Minnesota Department of **Human Services**

March 18, 2005

The Honorable Tim Pawlenty
Governor of the State of Minnesota
130 State Capitol
75 Rev. Dr. Martin Luther King Jr. Blvd.
St. Paul, MN 55155

Dear Governor Pawlenty:

At your direction, the Department of Human Services has investigated the possibility of expanding the Minnesota RxConnect and Advantage-Meds programs to include a European component. The enclosed report details the findings of the study completed by DHS staff that involved both background research and onsite visits of facilities in the United Kingdom.

Actions taken by pharmaceutical manufacturers and those being contemplated by the Canadian Health Minister threaten to cut off Minnesota's access to safe and affordable Canadian prescription drugs. Based on our research and onsite visits, we believe that personal use quantities of prescription drugs can be safely imported from the United Kingdom.

We have concluded that Minnesota citizens should continue to have access to safe and affordable prescription drugs and that the State of Minnesota should develop an option for the personal importation of selected prescription drugs from licensed British pharmacies by Minnesota citizens. As with the initial Canadian pharmacies involved in Minnesota RxConnect, safety was our key concern.

Specifically, we recommend that the State of Minnesota:

1. Encourage the continued operation of the licensed Canadian pharmacies that supply prescription drugs to Minnesotans.

   These pharmacies provide a valuable service to the citizens of this state who need access to affordable prescription drugs. We reject the notion that they are engaging in any unethical practices and we do not believe that there is any evidence to suggest that the Canadian supply of prescription drugs is jeopardized by their operations.

Consequently, we recommend that Minnesota join in efforts to encourage the Canadian government to allow these pharmacies to continue operating without excessively burdensome restrictions. If these pharmacies are entirely shut down by the Canadian government, Minnesota citizens who rely on their services will needlessly suffer.

2. Work with Canadian pharmacies affiliated with Minnesota RxConnect to develop an option for the personal importation of medications from the United Kingdom.

   Having inspected the British pharmacies affiliated with Total Care and Granville, two of our existing Minnesota RxConnect pharmacies, we recommend this option. We further recommend that the drugs dispensed by the British pharmacies not be limited to products marketed only to the United Kingdom. As explained in the report, we believe that the drugs imported for use in the United Kingdom through the parallel importation process are both safe and effective.

With your approval we will immediately begin work on the necessary changes so that Minnesota citizens will continue to have access to safe, affordable prescription drugs.

Yours sincerely,

Kevin Goodno
Commissioner

Importation of Prescription Drugs from Europe: A Report to Commissioner Kevin Goodno

Minnesota Department of Human Services
Brian Osberg, Assistant Commissioner for Health Care
Cody Wiberg, Pharm.D., R.Ph., Pharmacy Program Manager

March 16, 2005

Introduction

In September 2003, Governor Tim Pawlenty directed the Minnesota Department of Human Services (DHS) to review the feasibility of importing prescription drugs from Canada. As a result of that review and discussions with the Departments of Administration and Employee Relations, a three-phase plan was recommended to and approved by the Governor. The first two phases, which set up Web sites with information and links to order Canadian prescription drugs, have been implemented. The third phase would involve obtaining approval from the United States Food and Drug Administration (FDA) for a pilot project that would allow Minnesota pharmacies to participate in the importation of prescription drugs. Discussions with the FDA have not been successful to date.

The first phase involved establishing a Web site to provide information to the public about issues surrounding affordable prescription drugs and about ordering those drugs from featured Canadian pharmacies. Since its inception, the Minnesota RxConnect Web site has had over 180,000 visits and the four affiliated pharmacies have filled over 10,000 prescriptions. DHS has not received any complaints or other information to suggest any problems with the safety or effectiveness of the medications shipped by the pharmacies.

In the second phase, the Department of Employee Relations (DOER) established the Advantage-Meds Web site for state employees and their dependents. That Web site allows individuals covered by the Minnesota Advantage health plan to order up to a three-month supply of selected brand name, maintenance medications from one of the pharmacies affiliated with Minnesota RxConnect. By the end of December 2004, 1,861 members had enrolled in the Advantage-Meds importation program and 3,166 prescriptions had been ordered. DOER estimates that an average of $98 per prescription was saved, with the state saving $53 and the member saving $45 in co-payments.

The success of these two programs is being threatened by the actions of large pharmaceutical manufacturers. Pfizer, GlaxoSmithKline, Eli Lilly, AstraZeneca, Wyeth, Merck and other manufacturers are trying to prevent the purchase of their drugs by the Canadian pharmacies affiliated with the state Web sites. As a result, the pharmacies have experienced sporadic shortages of some drugs and have paid a higher price for the products they can obtain.

Unfortunately, the federal Canadian government may pose an even greater threat than the manufacturers. Late last year, Health Minister Ujjal Dosanjh began publicly criticizing the mail order pharmacies that serve Americans. Minister Dosanjh contends that the pharmacies operate in an

unethical manner because Canadian physicians issue prescriptions without examining the American patient. Canadian laws are such that the pharmacies are required to have a Canadian physician reissue the prescription. It would be unethical for a Canadian physician to write a prescription for a patient who had not been seen by any physician. But the patients ordering from the pharmacies affiliated with the state programs are seen by their own physicians and are required to send a prescription written by their doctor to the Canadian pharmacy. Thus, the Canadian physician is in reality providing an additional screening of the prescription for any potential errors or problems.

Minister Dosanjh also recently expressed concern that the Canadian prescription drug supply will be in jeopardy if the mail order pharmacies continue to operate. There is no reason to believe that the current volume of prescriptions being shipped to Americans will threaten the Canadian supply. In fact, Minister Dosanjh apparently came to that conclusion himself in October 2004. According to the *Toronto Star* (Oct. 17, 2004), while speaking in Vancouver Oct. 16, he stated that the two primary concerns about the Canadian Internet pharmacy industry had been satisfied. He said this about his concerns: “One is the safety of Canadians, one is the supply of the drugs, both are safe at this point." It is not clear what happened to change his mind because he also stated that annual Canadian Internet pharmacy sales have stabilized at about $697 million.

Minister Dosanjh has threatened to take actions that might result in the end of the Canadian international pharmacy industry, at least as it currently exists. For example, he has stated that he might seek passage of new regulations forbidding Canadian physicians from reissuing prescriptions for U.S. residents who they have not personally examined and that he might prohibit prescriptions for foreigners who are not present in Canada. He has also talked about banning the export of certain drugs widely used by Canadians to prevent shortages. Whether any of these actions will be taken is not at all clear; however, March 11, Minister Dosanjh said he is “nowhere near a decision” concerning restrictions (Reuters, March 15). Then March 15, he spoke at the University of Calgary and said he was going to “do away with unethical practices (and) make sure doctors sign prescriptions in the context of a healthy doctor-patient relationship." (*Calgary Herald*, March 15)

Despite the threat posed by manufacturers, two of the Canadian pharmacies affiliated with the state Web sites have developed plans that should allow them to continue supplying Americans with affordable prescription drugs. Their plans should also ease the supply concern expressed by Minister Dosanjh. The pharmacies have developed relationships with licensed pharmacies in the United Kingdom whereby the U.K. pharmacy acts as the fulfillment center for certain drugs that the Canadian pharmacy has difficulty purchasing.

Due to a concern about these threats, Governor Pawlenty asked DHS to evaluate the possibility of expanding the Minnesota RxConnect and Advantage Meds programs to include a European component. This report details the findings of a study completed by DHS staff that involved background research and onsite visits of facilities in the United Kingdom.

Background Information

DHS Pharmacy Program staff conducted background research to learn about the pharmaceutical system in the United Kingdom. Key findings concerning the regulation of prescription drug products, pharmaceutical distribution systems, pharmacy and medical training and licensure, and pharmacy practice are presented here.

United Kingdom and European Regulatory Agencies

Several U.K. and European Union agencies and organizations regulate various aspects of the pharmaceutical system. The **U.K. Medicines and Healthcare Products Regulatory Agency (MHRA)** replaced the Medical Devices Agency (MDA) and the Medicines Control Agency (MCA) in April 2003. The MHRA is an agency of the U.K. Department of Health and is committed to "safeguarding public health by ensuring that medications, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness." MHRA activities relating to prescription drugs include:

- Licensing of medications before marketing and when changes are made to a medication
- Regulation of clinical trials
- Issuing safety warnings
- Assessment of and communications about defective medications
- Monitoring of medications and acting on safety concerns after marketing
- Enforcing standards of pharmaceutical manufacturing and wholesaling
- Setting quality standards for drugs through the British Pharmacopoeia
- Providing advice and guidance on medications.

Detailed information about the history and current status of pharmaceutical regulation in the United Kingdom can be found on the MHRA Web site at: http://medicines.mhra.gov.uk.

The **European Medicines Agency (EMEA)** is a body of the European Union with headquarters in London. According to the EMEA Web site:

> … it began its activities in 1995, when the European system for authorizing medicinal products was introduced, providing for a centralized and a mutual recognition procedure. The EMEA coordinates the evaluation and supervision of medicinal products throughout the European Union. The Agency brings together the scientific resources of the 25 EU Member States in a network of 42 national competent authorities. It cooperates closely with international partners [including the FDA].

Approximately 3,500 European experts contribute to the scientific work of the EMEA and its committees. EMEA works to ensure that member states of the European Union mutually recognize pharmaceuticals that are approved by individual member states. In addition, there is a mechanism by which EMEA approves the use of a drug throughout the European Union after a single evaluation is

carried out through the EMEA Committee for Medicinal Products for Human Use (rather than separate evaluations by the relevant regulatory agencies in each member state). The EMEA Web site also contains additional information: http://www.emea.eu.int.

Many of the same activities carried out by the MHRA and the EMEA are carried out in the United States by the FDA. The standards used by the MHRA and EMEA are comparable to those used by the FDA. In fact, the FDA recognizes the value of international standardization, or harmonization, of the criteria and procedures used for approving and regulating prescription drugs. The International Activities page of the Web site of the FDA Center for Drug Evaluation and Research (http://www.fda.gov/oia/homepage.htm) states:

> The drug regulatory systems in all three regions share the same fundamental concerns for the safety, efficacy, and quality of drug products. However, many time-consuming and expensive clinical trials have had to be repeated in all three regions. An ICH goal is to minimize unnecessary duplicate testing during the research and development of new drugs. Another goal is to develop guidance documents that create consistency in the requirements for new drug approval.

The three regions referred to are the United States, the European Union and Japan, and ICH is the International Conference on Harmonization. While the FDA does not appear to have reached a final agreement with the European Union regarding mutual recognition of standards for drug approval and manufacturing, it does appear to be working towards that goal.

In summary, the standards for approving the use and manufacture of prescription drugs in the United Kingdom and the European Union seem to be comparable to the standards used in the United States. Brand name drugs that are shipped to Americans from the U.K. pharmacies inspected by DHS staff are made by the same manufacturers that make the equivalent U.S. brand name products. In many cases, they have the same brand name and they look identical to the U.S. products. There is no reason to believe that drugs used in Europe that have the same active ingredient, at the same strength and in the same dosage form, should be less effective or safe than their U.S. equivalents. That might be expected given that in the United Kingdom, at least, the government has been regulating medicinal products since the reign of King Henry VIII.

The **Royal Pharmaceutical Society of Great Britain** (RPSGB) is the regulatory and professional body for pharmacists in England, Scotland and Wales. Its primary objective, as stated on its Web site, "is to lead, regulate and develop the pharmacy profession." It is akin to the Minnesota Board of Pharmacy and to pharmacy regulatory agencies in Canada, such as the Alberta College of Pharmacists. Like its North American counterparts, the RPSGB performs activities involving "controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register [i.e. revoking licensure]."

The RPSGB has formulated standards for pharmacy practice that appear to be at least as good as the standards established by the Minnesota Board of Pharmacy. In some cases, such as the certification

of pharmacy support staff, the RPSGB standards are more stringent than Minnesota standards. Additional information can be obtained from the RPSGB Web site: http://www.rpsgb.org.uk.

The **General Medical Council (GMC)** regulates the practice of medicine in the United Kingdom. According to its Web site, it has "strong and effective legal powers designed to maintain the standards the public have a right to expect of doctors" and it is "not here to protect the medical profession" but instead exists "to protect patients." It is similar to the Minnesota Board of Medical Practice. The standards for medical practice established by the GMC appear to be comparable to the standards used in this state. The GMC Web site is at: http://www.gmc-uk.org. Additional details concerning U.K standards for the practice of both pharmacy and medicine are described below.

Training and Registration of Physicians in the United Kingdom

The training and licensure of U.K. physicians is relevant because British pharmacies can only fill prescriptions written by U.K. prescribers. The GMC establishes standards for undergraduate medical training, initial training as a new doctor (internship), specialist training and continued professional development. The typical course of undergraduate medical training in one of the 33 U.K medical schools lasts for five to seven years and leads to Bachelor of Medicine and/or Bachelor of Chiurgery degrees. Medical school graduates then participate in an internship, which normally lasts for 12 months and is called general clinical training or the pre-registration house officer (PRHO) year. After completion of general clinical training, a physician must register with the GMC. Most physicians then complete additional specialist training – even those who intend to go into general practice.

The GMC promotes adherence to good standards of medical education through a quality assurance process. The GMC requires each medical school to report on adherence to educational quality standards. In the last few years, GMC has conducted two rounds of visits to all established medical schools in the United Kingdom to verify that the schools are meeting the quality standards. The schools are asked to update information each year and the GMC plans to visit each school at least twice in any 10-year period.

The Minnesota Board of Medical Practice allows graduates of medical schools listed in the World Directory of Medical Schools to be licensed in Minnesota after obtaining Educational Commission for Foreign Medical Graduates certification, completing additional training in the United States or Canada and passing an examination. Almost all U.K. medical schools are listed in the World Directory of Medical Schools.

The GMC has issued guidance on continuing professional development that informs physicians that they must keep their knowledge and skills up to date throughout their career and regularly participate in educational activities that maintain and further develop their competence. The GMC is in the process of developing a revalidation process that will require physicians to regularly demonstrate that they are keeping their knowledge base and skills up to date.

Training and Licensure or Certification of Pharmacists and Pharmacy Support Staff

To practice pharmacy in the United Kingdom, an individual must complete a four-year degree in pharmacy from a school of pharmacy accredited by the RPSGB. There are 19 schools of pharmacy in the United Kingdom. The curricula at accredited pharmacy schools include courses on medicinal chemistry, pharmaceutics, physiology, biochemistry, microbiology, pathology, pharmacology and pharmacy practice. The individual must also complete one year's practical training in a community or hospital pharmacy and pass a registration examination.

The RPSGB recently began voluntary registration of pharmacy technicians and it is seeking authority to make registration mandatory. To register, pharmacy technicians must demonstrate that they hold one of several "qualifications" that are obtained through a combination of didactic and experiential training. After a transitional period, there will be a single national standard for qualification as a pharmacy technician – the Pharmacy Services Scottish/National Vocational Qualification (S/NVQ) level 3, which will have to include an accredited didactic program. Even dispensary assistants who function at a lower level than technicians will be required to meet the lower Pharmacy Services S/NVQ level 2 standards.

Currently, all pharmacy technicians within Minnesota must be registered with the Minnesota Board of Pharmacy. They must be at least 16 years of age, and be knowledgeable of the pharmacy practice laws/rules regarding duties that they can and cannot perform. The Board of Pharmacy has provided technicians with guidelines to assist them in gaining required knowledge. It also provides them with information about the Pharmacy Technician Certification Board (PTCB), which "develops, maintains, promotes and administers a high-quality certification and recertification program for pharmacy technicians." A pharmacist-in-charge is also required to submit an application to the board before utilizing technicians. The application asks for a description of in-house training of technicians and a description of how technicians will be used. However, there is currently no requirement in Minnesota that pharmacy technicians meet minimum levels of competency, as is the case in the United Kingdom.

Until recently, U.K. pharmacists were required to complete 30 hours of continuing education (CE) each year. (By comparison, the requirement is 30 hours every two years in Minnesota.) The RPSGB is in the process of replacing that requirement with a continuing professional development (CPD) program that emphasizes continuous quality improvement, not just continuing education. CPD is also mandatory for all registered and practicing pharmacy technicians. Neither CE nor CPD is required for certified pharmacy technicians in Minnesota.

Licensure and Inspection of Pharmacies and the Regulation of Pharmacy Practice

United Kingdom pharmacies are registered and inspected by the RPSGB, which has an Inspectorate staffed by pharmacists with substantial experience. The inspectors visit pharmacies regularly to ensure that legal requirements and professional standards of practice are observed. The Inspectorate's functions encompass investigation, enforcement, education and advice. Similarly, the Minnesota Board of Pharmacy employs pharmacist surveyors who regularly inspect pharmacies in this state.

The RPSGB *Code of Ethics and Standards*, as well as a dozen law and ethics facts sheets available on the Society's Web site, were reviewed for this report. Based on that review, it appears that pharmacy regulations compare favorably with the pharmacy laws and regulations of this state. Discussions with U.K. pharmacists and inspections or visits to several U.K. pharmacies helped confirm the adequacy of U.K. pharmacy standards.

Exportation of Drugs from the United Kingdom by Pharmacies

A U.K. pharmacist is allowed to export prescription medications under certain circumstances. According to the RPSGB exportation fact sheet, "persons lawfully conducting a retail pharmacy business may sell by way of *wholesale* dealing provided that the sale constitutes no more than an inconsiderable part of the business." More importantly, a pharmacist may export a drug when filling a prescription written by a medical practitioner registered with the GMC. Thus, as is the case in Canada, prescription drugs can be shipped to an American patient by a U.K. pharmacist only if a registered U.K. physician has issued a prescription for the patient.

United Kingdom Pharmaceutical Price Regulation Scheme

Brand name prescription drugs cost less in the United Kingdom than they do in the Unites States because prices are *indirectly* controlled in the U.K. through the Pharmaceutical Price Regulation Scheme (PPRS). In essence, the U.K. government negotiates an agreement with pharmaceutical manufacturers that controls the overall profits companies are allowed to make through sales to the British National Health Service. The PPRS does not apply to generic prescription drugs or to over-the-counter medications. The prices of newly introduced, individual drug products are not controlled under the PPRS. Manufacturers have control over the pricing for new products – as long they remain within their negotiated profit targets. A manufacturer also has control over the pricing for new versions of products for five years from the date of the original marketing authorization.

Manufacturers have apparently tried to stifle the parallel importation of drugs into the United Kingdom through price manipulations that they are allowed to make under the PPRS. In response to a reduction in prices negotiated by the British government, some manufacturers have reportedly lowered the prices of their drugs that are parallel imported and maintained the price of other products. This allows the manufacturers to keep within the lower profit target. It also discourages parallel importation because the lowered U.K. prices of the drugs are much closer to the PI prices. Manufacturers have also mounted a number of legal challenges to parallel importation based on copyright infringement. U.K. and other European courts have largely ruled against the manufacturers, however.

Parallel Importation

Critics of the importation of prescription drugs from Europe point to parallel importation as a potential problem. Parallel importation is not a problem; parallel importation is a potential solution to the escalation of pharmaceutical costs in this country. DHS staff had the opportunity to visit two parallel importation facilities in the United Kingdom. DHS staff also had discussions with

representatives of a third parallel importer. Staff concluded that parallel importation, as it is practiced in the European Union, is a safe and cost-effective method of drug distribution.

A parallel importer in the United Kingdom must be registered by the MHRA. In addition, it must obtain a license for each product it wants to import from another European nation. The imported drug must be approved for use in the United Kingdom, in the country from which it is imported and/or by the European Medicines Agency. It must be therapeutically equivalent to the comparable U.K. product. The MHRA works with the appropriate regulatory agency in the country from which the drug is imported to obtain the information needed to ensure that only those products that comply with U.K. criteria for parallel importation are granted a license.

The parallel importer must keep meticulous records that detail the sales and shipment history of each box of drugs that is imported – from manufacturer to foreign wholesaler to parallel importer, and the shippers in between. (These records are sometimes referred to as a "drug pedigree" or chain of custody documentation.) Products imported into the U.K. typically come from Greece, Italy or Spain.

Prescription drug products in Europe are supplied differently, and perhaps, more safely than they are in the United States. In this country, most drugs are shipped to pharmacies in bulk bottles. When filling a prescription, the pharmacy often must open the bottle, pour some of the product onto a tray and count out the required number of tablets or capsules. In Europe, all drugs are shipped and dispensed in boxes that contain blister-dosed cards of the drug.

After verifying the chain of custody of an imported product, the parallel importer partially repackages it. This is necessary because the original packaging often has information presented in a language other than English. New boxes and patient information leaflets are printed in English. Labels with required information, such as drug names, lot numbers and expirations dates, are also printed. Those labels are affixed to the back of the blister-packs of drugs. The blister-packs are never opened so that product integrity is maintained. Once properly labeled, they are repacked with the English leaflets into the new box. The parallel importer must have this entire repackaging procedure approved by the MHRA as part of the licensing process. Any changes to an approved procedure require approval by the MHRA.

Approximately 20 percent of the drugs dispensed to patients in the United Kingdom are parallel imports. In fact, the British National Health Service reduces reimbursement to pharmacies for certain drugs that are commonly obtained through parallel importation. Consequently, U.K pharmacies have to dispense parallel import products because they would lose money if they exclusively dispensed the U.K. version of these drugs. Britons don't appear to be suffering adverse consequences due to prescription drugs that are imported from Greece, Italy and Spain.

European standards for drug manufacturing and distribution appear to be comparable to those used in the United States and certainly rigorous enough to adequately protect patients in Europe. If parallel importation can work successfully in Europe, there is no reason to believe that it couldn't work for the United States as well.

Inspections

In researching a European option, DHS worked with two of the pharmacies affiliated with the Minnesota RxConnect program, Total Care Pharmacy of Calgary, Alberta, and Granville Pharmacy of Vancouver, British Columbia. In response to the attempts of pharmaceutical manufacturers to cut off their supply of prescription drugs, these pharmacies began developing working relationships with pharmacies in the United Kingdom quite some time ago.

In early March, Brian Osberg, DHS assistant commissioner for health care, and Cody Wiberg, Pharmacy Program Manager, Pharm.D., R.Ph., traveled to the United Kingdom and visited pharmacies, wholesalers and parallel importers. Two U.K. pharmacies affiliated with the Canadian pharmacies mentioned above were inspected. The relationships between each of the Canadian pharmacies and their U.K. partners are similar.

After providing consent to the Canadian pharmacy, an American patient can chose to have prescriptions filled by the U.K partner pharmacy. The patient provides the Canadian pharmacy with all necessary information and documentation, including a medical history questionnaire and a written prescription from an American physician. The Canadian pharmacy verifies the information provided, checks the prescription for accuracy and potential problems, and resolves any problems by contacting the patient or the American physician as necessary.

The Canadian pharmacy then assigns the prescription to the U.K. pharmacy to be filled. All relevant information is transmitted to the U.K pharmacy via a secure electronic link. Information sent to the U.K. pharmacy includes the medical questionnaire, patient profile and a scanned copy of the original U.S. prescription. A physician registered by the U.K.'s GMC reviews all the information and if he or she deems it appropriate, issues a prescription for the same drug and with the same directions as the original U.S. prescription. If the U.K. physician has any questions or concerns, the prescription is tasked back to the pharmacy for follow up with the U.S. prescriber.

According to the British pharmacists interviewed, the U.K. physicians have at times refused to authorize prescriptions. For example, after Vioxx® was withdrawn from the U.S. market, some U.K. physicians would not authorize prescriptions for the related drug, Celebrex®, until the U.S. physician was contacted and the appropriateness of continued use was verified.

Once the U.K. physician does issue a prescription, the U.K. pharmacy fills it. A technician verifies that the U.K. prescription matches the original U.S. prescription and prepares the necessary paperwork and labels. The prescription is then filled by another technician. The U.K. pharmacist then does a final check by reviewing all of the information sent by the Canadian pharmacy and by checking the filled product against both the U.K. and the original U.S. prescriptions. The prescription is shipped directly to the American patient.

The process is such that at least two pharmacists, one Canadian and one British, and one physician check the prescription before it is shipped to the patient. As noted above, the prescription filling

processes of both Canadian/British partnerships reviewed were very similar. The following is information about each U.K. pharmacy noted while conducting inspections. Information about the prescription filling process will not be repeated.

Pharmacy A is affiliated with Total Care Pharmacy and is located in a modern, well maintained building in a business park. It is registered by the RPSGB, as are the pharmacists and the pharmacy technicians. The technicians have a Pharmacy Services S/NVQ Level 3 Qualification. The physicians associated with the pharmacy are registered by the GMC.

The pharmacy was recently inspected by RPSGB and no deficiencies were noted. It is exclusively a mail order pharmacy with no walk-up business and with a current volume of 200 prescriptions per day. The facility is clean, well ordered and it appears to be adequately lit. The pharmacy has a detailed standard operating procedures manual and operations seemed to be very efficient during the inspection.

The pharmacy obtains prescription drugs from registered U.K. wholesalers and it dispenses products originally marketed to the U.K and parallel import products. No drugs requiring refrigeration or other special handling are dispensed. The pharmacy manages its inventory so that it rarely has expired products, but does check for and remove outdated drugs from the dispensing area. It has a proactive policy for handling drug recalls.

One *potential* issue involving the use of two different computer software systems was noted. One system allowed the pharmacy to connect via a secure link to Total Care Pharmacy. Another was used to process the prescriptions in the dispensary. However, during the visit, the pharmacy was in the process of converting totally to the pharmacy software developed by Total Care. And, of course, a pharmacist does check every prescription against the original U.S. prescription before it is dispensed in order to catch any mistakes, including those that might be caused by transcription errors.

Pharmacy B is affiliated with Granville Pharmacy and it is also located in a modern and well maintained building in a business park. Like Pharmacy A, it is exclusively a mail order pharmacy and is registered by the RPSGB, as are the pharmacist and the pharmacy technicians. The physicians associated with the pharmacy are registered by the GMC. This pharmacy was recently inspected by the RPSGB with no deficiencies noted.

The facility is clean, well ordered and it appears to be adequately lit. As required of U.K. pharmacies, Pharmacy B has a standard operating procedures manual. Pharmacy staff appeared to carry out their tasks efficiently and accurately while we were inspecting the facility. It currently fills a relatively small number of prescriptions, approximately 50 to 60 per day.

The pharmacy obtains prescription drugs from registered U.K. wholesalers but, unlike Pharmacy A, it currently dispenses only products originally marketed for use in the U.K. It could readily obtain and ship parallel import products but has not yet done so. Granville Pharmacy and the British pharmacy decided to limit drugs to U.K. products while they developed their partnership. They will probably start dispensing parallel import products in the near future. No drugs requiring refrigeration or other special handling are dispensed. Like all of the Canadian and British pharmacies visited by

DHS staff, the pharmacy manages its inventory so that expired products are rare, but does check for and remove outdated drugs from the dispensing area. It has a proactive policy for handling drug recalls.

DHS staff noted only one *potential* issue, the same one as noted for Pharmacy A. The software system that links Granville to its British partner is not directly connected to the software used to dispense the prescription. Both pharmacies indicated a willingness to move to an upgraded, unified system. Again, the pharmacist does a final check by comparing the prepared product with the original U.S. prescription which minimizes the chance of a transcription error.

Options

Maintain status quo

One option is to maintain the Minnesota RxConnect and Advantage-Meds programs as currently structured. The primary advantage of this option is that no further work would be required beyond the routine activities necessary to administer the programs. There are two primary disadvantages of maintaining the status quo.

First, the efforts of pharmaceutical manufacturers to cut off the supply of prescription drugs and the actions that are being proposed by the Canadian health minister, threaten the entire Canadian international pharmacy industry. In a matter of weeks, the operations of the pharmacies affiliated with state programs may be drastically curtailed. Should that happen, the state and its employees might lose the savings that the Advantage-Meds program has afforded. Far more importantly, citizens who have come to rely on Minnesota RxConnect for access to safe and affordable medications might be back to making hard decisions about whether to have their prescriptions filled or to buy food.

Second, the actions of the pharmaceutical manufacturers, combined with the weakening of the U.S. dollar in relation to the Canadian dollar, have resulted in increased Canadian prescription drug prices. The prices of drugs shipped by the U.K. pharmacies partnering with Total Care and Granville are sometimes, but not always, lower than the Canadian prices. If manufacturers continue to limit supplies to pharmacies affiliated with state programs, Canadian prices may increase even further. As an example of the current situation, the prices listed March 15 on Total Care's Web site for Lipitor 10mg were $1.92 per tablet when shipped from Canada and $1.80 when shipped from their U.K. partner pharmacy. By contrast, the price listed on the Web site of a large American pharmacy chain was $2.28 per tablet, or 27 percent more than the U.K. price.

I-Save Rx Program

Another option is to join the coalition of states participating in the I-Save Rx program. This program was established by the state of Illinois after being recommended by that state's Office of the Special Advocates for Prescription Drugs. The program was launched in October 2004. The program is also open to residents of the states of Wisconsin, Missouri, Kansas and Vermont.

I-Save Rx contracts with CanaRx, a company located in Ontario, to act as a clearinghouse for the program. A resident of one of the states participating in I-Save Rx must enroll in the program, although there is no enrollment fee. Enrollment forms can be downloaded from the program's Web site or obtained by calling a toll-free number. The Web site has a feature that allows users to check the prices of prescription drugs. Initial I-Save Rx users would need to do the following to order a prescription medication:

- Obtain the forms necessary to enroll (from the Web site or by mail)
- Enroll in the program
- Fill out the enrollment form and medical history questionnaire
- Send the forms and written copies of prescriptions to be filled to CanaRx.

CanaRx is not a pharmacy, but it apparently has a pharmacist check the medical histories and prescriptions supplied by customers for any potential problems. When this check is completed, the prescription is forwarded to a physician for review and reissue. Once reissued by the physician, the prescription is filled at one of 60 pharmacies in Canada, the United Kingdom or Ireland. These pharmacies are licensed and, in addition, are inspected by employees of the state of Illinois.

About 3,000 people from the five states participating in I-Save Rx have enrolled in the program since its inception. (*Chicago Sun-Times*, March 14, 2005). DHS staff has unconfirmed information that about 4,500 prescriptions were filled through the I-Save Rx program during its first four months of operation. By way of contrast, 1,861 Minnesota state employees or their dependents had signed up for the Advantage-Meds program by the end of December and had ordered 3,166 prescriptions. Through February 2005, 10,038 prescriptions had been ordered by people using the Minnesota RxConnect Web site. That is a respectable number given that many seniors in this state are members of the Minnesota Senior Federation, which has its own very successful importation Web site.

Had Minnesota not already established the Minnesota RxConnect and Advantage-Meds programs, it might be worth further investigating the I-Save Rx program. The larger network of pharmacies employed by I-Save Rx might reduce the risk of drug shortages due to the targeting of specific pharmacies by drug manufacturers. However, participating in the I-Save Rx program is not a good option at this time for the following reasons:

- Minnesota RxConnect was designed to be about more than just importing drugs from Canada or other countries. A section of the Web site, "Your Savings Options," gives advice to consumers on how to lower their prescription drug costs. It also provides information that can help people obtain lower cost medications from a variety of sources, including DHS-administered programs. The Minnesota RxConnect online program was designed to complement the RxConnect phone service administered by the Minnesota Board on Aging and the Senior LinkAge Line®. That service is available to all Minnesotans, regardless of age or income, and it helps people apply for the patient assistance programs offered by pharmaceutical manufacturers. Although I-Save Rx participating states do provide information to their citizens similar to what is provided on Minnesota RxConnect, the I-Save Rx Web site is designed solely to help people import medications from Canada, the United Kingdom or Ireland.

- Minnesota RxConnect is somewhat easier to use than the I-Save Rx Web site. In addition to printing out first-time customer forms, someone using the Web site can print out an order form that lists the medications they want to purchase. The Advantage-Meds Web site is even easier to use in that forms can be filled out and orders can be placed online. (Of course, a written prescription by the individual's Minnesota physician must still be mailed or faxed to the pharmacy.)
- The pharmacies affiliated with state programs have signed an agreement to honor the prices that they supply and which are updated on a monthly basis. The prices listed on the I-Save Rx Web site are not guaranteed.
- The state has a good working relationship with all of the pharmacies affiliated with the programs. This is particularly important for the Advantage-Meds program because of the billing arrangements necessary for that program.
- From the start of the programs, the state intended to involve Minnesota pharmacies in the importation process if at all possible. As mentioned above, there have been some discussions with the FDA. Although those discussions have not yet yielded results, the state still intends to do its best to develop a pilot program that would address many of the concerns of the FDA. It has worked with the pharmacies affiliated with the programs on a model that would allow Minnesota pharmacies to become involved.
- Since it is believed that the state should continue to run the current programs, there is no need to take on the additional work and possible expenses associated with participating in the I-Save Rx program.

Work directly with pharmacies located in the United Kingdom

A third option is to partner directly with one or more pharmacies located in the United Kingdom. Essentially, this would duplicate the process involved when Minnesota RxConnect was established. There have been discussions with one British company that is interested in establishing a direct partnership with the state. Should the Canadian government act to entirely shut down the pharmacies affiliated with the state programs, this may be an option to pursue.

It may be unlikely that the Canadian government will entirely shut down the pharmacies. However, the Canadian government will most likely take actions that make it more difficult for the pharmacies to fill prescriptions with Canadian products. Such actions might be taken in just a few weeks. Consequently, there might not be enough time to work out direct arrangements with British pharmacies. Also, there aren't many British pharmacies that have the same level of experience with *all* aspects of mail order pharmacy as do the Canadian pharmacies. For example, the British pharmacies visited were very good at filling prescriptions accurately and efficiently. However, they did not have experience at establishing the sophisticated Web sites and call centers that the Canadian pharmacies operate.

Work with Canadian Pharmacies Affiliated with Minnesota RxConnect and Advantage-Meds

The last and most preferable option is to work with Total Care and Granville pharmacies to develop an enhancement of Minnesota's current programs. As mentioned above, these two pharmacies have developed relationships with British pharmacy partners. Working with Total Care and Granville to develop a European option has several advantages:

- Maintaining the status quo is not an option. The state must take action to preserve the access that Minnesota citizens have to affordable medications because of the threats mentioned above.
- Keeping the basic structure of the Minnesota RxConnect program intact is important because, as mentioned above, it was designed to complement other efforts to help people access affordable prescription drugs, especially the RxConnect phone service.
- The state already has a good working relationship with key personnel at Total Care and Granville. They have been responsive to requests and suggestions and have provided the people who use the programs with excellent service.
- This option can be put into place relatively quickly, especially compared to entering into a partnership directly with British pharmacies.
- As mentioned above, the state has worked out a billing arrangement with Total Care for the Advantage-Meds program. That arrangement is working quite well and there is no need to disrupt it at this time.
- The state has worked with its Canadian partners on a concept that would allow Minnesota pharmacies to become involved in the importation project. A pilot program based on this concept would be enhanced by the technical expertise the pharmacies have displayed in the development of pharmacy software. This model would answer many of the concerns voiced by both the FDA and the Canadian health minister.