of products from a country where the products are available at a lower cost for use in a country with higher costs. It is estimated that 70 percent of the parallel traded medications in Europe are headed for the UK, and they account for 20 percent of the prescriptions dispensed there. In the process of parallel trading pharmaceutical products are repackaged and relabeled and the information contained in such materials as package inserts is translated into the language of the importing country. Repackagers play an important role in parallel trading through their gathering of medications, obtaining the needed translations and conversions, and in the actual repackaging process. In the process of parallel trading medications that appear different, have different names, and come from different manufactured batches with different expiration dates may be mixed prior to repackaging. In the process of packaging and repackaging medications may cross numerous borders, which can cause difficulty in determining expiration dates. To address these issues, the I-SaveRx program limits medications acquired through the parallel importation mechanism to those manufactured in Ireland.

To date, few studies have evaluated the equivalency of foreign medications to their American counterparts. Such studies would need to compare at least four characteristics of a prepared dosage form including: presence of the proper amount of the active ingredient, lack of toxic or undesired chemicals, the stability of the finished product, and the ability of the finished dosage form to act properly in the body with regards to dissolution, absorption, and the ability to elicit

the desired effect. To date, none of the programs discussed in this report had implemented a quality assurance or drug testing program.

The use of the Internet is a primary vehicle for operation of importation programs raises some specific concerns. In at least two cases, copycat websites are using slightly different web addresses (e.g., one additional character or .net instead of .com) than the official importation program websites. These differences could easily result in individuals placing orders with non-program pharmacies—pharmacies that have not undergone the inspection and review process by program administrators. For example, using one non-program site, medications can be ordered from Chile, Israel, and Australia in addition to the United Kingdom and Canada. Pricing among these pharmacies also varies widely. Copycat websites can lead to confusion among consumers and potentially significant health risks related to drug safety, equivalence, and efficacy.

Issues involving prescription processing/preparation and medical records:

Just like in the United States, a pharmacist practicing in Canada or the UK requires a prescription to dispense a medication to a patient. In addition, the prescription must be written by a physician practicing in the country where the dispensing pharmacy is located. The importation models studied all required the prescription written by a physician in the United States to be rewritten by a physician practicing in the country where the medication was dispensed before it can be filled and shipped. This rewriting process is not primarily intended as a medical function but rather serves to provide the foreign pharmacist with a legal prescription for filling and record purposes.

In the I-SaveRx and Springfield Meds programs, CanaRx receives written prescriptions either directly from a patient or from the patient's US physician by fax or through the mail. These faxed or original prescriptions are then rewritten by the foreign physician and forwarded to the pharmacy for dispensing and shipment to the patient. Prior to rewriting the prescription, the foreign physician reviews the prescription for appropriateness by reviewing the patient's health information reported by the patient and the medications the patient has on record in the foreign country. This new foreign rewritten prescription is then entered into the pharmacist's computer to prepare the prescription label and complete the filling process. The additional steps in this process increase the chance of a transcription error.

Packaging is another potential safety issue arising from medications prepared in foreign pharmacies. In the United States prescriptions must be dispensed in child safe containers unless a patient specifically requests non-safety closures. In reviewing reports of dispensing practices of pharmacies visited in Canada, some did not prepare prescriptions in child safe containers and did not appear to have a mechanism in place to individually decide which patients would receive prescriptions in child safe or non child safe containers. Further, the use of blister packaged medications is not in and of itself a child safe packaging method.

The use of a medical history provided solely by the patient may not ensure that medications are appropriately prescribed. In some models studied, a PBM uses the patient's medical history to screen for interactions and dangerous combinations. However, this screening function may not be sufficient for patients whose medication regimen and profile are not complete. The fact that the foreign databases rely entirely upon patient self reported data presents a potential problem.

To address this area of concern, the Illinois Office of Special Advocate for Prescription Drugs proposed the creation of a local "Primary Care Pharmacist" to coordinate the patient's medications. A primary care pharmacist could play an important safety role by assuring a patient's entire medication record is reviewed for interactions, therapeutic duplications, and drug-disease conflicts. This level of safety assurance is difficult if not possible in a fractional system built on obtaining medications from numerous sources. Thus far, the primary care pharmacist system has not been implemented.

While there are great similarities in the practice of pharmacy in both Canada and the United States, differences exist. Canada is currently working to adopt the PharmD as the standard entry degree for its pharmacists as was done in the United States several years ago. Similar to the 50 states, the Canadian provinces have jurisdiction over the practice of medicine and pharmacy. And, just as with the different States, different provinces have different interpretations of what is proper for the professions of pharmacy and medicine. For example, different views exist regarding the appropriateness of Canadian physicians rewriting American prescriptions and regarding the exportation of Canadian medications into the United States. Further, the regulation of pharmacists in Canada is focused soley on the functions pharmacists perform for the residents of Canada. Canadian federal and provincial governments may not bring the same level of resources to bear in regulating activities targeted to residents of another country.

D. LEGAL ISSUES RELATED TO PRESCRIPTION DRUG IMPORTATION

Introduction

This section of the report addresses many of the legal issues raised by the prospect of legislation authorizing Connecticut and its residents to participate in a new or existing program that facilitates the purchase of lower-cost prescription drugs from pharmacies outside of the United States. It covers currently applicable and pending federal law, relevant Connecticut law, relevant Connecticut regulatory practices, potential tort liability issues facing participants in such a program, consumer protections that might be compromised through participation in such a program, and any additional legal implications of purchasing or facilitating the purchase of imported or reimported drugs. Throughout, the section highlights areas in which the State might face potential liability.

The primary area of legal concern for Connecticut around implementing an importation program is existing federal law under the Federal Food, Drug and Cosmetic Act. Under existing statutes and agency regulations, importation programs violate federal law in various respects. The FFDCA is under a good deal of pressure from all sides, however, and it is entirely possible that it will change in relevant ways in the near future. Existing State law gives rise to less concern. Although Connecticut may have to revisit some existing state laws, it would not require a major upheaval to approve such a program. Moreover, such a program may challenge Connecticut's regulatory efficacy in new ways, but should not prove detrimental to Connecticut's existing efforts to ensure the health and safety of its residents.

Consumers of imported and reimported prescription drugs should retain most if not all of their existing rights under federal and state law, including their rights of redress in the event that they are injured by a drug purchased through the program. While the State may risk certain types of liability under an importation scheme, measures taken by other states will likely mitigate this risk. Accordingly, the primary legal obstacle to lawful implementation of a reimportation/importation program is currently federal food and drug law. For all purposes, however, Connecticut would do well to avoid positioning itself as an importer or distributor of prescription drugs, while retaining an active regulatory in the service of protecting its residents.

1. The Federal Position on the Importation and Reimportation of Prescription Drugs

In essence, the federal position on the importation and reimportation of prescription drugs holds that this practice is, with very few exceptions, prohibited under current law and contrary to the health and safety of the American public. This position has received extensive airing on the part of the federal Food and Drug Administration, its parent agency the Department of Health and Human Services, and various officials in the Bush Administration. Many members of Congress, however, support legislation that will lift this ban imminently.

The FDA and HHS

Federal law regulates the manufacture and distribution of pharmaceuticals in the United States. Specifically, the Federal Food, Drug, and Cosmetic Act, codified at 21 USC § 301 *et seq.*, establishes the Federal Food and Drug Administration, which is responsible for protecting the public health by ensuring that "drugs are safe and effective." See § 393(b)(2)(B). The agency thus monitors the safety and efficacy of prescription drugs, including their approval, manufacturing and distribution. In addition to specifying approval, manufacturing and labeling procedures, among others, the FFDCA essentially creates a "closed" system for drug distribution.[32] Under only two situations may prescription drugs be legally imported according to the FFDCA: 1) those manufactured in foreign facilities inspected and approved by the FDA, see 21 USC §381(a); and 2) those manufactured in the US under approved conditions, subsequently exported, and then reimported into the US by the manufacturer. See 21 USC § 381(d)(1) (subject to limited exceptions, no drug "which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug"). Anyone other than the original manufacturer who reimports or causes the reimportation of FDA-approved drugs in violation of § 381(d)(1) commits a prohibited act under § 331(t).

The history of this provision marks the controversy over reimportation that has brewed for the past two decades. In 1987, The Prescription Drug Marketing Act amended the FFDCA by adding the express provision prohibiting the reimportation of domestically manufactured prescription drugs by anyone other than the manufacturer. Specifically, the provision requires the manufacturer to present records indicating that the product is the same as an FDA-approved drug currently distributed within the US, that the imported product has been handled properly,

[32] See Health and Human Services Task Force, Report on Prescription Drug Importation (2004) ("HHS Task Force Report") at VIII; Letter dated August 25, 2003 from William K. Hubbard, Associate Commissioner for Policy and Planning, FDA, to Gregory Gonot, Deputy Attorney General of California.

and that, where necessary, the product was re-labeled for the US market. See 21 USC § 381(d)(1).

Congress further amended the FFDCA in the Medicine Equity and Drug Safety Act of 2000 ("MEDS"), which authorized a five-year program allowing pharmacists and wholesalers to import certain prescription drugs from foreign suppliers in specified countries. Although the Act called for the Secretary of HHS to publish implementing regulations that would put these provisions into effect, it also required the Secretary first to "demonstrate to Congress that the implementation of this section will (1) pose no additional risk to the public's health and safety; and (2) result in a significant reduction in the cost of covered products to the American consumer." See FFDCA, § 804(l). Similarly, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") once again amended Section 804 of the FFDCA to replace the earlier provisions of the MEDS Act with new language implementing a prescription drug import program that focuses solely on Canada. Like the provisions it replaced, the MMA also requires certification to Congress by the HHS secretary regarding safety and cost. Successive HHS Secretaries Donna Shalala and Tommy Thompson declined to implement these provisions, as has current Secretary Mike Leavitt, because they were allegedly unable to make these demonstrations of safety and cost-savings.

Without the Secretary's certification, the program permitting importation of prescription drugs from Canada cannot take effect. Nothing in Secretary Leavitt's conduct since taking office in January of 2005 or statements issuing from HHS indicates that he is likely to provide such certification. The MMA also mandated two studies of issues surrounding the importation of prescription drugs, one by HHS, published in December 2004 as the *HHS Task Force on Drug Importation, Report on Prescription Drug Importation*, and one by designees of the President focusing on issues related to pharmaceuticals and trade. At this date, the latter report has not yet been issued.[33]

In addition to reimportation restrictions, drugs imported from foreign nations are subject to FFDCA provisions regarding traffic in unapproved new drugs, adulterated drugs, and/or misbranded or improperly labeled drugs. See §§ 351, 352, 353, and 355 (addressing adulterated, misbranded, improperly labeled and new drugs, respectively). FDA recently issued a new prescription drug information format that purports to simplify the information conveyed in the drug inserts to physicians and patients. The rule will go into effect later in 2006 for all new drugs and will eventually cover approved drugs already on the market. This new requirement may pose an additional hurdle to the requirement that any drugs produced for foreign markets

[33] The HHS Task Force Report has received criticism for its one-sidedness. One consultant from the United Kingdom who testified before the Task Force noted that the Report "isn't just overwhelmingly negative, it is entirely so. Every conceivable theoretical problem has been raised as an insurmountable barrier to importation." Among other things, he objected to the Report's characterization of the European parallel importation system as analogous to the trade of goods between Maryland and Virginia, since the European context involves far less centralized oversight than the domestic movement of goods. Instead, each nation generally imposes its own regulatory system. Donald Macarthur, *Personal Commentary on the HHS Task Force Report on Drug Importation*, January 26, 2005, available at http://www.fairdrugprices.org/hhs%20comment%20-%20Macarthur.pdf

comply fully with FDA standards of approved drugs.[34] Both the FDA and the Bureau of Customs and Border Protection (CBP) are responsible for examining importations that cross the nation's borders and for detaining any FDA-regulated products that may pose a health risk in the United States. Imported drugs are subject to detention by the FDA and CBP, which may deny entry to any products that appear to violate US law or regulatory standards.

As a general matter, the FDA is interested in two types of prescription drug imports: commercial imports by wholesalers and pharmacies and personal imports by consumers. In recent years the FDA has permitted individual consumers to import up to a 90-day supply of prescription medication into the United States without consequence under the FFDCA. Yet the agency has emphasized that its personal importation policy is not to be taken as an authorization for individuals to import limited supplies of prescription drugs at their own will, but is rather to be understood as an effort to provide guidance to the agency for the use of its discretion in enforcing these provisions of the FFDCA. The agency's policy on personal importations states that "FDA personnel may use their discretion to allow entry of shipments of violative FDA regulated products when the quantity and purpose are clearly for personal use, and the product does not present an unreasonable risk to the user. . . . Although FDA may use discretion to allow admission of certain violative items, this should not be interpreted as a license to individuals to bring in such shipments."[35] With respect to drugs imported for personal use, FDA personnel are instructed to consider issues of risk and availability within the United States.

Despite its general policy of nonenforcement, many drugs crossing the US borders for personal importation have already been seized by the FDA and CBP, some ordered as part of the I-SaveRx Program. One report suggested that over one-quarter of the shipments ordered through the I-SaveRx Program in the first two weeks of February, 2005, were detained at the border.[36] A recent article in the *Los Angeles Times* reported a significant increase in seizures of drugs ordered through Canadian pharmacies during December of 2005 and January of 2006. In the case of one pharmacy, the numbers increased from the usual average of fifteen seizures per month to over 800 seizures in January.[37] Such events suggest that, while the FDA may not target its resources toward enforcing the law against personal importation, neither is such activity immune from federal regulation.

The FDA's position on the importation of prescription drugs from foreign nations, whether through a program such as I-SaveRx or through individual foreign pharmacies licensed in a particular state, is clear and unequivocal: the FDA contends that such importation violates federal law and endangers the health and safety of US residents. In nearly identical language, the FDA has elaborated this position over a series of letters composed between February 2003 and November 2005 and addressed to officials in state and local government, representatives of

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[34] See FDA Announces New Prescription Drug Information Format to Improve Patient Safety, FDA Press Release, January 18, 2006.
[35] FDA Regulation Procedures Manual Chapter 9, Subchapter Personal Importations, available at http://www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html.

[36] See FDA *Seizes Some Medications from I-SaveRx Reimportation Program*, Kaiser Family Foundation Daily Health Policy Reports, March 10, 2005, available at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=28580
[37] *More Medicines From Abroad Seized*, L.A. Times, Feb. 11, 2006.

companies facilitating importation, and others, including CanaRx. After summarizing the provisions of the FFDCA that apply to importation, the agency writes in a letter to the Governor of Oregon:

> Thus, to comply with the Act when shipping prescription drugs to consumers in the United States, businesses and individuals must ensure, among other things, that the drugs sold (1) are FDA-approved; (2) comply with an applicable FDA approval in all respects and (3) if manufactured in the United States, are imported back into the United States only by the manufacturer. The businesses and individuals must also ensure that each drug meets all U.S. labeling requirements (sections 502 and 503(b) of the Act). In addition, the drug must be dispensed by a pharmacist pursuant to a valid prescription (section 503(b)(1) of the Act).
>
> Practically speaking, it is extremely unlikely that a foreign wholesaler or pharmacy could ensure that all of the applicable legal requirements for importation are met. Consequently, almost every time an individual or business ships a prescription drug from Canada or brings that drug into the United States for overnight shipment to a U.S. consumer, that individual or business violates the Act. Moreover, individuals, businesses, and their responsible personnel that cause those shipments also violate the Act (section 301 of the Act).[38]

As the sole agency charged with the responsibility of enforcing the FFDCA, the FDA's interpretation of the statute is entitled to great deference and would certainly bear substantial weight in any enforcement action the agency chose to bring against a state. Indeed, several courts have underscored the FDA's role in implementing and enforcing the statute.[39] In the letter quoted above and many other documents, the FDA has indicated that a state or municipality that facilitates importation of prescription drugs from Canada or other nations will likely violate the FFDCA and might be subject injunctive relief and even civil or criminal penalties.

Even if Connecticut's participation in the I-SaveRx Program or another importation program does not amount directly to acts prohibited by 21 USC § 331, the State nonetheless violates the FFDCA if its promotion of such programs "caus[e]" the prohibited acts. In 2003, a federal court issued a preliminary injunction against two corporate defendants that served as clearinghouses for Canadian pharmacies.[40] These clearinghouses, RxDepot, Inc. and Rx of Canada, LLC, facilitated prescription drug transactions according to a system nearly identical to that of CanaRx in its administration of the I-SaveRx Program. For providing these services, the clearinghouses received a 10-12 percent commission on each sale. They also actively sought other entities to run franchise affiliates of their operation.

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[38] Letter dated October 14, 2005 to the The Honorable Theodore R. Kulongoski, Governor of Oregon, from Randall W. Lutter, Acting Associate Commissioner for Policy and Planning, FDA, available at http://www.fda.gov/oc/opacom/hottopics/importdrugs/kulongoski101405.html

[39] See, e.g., Vermont v. Leavitt, 2005 US Dist. LEXIS 20864 (D. Vt., 2005); Andrews v. HHS, 2005 US Dist. LEXIS 5710 (D.D.C. 2005); United States v. RxDepot, 290 F. Supp. 1238 (N.D. Okl. 2003).

[40] RxDepot, 290 F. Supp. 2d at 1247.

The defendants admitted that they were engaged in the business of causing the shipment of US-manufactured and unapproved, foreign-manufactured prescription drugs from Canadian pharmacies to US consumers. Accordingly, the court noted that they "openly and notoriously violate[d] the law." Specifically, the clearinghouses "advertise and handle orders for Canadian pharmacies and are remunerated for their efforts. Their actions encouraging and facilitating the illegal importation of drugs amounts to a responsible share in the furtherance of these transactions prohibited by the FFDCA. Thus, their actions constitute the requisite 'causing' under 21 USC § 331."[41] Since this case was decided, the FDA has been including a discussion of the court's language and reasoning in its letters regarding reimportation programs.

While it is unclear whether Connecticut's participation in an existing drug importation program such as I-SaveRx or its development of a new program to facilitate the purchase of prescription drugs from Canada and other approved countries would fall within the category of conduct enjoined under RxDepot, this prospect has raised concern in other states investigating the legality of importation programs for prescription drugs. For example, the Kansas Attorney General opined that "at best, Kansas' involvement [in the I-SaveRx Program] comes perilously close to causing violations of the FFDCA and at worst does cause such violations."[42]

In its report on the feasibility of purchasing prescription drugs from Europe, Illinois points out that the federal government stated explicitly in its motion to dismiss a recent suit against HHS for not implementing reimportation regulations that "the government has not brought, and is not threatening to bring, a single criminal or civil judicial enforcement action against a consumer who has purchased drugs from Canada for personal use, by mail order or otherwise."[43] Many commentators agree, however, that the FDA has sent mixed messages with regard to its intent to enforce these provisions of the FFDCA in the context of personal reimportation, particularly against states that facilitate the activity.

Yet former FDA Commissioner and current Dean of the Yale School of Medicine David Kessler, who had long voiced reservations about opening up US borders to trade in prescription drugs, nonetheless testified in April 2005 before a Senate Health, Education, Labor and Pensions Committee hearing that "The choice before you is not the choice of imports or no imports . . . . We already have a system of importation of drugs that jeopardizes public health."[44] It is unclear whether or not increasing pressure on the federal government by critics of the reimportation ban and the stark recognition that US residents are purchasing prescription drugs in great quantities through foreign pharmacies will persuade the agency to change its doomsday position and implement regulations permitting reimportation of prescription drugs under the Medicare Modernization Act.

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[41] Id.
[42] Kansas Attorney General Opinion No. 2005-11, March 20, 2005, available at http://www.kscourts.org/ksag/opinions/2005/2005-11.htm. See also letter dated January 28, 2004 to The Honorable Kunar P. Barve from Kathryn M. Rowe, Assistant Attorney General, State of Maryland (cited in KS AG Opinion).
[43] Can Illinois Residents and Businesses Safely and Effectively Purchase Prescriptions Drugs from Europe? June 28, 2004, at 10. See also Andrews v. HHS, 2005 US Dist. LEXIS 5710 (2005), granting the Government's motion.
[44] GOP Spars Over Drug Import Bill, The Washington Post, April 20, 2005 at A23.

Potential Penalties

The FDA can pursue a variety of penalties against a person or entity that violates provisions of the FFDCA. The government may seek an injunction in federal court against the violating party. 21 U.S.C. § 332. Any drug alleged to be adulterated or misbranded is subject to seizure under the Act, 21 U.S.C. § 334, and drugs purchased through the I-SaveRx Program have been seized under this section. Under § 333, the violator may face criminal penalties as follows: 1) Violations of the Act's general prohibitions constitute misdemeanor offenses punishable by up to a year in prison or a fine of up to $1,000, or both. Misdemeanor violations of the Act are offenses for which no intent to mislead or defraud need be proved. 2) Where someone violates the Act with the intent to defraud or mislead or does so after a prior violation, that person may be guilty of a felony offense punishable by up to three years in prison or a fine of up to $10,000, or both. 3) If a person or business knowingly imports a drug in violation of the "American goods returned" provision of 21 U.S.C. § 381(d)(1), that violation constitutes a felony offense punishable by up to 10 years in prison or $250,000 in fines.[45] 4) In addition, any person or entity that aids and abets a violation of the Act or conspires to violate the act may also be criminally liable under federal criminal law for the separate offenses of aiding or abetting or conspiring to commit any criminal offense against the United States. 18 U.S.C. §§ 2, 371.

These designated penalties, however, do not capture the full range of possible fines. The Sentencing Reform Act of 1984 raised the limit on maximum penalties applicable to federal crimes such that, for example, a misdemeanor violation of the FFDCA is actually punishable by a fine of up to $100,000 for individuals and $ 200,000 for organizations. Likewise, felony violations are punishable by fines of up to $250,000 for individuals and $500,000 for organizations.

Finally, any person or organization that "caus[es]" a prohibited act under the FFDCA may face civil and criminal liability. 21 U.S.C. § 331 ("The following acts and the causing thereof are hereby prohibited"). Thus, as explained above, a business or state agency that facilitates the importation of unapproved prescription drugs or U.S. manufactured prescription drugs may be liable for "causing" violations of the Act. While the FDA has threatened to target states and municipalities under this provision, it has not done so to date. As of August 2004, moreover, the FDA had indicated that it was unlikely to sue the state of Illinois even when the I-SaveRx Program expanded to include countries other than Canada.[46]

One additional possibility is an action by the Centers for Medicare and Medicaid Services, which may refuse Medicaid funds to a state that directly imports drugs for its residents from foreign sources.[47]

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[45] See generally Letter of January 28, 2005 from William K. Hubbard, FDA Associate Commissioner for Policy and Planning, to Patrick Lynch, Attorney General of Rhode Island.

[46] See *FDA Signals Reluctance to Sue Illinois for Importing Drugs*, FDA Week, Aug. 20, 2004.

[47] See *CMS Could Refuse Medicaid Approvals for Rx-Importing States*, FDA Week, Dec. 10, 2004.

President George W. Bush

Although President Bush continues publicly to oppose legalizing reimportation of prescription drugs, he did sign a recent appropriations bill that contained a provision excluding from future free trade agreements language categorically restricting reimportation between the signatory nations. Upon signing the bill, however, the President noted that he considered this provision "an advisory" and will consider whether or not to enforce it. This bill will be discussed later in this Report.

State Responses to the Federal Position

States and municipalities have submitted to the FDA request after request for waivers of the reimportation ban as to proposed programs enabling residents to purchase lower-cost drugs through foreign pharmacies. Not one of these waivers has been granted. In addition, several government officials have solicited legal opinions from the FDA regarding the legality of pending or proposed legislation or programs establishing such programs. The FDA has also sent letters of warning to various entities involved in the facilitation of prescription drug importation, including CanaRx. Every document has reiterated the FDA position summarized above: such programs violate the FFDCA in every imaginable instance and give rise to potential liability for participants under the statute.

Although several states have proceeded with the I-SaveRx Program, and other states and municipalities have developed additional programs and policies that entail importation and reimportation even in the face of FDA's cautions, some states have put such programs on hold in response to federal resistance. For instance, within the past two months both the Nevada and Texas attorneys general have issued opinions arguing that pending laws permitting reimportation of prescription drugs violate federal law.

On Dec. 27, 2005, Nevada Attorney General George Chanos issued an opinion contending that a state law permitting residents to purchase lower-cost prescription drugs from Canada faces insurmountable legal obstacles. Under a Nevada law that took effect on July 1, 2005, state residents can purchase a 90-day supply of medication from licensed Canadian pharmacies through a state-run website. Four licensing applications pending from Canadian pharmacies compelled the Board of Pharmacy to seek Chanos' interpretation of a provision in the law requiring reimported drugs to be approved by the FDA. AG opinions have no force of law in Nevada, so the Pharmacy Board will have to decide whether or not to proceed with the licensing applications.[48]

In Texas, the Attorney General struck down a recently enacted law requiring the Texas Board of Pharmacy to provide information on a website that assists state residents in purchasing prescription drugs from approved Canadian pharmacies inspected by the Board. The program was placed on hold to give state attorneys time to review a complaint from the FDA. Abbott opined that the statute violated the federal Food, Drug and Cosmetic Act because, among other

[48] Opinion available at http://ag.state.nv.us/agopinions/2005/sb5.pdf.

things, the program "caused" the reimportation of prescription drugs.[49] Although the Attorney General of Kansas took the same position with regard to the illegality of importing prescription drugs under federal law, Kansas has joined the I-SaveRx Program.

While California has refrained from passing importation legislation in light of the FDA's position, Governor Schwarzenegger recently submitted a letter to congressional leaders urging them to ease federal restrictions on the importation of safe and lower-cost medicines from abroad. The size and influence of California may underscore Schwarzenegger's call to action.[50] Shortly after Schwarzenegger linked drug importation to lower health care costs for residents of California, however, former HHS Secretary Tommy Thompson wrote an op-ed piece for the San Diego Union-Tribune contending that importation continues to pose serious safety concerns and that the new Medicare prescription drug plan accomplishes the same result as drug importation: lower-cost drugs for seniors.[51]

Some states also provide disclaimers on their web sites around the decision of a consumer to engage in importation. For example, once a consumer begins the process of ordering prescription drugs through Wisconsin's program linking directly to approved Canadian pharmacies, she can click on a link for "Important Information Regarding the Legality of Purchasing Medications From Canada." The following statement appears:

> There are certain unavoidable risks inherent with the purchase of medication. As with all important purchases you make, education about your needs and the product to be purchased will best minimize these risks. The State of Wisconsin has exercised its discretionary authority to visit the physical locations of the web site pharmacies listed on this site, and is confident that the prescription medications listed by these pharmacies on this web site will be dispensed in a safe manner.
>
> However, the State of Wisconsin currently does not license these pharmacies, which are otherwise licensed by the relevant provincial authorities in Canada. Furthermore, while the United States Food and Drug Administration has implemented a personal use importation policy that results in enforcement discretion on the importation of drugs from Canada, it is the federal government's position that applicable federal law currently prohibits such importation. The user of this web site assumes sole responsibility for any decisions made based upon visiting this web site, including the purchase of any and all prescription medications from the Canadian pharmacies listed herein. The State of Wisconsin, as well as its officers and employees, makes no representation as to the legality of the importation or reimportation of pharmaceuticals from Canada, and it expressly disclaims any and all liability from such importation or reimportation or the use of any products so acquired.[52]

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[49] Opinion No. GA-0384 of the Attorney General of Texas (Greg Abbott), December 21, 2005, available at: http://www.oag.state.tx.us/opinions/ga/ga0384.pdf.
[50] See *A plea to lift ban on drug imports*, The Christian Science Monitor, January 18, 2006, available at: http://www.csmonitor.com/2006/0118/p02s02-uspo.htm
[51] *Californians should reject drug importation*, San Diego Union-Tribune, January 19, 2006.
[52] Available at http://drugsavings.wi.gov/medicinesummary.asp?drugid=109&linkid=17&locid=2.

The Report discusses such waivers in more detail below.

In sum, the Bush Administration has taken a strong position against legalizing the importation and reimportation of prescription drugs. Under current federal law as interpreted thus far, reimportation programs are most likely illegal. It is unclear what if any effect a disclaimer like Wisconsin's may have on a state's potential liability for "causing" a violation of federal law.

2. Pending federal legislation that pertains to reimportation

Three pending bills would dramatically affect federal reimportation laws: (1) The Pharmaceutical Market Access Act of 2005 (S. 109, introduced by Senator Vitter on January 24, 2005, and H.R. 328, introduced by Representative Gutknecht on January 25, 2005); (2) The Safe Importation of Medical Products and Other Rx Therapies Act of 2005, or the Safe IMPORT Act of 2005 (S. 184, introduced by Senator Gregg on January 226, 2005, and H.R. 753, introduced by Representative Bradley on February 10, 2005); and The Pharmaceutical Market Access Act and Drug Safety Act of 2005 (S. 334, introduced by Senator Dorgan on February 9, 2005, and H.R. 700, introduced by Representative Emerson on the same day). All three would amend the FFDCA with respect to the importation of prescription drugs.

The Pharmaceutical Market Access Act of 2005 (S. 109/ H.R. 328)

The Pharmaceutical Market Access Act of 2005 ("PMAA") would require the Secretary of Health and Human Services to promulgate regulations permitting pharmacists, pharmacies, wholesalers, and individuals to import qualifying drugs from certain countries into the United States. The Secretary would be required to: (1) educate consumers with regard to the availability of qualifying drugs for import for personal use; (2) inspect the facilities and records of importers and registered exporters to ensure compliance with this Act; and (3) establish a registration fee program to collect an annual fee from registered exporters.

Under this Act, a prescription drug is deemed to be misbranded unless its packaging complies with the requirements for counterfeit-resistant technologies. It also declares that selling or importing a patented drug in the United States that was first sold abroad by or under authority of the owner or licensee of the patent does not constitute patent infringement. The PMAA would allow the Secretary to suspend or terminate the registration of an exporter for failing to maintain substantial compliance with all registration conditions.

The Safe Importation of Medical Products and Other Rx Therapies Act of 2005 (Safe IMPORT Act of 2005 – S. 184/H.R. 753)

This Act would permit personal use importations immediately and would require a one-year waiting period after enactment until commercial imports could begin. A provision would allow the Secretary of HHS to designate additional countries from which to permit importation in three years. The Safe IMPORT Act requires the Secretary to give high priority to enhancing the information management systems of the FDA to improve the detection of intentionally adulterated prescription drugs. It also regulates Internet pharmacies. For instance, it attempts to make Internet programs involved in the purchase and sale of prescription drugs safer by

requiring the Secretary to promulgate regulations requiring designated payment systems, including credit card companies, to prevent sales by unlicensed Internet pharmacies. As an additional safety measure, the Act allows the FDA to detain or temporarily hold prescription drug shipments based on credible information that a drug presents a risk to the public health.

Under this bill, the Secretary has the power to: (1) suspend or debar importation of a particular drug or dosage that poses such a risk or by a particular importer who violates Act requirements; (2) require owners of prescription drugs that have been refused admission into the United States to indicate that information on the drug containers; and (3) authorize other Federal and State officials to conduct inspections to enforce compliance with this Act. A prescription drug offered for importation is deemed misbranded if it has previously been refused admission, unless the person reoffering the drug affirmatively establishes that it complies with applicable requirements. It also sets forth anti-counterfeiting provisions.

The Pharmaceutical Market Access and Drug Safety Act of 2005 (S. 734/H.R. 700) ("PMADSA")

This Act would allow imports of prescription drugs from registered exporters 90 days after enactment and imports from registered importers one year after enactment, but limits such importation to registered importers and individuals for personal use. It establishes registration conditions for importers and exporters and requires the Secretary to inspect places of business, verify chains of custody, inspect facilities, and determine compliance with registration conditions. Moreover, the Act requires the Secretary to educate consumers regarding prescription drug importation and attempts to monitor the Internet programs that allow online purchase and sale of prescription drugs.

The PMADSA sets forth provisions governing the importation of qualifying drugs that are different from US label drugs, including standards for judging such differences. Under this legislation, manufacturers would be prohibited from: (1) discriminating against registered exporters or importers; (2) causing there to be a difference in a prescription drug distributed in the United States and one distributed in a permitted country; (3) engaging in actions to restrict, prohibit, or delay the importation of a qualifying drug; or (4) engaging in any action that the Federal Trade Commission (FTC) determines discriminates against a person who engages or attempts to engage in the importation of a qualifying drug. A provision directly addresses patent concerns, stating that the resale in the United States of prescription drugs that were properly sold abroad is not patent infringement.

Pending Legislation and Internet Pharmacies

The PMAA has no provisions specifically related to Internet pharmacy procedures, but includes qualified Internet pharmacies among other registered exporters and the extensive associated requirements. In contrast, the Safe IMPORT Act and the PMADSA do address Internet pharmacy procedures: they detail standards for registration, posted information, prescriptions, and relationship to medical care.

The Safe IMPORT Act (Gregg-Bradley Bills) presents an extensive statutory and regulatory structure for Internet pharmacies, placing it within the FFDCA, but set apart from the importation sections. In addition to registration the bills would require that Internet pharmacies provide specific professional services, including confidential patient medication profiles, "interactive and meaningful consultation by a licensed pharmacist," and verification of prescription validity. They require advance notice of commercial shipments of prescription drugs, and include a licensing fee. Providers of interactive computer services would be liable if they accept advertising for a prescription drug from an unlicensed Internet pharmacy or accept advertising stating that a physician's prescription is not needed to obtain a prescription drug.

The PMADSA (Dorgan-Emerson Bills) would require that detailed information be accessible on the Internet site, covering pharmacist credentials, address and telephone contacts, and the name and professional licensure information of the person, if any, who provides for medical consultations through the site for purposes of providing prescriptions. No one could dispense or sell a drug if the purchaser or patient who communicated through the Internet did not have a valid US prescription. The dispenser of the prescription drug must have a "qualified medical relationship with the patient."

The AARP has endorsed the Dorgan bill over the others because it believes that the PMADSA would most successfully curtail a drug company's ability to limit the supply of pharmaceuticals to foreign pharmacies.[53] While no action has been taken with respect to the first two bills, Senator Dorgan successfully offered his drug reimportation provision as an amendment to the FTC reauthorization bill (S. 1392), which was approved by the Senate Commerce, Trade and Transportation Committee in July of 2005.

3. Review of applicable state law

Several provisions of existing Connecticut law may require amendment if the State enacts a law facilitating the importation of prescription drugs from foreign pharmacies. In particular, the Pharmacy Practice Act, which regulates the practice of pharmacy within the state, currently contains provisions that would require re-examination in light of legislation authorizing an importation program. Moreover, the legislature might want to consider whether such a program would conflict with any provision of the Retail Drug Control Act. Finally, importation under the current federal regulatory scheme might contravene a provision of the Connecticut Uniform Food, Drug and Cosmetic Act.

The Pharmacy Practice Act

The Pharmacy Practice Act, under the jurisdiction of the Connecticut Department of Consumer Protection, establishes a Commission of Pharmacy responsible for implementing the Act, promulgating relevant regulations, and generally overseeing the practice of pharmacy in the

[53] "AARP Backs Prescription Drug Import Legislation," available at http://www.aarp.org/legislative/prescriptiondrugs/rxprices; see also "Prescription Drug Importation: Can It Help America's Seniors?" Introductory remarks by William Novelli, AARP CEO, Conference Prescription Drug Affordability: Importation and Safety conference, June 22, 2005, available at http://www.aarp.org/health/affordable_drugs/a2004-06-29-importlegislation.html.

State. Conn. Gen. Stat. 400j § 20-570 – § 20-630 (2005). This statute mandates the licensing and registration of every pharmacy and pharmacist engaging in the practice of pharmacy in Connecticut. A reciprocity rule provides that if a pharmacist is duly licensed under the laws of another state, possesses qualifications equal to or greater than those required by Connecticut, and meets specified additional requirements, he or she may legally practice pharmacy here. The Act also requires the commissioner to employ inspectors "whose duty it shall be to inspect all pharmacies and other places in which drugs or devices are or may be dispensed or retailed . . . ." § 20-577(b). Subparagraph (c) of this section specifies that the commissioner shall inspect every retail pharmacy not less than once every four years.

One question that might arise under these provisions is whether the entities engaged by the State as part of a prescription drug importation program could be said to be "practicing pharmacy" in Connecticut. If so, under current law they would need to be licensed here. Participating pharmacies currently require an approved license, which under the terms of the statute is only available in the United States or its Territories. On its website, I-SaveRx contains the following disclaimer: "The I-SaveRx Program is not a licensed pharmacy and is not engaged in the practice of pharmacy."

In addition, under the provision addressing prescriptions and electronic data intermediaries, the Act authorizes an electronic data intermediary to "transfer electronically transmitted data between a prescribing practitioner licensed and authorized to prescribe and a pharmacy of the patient's choice, licensed pursuant to this chapter or licensed under the laws of any other state or territory of the United States." § 20-614(d)(2). Hence an electronic data intermediary would not be permitted under Connecticut law to transmit relevant data to a pharmacy without a valid license.

Exclusion of a foreign pharmacy licensed outside of Connecticut and the United States occurs again in the sections of the Act that address nonresident pharmacies. Here, too, the Act currently requires a valid license, permit or registration to practice pharmacy in some state within the US; in order lawfully to ship prescription drugs into Connecticut, a nonresident pharmacy must fulfill certain requirements such as registering with the Department of Consumer Protection if approved by the Pharmacy Commission. See § 20-627 and § 20-628. Once more, the Act would have to address foreign licensing to bring this provision in line with any reimportation legislation. Without inclusion as a duly licensed nonresident pharmacy, no foreign pharmacy could legally ship prescription drugs into Connecticut or advertise its services here.

The licensing provisions that currently exclude foreign pharmacists and pharmacies are easily amended, however, with the addition of language such as "or approved foreign country" after "United States." Connecticut could also enact a provision similar to one in the Illinois Pharmacy Practice Act of 1987:

> The Department may, in its discretion, license as a pharmacist, without examination, on payment of the required fee, an applicant who is so licensed under the laws of another US jurisdiction or another country, if the requirements for licensure in the other jurisdiction in which the applicant was licensed, were, at the date of his licensure deemed by the Board to be substantially equivalent to the requirements then in force in this State.

Illinois Pharmacy Practice Act of 1987, § 225 ILCS 85/8.

The Uniform Food, Drug, and Cosmetic Act

Connecticut has adopted the Uniform Food, Drug and Cosmetic Act, which prevents the sale of adulterated and misbranded drugs. Other states have their own Food, Drug and Cosmetic Acts regulating the sale and distribution of prescription drugs. For example, Section 720.50 of the Illinois Food, Drug and Cosmetic Act provides requirements for the clear branding and labeling of drugs, among other things. Nothing about prescription drugs imported from foreign sources automatically challenges either Connecticut's Uniform Act or Illinois' Act. An imported or reimported drug may automatically qualify as "misbranded" under the Connecticut Act, however, "[i]f it is a legend drug . . . that is not administered, dispensed, prescribed or otherwise possessed or distributed in accordance with federal and state laws and regulations . . . ." Conn. Gen. Stat. § 21a-106 (k). This provision may raise concerns because, according to the FDA, no reimported drug is currently dispensed or distributed in accordance with federal law. Moreover, until Connecticut amends its Pharmacy Practice Act, the foreign pharmacy distributing such a drug is not properly licensed to do so in Connecticut.

Another section of the Connecticut Act applying to "Drugs dispensed on prescription" appears to mitigate the force of this provision, though, by qualifying that

> [a] drug dispensed on a written or oral prescription of a practitioner licensed by law to administer such drug, except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, shall, if such drug bears a label containing the name and place of business of the dispenser, the serial number and date of filling or refilling of such prescription, the name of such practitioner licensed by law to administer such drugs and the name of the patient, be exempt from the requirements of section 21a-106, except that no prescription for a legend drug or any derivative of any legend drug, shall be refilled except upon the order of the practitioner licensed by law to administer such drug. (§ 21a-109)

As long as any importation program that Connecticut might adopt would not constitute "a business of dispensing drugs pursuant to diagnosis by mail," the existence of a valid prescription and the presence of the required information on an appropriate label appear to insulate the transaction from allegations of misbranding.

4. State regulatory authority

Connecticut's regulatory authority over export prescription processing derives in large part from the statutes discussed above. This section of the report will not discuss the details of pharmacy standards in Connecticut or other states, but it will remark briefly on the application of State pharmacy standards to a new or existing importation program.

At the moment, Connecticut would have very little regulatory authority over export prescription processing. Connecticut could, however, develop new licensing standards applicable to foreign

pharmacies and pharmacists. Thus, the State would directly license all pharmacies approved to dispense prescription drugs to Connecticut residents, treating international pharmacists just like domestic ones that hail from other jurisdictions. In the alternative, as discussed above, the process of registration for nonresident pharmacies could be expanded to include foreign pharmacies. Through licensing and registration, the Commissioner of Consumer Protection could attempt to ensure that foreign pharmacies adhere to Connecticut standards. Finally, Connecticut can regulate the standards of the pharmacies with which it agrees to do business through contractual terms contained in the agreement between the pharmacy and the State. This approach most closely resembles the one at work in the I-SaveRx Program, under which a contract obligates CanaRx, the pharmacy benefits manager, to enforce those standards in the approved pharmacies.[54]

It should be noted that, in the context of its commentary on the recent Texas law requiring the Texas Pharmacy Board to license approved Canadian pharmacies, the FDA expressed doubt around the use of licensing and revocation in enforcing state standards. Specifically, the Agency charged that the Texas law failed to create a "mechanism to ensure compliance by Canadian pharmacies, other than a threat of cancellation of pharmacy licensees by the Texas Board of Pharmacy."[55] Thus, a combination of licensing and contractual terms providing for enforcement of Connecticut pharmacy standards would probably improve upon the efficacy of either one alone.

Each state has a Board of Pharmacy consigned with the responsibility of licensing and overseeing the practice of pharmacy in that state. These agencies function similarly across state lines, even if pharmacy standards vary slightly by state. Were Connecticut to join the I-SaveRx Program, its pharmacy practices would likely affect the existing standards under the program. The Illinois Special Advocate for Prescription Drugs represented that the I-SaveRx program applies pharmacy practice standards consistent with those of all participating states. According to the MOU between the State of Illinois and any state that wishes to join the I-SaveRx Program, oversight occurs through a Joint Working Group composed of two representatives from each participating state in order to "ensure adequate [State] input regarding the safe and effective administration of the I-SaveRx Program."[56] All states participating in the program agree upon a single set of Standards of Practice which, while initially based on Illinois pharmacy standards, now incorporate the most stringent of each state's standards.[57] Accordingly, Connecticut would likely find that the pharmacy standards required of foreign pharmacies approved for the I-SaveRx Program comport with Connecticut's and ensure equivalent safety measures.

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[54] See generally the contract dated October 1, 2004, between the State of Illinois and CanaRx, and particularly Schedule A listing the Standards of Practice.
[55] See Letter from Randall W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning, FDA, to Honorable Rick Perry, Governor of Texas at 1-2 (June 17. 2005).
[56] Memorandum of Understanding for states participating in the I-SaveRx Program, Item II.A.1.
[57] Nonetheless, Kansas posts the following statement on its website linking to I-SaveRx: Pharmacies that participate in the I-Save Rx program have all been physically inspected by Illinois investigators to ensure that they comply with US and Illinois safety standards. These pharmacies are not licensed or inspected by the Kansas Board of Pharmacy. Available at http://www.healthykansas.org/rx_resource_center_isave_rx.html.

5. Potential liability issues for participants in importation programs

In addition to potential liability under federal food and drug law, participants in these programs may face liability under theories of tort. This section focuses on two participants: prescribers and the State. Connecticut should consider the risk of tort liability it might incur if it establishes an importation program and the means of containing that risk.

Tort law

Although HHS in its Task Force Report and the FDA in many of its legal opinions warn that importation and reimportation of prescription drugs pose particular challenges under state tort law, these challenges seem rather minor.[58] At the time of this writing, no case law has yet developed on these issues.

Prescribers

A prescriber writes out or phones in a valid prescription for her patient. In the conventional scenario, the patient then goes to his local pharmacy to have the prescription filled. If the medication makes the patient sick, the prescriber may or may not be liable for the ensuing damage. This situation would be analyzed under state tort law and would include inquiries into the prescriber's compliance with professional standards of medical practice. What happens, however, when the original prescription is processed by a PBM for the purpose of filling it at a foreign pharmacy? Under the I-SaveRx Program and similar programs, several additional parties are involved in the transmission and review of prescriptions. In Canada, for instance, only a prescription signed by a Canadian physician permits pharmacies to dispense medication, so a Canadian doctor must rewrite a US customer's initial prescription.

When a consumer fills a prescription through a foreign pharmacy, the original prescriber may still be liable for malpractice in misdiagnosing or prescribing drugs that are unsafe for her patient, but it is highly unlikely that a prescriber will face additional liability for injuries resulting from the manufacture, storage, labeling, or distribution of a drug purchased from abroad. While the same distinction applies to drugs purchased from domestic sources, the involvement of additional health care providers and others in an importation program might seem to add to the danger that a problem will arise from a drug. It is unclear what, if any, effect the participation of a PBM like CanaRx and a foreign physician who rewrites the prescription in the supplying country would have on prescriber liability. But if anything, these additional parties serve as checks and balances on the original prescriber's judgments regarding potential drug interactions and the like. So, while more can potentially go wrong with the drug and its trajectory, more scrutiny is brought to bear on the prescription itself. Finally, the "learned intermediary" rule generally holds that physicians are in the best position to warn patients of potential side effects and injuries, given their knowledge of and proximity to the patient as compared to the manufacturer and, in many cases, the pharmacist. If the physician has specific concerns about the safety of drugs obtained through foreign pharmacies, she has an ethical and possibly a legal

[58] See generally HHS Task Force Report, Chapter 10, Liability Issues Related to Importation.

obligation to warn her patient accordingly. The context of reimportation raises the possibility of a new duty to warn specifically of the fact and dangers of imported drugs.[59]

It is conceivable that physicians who knowingly write prescriptions for patients who plan to import those drugs from a foreign pharmacy might fall under the "causing" provision of § 331, which imposes liability on anyone "causing" a violation of the American Goods Returned provision. This seems highly unlikely, however. Other liability under the FFDCA seems even more remote. These doctors will not be directly involved in importing, distributing, or facilitating the importation or distribution of drugs that may not comply with FDA rules. Nonetheless, under a program such as I-SaveRx, it would seem safest for physicians not to transmit prescriptions directly to the Pharmacy Benefits Manager or to a foreign pharmacy, but rather to transmit prescriptions to the patient himself.

Nothing in current Connecticut law specifically prohibits physicians from writing prescriptions that their patients intend to fill in foreign pharmacies. Prevailing standards of care generally require an in-person examination or ongoing doctor-patient relationship when a physician writes a prescription for her patient. These standards are implicated when physicians practice "cybermedicine," engaging in diagnostic and prescriptive practices over the Internet. Connecticut doctors who write prescriptions that comply with state and federal requirements for their patients should not face additional liability merely because their patients fill those prescriptions through a program such as I-SaveRx.

Connecticut is a comparative negligence jurisdiction, which means that the parties to a tort action may share legal responsibility for the harm occasioned by their negligence. A fact-finder will apportion liability among any responsible defendants and, if applicable, the plaintiff, so long as a plaintiff's responsibility does not exceed the sum total of the others'; the plaintiff may recover from all responsible defendants according to their share of the liability. See Conn. Gen. Stat. § 52-572h 2004. Thus, several parties may share liability where a patient is harmed by a drug that he or she purchased abroad pursuant to a prescription from a US physician.

Conceivably, an injury arising out of an importation scenario might involve parties over whom a US court would have difficulty asserting jurisdiction, or parties whose assets are beyond the reach of the court. In such a case, those parties actually subject to the proper jurisdiction of the court might have to pay more damages under Connecticut's system of joint and several liability. Under this system, if damages against any liable party are deemed uncollectible, the remaining defendants will be responsible for the entire amount according to their percentage of fault. Such a situation is entirely speculative, however.

State liability

While a state-sponsored importation/reimportation program does not clearly alter the potential liability of any party in the distribution chain – including manufacturers, pharmacies, prescribers, and pharmacy benefits managers – it does add another possibly liable party to the mix: the state. Under a strict liability theory, certain actors in the chain of distribution may be liable toward the injured party irrespective of fault. If a defective pharmaceutical product, whether defective

[59] See HHS Task Force Report 103.

through design or manufacture, mislabeling, misbranding, adulteration or counterfeiting, injures a consumer, any party in the chain of distribution may be subject to suit. A negligence action could also lie against any party involved in the process by which a consumer fills a prescription through a foreign pharmacy, receives the drugs, and then is injured by the drugs. In sponsoring an importation program, a state may face tort liability if it fails to take reasonable measures to protect the health and safety of its residents.

As a general matter, Connecticut and its officers acting in their official capacity are immune to suit under the doctrine of sovereign immunity. A variety of exceptions to this general rule exist, however. For instance, sovereign immunity does not apply to actions against the state seeking injunctive or declaratory relief if such relief does not interfere with governmental functions. Moreover, the state has established a Claims Commissioner to hear and determine most claims for money damages in excessive of $7,500 arising against the State. See Conn. Gen. Stat § 4-142. The Commissioner decides whether the suit can proceed and may also provide limited compensation without suit. Connecticut has also waived its immunity in § 19a-24 as to lawsuits against the Commissioner of Public Health and other State medical officials.

Depending on whether or not the Commissioner of Public Health has a role in overseeing or implementing a prescription drug reimportation program, Connecticut may waive immunity as to suits by consumers injured through their participation in the program. If no specific waiver exists, it is likely that any such claims would go before the Claims Commissioner.

Measures to disclaim liability

States facilitating the importation of prescription drugs from foreign sources have gone to some lengths to disclaim any liability toward consumers participating in those programs. Connecticut should definitely consider including such a disclaimer on all written and electronic materials related to any importation program the State establishes.

For instance, the Kansas web page from which a consumer can link to I-SaveRx contains the following disclaimer:

> Before purchasing medications from Canadian pharmacies, you need to consider possible risks.
> There are risks associated with purchasing medications via the Internet or mail order, and those risks increase when the purchase occurs with a pharmacy or entity outside the United States. You need to be an informed consumer and take these risks into consideration before deciding if purchasing medications from another country is right for you and or your family. The State of Kansas accepts no legal liability or responsibility for the health decisions made by consumers based upon the information provided in this website.

It also posts “Legal Information” on the FDA’s position:

- The United States Food and Drug Administration (FDA) maintains that reimportation into the United States of prescription drugs that were originally produced in the United States is in violation of the United States Food, Drug and Cosmetic Act; and
- Importing medications made in other countries is in violation of the Food, Drug and Cosmetic Act if the medicine is not approved by the FDA or does not meet all of the FDA approval requirements.
- While the FDA has stated reimportation and importation is [sic] illegal, they have allowed individual consumers to purchase prescription drugs through Canada for personal use.

Finally, Kansas provides a link to the FDA's policy statement on personal importation.[60]

On Vermont's page linking to I-SaveRx, the State offers the following caveat to its residents:

> As informed and responsible consumers it is important to understand that there are risks associated with purchasing and using any medications and that these risks may increase when purchases are made over the Internet. We strongly encourage you to consult with your health care providers and educate yourself about the prescription drugs you are currently taking and those you are thinking of ordering in an effort to prevent any drug interactions or adverse drug reactions. Please remember that the State of Vermont does not license the pharmacies that will fill your order and that the State of Vermont accepts no legal liability or responsibility for your decisions regarding purchases of prescription drugs based on the information provided in this web site.[61]

Wisconsin's disclaimer is not as clearly evident on its web site. In order to read any information on the legality of importing prescription drugs from Canada, the consumer must click on the page directing her to the prescription medication list. There she can also click on and read an extensive disclaimer denying all tort liability, any warranties, any endorsement of third party statements appearing on the site, and many other items.

Finally, on the I-SaveRx website, Illinois posts a warning that highlights the specific risks posed by mail-order purchase of prescription drugs, points to the different regulatory systems of the United States, Canada and the United Kingdom, acknowledges the FDA's position on the illegality of reimportation, and disclaims regulatory authority over participating pharmacies.

It is unclear to what extent these waivers will be enforceable in court. Certainly a state's gross negligence in failing to inspect or properly monitor the entities involved in its importation program would weigh against the complete enforcement of such a waiver. Each of the existing waivers warns the consumer of the various risks entailed in purchasing drugs through such a program, and each emphasizes that the decision to do so is the consumer's. If accepted, such waivers would likely provide a complete defense of assumption of the risk to any negligence action. As suggested above, however, the state bears a duty toward its residents to protect their

[60] Available at http://www.healthykansas.org/rx_resource_center_isave_rx.html.
[61] Available at http://www.ahs.state.vt.us/ISaveRXVT.cfm

welfare and safety, and if its acts or omissions in the context of promoting an importation program clearly violate that duty, it is possible that a waiver would not shield it from liability.

6. Consumer protection and privacy

As discussed above, tort suits arising out of imported or reimported prescription drugs may become somewhat more complicated than other suits because of the lengthy chain of distribution and its geographical breadth. In theory, a Connecticut resident who became sick from a prescription drug supplied by a Canadian pharmacy would have the same rights of redress against the manufacturer and the pharmacy that he would if he were a Canadian resident who picked up the drug at the corner pharmacy. But, the addition of parties and steps into the process of purchasing drugs might make it more difficult for the person from Connecticut to pursue claims against these parties.

American courts must establish personal jurisdiction over any defendant to a lawsuit. According to the U.S. Supreme Court, the constitutional threshold for personal jurisdiction requires at least "minimum contacts" with the jurisdiction in question.[62] In Connecticut, any corporation that transacts business in the state is potentially subject to suit here. In addition, every foreign corporation is subject to suit in Connecticut if the plaintiff's cause of action arises:

> (1) Out of any contract made in this state or to be performed in this state; (2) out of any business solicited in this state by mail or otherwise if the corporation has repeatedly so solicited business, whether the orders or offers relating thereto were accepted within or without the state; (3) out of the production, manufacture or distribution of goods by such corporation with the reasonable expectation that such goods are to be used or consumed in this state and are so used or consumed, regardless of how or where the goods were produced, manufactured, marketed or sold or whether or not through the medium of independent contractors or dealers; or (4) out of tortious conduct in this state, whether arising out of repeated activity or single acts, and whether arising out of misfeasance or nonfeasance. Conn. Gen. Stat. § 33-929(f) (2004)

Hence Connecticut residents would be able to bring most tort or contract actions in Connecticut courts against most foreign entities transacting business through an importation program.

Nonetheless, some potentially liable parties might still evade the reach of Connecticut courts, such as foreign distributors that sell only to foreign companies, or foreign drug manufacturers that sell only to foreign companies. In addition, litigation against foreign entities in Connecticut courts might face obstacles such as the potential need for foreign discovery from nonparties, which, while not impossible, may prove difficult to obtain. Finally, there is some concern that U.S. courts would choose to apply foreign law to certain suits involving imported drugs and might even move those cases to foreign courts.

One way to alleviate some of these concerns is to include in contracts between Connecticut and other participating parties, as well as contracts between the consumer and the foreign entity with

[62] See International Shoe v. Washington, 326 US 310 (1945).

which he is dealing directly, provisions in which the foreign entity consents to the jurisdiction of Connecticut courts and to the application of Connecticut law.

It is far from clear what effect importation and reimportation will have on tort litigation against parties in the chain of distribution for prescription drugs. The disclaimers cited above emphasize informed consent in all aspects of the process on the part of the purchaser. While the purchaser is not consenting to unsafe pharmaceutical products, she is consenting to a process that differs from the one in place for domestic distribution. A state can protect its residents from importation-related injuries through a rigorous process of oversight. Moreover, consumer protection laws continue to apply to these transactions and to prohibit deceptive and injurious trade practices

Privacy concerns

Federal law provides certain privacy rules protecting confidential medical information from disclosure. Foreign pharmacies do not appear to be covered directly by the Health Insurance Portability and Accountability Act ("HIPAA"). See generally 42 US.C. 1320d-2. According to the Office for Civil Rights at HHS, the HIPAA Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule), 45 CFR Part 160 and Subparts A and E of Part 164, applies only to covered entities, defined as (a) a health care clearinghouse; (b) a health plan; or (c) a health care provider who transmits any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard. In one instance, the Office of Civil Rights deemed pharmacy clearinghouses entities not covered by the Rule, because customers pay directly for their services without third party billing or insurance.[63]

The I-SaveRx website and CanaRx's own website make no mention of HIPAA privacy rules. Instead, in its AUTHORIZATION & CONSENT section, the I-SaveRx website contains two statements regarding the specific use of a customer's medical information for the purpose of filling a prescription to which the customer must consent.

On Wisconsin's website enabling residents to order prescription drugs from Canada, the State includes within its list of FAQ's the question "Are my transactions confidential?" In response, the State notes that "The Government of Canada regulates what their pharmacies can and cannot do with your private medical information. If you have any questions, please ask the pharmacy about their policies and practices in handling your medical information." Although consumers might well find this confusing, the option to order prescription drugs from approved Canadian pharmacies is separate from the option to participate in the I-SaveRx Program, which is accessible through its own link on the Wisconsin webpage. This statement suggests that with respect to direct purchase of prescription drugs from approved Canadian pharmacies, Wisconsin does not guarantee compliance with state or US privacy laws.

In its contract with CanaRx valid through the fiscal year 2006 to administer the I-SaveRx Program, however, the State of Illinois includes a privacy and HIPAA compliance provision as a requirement of doing business with the state:

[63] See HHH, Letter from Susan McAndrew, Senior Policy Specialist/HIPAA, Office for Civil Rights, to S. Lawrence Kocot, Senior Vice President and General Counsel, NACDS, Mar. 4, 2004

> HIPAA & Privacy Compliance: Neither CanaRx nor any pharmaceutical entity it engages may disclose, divulge, or otherwise make available to any third party, other than a prescribing doctor, in whole or in part, any information in respect of any individual Program Participant, except with either the expressed consent of the resident or if the information is used under planning, research and evaluative analyses, or on an aggregated basis for management and reporting under the Business partner rules within HIPAA. The CanaRx physicians and pharmacies may contact Illinois 'I-SaveRx' Program Participants for purposes of evaluating the appropriateness of the prescriptions ordered.[64]

Therefore, while regulation across the border with respect to privacy and confidentiality rules might prove difficult or impossible, the I-SaveRx Program appears to guarantee compliance with US standards by virtue of this contractual provision. This seems to be the best option at the moment for guaranteeing compliance with HIPAA when dealing with a foreign pharmacy.

7. Additional liability issues

Importers and distributors of imported drugs may be subject to liability for violation of intellectual property rights belonging to the pharmaceutical companies. To the extent that the state is considered to be an importer or distributor, it may share this liability.

Pursuant to the Copyright and Patent Clause of the US Constitution, Congress has legislated broadly in the area of intellectual property. Inventors of pharmaceuticals can avail themselves of patents and other intellectual property protections for their products. Patents are country-specific, meaning that an inventor must apply for a patent in each country where she seeks patent protection. A US patent protects the right of its holder to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention. But once the holder sells the product, the new owner may generally resell it at will since the first sale is said to exhaust the holder's right to control distribution. Under US patent law, a patent holder can engage in price discrimination in different countries because the holder has the right to enjoin unauthorized distribution, including parallel importation, in foreign markets.[65]

While parallel trade may take place between European Union countries without threat to the patent holder's rights, the general rule in the US has been that once a patent holder consents to use of its patent in another country, it can no longer control the importation of patented products into the US. A recent Federal Circuit ruling, however, casts doubt on this rule. In *Jazz Camera Photo v. International Trade Comm'n*, 264 F.3d 1094 (Fed. Cir. 2001), the court announced a rule that appears to confer on the patent holder an ongoing right to prevent importation into the US market even over a product produced in a foreign jurisdiction. This case limited the patent exhaustion to sales within the US, declining to apply it to a patent holder that sells its product in a foreign market. Thus a distributor or consumer who imports a US-patented drug into the United States without the patent owner's consent may face patent infringement claims.

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[64] State of Illinois, CanaRx Services, Inc., I-SaveRx Contract, October 1, 2004.
[65] See generally HHS Task Force Report, Chapter Nine, Intellectual Property Rights; see also Importing Prescription Drugs: Objectives, Options, and Outlook, Susan Thaul & Donna U. Vogt, CRS Rep. for Congress, Updated December 8, 2005.

Commentators have therefore expressed concern that importers and distributors of imported drugs could be subject to patent infringement liability as well as liability for trademark and copyright infringement with respect to the trademarks and possibly written materials associated with particular products.[66] The HHS Task Force on Drug Importation warns further that state officers may be subject to declaratory or injunctive relief under federal intellectual property laws, although states appear under relevant case law and the 11th Amendment to remain immune to patent infringement suits.[67]

Finally, on the other side of things, pharmaceutical companies may, in response to reimportation, enter into private agreements with foreign entities that restrict sales into the US of their products, as long as these do not violate antitrust law.

Recently negotiated free trade agreements with Singapore, Australia, and Morocco contain restrictions on parallel trade that might subject the United States to international trade suits by the drug industry if Congress implements prescription drug importation legislation. Hence this language presents a major obstacle to the passage of importation legislation that would compromise protected patent rights. It also exceeds the governmental obligations toward intellectual property rights required by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), which was added to the General Agreement on Tariffs and Trade (GATT) treaty in 1994. For example, the recent free trade agreement with Australia (AUSFTA) contains the following provision:

> Each party shall provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from a patented process, without consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory, at least where the patentee has placed restrictions on importation by contract or other means.[68]

Federal legislation enacted in late 2005 would exclude from future free trade agreements such language specifically protecting the intellectual property rights of pharmaceutical companies from aspects of trade liberalization. The FY 2006 Science, State, Justice, Commerce and Related Agencies Appropriations Act, which President Bush signed into law in late November 2005, incorporates an amendment mandating that no funds made available in the Act be used to include in any new free trade agreement the restrictive language on patent protection and the importation of pharmaceutical products contained in the Australia, Morocco or Singapore agreements. **P.L. 109-108 § 631 (109th Congress).** Upon signing the bill, however, the President announced that he considered the provision merely advisory and not binding.[69] **.**

[66] HHS Task Force Report 92 - 95
[67] Id.
[68] Australia – United States Free Trade Agreement § 17.9(4) (available at http://www.ustr.gov/Trade_Agreements/Bilateral/Australia_FTA/Final_Text/Section_Index.html).
[69] President Bush Signs Spending Bill with Provision on Prescription Drug Reimportation, available at http://www.medicalnewstoday.com/medicalnews.php?newsid=34227.

8. Legal Issues—Conclusion

If Connecticut were to join or initiate a program facilitating the importation of prescription drugs from Canada, several legal issues would require close consideration. First, such a 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 and have directed consumers to the materials on the FDA's position via the Internet. Individual consumers importing drugs for personal use seem to face little danger under the FFDCA, although shipments of drugs do get seized at US borders with some regularity. Nonetheless, legislation pending in Congress promises to lift the ban on reimportation, so if such legislation passes then some importing and reimporting activities will be permitted.

When contemplating an importation program, Connecticut will need to revisit certain existing laws regarding pharmacy practices and the distribution of prescription drugs. The State will likely be able to impose its own standards of practice on foreign pharmacies approved for participation in the program, although it is not clear how enforceable these standards will be. In implementing such a program, Connecticut opens itself up to potential tort liability; 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. Finally, Connecticut may run afoul of intellectual property law if it were to be considered an importer or distributor of certain pharmaceutical products.

In short, Connecticut will fare best if it takes as remote a role as possible in implementing importation programs for the purpose of reducing potential liability, although it is also advised to take an active regulatory role to ensure the health and safety of its residents.

E. THE ECONOMIC IMPACT OF DRUG IMPORTATION PROGRAMS

Introduction

The primary reason that states and municipalities have become involved in prescription drug importation is economic. In the face of escalating financial pressures, cities like Springfield have slowed the pace of health benefits spending by encouraging city-covered populations to use Canadian pharmacies. Typically, when electing to use a Canadian pharmacy, participant co-payments are waived. In some cases, co-payments for domestically purchased prescriptions have been increased.

In addition to importation programs designed to address state spending on prescription drugs for employees and retirees, states have also considered importation of prescription drugs as a means of reducing costs of Medicaid programs and for prison populations. However, no state has implemented any plan in this area. State Medicaid programs currently receive rebates from drug manufacturers and cost sharing from the federal government for prescription drug costs, which

may offset costs in a manner sufficient to preclude implementation of state-sponsored importation for these populations.

Several states have also developed programs for use by any state resident. Likely participants are persons without prescription drug insurance coverage or those who have high prescription drug costs. These state programs attempt to improve and maintain the health of uninsured and underinsured populations by facilitating access to a source of prescription drugs that is more economically feasible for families and individuals with lower incomes.

The lower prices for pharmaceutical products in foreign countries are made possible through government price controls in foreign countries and favorable currency exchange rates. Economic issues studied by UCHC include the costs of developing and operating an independent importation program, costs of joining an existing state program, and estimates of savings for governments and consumers.

1. Program start-up and recurring costs

Costs to start independent program

The State of Illinois has invested heavily in the I-SaveRx program. The largest single expense item was related to travel to conduct research and inspect pharmacies. Inspection costs vary depending on the number of pharmacies in the network and the number of people required to conduct an adequate inspection. Illinois used one or two people for inspections of Canadian pharmacies and two people for inspections of pharmacies in the United Kingdom. Pharmacies from several areas in Canada were inspected, so a fair amount of intra-Canadian airline travel was required. In the United Kingdom, pharmacies in Southern England, Northern Scotland, and Northern Ireland were inspected. Lodging and airfare were the major expenses for the UK inspections.

Other major start up costs were associated with contracting with a pharmacy benefits management company to provide program services such as website development and customer service.

Operating costs included additional travel and other expenses related to re-inspecting approved foreign pharmacies as well as the investigation of pharmacies, pharmaceutical laws, and drug safety systems in additional countries (e.g., Australia and New Zealand). Illinois officials have not released detailed information related to the cost of developing and implementing the I-SaveRx program.

Minnesota has never quantified costs of the Advantage-Meds and MinnesotaRxConnect programs, but they appear to be significant. As in Illinois, primary start-up expenses were for staff to travel to Canada and the UK for pharmacy inspections. Since Minnesota does not contract with a PBM, the state relied upon existing staff from various divisions in the Department of Human Services (administration, pharmacy, information technology, legal, marketing, etc.) to develop the programs. Current program personnel stated that on-going costs are considerably less than planning and implementation costs. Minnesota has not identified

specific program costs, since the work involved is performed by existing personnel in the Department of Human Services and Department of Employee Relations.

Costs to join an existing program

Illinois has not charged the four states that have joined I-SaveRx to this point. Prior to joining I-SaveRx, Vermont used existing personnel to investigate the safety, equivalence, efficacy, and legal issues of the Illinois process. It has not committed significant additional resources for ongoing management of their state's participation in I-SaveRx. Thus, the most costly component of joining an existing program is promoting the program within the state and marketing the program to target populations. Ultimately, these costs are optional, but marketing and outreach activities could have a major impact on participation. Vermont has not invested greatly in marketing and outreach, and program participation has been sluggish. Other costs include providing state representation in the I-SaveRx Joint Work Group. The Joint Work Group has met semi-annually to discuss program development and operations.

Generally, importation programs are used exclusively by residents of the city or state that developed the program, however, Illinois has welcomed other states to participate in I-SaveRx. Another example of a state prescription drug importation partnership is the agreement between Wisconsin and Washington. The State of Wisconsin website includes a link to a state-inspected Canadian mail-order pharmacy and, through an interstate agreement, allows Washington State residents to access the program through a web link.

Particularly for programs designed for state or city covered populations, it is not feasible for customers outside the system to use the program. For example, to use the Springfield program you must have employee insurance coverage through the city. For MinnesotaRxConnect, the discounted prices Minnesota negotiated with Canadian pharmacies are limited to eligible populations verified at the pharmacy level through customer zip code or other means. However, the MinnesotaRxConnect website does not restrict access to Minnesota residents only. While a customer from another state may use the MinnesotaRxConnect website for enrollment and prescription ordering, and Canadian pharmacies in the Minnesota program may fill a prescription for someone in another state who uses the Minnesota website, they may be charged a higher price than that charged to a Minnesota resident.

The advantages for a state that starts its own importation program include independent decision making and greater control over program components. However, international travel expenses and other start-up costs are significant, and it would appear that little return on investment is achieved by recreating the comprehensive research and investigation conducted by Illinois and other states. Joining an existing state program has been accomplished through different processes. The four states that joined I-SaveRx did so through state executive branch action and in the case of Vermont through legislative and executive action. The partnership between Wisconsin and Washington was forged and fostered by their respective state governors.

2. Cost savings and program participation

Illinois, Massachusetts, and other states have estimated cost savings related to prescription drug importation. In Illinois, estimates of costs savings for an employee and retiree program were nearly $91 million annually, $56 million in state savings and $34 million in waived co-payments.[70] These estimates have been disputed because they were based on 100 percent participation by employees and retirees. Illinois has not been able to demonstrate participation levels because it has not implemented an employee and retiree program.

An analysis conducted in Massachusetts was based on the percentage of mail-order prescription drug purchases (18 percent) by eligible state-covered populations. The Massachusetts analysis also included the loss of rebates to the state from drug manufacturers. It concluded that estimated net state savings would total $1.4 million annually, not including program start-up and annual operating costs. If included, these costs would further reduce state savings.[71]

Minnesota recently released an activity report on its employee program, Advantage-Meds. During the period from May 13, 2004 to December 31, 2005, prescription drug costs for the Advantage-Meds program totaled $1,604,258. Of an eligible 48,000 employees and 72,000 dependents, 2,635 members enrolled. Members placed 9,219 orders, which represents about 1 percent of the total drugs purchased by all eligible members. For the period from May 13, 2004 to December 31, 2004, the State estimates that Advantage-Meds reduced state costs by $53 per prescription, which translates to a total of $162,000. Waived co-payments saved participants $45 per prescription. A total of approximately $300,000 was saved by the program and its members.[72]

An estimate of participant savings for MinnesotaRxConnect customers can be calculated by applying the state savings rate to the number of prescriptions filled. Through the program, 17,929 prescriptions have been filled since program inception through December 2005. At an estimated savings of $53 per prescription, total drug cost savings for participants is estimated at $950,237. It is likely that the vast majority of MinnesotaRxConnect customers do not have prescription drug insurance coverage. Minnesota does not have any records of any privately insured individuals using MinnesotaRxConnect. It advises users who are privately insured to "Please contact your health insurance company to find out if the cost of prescriptions purchased from a Canadian pharmacy is reimbursable or can be applied to a deductible under your insurance policy."[73]

While Minnesota negotiates prices with individual pharmacies, Illinois relies on their PBM agreement with CanaRx. As part of their PBM agreement, Illinois and participating states are guaranteed at least a 25 percent savings (not including shipping) on prescription drug costs compared to mail order and Internet pharmacies based in the US. Prices of available drugs on the I-SaveRx website are periodically compared to the average of the Internet prices of the same

[70] Kamath, Ram and McKibbin, Scott. October 2003.
[71] Rowland, Christopher. State Panel: Drug Plan Isn't Worth the Savings Canada Imports Seen Bringing Liability Risks. The Boston Globe. November 21, 2003.
[72] Strebe, Paul. January 2006.
[73] Personal communication, Richard Doering, February 2006.

brand name, same strength drugs on www.drugstore.com and two other large volume US based Internet pharmacies to ensure that the I-SaveRx prices meet the 25 percent savings target. (In some instances a particular drug and dose may not meet the 25 percent savings target because the 25 percent savings guarantee applies to the average of several drugs in the same class).

The I-SaveRx website lists several examples to demonstrate the savings available through the program. Table 1 lists examples from the I-SaveRx website.

Table 1: Illinois I-SaveRx Program: Sample of Prescription Drug Prices

Prescription Drug (3 months supply)	I-SaveRx Price (Includes shipping)	Avg. U.S Mail Order Price	Percent Savings
Respiratory medications			
Advair	$264.90	$480.60	45%
Singulair	171.90	279.90	39%
Ventolin	37.90	120.00	68%
Allegra	69.90	151.20	54%
Nasacort AQ	75.90	223.80	66%
Zyrtec	86.90	209.00	58%
Antidepressant medications			
Wellbutrin SR	$135.90	$351.00	61%
Prozac	209.90	447.00	53%
Zoloft	142.90	225.12	37%
Effexor XR	208.90	340.00	39%
Paxil	112.90	236.70	52%
Diabetic prescription drugs			
Glucophage	$32.90	$63.84	48%
Actos 30mg	244.90	452.76	46%
Diabeta	63.90	151.20	58%
Prandin	83.90	230.00	64%
Precose	41.90	70.20	40%
Breast Cancer Medications			
Tamoxifen 20mg	$41.90	$153.00	73%
Aromasin 25mg	545.90	686.70	21%
Zofran 8mg	492.90	1048.80	53%
Anzemet 50mg	172.90	830.25	79%
Heart medications			
Lipitor	$186.90	$285.60	35%
Zocor	219.90	364.56	40%
Plavix	249.90	329.28	24%
Pravachol	203.90	279.90	27%

Source: www.I-SaveRx.net, accessed December 9, 2005.

For the period October 2004 to June 30, 2005, the Illinois Governor's Office stated that "almost 61,000 interested citizens have requested an enrollment form…; 14,600 have completed the enrollment process; and over 10,000 orders have been placed through the program, each with an average savings of 25 to 50 percent."[74] As of January 16, 2006, over 18,300 total orders had been placed (includes orders from all participating states).[75] The Office of the Special Advocate for Prescription Drugs projected sales figures are $4.75 million with savings of $1.9 million,[76] which is an average savings of $103 per order.

The primary targeted group for I-SaveRx program participation would seem to be persons without prescription drug insurance coverage. The Kaiser Family Foundation estimates that there are 1,768,000 nonelderly uninsured persons in Illinois.[77] An unspecified proportion of these people probably do not require a maintenance prescription drug or drugs for a chronic condition. Still, of an estimated target population of over 1.7 million people in Illinois, only 14,600 (less than 1 percent) had completed the enrollment process during the first 9 months of the program's existence. Despite demonstrated potential for cost savings, participation in I-SaveRx seems to be limited, but the value of the program to individual enrollees may be significant if the overall estimated savings of $1.9 million are accurate.

"Springfield Meds" has had a major impact on the city budget. According to newspaper reports, 3,200 city employees and other city-covered populations used the program, and the city saved and estimated $2.5 million in prescription drug costs in its first year of operation.[78] Relative to the state-sponsored programs, Springfield has achieved good results in terms of the rate of enrollment and savings. Springfield has a three-tiered structure of co-payments ($10, $20, or $35 per prescription), which are waived for program participants.

For an economic analysis of the potential impact of a prescription drug importation program in Connecticut, UCHC researchers contracted with IMS Health to obtain the fifty most prescribed drugs in Connecticut purchased through mail order pharmacies by number of prescriptions and dollars expended. Estimates of prices of prescribed drugs available domestically through mail order (including shipping costs) were acquired at www.drugstore.com, a common source for many mail order prescription drug purchasers. Table 2 compares these prices to the lowest prices available for MinnesotaRxConnect orders (including shipping). Table 3 compares www.drugstore.com prices to the lowest prices available for I-SaveRx orders (including shipping). Following the price comparisons of U.S. mail order and importation programs is a description of the 340B program (a federally sponsored program for lower priced pharmaceuticals through safety net providers) and price comparisons and discussion of the 340B program, U.S. mail order, and importation program prices.

[74] Kamath, Ram and McKibbin, Scott. June 2005.
[75] Personal communication, Cindy Laware, January 2006.
[76] Personal Communication, Maria J. Rosales, Office of the Special Advocate for Prescription Drugs, State of Illinois, January 2006.
[77] The Kaiser Commission on Medicaid and the Uninsured. Health Insurance Coverage in America 2004 Data Update. November 2005.
[78] Connolly, Ceci. July 15, 2004.

Table 2: The Fifty Most Prescribed Drugs in Connecticut[79], Retail Mail-Order Prices through www.drugstore.com and www.MinnesotaRxConnect.com

Connecticut Mail Order Rank	Drug Name	US Mail Order Unit Price	MNRxConnect Unit Price	Percent Savings	MN Source Country	Savings per 3-month period
1	LIPITOR (20mg)	$3.24	$2.33	28%	Canada	$81.90
2	TOPROL-XL (100mg)	$1.24	N/A	--	--	--
3	NORVASC (5mg)	$1.48	$1.15	22%	UK	$29.70
4	FOSAMAX (5mg)	$2.42	$2.16	11%	Canada	$23.40
5	ZOCOR (20mg)	$4.13	$1.79	57%	UK	$210.60
6	NEXIUM (20mg)	$4.24	$2.18	49%	UK	$185.40
7	ZETIA (10mg)	$2.37	$1.96	17%	Canada	$36.90
8	ZOLOFT (100mg)	$2.47	$1.89	23%	Canada	$52.20
9	SINGULAIR (4mg)	$2.92	$2.07	29%	Canada	$76.50
10	PREVACID (30mg)	$4.04	$2.02	50%	UK	$181.80
11	PRAVACHOL (20mg)	$2.86	$2.12	26%	UK	$66.60
12	LEXAPRO (10mg)	$2.18	N/A	--	--	--
13	DIOVAN (80mg)	$1.58	$1.64	-4%	Canada	-$5.40
14	ADVAIR DISKUS (100-50mcg)	$1.83	$1.40	23%	UK	$38.70
15	ACTONEL (5mg)	$2.42	$2.20	9%	UK	$19.80
16	PLAVIX (75mg)	$3.91	$3.17	19%	Canada	$66.60
17	ALTACE (2.5mg)	$1.36	$0.91	33%	UK	$40.50
18	ZYRTEC (10mg)	$1.83	$0.75	59%	UK	$97.20
19	PROTONIX (40mg)	$3.47	$2.35	32%	UK	$100.80
20	FLOMAX (0.4mg)	$1.80	$1.14	37%	Canada	$59.40
21	ACTOS (30mg)	$5.01	$2.77	45%	UK	$201.60
22	LOTREL (5-10mg)	$2.12	N/A	--	--	--
23	AVANDIA (4mg)	$2.93	$2.11	28%	UK	$73.80
24	DIOVAN HCT (160-12.5mg)	$1.86	$1.84	1%	Canada	$1.80
25	AVAPRO (150mg)	$1.43	$1.29	10%	Canada	$12.60
26	AMBIEN (5mg)	$2.86	N/A	--	--	--
27	EFFEXOR XR (75mg)	$2.91	$1.88	35%	Canada	$92.70
28	ALLEGRA (60mg)	$1.26	$1.00	21%	Canada	$23.40
29	EVISTA (60mg)	$2.63	$2.10	20%	UK	$47.70
30	COZAAR (50mg)	$1.51	$1.28	15%	Canada	$20.70
31	CELEBREX (200mg)	$2.67	$1.52	43%	Canada	$103.50
32	VYTORIN (10-20mg)	$2.66	N/A	--	--	--
33	PREMARIN (0.625mg)	$0.96	$0.36	63%	Canada	$54.00
34	FLONASE (50mcg 16g bottle)	$66.00	$42.43	36%	UK	$70.71
35	CRESTOR (10mg)	$2.62	$1.81	31%	UK	$72.90
36	WELLBUTRIN XL (150mg)	$2.91	N/A	--	--	--
37	COREG (6.25mg)	$1.61	$0.99	39%	UK	$55.80
38	HYZAAR (100-25mg)	$2.01	$1.43	29%	Canada	$52.20
39	BENICAR (20mg)	$1.56	N/A	--	--	--
40	ACIPHEX (20mg)	$4.08	$2.09	49%	UK	$179.10
41	CLARINEX (5mg)	$2.12	$1.12	47%	Canada	$90.00
42	XALATAN (2.5ml bottle)	$51.33	$50.75	1%	UK	$1.74
43	DETROL LA (2mg)	$2.82	$2.10	26%	Canada	$64.80
44	NASONEX (17g inhaler)	$64.00	N/A	--	--	--
45	PROSCAR (5mg)	$2.69	$1.46	46%	UK	$110.70
46	AVALIDE (300-12.5mg)	$1.91	$1.35	29%	Canada	$50.40
47	VIAGRA (50mg)	$9.40	N/A	--	--	--
48	LANTUS (10ml vial)	$67.67	N/A	--	--	--
49	MOBIC (7.5mg)	$2.84	$0.90	68%	UK	$174.60
50	YASMIN 28 (.03mg)	$1.45	N/A	--	--	--
Notes	Strength selected for comparison	Source: drugstore.com accessed 1/25/2006	N/A =Not available accessed 1/25/2006			Typically 90 units
		prices include shipping				

[79] Provided through contract with IMS Health. The most prescribed drugs by number of prescriptions issued for the period December 1, 2004 to November 30, 2005.

Table 3: The Fifty Most Prescribed Drugs in Connecticut[80], Retail Mail-Order Prices through www.drugstore.com and www.I-SaveRx.net

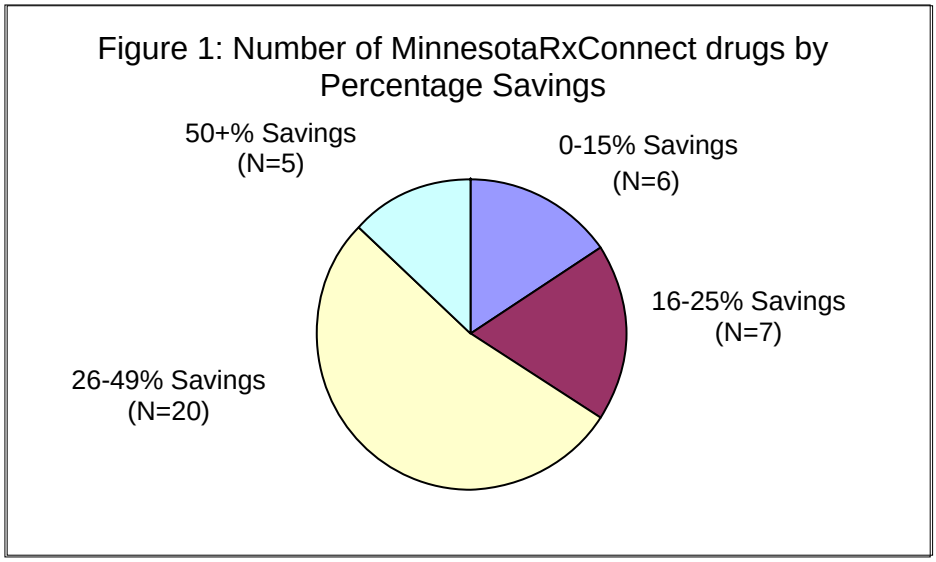
Connecticut Mail Order Rank	Drug Name	US Mail Order Unit Price	I-SaveRX Unit Price	Percent Savings	IL Source Country	Savings per 3-month period
1	LIPITOR (20mg)	$3.24	$2.37	27%	UK	$78.30
2	TOPROL-XL (100mg)	$1.24	$0.54	56%	Canada	$63.00
3	NORVASC (5mg)	$1.48	$1.36	8%	UK	$10.80
4	FOSAMAX (5mg)	$2.42	$1.92	21%	Canada	$45.00
5	ZOCOR (20mg)	$4.13	$2.67	35%	UK	$131.40
6	NEXIUM (20mg)	$4.24	$1.80	58%	UK	$219.60
7	ZETIA (10mg)	$2.37	$2.06	13%	Canada	$27.90
8	ZOLOFT (100mg)	$2.47	$2.24	9%	Canada	$20.70
9	SINGULAIR (4mg)	$2.92	$1.79	39%	Canada	$101.70
10	PREVACID (30mg)	$4.04	$2.19	46%	UK	$166.50
11	PRAVACHOL (20mg)	$2.86	$2.32	19%	Canada	$48.60
12	LEXAPRO (10mg)	$2.18	N/A	--	--	--
13	DIOVAN (80mg)	$1.58	$1.54	3%	Canada	$3.60
14	ADVAIR DISKUS (100-50mcg)	$1.83	$1.30	29%	UK	$47.70
15	ACTONEL (5mg)	$2.42	$1.85	24%	UK	$51.30
16	PLAVIX (75mg)	$3.91	$3.04	22%	Canada	$78.30
17	ALTACE (2.5mg)	$1.36	$0.93	32%	UK	$38.70
18	ZYRTEC (10mg)	$1.83	$0.89	51%	Canada	$84.60
19	PROTONIX (40mg)	$3.47	$2.05	41%	UK	$127.80
20	FLOMAX (0.4mg)	$1.80	$1.34	26%	Canada	$41.40
21	ACTOS (30mg)	$5.01	$2.98	41%	UK	$182.70
22	LOTREL (5-10mg)	$2.12	N/A	--	--	--
23	AVANDIA (4mg)	$2.93	$2.29	22%	UK	$57.60
24	DIOVAN HCT (160-12.5mg)	$1.86	$1.54	17%	Canada	$28.80
25	AVAPRO (150mg)	$1.43	$1.32	8%	UK	$9.90
26	AMBIEN (5mg)	$2.86	N/A	--	--	--
27	EFFEXOR XR (75mg)	$2.91	$2.14	26%	Canada	$69.30
28	ALLEGRA (60mg)	$1.26	$0.67	47%	Canada	$53.10
29	EVISTA (60mg)	$2.63	$1.90	28%	UK	$65.70
30	COZAAR (50mg)	$1.51	$1.59	-5%	Canada	($7.20)
31	CELEBREX (200mg)	$2.67	$1.81	32%	Canada	$77.40
32	VYTORIN (10-20mg)	$2.66	N/A	--	--	--
33	PREMARIN (0.625mg)	$0.96	N/A	--	--	--
34	FLONASE (50mcg 16g bottle)	$66.00	$35.33	46%	UK	$92.01
35	CRESTOR (10mg)	$2.62	N/A	--	--	--
36	WELLBUTRIN XL (150mg)	$2.91	N/A	--	--	--
37	COREG (6.25mg)	$1.61	$1.00	38%	UK	$54.90
38	HYZAAR (100-25mg)	$2.01	$1.59	21%	Canada	$37.80
39	BENICAR (20mg)	$1.56	N/A	--	--	--
40	ACIPHEX (20mg)	$4.08	$2.00	51%	UK	$187.20
41	CLARINEX (5mg)	$2.12	$0.83	61%	UK	$116.10
42	XALATAN (2.5ml bottle)	$51.33	N/A	--	--	--
43	DETROL LA (2mg)	$2.82	$2.47	12%	Canada	$31.50
44	NASONEX (17g inhaler)	$64.00	unable to determine	--	--	--
45	PROSCAR (5mg)	$2.69	$1.43	47%	UK	$113.40
46	AVALIDE (300-12.5mg)	$1.91	$1.56	18%	Canada	$31.50
47	VIAGRA (50mg)	$9.40	N/A	--	--	--
48	LANTUS (10ml vial)	$67.67	N/A	--	--	--
49	MOBIC (7.5mg)	$2.84	$1.02	64%	UK	$163.80
50	YASMIN 28 (.03mg)	$1.45	N/A	--	--	--
Notes	Strength selected for comparison	Source: drugstore.com accessed 1/25/2006	N/A =Not available accessed 1/25/2006			Typically 90 units
		prices include shipping				

[80] See footnote 79 on page 45.

Thirty-nine of the fifty most prescribed brand name drugs in Connecticut are available through the MinnesotaRxConnect program. Thirty-eight of the thirty-nine have lower retail prices if purchased through a MinnesotaRxConnect pharmacy rather than www.drugstore.com. Twenty-five of the thirty-eight drugs have savings of over 25 percent, and five drugs have savings of at least 50 percent if purchased through a MinnesotaRxConnect pharmacy. Table 4 lists the drugs for which the greatest savings for a three month supply available. Figure 1 shows the distribution of drugs by percent of savings available through a MinnesotaRxConnect pharmacy.

Table 4: Highest dollar amounts of savings for a three month supply of brand name drugs through MinnesotaRxConnect

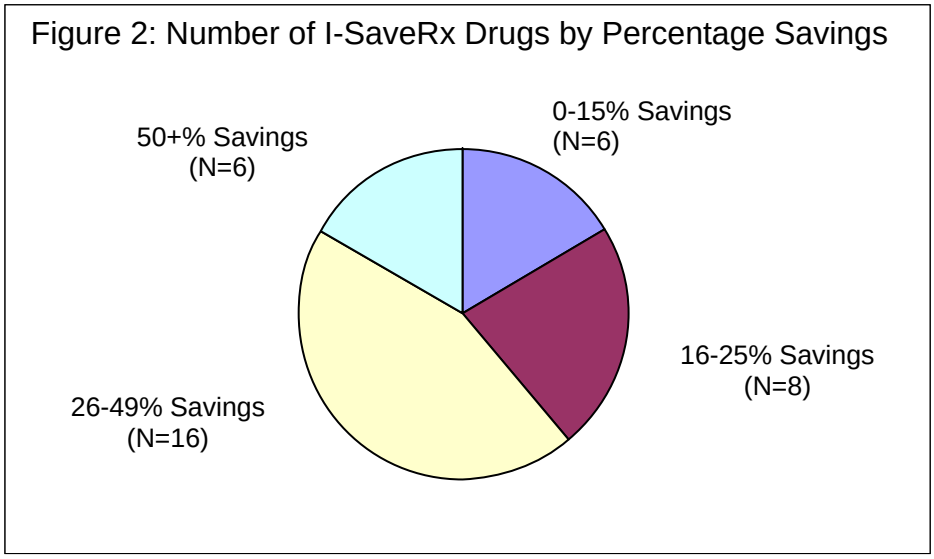
Connecticut Rank	Drug Name	Source Country	Amount saved for three month supply
5	Zocor	UK	$210
21	Actos	UK	$201
6	Nexium	UK	$185
10	Prevacid	UK	$181
40	Aciphex	UK	$179
49	Mobic	UK	$174



Through I-SaveRx, thirty-seven of the fifty most prescribed brand name drugs in Connecticut are available. Thirty-six of the thirty-seven drugs have lower retail prices if purchased through I-SaveRx rather than www.drugstore.com. Twenty-two of the thirty-six drugs have savings of over 25 percent, and six drugs have savings of at least 50 percent. Table 5 lists the drugs for which the greatest savings for a three month supply available. Figure 2 shows the distribution of drugs by percent of savings available through I-SaveRx.

Table 5: Highest dollar amounts of savings for a three month supply of brand name drugs through I-SaveRx

Connecticut Rank	Drug	Source Country	Amount saved for three month supply
6	Nexium	UK	$219
40	Aciphex	UK	$187
21	Actos	UK	$183
10	Prevacid	UK	$166
49	Mobic	UK	$163



It is important to note that estimated savings listed above are not based on actual expended amounts for prescription drugs in Connecticut, rather, estimated savings are based on unit price differences for drugs between www.drugstore.com and the selected importation program websites. It is not possible to estimate total savings for a particular drug because IMS reports the number of prescriptions filled but not the length of time each prescription covers. For instance, IMS reports that there were 34,500 mail-order prescriptions for Zocor in Connecticut at a total patient price of $5,732,586 for the specified period. Thus, the average cost of a mail-order prescription for Zocor for the specified time period is $166. Prescriptions for Zocor could cover 30, 60, or 90 days, depending on the patient's treatment plan and physician recommendations. With the available data, it is not possible to determine the number of the 34,500 prescriptions for Zocor that fall into each prescription period, therefore we cannot calculate a unit price or estimate total savings that would be realized if all or a defined percentage of Zocor prescriptions were filled using an existing importation program.

The 340B Drug Pricing Program is a federal program that requires drug manufacturers to provide outpatient drugs to certain covered entities (e.g., "safety net" providers, such as federally qualified health centers) at a reduced price.[81] Through the 340B program in Connecticut, all 50 of the 50 most prescribed drugs are available. Additionally, drugs excluded from importation programs because they are controlled substances or require special handling are not excluded from the 340B program. Table 6 compares drug prices between the Connecticut 340B Drug Pricing Program, US Mail Order, and importation programs. The least expensive alternative is highlighted.

[81] For details about the 340B Drug Pricing Program, see http://pssc.aphanet.org/pdfs/340b_handbook.pdf.

Table 6: The Fifty Most Prescribed Drugs in Connecticut[82], State of Connecticut 340B Prices, Retail Mail-Order Prices through www.drugstore.com, www.I-SaveRx.net, and MinnesotaRxConnect

Connecticut Mail Order Rank	Drug Name	US Mail Order Unit Price	Connecticut 340b Unit Price	I-SaveRx Price	MNRxConnect Price
1	LIPITOR (20mg)	$3.24	$2.21	$2.37	$2.33
2	TOPROL-XL (100mg)	$1.24	$0.57	$0.54	N/A
3	NORVASC (5mg)	$1.48	$0.91	$1.36	$1.15
4	FOSAMAX (5mg)	$2.42	$1.37	$1.92	$2.16
5	ZOCOR (20mg)	$4.13	$1.94	$2.67	$1.79
6	NEXIUM (20mg)	$4.24	$2.56	$1.80	$2.18
7	ZETIA (10mg)	$2.37	$1.64	$2.06	$1.96
8	ZOLOFT (100mg)	$2.47	$1.56	$2.24	$1.89
9	SINGULAIR (4mg)	$2.92	$1.79	$1.79	$2.07
10	PREVACID (30mg)	$4.04	$1.56	$2.19	$2.02
11	PRAVACHOL (20mg)	$2.86	$0.68	$2.32	$2.12
12	LEXAPRO (10mg)	$2.18	$1.48	N/A	N/A
13	DIOVAN (80mg)	$1.58	$1.77	$1.54	$1.64
14	ADVAIR DISKUS (100-50mcg)	$1.83	$1.27	$1.30	$1.40
15	ACTONEL (5mg)	$2.42	$1.21	$1.85	$2.20
16	PLAVIX (75mg)	$3.91	$2.22	$3.04	$3.17
17	ALTACE (2.5mg)	$1.36	$0.40	$0.93	$0.91
18	ZYRTEC (10mg)	$1.83	$1.31	$0.89	$0.75
19	PROTONIX (40mg)	$3.47	$1.50	$2.05	$2.35
20	FLOMAX (0.4mg)	$1.80	$1.01	$1.34	$1.14
21	ACTOS (30mg)	$5.01	$3.27	$2.98	$2.77
22	LOTREL (5-10mg)	$2.12	$2.06	N/A	N/A
23	AVANDIA (4mg)	$2.93	$1.75	$2.29	$2.11
24	DIOVAN HCT (160-12.5mg)	$1.86	$0.65	$1.54	$1.84
25	AVAPRO (150mg)	$1.43	$0.92	$1.32	$1.29
26	AMBIEN (5mg)	$2.86	$0.98	N/A	N/A
27	EFFEXOR XR (75mg)	$2.91	$1.62	$2.14	$1.88
28	ALLEGRA (60mg)	$1.26	$0.64	$0.67	$1.00
29	EVISTA (60mg)	$2.63	$1.54	$1.90	$2.10
30	COZAAR (50mg)	$1.51	$0.77	$1.59	$1.28
31	CELEBREX (200mg)	$2.67	$1.74	$1.81	$1.52
32	VYTORIN (10-20mg)	$2.66	$1.85	N/A	N/A
33	PREMARIN (0.625mg)	$0.96	$0.15	N/A	$0.36
34	FLONASE (50mcg 16g bottle)	$66.00	$18.96	$35.33	$42.43
35	CRESTOR (10mg)	$2.62	$1.73	N/A	$1.81
36	WELLBUTRIN XL (150mg)	$2.91	$1.67	N/A	N/A
37	COREG (6.25mg)	$1.61	$1.15	$1.00	$0.99
38	HYZAAR (100-25mg)	$2.01	$0.87	$1.59	$1.43
39	BENICAR (20mg)	$1.56	$0.44	N/A	N/A
40	ACIPHEX (20mg)	$4.08	$1.55	$2.00	$2.09
41	CLARINEX (5mg)	$2.12	$1.43	$0.83	$1.12
42	XALATAN (2.5ml bottle)	$51.33	$27.69	N/A	$50.75
43	DETROL LA (2mg)	$2.82	$1.38	$2.47	$2.10
44	NASONEX (17g inhaler)	$64.00	$19.72	unable to determine	N/A
45	PROSCAR (5mg)	$2.69	$1.49	$1.43	$1.46
46	AVALIDE (300-12.5mg)	$1.91	$0.70	$1.56	$1.35
47	VIAGRA (50mg)	$9.40	$6.50	N/A	N/A
48	LANTUS (10ml vial)	$67.67	$28.79	N/A	N/A
49	MOBIC (7.5mg)	$2.84	$1.42	$1.02	$0.90
50	YASMIN 28 (.03mg)	$1.45	$0.45	N/A	N/A
			Does not include dispensing fee of $8.00 per prescription. Source: State of Connecticut Dept. of Social Services.	**Includes shipping N/A = Not available accessed 1/25/06**	

[82] See footnote 79 on page 45.

When compared to sample US Domestic mail order prices, I-SaveRx prices, and MinnesotaRxConnect prices, State of Connecticut 340B prices are the least expensive alternative for thirty-nine of the fifty most prescribed drugs in Connecticut. I-SaveRx prices are least expensive for six drugs and MinnesotaRxConnect prices are least expensive for six drugs. One drug (Diovan) is more expensive through Connecticut 340B pricing than through www.drugstore.com.

3. Discussion of Economic Issues

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 inspect pharmacies. The state would have to determine if existing personnel in selected state agencies have the necessary expertise in program planning and pharmaceuticals to develop and manage the program or if additional hiring would be required. The investment in an independent program would allow Connecticut to conduct its own inspections of foreign pharmacies and pharmaceutical systems and make its own judgments about the safety, equivalence, and efficacy of foreign medications; ensure that Connecticut enrollees receive highest priority in filling of prescriptions (a valid concern in light of previously noted threats from Health Canada and the U.S. pharmaceutical companies); and would provide direct control of program components such as PBM involvement, drug formularies, sources of foreign drugs, and price negotiation. On the other hand, an independent program may also increase liability should the FDA decide to take action beyond issuing warning letters. If targeted enrollment includes state employees and other state-covered populations an incentive beyond waived co-payments for state employees would appear to be necessary.

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, requires unqualified acceptance of the state's findings substantiating the safety of the imported medication, would risk foreign pharmacies placing lower priority on filling orders from Connecticut enrollees, and limits the ability to negotiate drug pricing and other program components. If a Memorandum of Understanding were based on existing MOUs between Illinois and its partner states, the sponsoring state could also 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.

Several factors might limit the economic value of any drug importation program in Connecticut. The primary motivator for employee and retiree participation in these programs is the opportunity for waived co-payments. Waived co-payments in the range charged by the City of Springfield for domestic drugs can result in significant savings for employees or retirees, especially for those taking multiple brand name prescription drugs for chronic conditions. It is not unusual for a patient to take a maintenance drug over the course of several years to help manage a chronic condition.

Despite the projection in Illinois that a large percentage of state-covered populations would participate in I-SaveRx to take advantage of waived co-payments, Illinois has not implemented a specific program for state-covered populations. In Minnesota's Advantage-Meds program, only 1 percent of eligible state drug costs have shifted to foreign sources. Current prescription drug

co-payments for Connecticut employees are substantially lower than co-payments for Springfield and Minnesota employees and it may be difficult to raise employee or retiree co-payments in the near term in Connecticut. Thus, the incentive for Connecticut state employees is substantially lower and may remain so for the next several years.

An importation program could still economically benefit persons who are uninsured or underinsured and who do not have access to 340B prices. For Connecticut residents who for various reasons are currently purchasing prescription drugs through Internet pharmacies, an importation program may increase the safety of the drugs they are currently obtaining independently.

F. ADDITIONAL ISSUES

1. Domestic programs for affordable drugs for persons without prescription drug insurance coverage

Drug companies and state and local governments sponsor programs that provide assistance in acquiring prescription drugs to qualified individuals. Many state and local government programs (e.g., CONNPACE) are designed to financially assist senior citizens with prescription drug purchases. Pharmaceutical companies also sponsor assistance programs, generally for low-income individuals or people who meet other qualifications as determined by the companies. With the advent of Medicare Part D, some drug assistance programs have been redesigned or scaled back since seniors are now eligible for prescription drug coverage through Medicare and some drug companies are concerned about their assistance programs running afoul of the new Medicare law.[83]

Please see Appendix 2 for a directory of PhRMA member company patient assistance programs.[84]

2. Potential Impact of Medicare Part D

The precise demographic characteristics of participants of prescription drug importation programs are unknown. We do know that in recent years, senior citizens and others have accessed Canadian prescription drugs by traveling across the border and via Internet and telephone. Since many maintenance prescription drugs are used to treat chronic conditions associated with old age, it is probably safe to say that importation programs, particularly those designed for un- and underinsured populations, have benefited many senior citizens who are now eligible for Medicare Part D. Early indications show that senior citizens eligible for Medicare Part D are not rushing to voluntarily enroll in the benefit. As the enrollment period continues, this trend may change, but at present the much needed financial relief available through the program is not being fully accessed.

A recent AARP bulletin compared total drug costs through a Medicare Part D plan versus through a Canadian mail-order pharmacy for a sample of individuals. These individuals have

[83] Connelly, Ceci. Drugmakers to Cut Off Some Free Prescriptions. Washington Post. January 27, 2006.
[84] Also available at http://www.pparx.org/PPA_Directory.pdf.

different prescription drug needs and live in different states. In four of the five scenarios the chosen Medicare Part D plan provided more savings to consumers than Canadian drugs.[85] It may well be that the AARP analysis did not use the discounted prices that state and local importation programs have negotiated, and therefore may not be a valid direct comparison to state and local importation programs. The AARP bulletin also states that spending on drugs from Canada will not count toward the $3,600 out-of-pocket spending ceiling that triggers the catastrophic coverage provided in Medicare Part D.

A report prepared for Rep. Henry A. Waxman by the Special Investigations Division of the US House of Representatives Committee on Government Reform—Minority Staff reached different conclusions. The report compares prices for the "ten-best selling drugs among seniors in 2004" and found that that Medicare drug plan prices are "Over 60% higher than the prices available to consumers in Canada."[86] At this early stage in the implementation of Medicare Part D, it is difficult to determine the impact that the benefit will have on prescription drug importation programs.

3. Recent Developments in other States and Cities

The Attorneys General of Nevada and Texas recently halted state programs developed along the lines of the Minnesota program. A Washington, DC law authorizing importation did not receive the necessary approval from Congress.

In a letter to congressional leaders in January 2006, Governor Schwarzenegger of California urged lawmakers to ease federal restrictions on purchasing prescription drugs outside the United States. The letter noted that 45 million Americans without health insurance, including 7 million in California, have limited access to affordable medications. The Governor himself has vetoed four bills that would have allowed prescription drug importation from Canada because importation is currently contrary to federal law.

The State of New Hampshire website includes a link to "New Hampshire's Medicine Cabinet," which includes some of the most useful components of existing websites sponsored by states. Like Minnesota's website, it focuses on patient safety by including patient information (monographs) for prescription drugs and over-the-counter medications. In addition it includes information about herbs and supplements and helps residents locate local pharmacies through a pharmacy directory and compare prices and availability of prescription drugs at pharmacies throughout the state. Similar websites have been set up by the Attorneys General in Connecticut and New York, respectively. The New Hampshire website also provides a link to a Canadian pharmacy that enables citizens to compare prices and order prescription drugs from Canada.

[85] Barry, Patricia. The New Math: Cheaper than Canada? The drug benefit may be the better deal. AARP Bulletin. January 2006.
[86] New Medicare Drug Plans Fail to Provide Meaningful Drug Price Discounts. Prepared for Rep. Harry A. Waxman. United States House of Representatives, Committee on Government Reform—Minority Staff, Special Investigations Division. November 2005.

4. Seizure of drugs by US Customs and Border Protection

Ordering a prescription drug over the Internet from a foreign pharmacy incurs the risk that the shipment will be seized by US Customs and Border Protection. When this occurs, the person whose drug shipment was seized has no legal recourse against the federal government, the state sponsoring the drug importation program, or the foreign pharmacy that shipped their order. Generally, foreign pharmacies have re-shipped orders that were seized. Thus far the foreign pharmacies have considered the cost of replacing seized shipments as a cost of doing business, but they have no contractual obligation to continue doing so. This mitigates the economic risk to the consumer. The health risk is not so easily mitigated. If an individual runs out of medicine as the result of a seized shipment, they are advised by importation program administrators to ask their physician to help them acquire an adequate quantity of medication to take until their re-shipped order arrives from the foreign pharmacy.

A recent newspaper article[87] indicates that federal officials have seized prescription drug 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. The FDA has stated that while it focuses enforcement efforts and resources on wholesale importation, seizure of packages sent to individuals in the U.S. from foreign pharmacies is within its realm of responsibility and occurs on the basis of the availability of personnel.

G. CONCLUSION

Unfortunately, the health benefits provided by prescription drugs are not being fully realized, especially by those who do not have insurance coverage for prescriptions. The financial strain experienced by many individuals and families due to the high cost of prescription drugs has spurred the growth of personal importation of prescription drugs from foreign countries. Canadian pharmaceutical sales to US residents through the Internet and in person totaled $760 million in 2004.[88] An equivalent amount is estimated to enter the US through other countries.[89] Personal importation of prescription drugs has garnered the attention of governments, public health officials, personal physicians, and the general public. All are rightly concerned about the legal implications and the safety, equivalence, and efficacy of the drugs being imported.

The FDA has steadfastly maintained that it cannot ensure the safety of imported prescription drugs and that, in any case, importing prescription drugs is illegal. The FDA response to date has been to discourage prescription drug importation, but not devote the required resources for seizure of significant quantities of personal use imported medication or implement a structured program to assess the quality of medications imported from foreign sources. The FDA also has not enforced its legal authority to prohibit states and local governments from sponsoring drug importation programs.

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[87] Girion, Lisa. More Medicines From Abroad Seized. The Los Angeles Times. February 11, 2006.
[88] Medical Marketing & Media, "The IMS Health Report—Pressure Zone," May 2005, p. 45 at http://offlinehbpl.hbpl.co.uk/misc/MMM/features/May05%20IMS.pdf.
[89] US Department of Health and Human Services Task Force on Drug Importation, *Report on Prescription Drug Importation*, December 2004.

Prescription drug importation programs are technically illegal, but because the law is not being enforced, state and local governments have openly enabled their residents to violate federal regulations. Consumers who ultimately use the programs have apparently decided that the safety and equivalence issues and legal arguments are less compelling than the economic advantages. With one or two notable exceptions, participation in state and local government sponsored programs is minimal when viewed in terms of the population of eligible enrollees.

Current program administrators in other states have taken steps to address threats from pharmaceutical manufacturers to limit shipments of prescription drugs to Canada pharmacies that supply customers in the United States and from the Canadian Health Minister to review licenses of Canadian physicians who re-write prescriptions for patients they do not see in person. Illinois and Minnesota (and perhaps other states and municipalities) have expanded source countries to include the United Kingdom and Ireland and are investigating the feasibility of including additional countries in Europe and the South Pacific.

Medicare Part D would seem to have the potential to have a more significant affect on participation than the potential actions of the pharmaceutical industry or the Health Minister of Canada. As Medicare Part D enrollment efforts continue, increased enrollment and access are likely to occur. Likewise, programs that have the potential to offer favorably priced domestic medications through entities such as FQHCs (e.g., 340B pricing) appear to be a viable alternative to importation activities. Presently in Connecticut there are a number of FQHCs operating pharmacy programs utilizing this mechanism and as planned expansion to additional FQHCs occurs, more uninsured and underinsured persons should gain access more affordable prescription drugs.

The target population for a Connecticut importation program would likely focus on uninsured and underinsured residents, or other residents who for various reasons are currently purchasing prescription drugs through Internet pharmacies, rather than state-covered populations. Vermont's participation in I-SaveRx might provide a valid comparison to Connecticut. Vermont, like Connecticut, has one of the lowest rates of residents lacking health insurance in the country,[90] and the low numbers of uninsured in Vermont may help explain the low rate of participation. Some of the target population in Vermont may now be eligible for (or have even enrolled in) Medicare Part D, but have ordered prescription drugs from Internet pharmacies in the past with no adverse effect and plan to continue to do so for financial reasons.

State and municipality sponsored importation programs appear to offer higher levels of safety, accountability, and regulation than uncontrolled personal importation. Importation program planners seem to have implemented some of the most comprehensive systems to ensure patient safety that are available in personal international pharmaceutical commerce, however, forces beyond the control of even the most safety conscious programs may undermine these quality control and safety measures and can ultimately result in the type of serious dangers that the FDA has identified.

[90] America's Health Rankings—2005 Edition. United Health Foundation. Available at http://www.americashealthrankings.org. In Vermont, 11.2 percent of the population lacks health insurance. In Connecticut, 11.6 percent of the population lacks health insurance.

H. ACKNOWLEDGEMENTS

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I. APPENDICES

1. Sample Memorandum of Understanding between Illinois and another state for participation in the State of Illinois' I-SaveRx Program
2. PhRMA Directory of Member Company Patient Assistance Programs
3. I-SaveRx Available Drugs List
4. MinnesotaRxConnect Available Drugs List
5. RIMeds Available Drugs List
6. I-SaveRx Order Form, Medical History, Customer Warning and Information, and CanaRx Terms of Agreement
7. GAO Highlights, Internet Pharmacies: Some Pose Safety Risks for Consumers, June 2004.
8. Executive Summary, HHS Report on Prescription Drug Importation, December 2004.

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Appendix 1
Sample MOU for I-SaveRx

WORKING DRAFT IN PROGRESS
FOR DISCUSSION PURPOSES ONLY

MEMORANDUM OF UNDERSTANDING

This memorandum outlines the Mutual Understanding between the State of [State] and the State of Illinois regarding alternate access for each State's residents to safe and affordable prescription drugs from Canada, Ireland, and the United Kingdom through the State of Illinois' I-SaveRx Program.

Illinois has expended significant time and resources in inspecting and ensuring the safety of pharmacies in Canada and Europe. It has contracted with a pharmacy benefit manager ('PBM"), CanaRx Services, Inc. ("CanaRx"), for services including the provision of certain prescription drugs from Canada, Ireland and the United Kingdom, in a safe and affordable manner to participating citizens.

Because residents of [State] also require alternate access to safe prescription drugs that are not available in the United States at affordable prices, [State] wishes to join and work with Illinois to provide [State] residents with an alternate program to secure safe and affordable prescription drugs,

I. Program Operation

A. Web Site

[State] and Illinois will maintain separate web sites that each provide a link to www.I-SaveRx.net. In its Pharmacy Benefits Management Agreement with CanaRx (the "PBM Agreement"), Illinois shall specify that citizens with [State] zip code addresses shall be provided access to the services available through the I-SaveRx Program, and that [State] residents shall be considered "Program Participants", as that term is defined in the PBM Agreement. The operation and administration of the web site accessed via the I-SaveRx site will be the responsibility of CanaRx, as is outlined in the PBM Agreement,

B. Drug Supply/Capacity

Both Illinois and [State) shall work together to ensure adequate supply of prescription drugs from the program countries. In the event that demand exceeds the supplies available, Illinois shall have first priority over all other Program Participants.

II. [State] Independent Oversight

A. Standards of Practice

The Joint Work Group

To ensure adequate [State] input regarding

, the safe and effective administration of the I-SaveRx Program, [State] shall be part of the Joint Work Group (the "JWG"), composed of two representatives from each participating State. The JWG shall meet or confer on an as-needed basis.

Appendix 1
Continued

WORKING DRAFT IN PROGRESS
FOR DISCUSSION PURPOSES ONLY

2. Compliance

Illinois will act as the primary administrator of the PBM Agreement with CanaRx. To ensure the safety of their respective residents, [State) and Illinois have agreed upon a single set of Standards of Practice, outlined in Schedule A of the PBM Agreement. These Standards of Practice are incorporated into the PBM Agreement between Illinois and CanaRx. Under the PBM Agreement, CanaRx and the pharmacies participating in the network set up by CanaRx (the "Network Pharmacies") are obligated to comply with the agreed upon-Standards of Practice. The term "Network Pharmacies" shall have the same meaning that it does under the PBM Agreement.

3. Monitoring

Any reports issued by CanaRx or local regulatory authorities regarding the Network Pharmacies' compliance, or lack thereof, with the Standards of Practice shall be provided to [State). The JWG shall determine the specific types of data that should be included in any such reports issued by CanaRx and the periodic basis on which such reports will be issued.

4, Modification

In the event that Illinois or CanaRx wishes to modify the agreed upon Standards of Practice, Illinois will notify [State] in writing at least fifteen (15) days prior to the planned implementation of such amendment or modification. The Standards of Practice may not under any circumstances be modified or amended without the full and unanimous consent of the JWG. Additionally, the JWG will review the Standards of Practice periodically for the purpose of considering modifications or amendments.

5. Violation

In the event that the Standards of Practice are violated by one of the Net-work Pharmacies, (State] may provide written notice to Illinois and CanaRx of such violation. Upon receiving such written notice from [State), Illinois shall instruct CanaRx to immediately suspend such pharmacy from the list of Network Pharmacies eligible to fill prescriptions for Program Participants, pending further review by CanaRx and the participating States**,** which may result in either reinstatement or exclusion from participation in the program.

6. Additional Participating States

In the event that other States, in addition to [State], join Illinois in providing alternate access to prescription drugs through the I-SaveRx Program, Illinois shall provide written notice to [State). Further, Illinois shall ensure that such addition of other states will not in any way render less stringent the Standards of Practice agreed upon between [State) and Illinois.

Appendix 1
Continued

WORKING DRAFT IN PROGRESS
FOR DISCUSSION PURPOSES ONLY

B. Inspections

Under the PBM Agreement, Illinois may conduct on-site inspections of the Network Pharmacies with or without advance notice. [State] may also participate in such inspections along with Illinois. To the extent that additional pharmacies are added to the list of Network Pharmacies, [State] may independently inspect those pharmacies as well. [State] will provide in writing to Illinois any plans or intentions of [State] to independently inspect fourteen (14) days prior to such inspection, unless the inspection is an investigation of a complaint.

C. Drug List

Under the PBM Agreement, only those, prescription drugs that are approved by Illinois will be filled by the Network Pharmacies for the I-SaveRx Program Participants. The JWG shall review the approved Drug List periodically and consider any proposed changes. The approved Drug List may not be modified without the consent of the JWG' Only in the event that the JWG cannot agree on a proposed modification to the Drug List**,** the voting power of the JWG shall be determined by the respective populations of Illinois Wisconsin, and [State].

III. Marketing, Press Relations and Outreach

[State] and Illinois will coordinate, where mutually beneficial, press and outreach efforts**.** Additionally, with input from Illinois, [State] will independently promote the I-SaveRx Program. [State] will use the name, logo, web site, and marketing materials that have been developed by Illinois; however, the [State] State Seal and the Governor's name may be added to the materials. [State] understands that CanaRx will pay I-SaveRx acquisition fees to the program to be used for such activities as marketing, outreach and additional inspections. [State] shall be entitled to such pool of acquisition fees in an amount proportional to the percentage of I-SaveRx prescription drug sales attributable to (State] zip codes.

IV. Cancellation

[State) or Illinois may withdraw from this Mutual Understanding, and terminate this cooperative relationship, at any time, with or without cause, upon written notice to the other State.

V. Liability

Neither the State of [State] nor its agencies, employees, agents, or representatives taking any act as a result of this Mutual Understanding will have any liability for the acts or omissions of the State of Illinois or its agencies, employees, agents, or representatives in carrying out the activities governed by this Mutual Understanding. Neither the State of

Appendix 1
Continued

WORKING DRAFT IN PROGRESS
FOR DISCUSSION PURPOSES ONLY

Illinois nor its agencies, employees, agents, or representatives taking any act as a result of this Mutual Understanding will have any liability for the acts or omissions of the State of [State] or its agencies, employees, agents, or representatives in carrying out the activities governed by this Mutual Understanding.

Acknowledged and Agreed to, Month XX, 200x:

THE STATE OF ILLINOIS	THE STATE OF (STATE]
By:	By:
_____	_____

4

Appendix 2
Directory of PhRMA Member Company Patient Assistance Programs

New Medicines. New Hope.®
Partnership for Patient Assistance
www.PPARx.org
1-888-4PPA-NOW

PhRMA companies have long been worldwide leaders not only in pharmaceutical innovation, but also in philanthropic initiatives—and their long-standing patient assistance programs are especially helpful. This Directory, www.PPARx.org and 1-888-4PPA-NOW (1-888-477-2669), further their goal of helping to make medicines available to those who need them.

3M Pharmaceuticals
3M Patient Assistance Program
P 1-800-328-0255 | **F** 1-651-733-6068

Abbott Laboratories
Abbott Patient Assistance Program
P 1-800-222-6885 | **F** 1-847-937-9826
Abbott Virology Patient Assistance Program
P 1-800-222-6885 | **F** 1-847-935-4789
HUMIRA Medicare Assistance Program
P 1-800-4-HUMIRA (1-800-448-6472) | **F** 1-866-323-0661
Ross Medical Nutritionals Patient Assistance Program
P 1-800-222-6885 | **F** 1-847-935-4789
Ross Metabolic Formula and Elecare Patient Assistance Program
P 1-800-222-6885 | **F** 1-847-935-4789

Agouron Pharmaceuticals, Inc.
Agouron Patient Assistance Program | **P** 1-888-777-6637

Amgen
Encourage Foundation (Enbrel)
P 1-888-4-ENBREL (1-888-436-2735) | **F** 1-888-508-8083
Safety Net Foundation (Kineret)
P 1-866-KINERET (1-866-546-3738) | **F** 1-866-203-4926
Safety Net Program | **P** 1-800-272-9376 | **F** 1-888-508-8090

AstraZeneca, LP
AstraZeneca Foundation Patient Assistance Program
P 1-800-424-3727

Aventis Oncology
PACT+ Program (Providing Access to Cancer Therapy)
P 1-800-996-6626 | **F** 1-800-996-6627

Aventis Pasteur
Aventis Pasteur Indigent Patient Program/NORD
P 1-877-798-8716

Appendix 2
continued

Aventis Pharmaceuticals Inc.
Aventis Patient Assistance Program | **P** 1-800-221-4025
Lovenox Patient Assistance Program
P 1-800-632-8607 | **F** 1-888-875-9951

Bayer Pharmaceuticals Corporation
Bayer Patient Assistance Program | **P** 1-800-998-9180

Berlex Laboratories, Inc.
Berlex Patient Assistance Program
P 1-888-237-5394, option 6, option 1 | **F** 1-973-305-3545
Berlex Oncology Camcare | **P** 1-800-473-5832
Leukine Reimbursement Hotline | **P** 1-800-321-4669
The Betaseron Foundation

P 1-800-948-5777 | **F** 1-877-744-5615

Biogen Idec, Inc.
Avonex Access Program | MS Active Source
P 1-800-456-2255 | **F** 1-617-679-3100

Boehringer Ingelheim Pharmaceuticals, Inc.
Boehringer Ingelheim Cares Foundation | **P** 1-800-556-8317
www.RxHope.com

Bristol-Myers Squibb Company
AmeriCares Oncology/Virology Access Program | **P** 1-800-272-4878
Bristol-Myers Squibb Patient Assistance Foundation
P 1-800-736-0003 | **F** 1-800-736-1611

Celgene Corporation
Celgene Therapy Assistance Program
P 1-888-423-5436, option 3 | **F** 1-800-822-2496

Centocor, Inc.
Remicade Patient Assistance Program
P 1-866-489-5957 | **F** 1-866-489-5958

Cephalon, Inc.
Actiq Patient Assistance Program
P 1-877-229-1241 | **F** 1-800-777-7562
Gabitril Patient Assistance Program | **P** 1-800-511-2120
Provigil Patient Assistance Program | **P** 1-800-675-8415

Eisai, Inc.
Aricept Patient Assistance Program
P 1-800-226-2072 | **F** 1-800-226-2059
Eisai AcipHex Patient Assistance Program
P 1-800-523-5870 | **F** 1-800-526-6651
Eisai Zonegran Patients in Need Program
P 1-866-347-3185 | **F** 1-866-428-4362

Appendix 2
continued

Eli Lilly and Company
Lilly Cares and Zyprexa Patient Assistance Program
P 1-800-545-6962
LillyAnswers Card | **P** 1-877-RX-LILLY

Enzon, Inc.
Financial Assistance Program for Abelcet

Ethicon, Inc.
Regranex Gel Patient Assistance Program
P 1-800-577-3788 | **F** 1-800-482-1896

Fujisawa Healthcare, Inc.
Prograf and Protopic Patient Assistance Programs
P 1-800-477-6472

Genzyme Corporation
The Charitable Access Program (CAP)
P 1-800-745-4447, ext. 16634

GlaxoSmithKline
Bridges to Access | **P** 1-866-PATIENT (1-866-728-4368)
Commitment to Access
P 1-8-ONCOLOGY-1 (1-866-265-6491)
Orange Card | **P** 1-888-ORANGE6

Janssen Pharmaceutica, Inc.
AcipHex Patient Assistance Program
P 1-800-523-5870 | **F** 1-800-526-6651 | www.janssen.com
Janssen Patient Assistance Program
P 1-800-652-6227 | **F** 1-888-526-5168 | www.janssen.com
Risperdal Patient Assistance Program
P 1-800-652-6227 | **F** 1-888-526-5170 | www.janssen.com
Senior Patient Assistance Program
P 1-888-294-2400 | **F** 1-888-770-7266

McNeil Consumer and Specialty Pharmaceuticals
MCSP Patient Assistance Program
P 1-866-PAP-4MCN (1-866-727-4626)

Merck and Co., Inc.
ACT (Accessing Coverage Today) for EMEND
P 1-866-EMEND Rx (1-866-363-6379)
F 1-866-EMEND Tx (1-866-363-6389)
Merck Patient Assistance Program | **P** 1-800-727-5400
The SUPPORT Program for Crixivan Reimbursement Support and
Patient Assistance Services for Crixivan | **P** 1-800-850-3430

Merck/Schering-Plough Pharmaceuticals
Merck/Schering-Plough Patient Assistance Program
P 1-800-347-7503

Appendix 2
continued

MGI Pharma, Inc.
MGI Pharma Patient Assistance Program
P 1-888-743-5711 | **F** 1-703-310-2534

Millennium Pharmaceuticals, Inc.
Integrilin Patient Assistance Program | **P** 1-800-232-8723
VELCADE Reimbursement Assistance Program
P 1-866-VELCADE (1-866-835-2233)

Novartis Pharmaceuticals Corporation
Novartis Patient Assistance Program | **P** 1-800-277-2254

Novo Nordisk Pharmaceuticals, Inc.
Diabetes Patient Assistance Program | **P** 1-866-310-7549
Hormone Therapy Patient Assistance Program | **P** 1-866-668-6336

Organon USA, Inc.
Organon Patient Assistance Program | **P** 1-800-241-8812
Arixtra Reimbursement Hotline | **P** 1-800-ARIXTRA, option 5

Ortho Biotech Products, L.P.
DOXILine | **P** 1-800-609-1083 | **F** 1-800-987-5572
ORTHOVISCline
P 1-866-633-VISC (1-866-633-8472) | **F** 1-800-987-5572
PROCRITline | **P** 1-800-553-3851 | **F** 1-800-987-5572

Ortho-McNeil Pharmaceuticals, Inc.
Ortho-McNeil Patient Assistance Program
P 1-800-577-3788 | **F** 1-800-482-1896

Pfizer, Inc.
Aricept Patient Assistance Program
P 1-800-226-2072 | **F** 1-800-226-2059
Connection to Care™ Patient Assistance Program
P 1-800-707-8990
FirstRESOURCE | **P** 1-877-744-5675 | **F** 1-877-744-5473
Pfizer Bridge Program | **P** 1-800-645-1280 | **F** 1-800-479-2562

Procter & Gamble Company
Procter & Gamble Patient Assistance Program
P 1-800-830-9049 | **F** 1-866-277-9329

Appendix 2
continued

Roche Laboratories Inc.
CellCept Patient Assistance Program | **P** 1-800-772-5790
Fuzeon Patient Assistance Program | **P** 1-866-487-8591
ONCOLINE Patient Assistance Program | **P** 1-800-443-6676, option 2
Pegassist Patient Assistance Program
P 1-877-PEGASYS (1-877-734-2797)
Roche HIV Therapy Assistance Program | **P** 1-800-282-7780
Roche Patient Assistance Program
P 1-877-75-ROCHE (1-877-757-6243) or 1-800-285-4484

Sankyo Pharma, Inc.
Sankyo Pharma Open Care Program | **P** 1-866-268-7327

sanofi-aventis
Patient Assistance Program
P 1-800-446-6267, option 2, option 4, option 2

Savient Pharmaceuticals, Inc.
Oxandrin Reimbursement and Patient Assistance Program
P 1-866-692-6374, option 2 | **F** 1-866-692-6375

Schering-Plough Corporation
Commitment to Care | **P** 1-800-521-7157
SP-Cares Patient Assistance Program | **P** 1-800-656-9485

Serono, Inc.
MS LifeLines Patient Assistance Program
P 1-877-447-3243 | **F** 1-866-227-3243
Saizen Patient Assistance Program
P 1-800-283-8088, ext. 2235 | **F** 1-781-681-2925
Serono Compassionate Care
P 1-888-275-7376 | **F** 1-781-681-2940
Serostim Assistance Program
P 1-888-628-6673 | **F** 1-203-798-2289

Sigma-Tau Pharmaceuticals, Inc.
Carnitor and Matulane Drug Assistance Programs/NORD
P 1-800-999-6673 | **F** 1-203-798-2291

Solvay Pharmaceuticals, Inc.
Solvay Patient Assistance Program
P 1-800-256-8918 | **F** 1-800-276-9901

Takeda Pharmaceuticals North America, Inc.
Takeda Patient Assistance Program
P 1-800-830-9159 or 1-877-582-5332 | **F** 1-800-497-0928
www.tpna.com

Appendix 2
continued

Together Rx™
(Discount card for products from Abbott, AstraZeneca, Aventis, Bristol-Myers Squibb, GlaxoSmithKline, Janssen, Novartis, Ortho-McNeil)
P 1-800-865-7211

Together Rx Access™
(Discount card for products from Abbott, AstraZeneca, Aventis, Bristol-Myers Squibb, GlaxoSmithKline, Janssen, Novartis, Ortho-McNeil, Pfizer, Takeda and TAP)
P 1-800-444-4106

Valeant Pharmaceuticals International
Patient Assistance Program | **P** 1-800-548-5100

Vistakon Pharmaceuticals, L.L.C.
Senior Patient Assistance Program
P 1-888-294-2400 | **F** 1-888-770-7266
Vistakon Pharmaceuticals Patient Assistance Program
P 1-866-815-6874 | **F** 1-800-544-2987

Wyeth
Wyeth Patient Assistance Program | **P** 1-800-568-9938
1100 Fifteenth Street, NW
Washington, DC 20005

New Medicines. New Hope.®

Appendix 3
I-SaveRx Available Drugs List
As of January 10, 2006

ACCOLATE
ACCUPRIL
ACCURETIC
ACEON
ACIPHEX
ACTONEL
ACTOS
ACULAR
ADALAT
ADVAIR Diskus
AGGRENOX
ALDARA
ALESSE
ALESSE-28
ALLEGRA
ALOMIDE
ALPHAGAN
ALTACE
AMERGE
ANZEMET
ARAVA
ARICEPT
ARIMIDEX
AROMASIN
ARTHROTEC
ASACOL
ATACAND
ATROVENT
AVALIDE
AVANDAMET
AVANDIA
AVAPRO
AVODART
AXERT
AZOPT
BETAGAN
BETOPTIC
BUSPAR
CASODEX
CELEBREX
CELEXA
CELLCEPT
CELONTIN
CLARINEX
CLIMARA
COMBIVENT
COMBIVIR
COMTAN
COREG
COSOPT
COZAAR
CREON
CYCLOCORT
CYTOXAN
DDAVP
DEPAKOTE
DESQUAM-X
DETROL
DETROL LA
DIABETA
DIAMOX
DIFFERIN
DIOVAN
DIOVAN HCT
DIPENTUM
DITROPAN
DOVONEX
EFFEXOR
EFFEXOR XR
ELIDEL
ELMIRON
ELOCON
ENTOCORT
Epivir
ESTRACE
EVISTA
EXELON
FAMVIR
FEMARA
FEMHRT
FLOMAX
FLONASE
FORADIL
FOSAMAX
GLUCOPHAGE
HYDREA
HYZAAR
IMDUR
IMITREX TABLET
IMITREX SPRAY
INDERAL
IOPIDINE
KEPPRA
LAMICTAL
LAMISIL CREAM
LAMISIL SPRAY
LAMISIL TABLET
LARIAM
LESCOL
LESCOL XL
LIPITOR
LOTENSIN
LUMIGAN
MAVIK
MAXALT
MAXALT RPD
METROCREAM
METROGEL
MICARDIS
MICARDIS HCT
MICRONOR
MINITRAN
MIRAPEX
MOBIC
MONOPRIL
NASACORT AQ
NASONEX
NEORAL
NEURONTIN
NEXIUM
NITRO-DUR
NORITATE
NORVASC
OGEN
Ortho Evra
ORTHO TRI-CYCLEN
ORTHO-CYCLEN
Ortho-Novum
PANCREASE
PANCREASE MT
PATANOL
PAXIL
PAXIL CR
PERMAX
PLAVIX
PLENDIL
PRAMASONE
PRANDIN
PRAVACHOL
PRECOSE
PREMARIN
PREVACID
PRINIVIL
PRINZIDE
PROAMATINE
PROCARDIA XL
PROGRAF
PROMETRIUM
PROSCAR
PROTONIX
PROTOPIC
PROVERA
PROZAC
PULMICORT
PURINETHOL
RAPAMUNE
REMERON
REMERON
REQUIP
RETIN-A
RIDAURA
RISPERDAL
SEREVENT
SEREVENT DISKUS
SEROQUEL
SINEMET CR
SINEMET-25/250
SINGULAIR
SORIATANE
Spiriva
STARLIX
SUSTIVA
SYNTHROID
TAMOXIFEN
TAZORAC
TENORETIC
TEVETEN
TIAZAC
TIMOPTIC-XE
TOPAMAX
TOPAMAX SPRINKLE
TOPROL XL
TRAVATAN
TRICOR
TRILEPTAL
TRIPHASIL
TRIZIVIR
Trusopt
ULTRAVATE
UNIPHYL
UROXATRAL
URSO
VALTREX
VASOTEC
VENTOLIN HFA
VIDEX EC
VIRACEPT
VIVELLE-DOT
WELLBUTRIN SR
WESTCORT
ZANTAC
ZARONTIN
ZAROXOLYN
ZERIT
ZESTORETIC
ZESTRIL
ZETIA
ZIAGEN
ZOCOR
ZOFRAN
ZOLOFT
ZOMIG
ZYBAN
ZYPREXA

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Appendix 4
Minnesota RxConnect Available Drugs List
As of January 24, 2006

ACCOLATE
ACCUPRIL
ACEON
ACIPHEX
ACTONEL
ACTOS
ACULAR
ADVAIR
AGGRENOX
AGRYLIN
ALBUTEROL
ALDACTAZIDE
ALDACTONE
ALDARA
ALDOMET
ALESSE 28 DAY
ALLEGRA (12HOUR)
ALLEGRA-D
ALLOPURINOL
ALPHAGAN
ALPHAGAN P
ALTACE
AMANTADINE
AMARYL
AMIODARONE
AMITRIPTYLINE
ANTIVERT
ARAVA
ARICEPT
ARIMIDEX
AROMASIN
ARTHROTEC
ASACOL
ATACAND
ATENOLOL
ATROVENT
ATROVENT NASAL
AVALIDE
AVANDAMET
AVANDIA
AVAPRO
AVELOX
AZATHIOPRINE
AZOPT
BACLOFEN
BENZTROPINE
BETAPACE
BETOPTIC
BETOPTIC S
BEXTRA
BREVICON 0.5/35 - 28 DAY
BUMEX
CAFERGOT
CAPTOPRIL
CARBIDOPA/LEVODOPA
CARDIZEM CD
CARDIZEM SR
CARDURA
CASODEX
CEFUROXIME
CELEBREX
CELEXA
CHOLESTYRAMINE SUGAR FREE
CIPRALEX
CIPRO
CLARINEX
CLEOCIN T
CLIMARA
CLONIDINE
COLCHICINE
COMBIPATCH
COMBIVENT
CONDYLOX
COREG
CORTEF
COSOPT
COUMADIN
COZAAR
CREON
CRESTOR
CYTOMEL
DECLOMYCIN
DEPAKENE
DEPAKOTE
DERMA-SMOOTH F/S OIL
DESYREL
DESYREL DIVIDOSE
DETROL
DETROL LA
DIABETA
DICLOFENAC SODIUM
DIDRONEL
DIFFERIN
DILANTIN
DILANTIN INFATABS
DILTIAZEM CD
DIOVAN
DIOVAN HCT
DIPROLENE
DITROPAN XL
DOSTINEX
DOVONEX
DOXAZOSIN
DOXEPIN
DOXYCYCLINE
EFFEXOR XR
EFUDEX
ELMIRON
ELOCON
ENTOCORT EC
ESTRACE
ESTRADERM
ESTRING VAGINAL RING
ETHAMBUTOL
EVISTA
EXELON
FEM HRT
FEMARA
FLEXERIL
FLOMAX
FLONASE
FLORINEF
FLOVENT DISKUS
FLUOXETINE
FLUVOXAMINE FOLIC ACID
FORADIL
FOSAMAX
FOSINOPRIL
FUROSEMIDE
GABAPENTIN
GEMFIBROZIL
GLUCOPHAGE GLYBURIDE
HIPREX
HYDROCHLOROTHIAZIDE
HYDROXYCHLOROQUINE
HYDROXYZINE HCl
HYTRIN
HYZAAR
IBUPROFEN
IMDUR
IMIPRAMINE
IMITREX
IMITREX NASAL SPRAY
IMITREX STATDOSE
IMURAN
INDAPAMIDE
INDERAL-LA
INDOMETHACIN
ISOPTIN SR
ISOSORBIDE DINITRATE
K-DUR 20
KEPPRA
KETOCONAZOLE
KETOPROFEN SR
LABETALOL
LAC HYDRIN
LAMICTAL
LAMICTAL CHEWABLE
LAMISIL
LASIX
LESCOL
LIDEX
LIPITOR
LISINOPRIL
LITHIUM CARBONATE
LITHIUM CARBONATE SR
LOPRESSOR
LOPROX
LOTENSIN
LOVASTATIN
LOZOL
LUMIGAN
LUVOX
LYSODREN
MACROBID
MAXALT
MEDROXYPROGESTERONE
MESALAMINE
METFORMIN

APPENDIX 4 CONTINUED

METHOTREXATE
METOPROLOL
METROCREAM
METROGEL
MEVACOR MICARDIS
MICARDIS HCT
MICRONOR
MINOCIN
MINOCYCLINE
MIRAPEX
MOBIC
MONOPRIL
NABUMETONE
NADOLOL
NAPROXEN
NAPROXEN ENTERIC COATED
NASACORT AQ
NASONEX AQ
NEURONTIN
NEXIUM
NITRO-DUR PATCHES
NITROFURANTOIN
NOLVADEX
NORITATE
NORTRIPTYLINE
NORVASC
NYSTATIN
OGEN
ORTHO 1/35 - 21 DAY
ORTHO 1/35 - 28 DAY
OXAPROZIN
OXYBUTYNIN
PAROXETINE
PATANOL
PAXIL
PAXIL CR
PERPHENAZINE
PILOPINE HS
PLAQUENIL
PLAVIX
PLENDIL
PRAVACHOL
PRAZOSIN
PRECOSE
PREDNISOLONE ACETATE
PREDNISONE
PREMARIN
PREMARIN VAGINAL
PREMPRO
PREVACID
PRIMIDONE
PRINZIDE
PROCARDIA XL
PROGRAF
PROMETRIUM
PROPAFENONE
PROPRANOLOL
PROPYLTHIOURACIL
PROSCAR
PROTONIX
PROTOPIC
PROVENTIL HFA
PROVERA
PROZAC
PROZAC LIQUID
PULMICORT RESPULES
PULMICORT TURBUHALER
PURINETHOL
QUESTRAN
QUININE
RANITIDINE
RELAFEN
REMINYL
RENOVA
RETIN-A
RETIN-A MICRO
RHINOCORT AQ NASAL SOL
RIFADIN
RISPERDAL
ROCALTROL
RYTHMOL
SECTRAL
SEREVENT
SEROQUEL
SINEMET
SINGULAIR
SOTALOL
SPECTAZOLE
SPIRONOLACTONE
SPORANOX
STARLIX
SUCRALFATE
SULFAMETH/TRIMETH DS
SULFAMETH/TRIMETH SS
SULFASALAZINE ENTERIC COATED
SULINDAC
SYNTHROID
TAMBOCOR
TAMOXIFEN
TAPAZOLE
TARKA
TEGRETOL
TEGRETOL XR
TENORETIC
TENORMIN
TERAZOSIN
TETRACYCLINE
THEOPHYLLINE
THIORIDAZINE
THYROID
TIAZAC
TILADE
TIMOLOL
TIMOPTIC
TIMOPTIC XE
TOFRANIL
TOPAMAX
TRAZODONE
TRICOR
TRIPHASIL 28 DAY
TRUSOPT OPHTH
ULTRAVATE
UNIPHYL
URSO
VAGIFEM
VALPROIC ACID
VALTREX
VASOTEC
VENTOLIN HFA
VERAPAMIL SR
VIOKASE 16
WARFARIN
WELLBUTRIN SR
XALATAN EYE DROPS
XENICAL
ZANTAC
ZAROXOLYN
ZELNORM
ZESTORETIC
ZESTRIL
ZETIA
ZITHROMAX
ZOCOR
ZOFRAN
ZOLOFT
ZOMIG
ZOVIRAX
ZYBAN
ZYLOPRIM
ZYPREXA
ZYPREXA ZYDIS
ZYRTEC
ZYRTEC SYRUP

Appendix 5
RIMeds Available Drugs List
As of December 30, 2005

ACCOLATE
ACCUPRIL
ACCURETIC
ACEBUTOLOL HCL
ACEON
ACIPHEX
ACTONEL
ACTOS
ACULAR
ACYCLOVIR
ADVAIR Diskus
AGGRENOX
AGRYLIN
ALBUTEROL
ALDACTAZIDE
ALDACTONE
ALDARA
ALESSE
ALLEGRA
ALOCRIL
ALOMIDE
ALPHAGAN
ALTACE
AMARYL
AMERGE
AMIODARONE HCL
ANAFRANIL
ANAPROX
ANSAID
ANZEMET
ARAVA
ARICEPT
ARIMIDEX
AROMASIN
ARTHROTEC
ASACOL
ATACAND
ATACAND HCT
ATENOLOL
ATROVENT
AVALIDE
AVANDAMET
AVANDIA
AVAPRO
AVODART
AXERT
AXID
AZATHIOPRINE
AZOPT
AZULFIDINE
AZULFIDINE EN
BACLOFEN
BACTROBAN
BENTYL
BENZAC AC
BETAGAN
BETAPACE
BETOPTIC S
BREVICON
BUMEX
BUSPAR
BUSPIRONE HYDROCHLORIDE
CAPOTEN
CARAFATE
CARDIZEM CD
CARDURA
CASODEX
CATAPRES
CAVERJECT SYSTEM
CELEBREX
CELEXA
CELLCEPT
CELONTIN
CITALOPRAM
CLARINEX
CLARITIN
CLIMARA
COLESTID
COMBIVENT
COMBIVIR
COMPAZINE
COMTAN
CORDARONE
COREG
CORGARD
CORTENEMA
COSOPT
COUMADIN
COZAAR
CREON
CRESTOR
CRIXIVAN
CUPRIMINE
CYCLOBENZAPRINE
CYCLOCORT
CYTOMEL
CYTOVENE
CYTOXAN
DANAZOL
DANTRIUM
DAYPRO
DDAVP
DEPAKENE
DEPAKOTE
DESMOPRESSIN ACETATE
DESQUAM-X
DESYREL
DETROL
DIABETA
DIAMOX
DICLOFENAC POTASSIUM
DICLOFENAC SODIUM
DIFFERIN
DIFLUNISAL
DILTIA XT
DIOVAN
DIPENTUM
DIPROLENE
DITROPAN
DOVONEX
DOXAZOSIN MESILATE
DOXYCYCLINE
EFFEXOR XR
EFUDEX
ELDEPRYL
ELIDEL
ELMIRON
ELOCON
EMCYT
EMLA CREAM
ENTOCORT EC
Epivir HBV
ERGODRYL
ERYSOL
ESTRACE
ESTRADERM
ESTROGEL
ETODOLAC
ETRAFON
EULEXIN
EVISTA
EXELON
FAMOTIDINE
FAMVIR
FELDENE
FEM HRT
FEMARA
FLOMAX
FLONASE
FLORINEF
FLOVENT
FLURBIPROFEN
FLUTAMIDE
FORADIL AEROLIZER
FOSAMAX
FUROSEMIDE
GABAPENTIN
GLICLAZIDE
GLUCAGON
GLUCOPHAGE
GLYBURIDE
HALOG
HYDREA
HYDRO VAL
HYDROXYCHLOROQUINE
HYDROXYUREA
HYTRIN
HYZAAR
IMDUR ER
IMITREX
IMODIUM
IMURAN
INDERAL LA
IOPIDINE
KALETRA SOFTGEL
KAYEXALATE
K-DUR
KEPPRA
KYTRIL
LAMICTAL
LAMISIL
LARIAM
LESCOL
LEVOBUNOLOL HCL
LEVOCARB CR
LEVODOPA/CARBIDOPA
LEXAPRO
LIDEX
LIPITOR
LIVOSTIN EYEDROPS
LOESTRIN
LONITEN
LOPID
LOPRESOR
LOTENSIN
LOTRISONE
LOVASTATIN
LOVENOX
LOXAPINE
LOZOL
LOZOL
LUMIGAN
LUPRON DEPOT
LUVOX
MALARONE
MANDELAMINE
MANERIX
MAVIK
MAXALT
MEDROL
MESTINON SR
METFORMIN HCL
METHAZOLAMIDE
METHOTREXATE
METOPROLOL TARTRATE
METROCREAM
METROGEL
MEVACOR
MICARDIS
MICRONOR
MIDAMOR
MINIPRESS
MINITRAN
MINOCIN
MIRAPEX
MOBIC
MOCLOBEMIDE
MODURETIC
MYLERAN
NABUMETONE
NALCROM
NAPROSYN E
NARDIL
NASACORT AQ
NASONEX
NAVANE
NEORAL
NEURONTIN
NEXIUM
NIASPAN
NILANDRON

APPENDIX 5 CONTINUED

NITRO-DUR
NITROLINGUAL
PUMPSPRAY
NIZATIDINE
NIZORAL SHAMPOO
NORGESIC
NORITATE
NORPACE
NORVASC
OGEN
ORAP
ORTHO
Ortho Evra
ORTHO TRI-CYCLEN
ORTHO-CEPT
ORTHO-CYCLEN
Ortho-Novum
OVRAL
OXSORALEN
PANCREASE
PANOXYL
PARLODEL
PARNATE
PAROXETINE
PATANOL
PAXIL
PENTASA
PEPCID
PERMAX
PERPHENAZINE
PILOPINE HS
PIROXICAM
PLAQUENIL
PLAVIX
PLENDIL
PLEXION TS
PODOFILOX
PRAMASONE
PRANDIN
PRAVACHOL
PRECOSE
PREMARIN
PREVACID
PRILOSEC
PRINIVIL
PRINZIDE
PROAMATINE
PROCAINAMIDE HCL
PROCARDIA
PROCTOFOAM HC
PROGRAF
PROGYLCEM
PROMETRIUM
PRONESTYL-SR
PROPAFENONE HCL
PROPECIA
PROPRANOLOL HCL
PROSCAR
PROSTIGMIN
PROTONIX
PROTOPIC
PROVERA
PROZAC
PULMICORT Turbuhaler
PURINETHOL
QVAR
RANITIDINE HCL
RAPAMUNE
RAZADYNE
RELAFEN
REMERON
RENAGEL
RENOVA
REQUIP
RETIN-A
REYATAZ
RHINOCORT AQ
RIDAURA
RIMSO
RISPERDAL
ROCALTROL
ROGAINE
RYTHMOL
SANSERT
SECTRAL
SELEGILINE HCL
SEREVENT
SEROQUEL
SINEMET
SINEQUAN
SINGULAIR
SORIATANE
SOTALOL
Spiriva
SPIRONOLACTONE
SPORANOX
STARLIX
SUCRALFATE
SULCRATE PLUS
SUPREFACT
SUSTIVA
SYNALAR
SYNAREL NASAL
SYNTHROID
TAMBOCOR
TAMOXIFEN Citrate
TAZORAC
TEGRETOL
TENORETIC
TENORMIN
TERAZOSIN HCL
TEVETEN
TIAZAC
TICLID
TICLOPIDINE HCL
TIMOLIDE
TIMOLOL
TIMOPTIC
TOFRANIL
TOPAMAX
TOPICORT
TOPROL XL
TRANDATE
TRAVATAN
TRAZODONE HCL
TRICOR
TRI-CYCLEN
TRILEPTAL
TRIPHASIL
TRIZIVIR
Trusopt
ULTRASE MT
ULTRAVATE
UNIPHYL
URECHOLINE
UROXATRAL
URSO
VAGIFEM VAGINAL
VALTREX
VASERETIC
VASOTEC
VENTOLIN HFA
VERAPAMIL HCL
VERELAN SR
VIBRAMYCIN
VIDEX EC
VIRACEPT
VIRAMUNE
VIREAD (TENOFOVIR)
VISKEN
VIVELLE-DOT
VOLTAREN
VYTORIN
WARFARIN
WELLBUTRIN SR
WESTCORT
XELODA
YASMIN
ZADITOR
ZANAFLEX
ZANTAC
ZARONTIN
ZAROXOLYN
ZEBETA
ZELNORM
ZERIT
ZESTORETIC
ZESTRIL
ZETIA
ZIAGEN
ZOCOR
ZOFRAN
ZOLADEX
ZOLOFT
ZOMIG
ZOVIRAX
ZYBAN
ZYPREXA
ZYRTEC

ORDER FORM

I-SaveRx

Safe and Affordable

Prescription Drugs

RETURN YOUR COMPLETED AND SIGNED ORDER FORM:

MAIL TO: I-SaveRx
P. O. BOX 44650
Detroit, MI 48244-0650

OR

FAX TO: 1-866-715-6337 (toll-free)
Faxed prescriptions are accepted ONLY if sent directly from your physician's office.
International postage rates apply.

CUSTOMER SERVICE INFORMATION:

We have customer service representatives and pharmacist assistance available to assist you 24 hours a day, 7 days a week at 1-866-I-SAVE33 (1-866-472-8333) toll-free.

1-866-I-SAVE33
(1-866-472-8333)
www.I-SaveRx.net

ROD R. BLAGOJEVICH
GOVERNOR, STATE OF ILLINOIS

WELCOME TO I-SaveRx

I-SaveRx is a program designed to save you 25 to 50 percent on safe prescription medication refills.

ORDER FORM INSTRUCTIONS

1. Complete and Sign the enclosed Order Form
2. Obtain an original refill prescription for all medications you want to order through I-SaveRx from your doctor. Each prescription should be written for a 3-month supply of the medication with three refills.
3. Submit your completed Order Form AND the original refill prescription(s) to I-SaveRx by either:
   (a) Having your Doctor's office fax these materials to 1-866-715-6337, OR
   (b) Mailing these materials to I-SaveRx, P.O. Box 44650, Detroit, MI 48244-0650. (Please note that international postage rates apply.)
4. An I-SaveRx representative will contact you when your order has been received to confirm the order and take payment.
5. Your medications will arrive in the mail directly from the pharmacy in about 20 days.

IMPORTANT WARNING AND INFORMATION REGARDING THE SAFETY AND LEGALITY OF PRESCRIPTION DRUGS PURCHASED FROM OTHER COUNTRIES

Purchasing prescription drugs by mail order from another country involves certain unavoidable risks. As with any prescription drug purchase, you should educate yourself about your needs and the product to be purchased to minimize your risks. You should always inspect your purchases carefully to ensure that you have received the correct quantity of the correct medication in the correct dosage. You should also check your shipping packages carefully to ensure that your purchases have not been damaged or tampered with during shipping. If you have any questions or doubts about any prescription drugs received through the mail, you should talk to a doctor or pharmacist before you begin taking the medication. Take medication only as instructed by your doctor. Do not take medication that has not been prescribed for you, that does not match your prescription, or that appears to have been damaged or tampered with. If you have symptoms after you begin taking a new medication, talk to a doctor or pharmacist right away. Failure to follow these warnings could result in serious injury or death.

The Canadian, Irish, or United Kingdom regulatory bodies have approved all medications available through this program to be safe for use within their own respective countries. Prescription drugs purchased from other countries fall outside of the regulatory system for prescription drugs purchased in the United States. Canada and United Kingdom have their own regulatory systems to protect the safety of prescription drugs, and those systems differ in certain respects from the system in the United States. Prescription drugs purchased from other countries, for example, may be labeled or packaged differently than prescription drugs purchased in the United States, or manufactured in different facilities. The State of Illinois has investigated the regulatory systems of Canada, Ireland, and the United Kingdom, and believes that they are safe and effective.

The United States Food and Drug Administration (the "FDA"), however, has taken the position that the purchase of prescription drugs from outside of the United States can be unsafe and illegal. To learn more about the FDA's position, please go to http://www.fda.gov/importeddrugs/. The State of Illinois, its officers, and its employees make no representation as to the legality of the importation or reimportation of pharmaceuticals from other countries.

The State of Illinois does not license pharmacies outside of Illinois, and the pharmacies in Canada and United Kingdom participating in this program are not licensed Illinois pharmacies. All pharmacies participating in this program are required to consent to regular inspections by Illinois pharmacy inspectors. The State of Illinois has inspected all of the participating pharmacies, and has concluded that they meet the same conditions required of licensed Illinois pharmacies. The State of Illinois will continue to inspect those pharmacies in the future, and to remove from this program any pharmacy that does not comply with Illinois standards. Nevertheless, the State of Illinois cannot guarantee the safety of any particular prescription drug purchase. The State of Illinois makes no representations or warranties as to the safety or efficacy of prescription drugs purchased from foreign sources.

The **I-**SaveRx program is not a licensed pharmacy and is not engaged in the practice of pharmacy.

I-SaveRx
Safe and Affordable
Prescription Drugs

FAX: DIRECTLY FROM YOUR DOCTOR'S OFFICE WITH YOUR PRESCRIPTIONS
TOLL-FREE TO: **1-866-715-6337**

MAIL TO: I-SaveRx, P.O. BOX 44650, CanaRx Services Inc., Detroit, MI 48244-0650

PHONE TOLL-FREE: 1-866-I-SAVE33 (1-866-472-8333)

(If you require more space for any information in this order form, please attach a separate piece of paper.)

PATIENT INFORMATION:

Phone (Home) _____ Phone (Work) _____

First Name (please print) _____ Initial _____ Last Name _____

Street Address _____

City/State _____ Zip Code _____ ENGLISH/SPANISH Language Preference _____

NOTE: If acceptable to the prescribing physician, each prescription should request a 3-month supply of medication with 3 refills. **New-to-you medications must be tried for a period of 30 days before ordering through the I-SaveRx Program.** You may be contacted by one of our representatives, physicians or the network pharmacy filling the prescription to discuss or confirm your order.

List of all prescription and over-the-counter medications, herbal, nutritional and vitamin supplements currently taken. (This is NOT a prescription.)	STRENGTH	DAILY USE	STARTED TAKING ON

MEDICAL HISTORY ○ Male ○ Female Birthdate DD / MM / YY

1) Operations: e.g., Hysterectomy, Gall bladder, Heart operations, etc. _____

2) Hospitalization: (stays in hospital during the past 5 years) _____

3) Present Illness: (ongoing) e.g., Diabetes, Heart disease, Osteoporosis, etc. _____

4) Drug Allergies: ○ NO ○ YES If yes, please specify _____

PAYMENT INFORMATION:

Cardholder Name _____ Credit Card Number _____ Expiry Date (MM / YY) _____

○ VISA ○ MASTERCARD ○ CERTIFIED CHECK* ○ INTERNATIONAL MONEY ORDER*

* Made payable and mailed directly to CanaRx Services Inc.

Signature of Cardholder _____ DATE: DD / MM / YY

I confirm that a U.S. physician will regularly monitor me and that I have had a physical examination within the past 12 months.
I certify that I have read and understood the CanaRx Terms of Agreement and the Warning Statement, and that the information provided by me is accurate and true.

SIGNATURE OF PATIENT: _____ DATE: DD / MM / YY

THIS FORM MUST BE ACCOMPANIED BY THE WRITTEN PRESCRIPTION(S) OF YOUR U.S. PHYSICIAN.

CanaRx TERMS OF AGREEMENT

CONFIRMATION AND REPRESENTATIONS

I, the undersigned, am entering into this agreement with *CanaRx Services Inc.* in order that I may obtain access to medically necessary prescription drugs at low costs.

1) I am of the age of majority in the jurisdiction in which I ordinarily reside;

2) I am not restricted from making my own medical decisions under the laws of the jurisdiction in which I ordinarily reside;

3) The medication(s) that I have requested that CanaRx Services Inc. facilitate my obtaining were prescribed by a duly qualified and licensed medical practitioner in the United States;

4) I have not violated any laws in the jurisdiction in which I ordinarily reside in obtaining the prescription for the ordered product;

5) This prescription has not been altered in any way nor has it been filled previously. I agree to mail the original copy of the prescription to CanaRx Services Inc.;

6) I am under the ongoing care of a physician in my residing jurisdiction (my "U.S. physician"), and therefore, I am not seeking or relying on any medical information from CanaRx Services Inc. or any CanaRx contracted physician;

7) My prescription will not be used in any way whatsoever except as prescribed by my medical practitioner who originally issued the prescription;

8) I will not permit anyone else to use the prescription or any medication(s) which I receive;

9) I will use any medication(s) obtained for me by CanaRx Services Inc. strictly in accordance with the instructions provided by the physician who prescribed the medication(s); and

10) In the event that I suffer any side effects from any medication(s) I receive through the services of CanaRx Services Inc., I will immediately contact my U.S. physician.

AUTHORIZATION AND CONSENT

I further provide my authorization and consent to the following:

1) I hereby appoint CanaRx Services Inc. and its delegates or contractors as my agent and attorney for the purposes of obtaining a prescription from the CanaRx Network Pharmacy, which corresponds to the prescription provided by my U.S. physician.

2) I authorize CanaRx Services Inc. and its delegates or contractors to arrange delivery of the medication(s) prescribed to me on the terms outlined in this agreement and to the same extent as if I personally took such steps.

3) I consent and authorize CanaRx Services Inc. to collect my personal medical information and to maintain on file the information necessary to verify and process future orders, including but not limited to my full name, address, phone number, complete medical history and payment information.

4) I authorize my U.S. physician and CanaRx Services Inc. to release any and all information required in connection with my physical condition, including but not limited to all X-rays, medical records, medical reports, progress notes, nurses' notes, reports on diagnostic tests, medical opinions and /or any other knowledge or information which they may possess to a CanaRx contract physician who may be required to review my health record for the purposes of being in a position to evaluate the medical necessity and indications for prescription medication.

5) I authorize the CanaRx contracted physician to contact my U.S. physician to discuss my prescription if necessary.

6) I further authorize the CanaRx contracted physician to issue a prescription for medication(s) I have ordered only if he/she deems it advisable and appropriate.

7) I further authorize the CanaRx contracted physician to release any and all information they may require to any CanaRx Network Pharmacy for the purpose of having my prescription(s) filled.

ACKNOWLEDGMENT AND RELEASE

I hereby make the following acknowledgments and releases to *CanaRx Services Inc.,* including all of its employees, its contractors, including physicians, pharmacists, pharmacy technicians, nurses, receptionists and staff:

1) I acknowledge that my U.S. physician is my primary physician and the CanaRx contracted physician is being asked only to review the information contained in the Personal Medical History for the purpose of authorizing any properly prescribed medication(s) for fulfillment from a CanaRx Network Pharmacy.

2) I acknowledge that CanaRx Services Inc. has made no representations or warranties to me, including, without limitation, representations or warranties regarding the use of fitness for any particular purpose of the medication(s) delivered (including, without limitation, its appropriateness for curing or helping relieve any particular ailment, illness or disease, or its potential or actual side or adverse effects whether previously known or unknown).

3) I acknowledge that I wish to obtain a prescription from a CanaRx contracted physician and have enlisted the services of CanaRx Services Inc. to facilitate this matter. I understand and appreciate that the CanaRx contracted physician will rely on the accuracy of the examination and prescription provided by my U.S. physician.

4) I acknowledge that child protective packaging may not be used by the CanaRx Network Pharmacy filling my prescription and I release CanaRx Services Inc. and all of their officers and directors, agents, employees and contractors from any and all causes of action with respect to errors or omissions by the company or agency responsible for transporting my order.

5) I acknowledge that CanaRx Services Inc. requires payment in full prior to shipment and that my order may not be returned for a refund or an exchange.

June 2004

INTERNET PHARMACIES

Some Pose Safety Risks for Consumers

GAO Accountability • Integrity • Reliability

Highlights

Highlights of GAO-04-820, a report to the Chairman, Permanent Subcommittee on Investigations, Committee on Governmental Affairs, U.S. Senate

Why GAO Did This Study

As the demand for and the cost of prescription drugs rise, many consumers have turned to the Internet to purchase drugs. However, the global nature of the Internet can hinder state and federal efforts to identify and regulate Internet pharmacies to help assure the safety and efficacy of products sold. Recent reports of unapproved and counterfeit drugs sold over the Internet have raised further concerns.

GAO was asked to examine (1) the extent to which certain drugs can be purchased over the Internet without a prescription; (2) whether the drugs are handled properly, approved by the Food and Drug Administration (FDA), and authentic; and (3) the extent to which Internet pharmacies are reliable in their business practices. GAO attempted to purchase up to 10 samples of 13 different drugs, each from a different pharmacy Web site, including sites in the United States, Canada, and other foreign countries. GAO determined whether the samples contained a pharmacy label with patient instructions for use and warnings on the labels or the packaging and forwarded the samples to their manufacturers to determine whether they were approved by FDA and authentic. GAO also confirmed the locations of several Internet pharmacies and identified those under investigation by regulatory agencies.

www.gao.gov/cgi-bin/getrpt?GAO-04-820.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Marcia Crosse at (202) 512-7119 or Robert J. Cramer at (202) 512-7455.

What GAO Found

GAO obtained most of the prescription drugs it targeted from a variety of Internet pharmacy Web sites without providing a prescription. GAO obtained 68 samples of 11 different drugs—each from a different pharmacy Web site in the United States, Canada, or other foreign countries, including Argentina, Costa Rica, Fiji, India, Mexico, Pakistan, Philippines, Spain, Thailand, and Turkey. Five U.S. and all 18 Canadian pharmacy sites from which GAO received samples required a patient-provided prescription, whereas the remaining 24 U.S. and all 21 foreign pharmacy sites outside of Canada provided a prescription based on their own medical questionnaire or had no prescription requirement. Among the drugs GAO obtained without a prescription were those with special safety restrictions and highly addictive narcotic painkillers.

GAO identified several problems associated with the handling, FDA approval status, and authenticity of the 21 samples received from Internet pharmacies located in foreign countries outside of Canada. Fewer problems were identified among pharmacies in Canada and the United States. None of the foreign pharmacies outside of Canada included required dispensing pharmacy labels that provided instructions for use, few included warning information, and 13 displayed other problems associated with the handling of the drugs. For example, 3 samples of a drug that should be shipped in a temperature- controlled environment arrived in envelopes without insulation. Manufacturer testing revealed that most of these drug samples were unapproved for the U.S. market; however, manufacturers found the chemical composition of all but 4 was comparable to the product GAO ordered. Four samples were determined to be counterfeit products or otherwise not comparable to the product GAO ordered. Similar to the samples received from other foreign pharmacies, manufacturers found most of those from Canada to be unapproved for the U.S. market; however, manufacturers determined that the chemical composition of all drug samples obtained from Canada were comparable to the product GAO ordered.

Some Internet pharmacies were not reliable in their business practices. Most instances identified involved pharmacies outside of the United States and Canada. GAO did not receive six orders for which it had paid. In addition, GAO found questionable entities located at the return addresses on the packaging of several samples, such as private residences. Finally, 14 of the 68 pharmacy Web sites from which GAO obtained samples were found to be under investigation by regulatory agencies for reasons including selling counterfeit drugs and providing prescription drugs where no valid doctor-patient relationship exists. Nine of these were U.S. sites, 1 a Canadian site, and 4 were other foreign Internet pharmacy sites.

In commenting on a draft of this report, FDA generally agreed with its findings and conclusions.

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EXECUTIVE SUMMARY

OVERVIEW

Introduction

In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, Pub. L. 108-173 (Medicare Modernization Act or MMA), which for the first time provided a prescription drug benefit for seniors and people with disabilities. The MMA also contained provisions that would permit the importation of prescription drugs into the U.S. if the Secretary of the Department of Health and Human Services (HHS) certifies that drugs imported from Canada pose no additional risk to public health and safety and that such imports would provide significant cost savings to American consumers. The MMA also requires the Secretary to conduct a study on the importation of drugs. The conference agreement for MMA included eleven issues for consideration. The Surgeon General of the U.S. Public Health Service, Dr. Richard H. Carmona, was charged with leading a task force of senior executives across the Federal government to conduct the analysis required by the MMA. The Task Force met with key constituencies numerous times throughout 2004 in public forums, received testimony from over one hundred presenters from around the world with all types of backgrounds, and received over one hundred written comments providing insight into these issues. This report is a summary of what the Task Force reviewed from the testimony and written comments for the specific questions posed in the MMA conference agreement and their findings based on this evaluation.

Background

In the early years of the twentieth century, pharmaceuticals in the U.S. were characterized by a large number of ineffective, often dangerous, compounds, the principal ingredient of which was often alcohol. The invention of penicillin in the 1930s marked the beginning of the modern era of drug development, when scientists were able to create powerful new chemicals that were safe and effective in killing bacteria. Since then, the world's investment in research and development (R&D) has produced many more safe and effective treatments to reduce pain and inflammation, regulate the cardiovascular system, impede the growth of cancer cells, and provide a host of other effective therapies for disease. The resulting discovery of new medications has enabled doctors to offer comfort for the sick and to prescribe from an extensive array of drugs to treat most human afflictions.

As this innovation began in the 1930s, Congress recognized the need for a strong oversight body to ensure that drugs were properly tested before being given to patients. The manufacturing of drugs needed equally rigorous oversight to ensure that drugs were made in a safe and consistent way. The Federal Food, Drug, and Cosmetic (FD&C) Act of 1938 and its 1962 amendments provided that oversight, by requiring that the U.S. Food and Drug Administration (FDA) approve each new drug as safe and effective before marketing and authorizing FDA to oversee the production of drugs, whether manufactured in a U.S. facility or imported from abroad.

By the 1980s, Congress recognized that some entities not subject to U.S. law were importing counterfeit drugs as well as improperly handled and stored drugs. For example, at that time, counterfeit birth control pills found their way into the U.S. drug distribution system. These types of activities posed significant risks to American consumers. Therefore, in 1987, Congress passed the Prescription Drug Marketing Act (PDMA), which, among other things, strengthened oversight of domestic wholesalers and added the "American goods returned" provision to the FD&C Act, which prohibits anyone

except a drug's manufacturer from importing into the U.S. a prescription drug that was originally manufactured in the U.S. and then sent abroad.

We recognize that there are different categories of "imported drugs" that potentially have different levels of associated risk. Currently, the only types of legally imported drugs are: 1) those that are manufactured in foreign FDA-inspected facilities and adhere to FDA-approval standards, or 2) those that are U.S.-approved and manufactured in the U.S., sent abroad, then imported back into the U.S. by the manufacturer under proper controls and in compliance with the FD&C Act. This latter category includes products that are truly re-imported. In both cases, the manufacturing process is subject to direct FDA oversight and the drug distribution system is "closed," and the manufacturer complies with FDA and other regulations to assure that the drug delivered to the pharmacy is of high quality.

Another category of imported drugs are those that are manufactured in a foreign facility that also manufactures the U.S.-approved version. In such a case, FDA would have inspected the U.S.-approved manufacturing process, but not the unapproved production lines; in this case, the foreign version may differ in certain respects from the U.S.-approved version. Although there may be significant similarities between the two versions, because of the potential differences and the fact that only the U.S.-approved drugs have been shown to meet U.S standards enforced by FDA, the foreign version cannot necessarily be considered equivalent to the U.S.-approved version.

A final category of imported drugs are unapproved drugs that are produced in foreign facilities that FDA has not inspected and, therefore, has no knowledge of, or experience with, the facility. Consequently, the safety and effectiveness of these drugs and the safety and security of their distribution systems are unknown. These drugs pose the greatest level of concern because they are not regulated within the U.S. drug safety system and little is known to U.S. regulators about the specifications to which they are made, the processes used to ensure their safety, and the integrity of their distribution. As the report describes, there is ample evidence that these are the types of drugs that consumers have received when they order prescription drugs from some international sources over the internet.

When a drug is imported into the U.S., FDA inspectors are required to confirm that the drug meets the necessary approval requirements. Such review of imported drugs is limited by the amount of resources available, given the substantial amount of legal and illegal prescription drugs that are imported daily. If there is a question of whether the drug can legally be imported and, thus, raises safety questions, FDA has the authority to detain the product and gives the importer several days to demonstrate the drug's acceptability (or, failing that, the drug is either refused admission and returned to its foreign source, if known, or destroyed.)

The conclusion of Congress reflected in current law is that the safety and effectiveness of imported drugs can only be assured for drugs legally imported into the U.S., as described above. In these cases, the chain of custody is known for a U.S.-approved drug manufactured in an FDA-inspected facility using FDA-approved methods as it travels through the U.S. distribution system. Much of the current public debate about the safety of broader importation comes down to issues regarding the additional oversight authorities, resources, and foreign government support that would be needed to assure the safety and effectiveness of other types of drugs, principally foreign drug purchases from international internet operations that are not subject to FDA's regulatory oversight.

Since the FD&C Act's passage in 1938, American citizens returning from overseas with foreign drugs have been advised that most of these drugs are not legal, but, as a matter of enforcement discretion, FDA has generally allowed those citizens to bring in small quantities for their personal use and advised them to consult with their physician. FDA created this enforcement discretion policy to allow American residents who became ill in another country to continue the treatment prescribed by a foreign healthcare practitioner until they could receive medical attention back home. That policy was not controversial until the latter part of the 1990's, when some citizens

began traveling regularly to other countries to fill their prescriptions, and especially when more Americans began ordering drugs via internet pharmacies located in other countries.

The Task Force understands what motivates more and more Americans to import drugs. Access to affordable prescription drugs, many of which are needed to treat life-threatening and serious conditions, is a daily concern and challenge for many Americans. As there has been a significant increase in drug utilization and in list prices for drugs in the U.S. over the last few years, spending by American consumers on prescription drugs has risen significantly. Over 40 percent of Americans take at least one prescription drug and, in an effort to lower their prescription drug bill, a relatively small but increasing number have turned to importing drugs.

Consequently, the Task Force believes that access to drugs that are safe and effective, as well as affordable, is a critical policy goal, and that all approaches to achieving this challenging goal should be explored thoroughly. Drugs that are affordable, but not safe and effective, could be more harmful to patients than not having the drugs at all. The difficult balance between the need for affordable prescription drugs and concerns over potential safety hazards that many imported drugs may pose is reflected in the public debate and controversies regarding drug importation policy in the U.S. The Task Force report presents a comprehensive overview of the evidence related to this balance, as well as a number of other critical issues, as requested by Congress, on the subject of prescription drug importation.

THE REPORT IN BRIEF

Chapter 1 –Scope, volume, and safety of unapproved drugs

The number of unapproved prescription drug products entering the U.S. is now very large. Nearly five million shipments, comprising about 12 million prescription drug products with a value of approximately $700 million, entered the U.S. from Canada alone in 2003, via internet sales and travel to Canada by American consumers. This report estimates that an equivalent amount of prescription drugs are currently coming in from the rest of the world, mostly through the mail and courier services.

Imported drugs are arriving from all corners of the world, including developed and emerging countries. Their scope is broad and includes tablets, capsules, inhalants, injectables, biologics, generics, brand name drugs, and controlled substances. Some of the arriving products appear to have been made in the U.S.; however, many are not. The majority of these currently imported drugs are unapproved by FDA and do not appear to conform in many aspects to the properly approved and manufactured products available in American pharmacies.

Numerous comments submitted to the Task Force described the current practice of internet purchases by American consumers who seek lower-priced drugs. Many state-licensed internet pharmacies provide a legitimate means for consumers to access safe and effective medicines, but others raise significant safety concerns.

Most of these drugs are purchased by individual consumers via internet, phone, or fax, from entities that focus on providing drugs to Americans and other long-distance purchasers. These entities generally are cross-border foreign pharmacies that may not primarily serve the citizens of the country in which they are located, and their methods for providing drug products may not be subject to the same oversight that foreign governments provide for drugs and pharmacies serving their own citizens. When consumers order prescription drugs over the internet from international sources, they generally receive drugs that do not have regulatory assurances of equivalence to U.S. products or of safety and security in the distribution process.

Some sellers of imported drugs are "rogue" internet pharmacies that pretend to be legitimate and operate behind facades. Many of the drugs sold over the internet claim to be interchangeable with the approved U.S. drug, but are not. Imported drugs include those that pose special concerns, such as drugs that require special handling, drugs with high

abuse potential, drugs that should be sterile, counterfeit drugs, improperly packaged drugs shipped loose in sandwich bags and envelopes, and drugs from countries that have differing and sometimes more limited regulatory authority to assure the safety of pharmaceuticals manufactured and exported from those countries. In sum, this report finds that American consumers currently purchasing drugs from overseas are generally doing so at significant risk.

Chapter 2 – Limits on resources and authorities

The Federal law governing drug safety in the U.S. establishes the standards by which FDA determines whether a prescription drug is "safe and effective" for sale in the U.S. These standards govern the way in which prescription drugs are manufactured, packaged, labeled, held, and shipped. Many of the prescription drugs that are imported into the U.S. now by individual citizens, via mail and courier services, fail to comply with some or all of these Federal standards. To ensure that imported prescription drugs are as safe as those that are legally sold in the U.S., an importation program for U.S.-approved drugs would have to ensure that the imported drugs meet the current (or equivalent) Federal standards. This report determines that it would be extraordinarily difficult to ensure that drugs personally imported by individual consumers could meet the necessary standards for a certification of safety to be made, especially if consumers continue to import prescription drugs in the same or increased numbers. Meanwhile, a commercial importation program could be feasible but would require new legal authorities, substantial additional resources and significant restrictions on the type of drugs that could be imported, which could increase the costs of imported drugs.

Chapter 3 – Impact on the pharmaceutical distribution system

The drug distribution network for legal prescription drugs in the U.S. is a "closed" system that involves several players (e.g., manufacturers, wholesalers, pharmacies) who move drug products from the point of manufacture to the end user, and provides the American public with multiple levels of protection against receiving unsafe, ineffective, or poor quality medications. This system evolved as a result of legislative requirements that drugs be treated as potentially dangerous consumer goods that require professional oversight to protect the public health. The result has been a level of safety for drug products that is widely recognized as the world's "gold standard." Legalized importation of drugs in such a way that creates an opening in the "closed" system will likely result in some increase in risk, as the evidence shows that weaknesses in the oversight of drug regulation and the distribution system have been exploited. For example, doing so would increase the opportunity for counterfeit and other substandard drugs to enter and be dispersed into the U.S. drug distribution system.

Chapter 4 – Role of new technologies

There are a number of anti-counterfeiting technologies that show potential for effectively assuring the authenticity of drugs and, thus, for combating the counterfeiting of drugs. Some examples include holograms, color shifting inks, and watermarks currently employed for U.S. currency. So-called "track and trace" technologies, such as radio-frequency identification (RFID) and sophisticated bar coding, can provide effective monitoring of a drug's movement from the point of manufacture and through the U.S. distribution chain. Although these new and emerging technologies are promising, until they are fully adopted internationally they cannot be adequately relied upon to secure the safety, efficacy, and integrity of the global market to safely import prescription drugs into the U.S.

Chapter 5 – Agency resources associated with drug importation activities

FDA currently has about 3,800 employees assigned to field activities (e.g., inspections) involved in protecting the many thousands of products that make up the Nation's food, drug, biologic, medical device, and veterinary drug supply. Of the 3,800 field staff, 450 are involved in investigative import activities. Only a limited number of FDA inspectors are available to staff the 14 international mail facilities in the U.S., where they historically have had to inspect a small number

of large commercial pharmaceutical imports. FDA managers have repeatedly noted that the large number of personal drug shipments coming into the international mail and courier facilities is overwhelming the available staff.

This report finds that despite significant efforts, including joint efforts with CBP and import alerts/bulletins, FDA currently does not have sufficient resources to ensure adequate inspection of current levels and categories of personal shipments of prescription drugs entering the U.S. With respect to commercial shipments, based on the information presented to the Task Force, FDA would need a meaningful investment, among other things, in new information technology and personnel, as well as appropriate standards to ensure adequate inspection of commercial quantities of drug products, if importation were legalized.

Chapter 6 – Role of foreign health agencies

Just as the U.S. is responsible for the safety and effectiveness of drugs made available to its citizens, foreign governments give priority to ensuring the safety of drugs used by their citizens. Foreign governments have little incentive and limited resources to ensure the safety of drugs exported from their countries, particularly when those drugs are transshipped or are not intended for import. No country expressed any interest or willingness to ensure the safety and effectiveness of drugs exported from their country in any expansion of legal U.S. importation. Although we specifically solicited them, few comments were submitted by foreign governments, and none outlined a specific strategy for new steps to collaborate with the U.S. government on the effective oversight of importation, suggesting that they are not willing or do not have the means to ensure the safety of exported products and that the primary safety responsibilities would have to remain with the U.S.

Chapter 7 – Effects of importation on prices and consumer savings

Consumers seek to import prescription drugs from other countries in part because they believe they can save money if they purchase their drugs from outside the U.S. In many instances, U.S. consumers have been able to purchase from abroad foreign versions of U.S.-approved brand name drugs at lower prices. However, based on an analysis of actual data on drug prices and volumes, this report finds that total savings to consumers from legalized importation under a commercial system would be a small percentage relative to total drug spending in the U.S. (about one to two percent). These savings are much smaller than some specific international comparisons of retail prices for certain drugs might suggest. Under any safe, legalized commercial importation program, when the scope is limited, intermediaries would likely capture a large part of the price differences. (This is based on evidence from European countries where some form of importation is legal.)

This report also finds that generic drugs are often cheaper in the U.S. compared to international prices for similar drugs. Other, independent studies have reached similar conclusions. The prices foreigners pay for generic drugs are on average 50 percent greater than the prices Americans pay for generic drugs. Furthermore, there is evidence that greater use of U.S.-approved generic drugs by Americans could reduce drug spending by billions of dollars annually. In addition, to the extent that prescription drugs are eligible for importation from the same company at a lower price than in the U.S., potential quantity constraints imposed by manufacturers or foreign governments would limit the eligible supply and the benefits to U.S. consumers.

Chapter 8 – Impact of importation on research and development and consumer welfare

One of the most frequently debated issues surrounding drug importation is whether the legalization of importation would reduce research and development (R&D), including spending on discovery, development, and launching of new drugs. Based on both an empirical analysis of drug data and a review of previous studies, this report finds that, by shifting sales to countries with price controls for new drugs, importation would reduce overall U.S. pharmaceutical industry revenues. Since revenues would fall without a reduction in the cost to produce new medicines, prof-

its would likely fall, as well as spending on R&D. Consequently, legalized importation would likely adversely affect incentives for R&D, thereby slowing the flow of new drugs. This report also finds that since annual R&D spending would drop, importation could result in between four to eighteen fewer new drugs being introduced per decade at a substantial cost to society. Furthermore, if there were a likely reduction in innovative new drugs, then the foregone consumer benefits associated with loss or delay in new therapies may significantly offset any anticipated savings from legalized importation, depending on uncertainties.

Chapter 9 – Impact on intellectual property rights

Intellectual property rights have evolved over many years to strike a balance between, on the one hand, providing incentives for innovation through grants of exclusive rights over new ideas or products and, on the other hand, ensuring that knowledge and products are widely disseminated and accessible to provide the maximum benefit to society now and in the future. As with most new ideas and products, inventors of pharmaceuticals may obtain patents and other intellectual property protections for their products that provide certain exclusive rights. The challenge policymakers face is to ensure that intellectual property protection for pharmaceuticals provides adequate economic incentives to develop new drugs while facilitating access to affordable medicines.

An exhaustive legal analysis of the implications of allowing importation of patented pharmaceuticals to which intellectual property protections apply would require further study. However, it is clear that importation could impact the intellectual property rights of developers of pharmaceutical products and could be subject to challenge under domestic law, including possibly the U.S. Constitution, and international intellectual property rules.

Chapter 10 – Liability issues related to importation

This report identifies the liability issues raised if importation is legalized for entities within the pharmaceutical distribution system. This report notes that allowing prescription drug importation would have uncertain effects on the litigation exposure of manufacturers, distributors, doctors, and pharmacists. To deal with these likely increased risks, entities in the pharmaceutical distribution chain may take additional costly defensive actions. Perhaps the largest source of additional liability and/or litigation risk under a drug importation system would be an increase in the number of injuries and poor disease outcomes if imported drugs are, as a class, less safe and effective.

KEY FINDINGS

This report details the diverse opinions expressed, the data collected, and Task Force findings based on the information presented. Some of the key findings of the Task Force are:

1) **The current system of drug regulation in the U.S. has been very effective in protecting public safety, but is facing new threats. It should be modified only with great care to ensure continued high standards of safety and effectiveness of the U.S. drug supply.** Americans have the benefit of one of the safest drug supplies in the world and generally have first access to the newest breakthrough drug treatments. Any legislation to permit the importation of foreign drugs should only be done in a way that provides the statutory authority and substantial resources needed to effectively regulate imported drugs and, most importantly, protect the public health by providing the same level of safety assurances available for drugs sold in the U.S.

2) **There are significant risks associated with the way individuals are currently importing drugs.** While some means of drug importation (e.g., traveling to Canada for certain brand name drugs available in both countries) may be relatively safe in specific instances, this is not the only way "importation" into the U.S. is occurring today. Many transactions are occurring via poorly-regulated and occasionally bogus internet operations that have been documented in some cases to provide consumers with inferior products that are not the same as the U.S.-approved ver-

sions. Also, treatment failures, which are not obvious adverse events, are a real concern with substandard drug products.

3) **It would be extraordinarily difficult and costly for "personal" importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs.** While wholesalers and pharmacists purchase, transport, and dispense imported drugs within our regulatory framework, American consumers making individual purchases from foreign sources outside our regulatory system, in particular those making long-distance purchases from internet sites or by fax or phone, face safety hazards that would be extraordinarily difficult to effectively address and prevent.

4) **Overall national savings from legalized commercial importation will likely be a small percentage of total drug spending and developing and implementing such a program would incur significant costs and require significant additional authorities.** The public rightly expects that, under any legal importation program, the imported drugs will be safe and effective. To accomplish this, additional safety protections would need to be added that would increase the costs of the program in an additive way as more safety measures are put in place. Substantial resources would also be needed to ensure adequate inspection of imported drug products. In addition to other factors that are likely to reduce potential consumer savings, these increased regulatory and program costs will also impact potential savings to consumers. Furthermore, intermediaries will likely capture at least half of any savings between the U.S. and price-controlled countries and potential quantity constraints imposed by foreign governments and manufacturers will likely further limit the supply of these drugs to U.S. consumers.

5) **The public expectation that most imported drugs are less expensive than American drugs is not generally true.** Generic drugs account for most prescription drugs used in the U.S. and are usually less expensive in the U.S. than abroad. Shopping around for price comparisons, asking a doctor or pharmacist for a generic alternative to a prescribed brand name drug, or using a Medicare or other prescription drug discount card is a proven method to save American consumers money on domestic prescription drugs while retaining the protections of a comprehensive safety regime.

6) **Legalized importation will likely adversely affect the future development of new drugs for American consumers.** This report estimates that R&D incentives will be lowered by legalized importation, resulting in roughly between four and eighteen fewer new drugs introduced per decade.

7) **The effects of legalized importation on intellectual property rights are uncertain but likely to be significant.** A host of legal and constitutional challenges are probable, and the effects on enforcement of intellectual property rights and on agreements with foreign countries are likely to be problematic. These effects could create additional disincentives to develop breakthrough medicines and further limit any potential savings that might have been realized.

8) **Legalized importation raises liability concerns for consumers, manufacturers, distributors, pharmacies, and other entities.** Consumers harmed by imported drugs may not have legal recourse against foreign pharmacies, distributors, or others suppliers. Entities in the pharmaceutical supply chain may take actions to protect themselves from liability that could ultimately raise the cost of drugs.