

Drug Importation: The Realities of Safety and Security

Bill Number:

Hearing Date: February 16, 2005, 10:00 am

Location: SD430

Witness:

The Honorable Tim Pawlenty

St. Paul, MN

Governor of Minnesota

Testimony

Chairman Enzi, Senator Kennedy, and members of the Senate Committee on Health, Education, Labor, and Pensions, it is an honor to be with you today.

As I entered this building this morning, I saw the tribute to Senator Everett Dirksen carved in the marble downstairs. It strikes a fitting tone for his hearing.

It honored Senator Dirksen for "his unerring sense of the possible that enabled him to know when to compromise; by such men are our freedoms retained."

In an increasingly polarized environment, we need to know when to compromise and practice the art of the possible.

If ever there was an issue that we can come together on this is it. The rising cost of prescription drugs has sparked a prairie fire that is spreading across our nation. Today we have an opportunity to make bold steps toward progress.

We've all heard the arguments about why Americans pay more for prescription drugs than other countries. But the bottom line is that Americans pay more than the rest of the world and the price differential puts prescription medicines out of reach for too many Americans. The current situation is unfair and untenable.

That's why in Minnesota we've decided to take action. We're taking a method, trying it and finding strong success.

Minnesota's Plan

The Minnesota Plan for Prescription Drugs has a very simple goal – to get a better deal for Minnesotans. We have established a program to facilitate the purchase of prescription drugs from Canada by individuals.

We have established two websites – [MinnesotaRxConnect.com](http://MinnesotaRxConnect.com) for all Minnesota citizens and [Advantage-Meds.com](http://Advantage-Meds.com) for state employees, retirees and their dependents.

Through [MinnesotaRxConnect](http://MinnesotaRxConnect.com), Minnesotans are able to determine if their prescription medications are available at a lower cost from a Canadian pharmacy, and if so, how to order them. The site focuses on maintenance drugs that can be shipped safely from Canada. Only reputable Canadian pharmacies licensed by a Canadian province, willing to have their facilities and safety protocols reviewed by the Minnesota Department of

Human Services are used. The four pharmacies affiliated with MinnesotaRxConnect have each been visited by pharmacists employed by the state of Minnesota, including Minnesota Board of Pharmacy inspectors. The site also lets consumers know if there is a lower cost generic alternative about which they should see their doctor.

In addition, MinnesotaRxConnect is about more than just Canadian importation. It provides tips about how to become an informed consumer of prescription medicines including links to other programs that might assist consumers in purchasing their medications, such as state and pharmaceutical manufacturer programs.

Those individuals wishing to take advantage of the program need to obtain a prescription from their own physician and send a copy of the prescription, an order form and a medical history questionnaire to the Canadian pharmacy. To comply with Canadian law, the prescription is reviewed and countersigned by a Canadian physician. Assuming that all is in order, the pharmacy ships the medication to the patient by mail in the manufacturer's original, sealed container whenever possible.

Since the launch of MinnesotaRxConnect a little over one year ago, the Canadian pharmacies have filled more than 9,000 prescriptions for people ordering through the site. We have received only a couple of complaints about the pharmacies regarding billing issues. Those complaints were quickly resolved by the pharmacies when the state contacted them. We have received no complaints about the quality, effectiveness or safety of the drugs.

Let me repeat – we have not received a single complaint, out of more than 9,000 prescriptions filled – regarding the quality, effectiveness or safety of the drugs that were purchased utilizing our prescription drug website.

The top complaint we have received is not regarding Canadian pharmacies or drugs, but about enforcement actions taken by the U.S. government. A number of packages shipped by the pharmacies affiliated with our websites have been seized by the FDA, Customs or the Postal Service. When notified, the pharmacies promptly ship another supply at no cost to the customer.

Consumers who use MinnesotaRxConnect must first visit with their personal physician and get a prescription from them. The prescription is reviewed by Canadian pharmacists who contact the U.S. physician to clear up any potential problems. The prescription and the patient's medical history are then sent to the Canadian physician for yet another review. A Canadian physician then countersigns the prescription.

Recently, the Canadian government has raised concerns about the practice of countersigning. Canada's Minister of Health has said he considers physician countersigning to be unethical. We disagree. We see the countersigning process as an additional safety check, one more opportunity for a medical professional to review the prescription for potential problems.

If the Canadian physician was the only doctor involved, it would be unethical for them to issue a prescription to someone they had never seen or examined. But in this process, the Canadian physician is only double-checking a process that first included the patient being examined by their doctor and that doctor issuing a prescription.

Unfortunately, there are some unethical web-based operations that will have a physician write prescriptions based only on an online questionnaire that the patient fills out. In such cases, no physician sees the patient. Our system ensures that this does not happen by requiring that the patient meet with and receive a prescription from their physician.

Through a second website, Advantage-Meds.com, state employees, retirees and their dependents can purchase certain prescription medicines at no cost through one of the Canadian mail order pharmacies affiliated with MinnesotaRxConnect.

During 2004 (May 13 - Dec 31):

1. 1,861 members enrolled
  - Eligible members include 48,000 employees and 72,000 dependents
  - A member can enroll but not order a drug
  - A member can order more than one drug
2. 3,166 drugs were ordered
  - An order is one three-month supply of one drug
  - Represents about 1% of the drugs purchased by members
3. 27,526 persons made 42,232 visits to the website
4. \$577,479 was spent by program
  - Average of \$76,992 per month (7.5 months)
  - Average cost of \$184 per drug (three month order)
5. Approximately \$300,000 was saved by program and members
  - \$98 per drug
  - \$53 to program in reduced costs
  - \$45 to members in waived co-payments
  - Results meet initial expectations

We recognize that these measures are not the long-term solution. They are, however, designed to provide short-term relief and to build pressure for long-term reform.

#### Ensuring Safety

Those who oppose reimportation often talk of great problems with safety. On this point, it is important to be clear about what we have done.

We reference services available from established, reputable, credible, accredited Canadian pharmacies. There is no evidence to suggest such pharmacies are unsafe. To the contrary, Minnesota Board of Pharmacy surveyors have visited the pharmacies and found no significant problems. Canadians are not dying or at risk because of their system. Assertions that a program like Minnesota's is unsafe suggests either the pharmacies we have chosen are unsafe or they are too inept to properly mail or deliver medicines safely. Neither is true. Moreover many reputable, established pharmacies in the U.S. already use

a mail order, Internet or phone order system. The FDA apparently thinks it works well for them. For example, the Veterans Hospital in Minneapolis mails out a large number of prescriptions to patients each week.

Our program should not be confused with the questionable Internet pharmacy or "storefront" marketing entities that offer or have offered their services to U.S. citizens with little or no oversight. We agree that such operations present an unreasonable safety risk to consumers.

Our Department of Human Services conducted a review of Canadian practices, similar but independent of that done by the State of Illinois. We came to the same conclusion that they did: the Canadian system is comparable to ours in safety standards.

There is a misperception that reimportation from Canada is some risky endeavor in which we give up safety to use a Third World apothecary just to save a dime. Canada's pharmaceutical regulatory system is strong and effective. At the state level, we continue to monitor and ensure that those pharmacies serving our citizens are held to the highest standards of safety.

Let me briefly explain to you some of the safety and security protocols we are using as part of our reimportation program:

1. The pharmacies associated with our website are licensed by the Canadian province in which they are located;
2. The pharmacies have agreed to allow unannounced inspections of their facilities, and the Minnesota Department of Human Services Pharmacy Program Manager, who is a pharmacist, has conducted unannounced follow-up visits to all four pharmacies;
3. Medications are dispensed in the manufacturer's unopened, safety-sealed containers in appropriate amounts whenever possible;
4. Medications shipped are approved for use in Canada by the Therapeutic Products Directorate of Health Canada, which uses standards similar to those of the FDA when approving drugs;

#### The Industry's Actions

Pharmaceutical manufacturers such as Merck, Pfizer, Eli Lilly and others have withheld supplies of prescription drugs from Canadian pharmacies that serve Americans.

Their actions are unfortunate. I urge this committee to review the comments and actions of the companies involved.

#### Minnesota is Ready to Lead the Way

The states are often called the "laboratories of democracy." The State of Minnesota is proving that again by moving ahead in implementing this prescription medicine plan.

Let us be the experiment. Let us try it. Let us continue to put the arguments to the test. If it doesn't work, we'll admit it. The current system is not "safe" because too many people

can't afford their medicine.

Thank you very much.