



KANSAS

GOVERNOR'S OFFICE OF HEALTH PLANNING AND FINANCE

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Testimony on House Bill 2337 to the House Health and Human Services Committee

**by Karen Braman
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**February 21, 2005
1:30PM**

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**Governor's Office of Health Planning and Finance
Karen Braman, Deputy Director**

House Health and Human Services Committee
February 21, 2005

House Bill 2337

Good afternoon Mr. Chairman and members of the Committee. I am Karen Braman, Deputy Director of the Governor's Office of Health Planning and Finance. I appreciate the opportunity to talk with you this afternoon about HB 2337.

HB 2337 would make the importation of prescription drugs illegal, a practice that the United States Food and Drug Administration (FDA) currently maintains is in violation of the United States Food, Drug and Cosmetic Act. While the FDA maintains that importation is illegal, it has allowed consumers to purchase prescription drugs through Canada for personal use, and has even established a "personal use" policy that explicitly allows this practice.

Over two million Americans, including Kansas citizens, have purchased pharmaceuticals from Canada and other countries because they are less expensive. The FDA has chosen not to prevent these purchases and to date has taken no enforcement action against individual citizens or the many importation programs in operation in cities and states across the country.

Citizens have turned to importation over the years because there is a great need. According to a recent Kaiser Family Foundation survey, 37 percent of seniors age 65 and

over have incomes at or below 150 percent of the federal poverty level—roughly \$14,000 per year. Seventy-one percent of seniors age 65 and over have two or more chronic conditions. Sixty-eight percent of Medicare enrollees have no drug coverage at all. As you can see, chronic disease coupled with poverty or near poverty means that many seniors who need life-saving medication are forced to make choices like splitting their medication, skipping doses or days of medication or not taking their medication altogether because they clearly cannot afford it.

If you were uninsured and with a limited income that was just high enough that you didn't qualify for assistance, yet needed your medication for high cholesterol, high blood pressure, diabetes, heart disease, or a host of other chronic diseases, wouldn't you want to have safe alternatives to obtain your medication at a lower cost? If you could obtain a three-month supply of Lipitor 80mg tablets that would cost you \$314.03 in the U.S. for \$215.61 from England, wouldn't you want that option? Or a 3-month supply of Nexium 20mg that would cost you \$393.97 in the U.S. for \$168.90 from Australia? Or a 3-month supply of Flonase that would cost you \$252 in the U.S. for \$89.90 from the U.K?

Opponents of prescription drug importation often refer to safety as their primary reason for opposition, but we know that there are mechanisms to ensure patient safety by regulating and monitoring pharmacies in Canada and other countries that import medications to the United States, and by tracking the medication using their unique identification numbers—similar to the National Drug Code (NDC) in our country. It is important to know that Canada and other countries approve medications for use in their countries and track

individual drugs just like the FDA does in the United States. As a matter of fact, Canada's chain of custody of pharmaceuticals is more tightly controlled than in the United States. In Canada, prescription drugs can flow only from the pharmaceutical manufacturer directly to the pharmacy or a wholesaler. In the United States, the chain of custody also includes repackagers, which introduces infinite opportunities for counterfeit medications to enter the system. The counterfeit Lipitor scare from a few years ago involved a repackager in Lexington, Nebraska and a Kansas City-based drug distributor.

Many Americans, including many Kansans support importation. An August 2004 survey conducted by the Kaiser Family Foundation found that 79 percent of Medicare enrollees favored importation of prescription drugs from Canada. The American Association of Retired Persons (AARP) supports Senate Bill 2328, the bipartisan bill sponsored by Senators Byron Dorgan (D-ND) and Olympia Snowe (R-ME) and 22 cosponsors, that would legalize the safe importation of prescription drugs from other countries.

And lack of access to prescription drugs is not just a problem for seniors. We know from the 2001 study of uninsured Kansans commissioned by the Kansas Insurance Department that over 240,000 Kansans are uninsured and the number is growing. The majority of uninsured Kansans are between the ages of 19 to 64 and make less than 200 percent of the FPL. Without insurance coverage, these hardworking individuals are struggling to pay for prescription medication.

In recent years, cities and states throughout the country have responded to the needs of their uninsured and those struggling to pay for medication by providing citizens access to programs that allow them to safely purchase prescription medication from Canada and other countries. These programs partner with pharmacies in other countries that have been inspected, approved, and found to meet pharmacy practice standards equivalent to those in the United States. City employees of Springfield, Massachusetts have been purchasing their prescription drugs from Canada for almost two years. Expedite Rx, a company based in Temple, Texas, has allowed individuals to safely import over 60,000 prescriptions from inspected, accredited pharmacies in other countries with no reported adverse events to date.

As a matter of fact, during the flu vaccine shortage this past flu season, the United States government imported tens of thousands of additional flu vaccine from Germany and France for use by American citizens.

When the Governor's Office of Health Planning and Finance began exploring prescription drug importation, the effort was supported by Senator Barnett. A November 15, 2003 Associated Press article, which I've attached to this testimony, describes Senator Barnett as a doctor who advises patients who cannot afford prescriptions at American prices to seek them at lower prices from Canada. Barnett said he does not want to hurt Kansas pharmacists but worries patients otherwise might go without medication. Senator Barnett was quoted as saying "I think anything pushing Congress to do more on the huge problem of prescription drug costs is a worthwhile effort", and "I think the pharmaceutical industry has Washington and Congress under its thumb."

While there are millions of individuals safely importing their prescription medications from other companies, we also recognize that there are unscrupulous storefront or businesses that operate without oversight or inspection by regulating agencies or private companies to ensure patient safety. We support any measure to keep such operations out of business and that will make importation of prescription drugs safe for Kansas citizens, but believe outlawing importation altogether is not the way to go.

The Dorgan-Snowe bill currently in Congress contains several important safety protections for consumers; such as requiring wholesalers and pharmacies to register with the FDA and preventing pharmaceutical companies from shutting off supply to those who engage in importation. We support efforts such as this that emphasize patient safety while still providing individuals access to lower cost medications, including those from other countries.

We agree that importation is not the long-term solution to escalating prescription drug prices, however, we do believe that it offers many individual citizens access to prescription drugs they would otherwise not have. Many Kansans are without prescription drug coverage and have incomes that are too high to qualify for assistance from pharmaceutical manufacturers or other safety net programs. Under the Governor's health care reform program, we are also working with Kansas pharmacists to establish a pooled buying program that would enable uninsured low-income Kansans to purchase generic medications at a much lower cost than they can now. But that won't help everyone, and we believe it is important to offer individuals a variety of options to lower their medications costs that we know are safe.

For these reasons, the Governor's office opposes HB 2337 and instead encourages the consideration and evaluation of all options to assist Kansans in obtaining lower cost medications, while emphasizing important safety precautions.

Posted on Sat, Nov. 15, 2003

Sebelius seeks study of drugs from Canada

Associated Press

TOPEKA - Gov. Kathleen Sebelius has ordered a top health care policy adviser to study how much money the state could save by purchasing prescription drugs from Canada for its employees and needy Kansas residents.

Sebelius hopes the study will pressure the federal government to address rising prescription costs, her spokeswoman, Nicole Corcoran, said Friday. Several other governors and some members of Congress want to lift the federal ban on importing drugs from Canada.

"She's hoping this will help urge the federal government to take action," Corcoran said. "It isn't, obviously, something that can be fixed at the state level at this time."

As for actually purchasing drugs from Canada, Corcoran noted the federal ban and said, "It's definitely not something we're pursuing."

Sebelius said she had assigned the study to Bob Day, director of her office of health planning and finance.

Supporting her action was state Sen. Jim Barnett, a doctor who advises patients who cannot afford prescriptions at American prices to seek them at lower prices from Canada. Barnett said he does not want to hurt Kansas pharmacists but worries patients otherwise might go without medication.

"I think anything pushing Congress to do more on the huge problem of prescription drug costs is a worthwhile effort," said Barnett, R-Emporia. "I think the pharmaceutical industry has Washington and Congress under its thumb."

But Kansas House Appropriations Committee Chairman Melvin Neufeld, R-Ingalls, said Sebelius -- and her fellow Democratic governors and members of Congress -- are raising Canadian drugs as an issue to embarrass President Bush, a Republican.

"It's more political rhetoric than reality," Neufeld said.

A majority of U.S. House members favored lifting the ban on importing Canadian drugs, but many of the lawmakers writing the final version of a prescription drug bill in Congress opposed the idea, as does Bush and the Food and Drug Administration.

Critics argue Canadian drugs may not be as safe as their American counterparts, while pharmaceutical companies contend that they will lose revenue that supports research.

FOR IMMEDIATE RELEASE:
February 16, 2005

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**GOVERNOR PAWLENTY'S TESTIMONY BEFORE THE U.S. SENATE COMMITTEE ON HEALTH,
EDUCATION, LABOR AND PENSIONS**

Washington, D.C. – Governor Tim Pawlenty testified this morning before the U.S. Senate Committee on Health, Education, Labor and Pensions regarding Minnesota's MinnesotaRxConnect.com website. The first in the nation website facilitates the purchase of prescription medicines from four Canadian pharmacies.

Following is the text of the Governor's submitted written testimony:

**GOVERNOR PAWLENTY'S TESTIMONY TO THE SENATE COMMITTEE ON HEALTH,
EDUCATION, LABOR, AND PENSIONS**

*(*Written testimony as submitted to the committee)*

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 for all Minnesota citizens and Advantage-Meds.com for state employees, retirees and their dependents.

Through MinnesotaRxConnect, 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):

- 1,861 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.

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