



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

March 18, 2004

•
Via Fax: (608)267-8983

The Honorable Jim Doyle
The Governor of Wisconsin
Office of the Governor
115 East State Capitol
Madison, Wisconsin 53702

Dear Governor Doyle:

It is with concern that we observe your recent creation of an internet site intended to encourage Wisconsin citizens to purchase unapproved, illegal drugs from foreign pharmacies. We strongly believe that the endorsement of the practice by a public official such as yourself undermines one of our nation's key consumer protection statutes and places your constituents at unnecessary risk of harm from unregulated pharmaceuticals.

As you may know, sixty-five years ago Congress enacted the Food, Drug, and Cosmetic Act to create a strong drug regulatory system requiring that drugs be carefully tested before marketing, produced under exacting standards overseen by the Food and Drug Administration, and dispensed by state-licensed pharmacies and pharmacists. That regulatory system has enabled our citizens to have the safest, most advanced drug supply in the world, and every day in this country millions of patients are successfully treated with safe and effective medications. Drugs made or distributed in other countries are not necessarily subject to our strict regulatory standards, and we are unable to assure that drugs imported from such places are safe and effective. FDA has, therefore, been vigilant in protecting unknowing patients from those who would lure our citizens to buy unproven, unapproved drugs from foreign countries. For a public official in this country to deny the value of that consumer protection system is disappointing.

Although the drugs that your citizens will purchase from the Canadian pharmacies to which you refer them will clearly be illegal under Federal law, our concerns are far greater than that. For example,

- A number of Canadian pharmacies that promote and sell drugs to Americans have been found substantially lacking in contemporary standards for safe pharmacy practices. I have attached our recent letter to Governor Tim Pawlenty, summarizing in some detail the inadequacies of those pharmacies found by his own pharmacy board officials when they visited Canadian internet pharmacies.

- I understand that you also dispatched officials from your staff to visit these Canadian pharmacies, and would ask that you release to the public the nature of the visits and their results (e.g., were the visits conducted by Wisconsin pharmacy regulators, were they preannounced brief visits or multi-day surprise inspections similar to those conducted in the United States, were substandard conditions identified similar to those found by the Minnesota Pharmacy Board inspectors, what agreements were reached between Wisconsin officials and the Canadian pharmacies to correct deficiencies seen in the Canadian pharmacies?).
- In response to the deficiencies described in the Minnesota pharmacy board inspections, the Canadian pharmacies acknowledged those problems and committed to correcting them. In this country, “we’ll do better next time” has not been an acceptable means of regulating our drug supply. Indeed, any of the almost three dozen deficiencies found by the Minnesota officials could have resulted in a fine, license suspension, or license revocation for a U.S. pharmacy.
- The drugs that your citizens will purchase from these pharmacies have not been manufactured, shipped or held within the oversight of the FDA, and Canadian drug regulators have said repeatedly that they will not assure that drugs exported from Canada meet American safety requirements.
- There are many other ways that the state could pursue providing affordable, but safe, medications to your citizens, and we would welcome the opportunity to discuss these with you further. When your staff person called me several weeks ago asking to meet with us on these matters, I readily agreed and he promised to call back to schedule such a meeting --but never did.
- In particular, Wisconsin’s Senior Care program for prescription drugs may well be an alternative to Canadian drugs that is both cheaper and safer. One prominent Wisconsin citizen was quoted as saying that she looked forward to savings from Canada for her five medications (furosemide, Fosamax, Xalatan, Cozaar, and Hyzaar). But it appears that she would pay substantially more for those five drugs from Canada than if she were to buy them from her local pharmacy under the Senior Care program.
- Let me give you another example. If you take the prices for five common drugs for seniors (Detrol for overactive bladder, Lipitor for elevated cholesterol, Accupril for blood pressure control, Aricept for Alzheimer’s Disease, and Prevacid for gastric reflux), the patient would pay only \$277.50 under the Senior Care program for 112 days of drugs. From the three Canadian pharmacies you have identified, the patient would pay over six

times that amount—a difference between \$14.25 per day for Canadian drugs versus only \$2.35 from the local pharmacy selling safe, regulated American drugs.

- Several of the drugs on the website to which you link your citizens have generic versions approved in the United States, and generic drugs in the U.S. generally cost less than both brand name and generic versions sold in Canada. So it is quite possible that unknowing citizens will buy drugs from Canada, on your recommendation, when they could have purchased the American version from their corner drug stores for less.

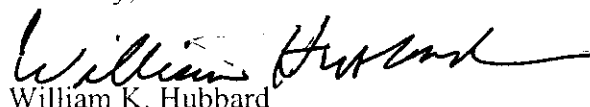
This week, Health and Human Services Secretary Tommy Thompson announced formation of a task force to hear views on whether and how a system could be crafted to allow the safe importation of drugs. I hope that you will provide your advice to that task force, either in person or by providing comment to a public docket that we have established to receive such views at: <http://www.fda.gov/OHRMS/DOCKETS/98fr/04n-0115-nm00001.pdf>.

Lastly, we reviewed the remarkable disclaimers that your internet site posts for your citizens who might purchase drugs from Canada. You recommend that Wisconsin citizens seeking cheaper drugs utilize three foreign pharmacies, yet your disclaimers say that the citizen “assumes sole responsibility for any purchase from the Canadian pharmacies listed,” and that the State “expressly disclaims any and all liability from such importation,” and “assumes no responsibility for anyone’s use of the information” on your web site. This includes no assurance that the product isn’t a “substitute” – i.e., no assurance that it is the real thing. This is in stark contrast the regulatory system for assuring drug safety that exists in the United States today. As mandated by law, it is FDA’s responsibility to assure safety and efficacy for all of the drugs, devices and medical products it approves. We continue to be concerned about programs such as your website that encourage citizens to go outside of the U.S. regulatory system. We do not recommend that citizens of Wisconsin or in other states purchase unapproved drugs from foreign businesses.

At the very least, I urge you to include among your disclaimers the further notice that the drugs your citizens might purchase are not necessarily approved by American medical authorities and may thus be unsafe for use.

We would be happy to discuss our concerns further with you at your convenience.

Sincerely,



William K. Hubbard

Associate Commissioner for Policy and Planning



February 23, 2004

Via Fax: (312)814-6183

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

Dear Governor Pawlenty:

Recently Minnesota launched a state-sponsored website called "Minnesota RXConnect." This website provides information on Canadian websites that illegally sell unapproved pharmaceuticals. We strongly believe that this state endorsement of foreign internet "pharmacies" is unsafe, unsound, and ill-considered. We appreciate the need to find safe ways to make affordable prescription drugs available to all Americans, but we urge you to reconsider your action and work with our help on legal, proven ways to provide greater access to more affordable pharmaceuticals that are assured to be safe and effective.

When you recommend to your citizens that they go outside of our regulatory system and enter into a "buyer beware" gray zone, you assist those who put profits before patient health. Your actions also shine a bright light on a path that can (and, indeed, is) used not only by profiteers masquerading as pharmacists, but by outright criminals who do not pause before actively feeding counterfeit drugs into the marketplace.

Your own taskforce has pointed out widespread, significant problems related to illegally purchasing non-FDA approved pharmaceuticals from foreign Internet pharmacies. Even Canadian pharmacies that participate in the Canadian Internet Pharmacy Association, which claims to "self-regulate" safety, were observed engaging in dangerous practices on a single voluntary, pre-announced "visit" by Minnesota State officials who have no regulatory authority over the foreign businesses. Even on these single, preannounced visits, your state officials noted dozens of safety problems, such as:

- One pharmacy had a technician, not a trained pharmacist, enter prescriptions into the pharmacy computer. This practice precluded a trained pharmacist from having an opportunity to catch any prescribing errors. Several pharmacies also

used unsupervised technicians, not trained pharmacists, to enter medication orders and to try to clarify questions involving the prescriptions. One pharmacy had its pharmacists check 100 new prescriptions or 300 refill prescriptions per hour, a volume so high that there is no way to assure safety.

- One pharmacy failed to label its products, but instead just shipped the labels unattached in the same shipping container, even when patients received multiple medications in one shipment.
- Drugs requiring refrigeration were being shipped un-refrigerated with no evidence that the products would remain stable.
- One pharmacy had no policy in place for drug recalls. Representatives of the pharmacy allegedly said that the patient could contact the pharmacy about a recall “if they wished”.
- Several pharmacies failed to conduct drug utilization reviews, failed to check patient profiles for allergies, and failed to check new prescriptions to verify their accuracy.
- Several pharmacies dispensed grossly improper amounts of medications, e.g., a 250-count bottle of Lanoxin, which is far larger than is consistent with good prescribing for this medicine.
- One pharmacy re-dispensed medicines that were not labeled and apparently had been previously returned by U.S. Customs and Border Protection.
- One pharmacy technician repeatedly scanned the same prescription bottle when checking an order of six separate bottles, instead of scanning and verifying the accuracy of each of the six bottles in the prescription order.
- Several pharmacies had poor storage practices and poor record keeping, making mishandling of prescriptions more likely.
- Several pharmacies failed to send any patient drug information to patients receiving prescription drugs.
- All of the pharmacies generally allowed customers to fax in their own prescriptions. This not only fails to assure the validity of the prescription; it means that patients can get multiple drug orders from a single prescription, including for more risky drugs.

- Several pharmacies appeared to make unsupervised pharmacy technicians responsible for contacting the American prescriber by telephone if something on the original prescription needed to be clarified. This is a task that a pharmacy technician would not be allowed to perform under Minnesota pharmacy laws and rules, even if pharmacist supervision was present.
- One pharmacy failed to apply child resistant safety caps to any of the prescription drug products shipped to the U.S.
- Only one of the pharmacies visited had a thermometer in their refrigerator to verify that labeled storage requirements were being met for refrigerated products. This is a requirement for all Minnesota pharmacies.
- Most facilities visited did not meet the minimum lighting standard that Minnesota pharmacies would be required to meet. In several of the pharmacies, the lighting was judged to be extremely poor with only half as many "foot candles of illumination" in the work area as are required for safety under Minnesota law.

Many drugs obtained through at least one of the pharmacies were apparently not even of Canadian origin, and many of the drugs were obtained from a difficult-to-follow path of writing and rewriting prescriptions across multiple Canadian provinces. Also disturbing was the statement from one of the pharmacy presidents who allegedly said, "We won't have any problems getting drugs. We have creative ways to get them." Given the clear evidence of questionable sources of these prescription drugs, do you or anyone know what methods are being used and might be used in the future to obtain these drugs, let alone to assure their safety?

Most importantly, a one-time preannounced "visit" to *any* Internet pharmacy is no substitute for the comprehensive system for assuring the safety of the prescription drugs used by Americans. Regulatory oversight by both federal and state authorities has been proven time and again to be essential to assure the safety and effectiveness of drugs not only in the State of Minnesota, but nationwide. And this is particularly germane today, as you well know by the egregious violations of good pharmacy practices that were prevalent on your single preannounced visit. The fact that your own website admits that you cannot assure the safety of foreign imports is cause for concern. This is very different than the situation here, where the Minnesota Pharmacy Board, backed by FDA and U.S. law enforcement, has the regulatory authority needed to assure the safety of the domestic drug supply.

We are also concerned that you chose not to make public the serious concerns about the safety of international Internet pharmacy practices noted by every provincial pharmacy board in Canada. When we met with you we noted the potential tort liability that a state could be subject to if a citizen purchases an unapproved, illegal drug on your advice, and suffers an injury as a result. Your failure to warn your citizens that you have found

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substantial deficiencies in these foreign pharmacies may well increase your vulnerability in this area.

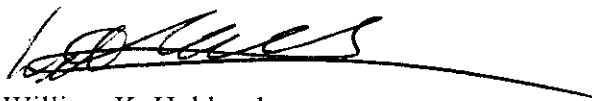
There are very good reasons why Health Canada (our counterpart across the border) continues to state that they cannot and will not guarantee the safety of drugs exported across the border through Internet pharmacies. Your continued support and active promotion of Minnesota ConnectRX is unwise and, most urgently, unsafe. At a minimum, your statement that you cannot assure the safety of drugs purchased from these sites seems like a questionable way to limit your own liability if and when Americans who visit these websites fail to get the quality care they deserve, or worse.

Your actions are especially concerning when there are many other safe, legal, and proven ways that the state could pursue with assistance from the Federal government to lower drug costs for Minnesotans. As we noted when we met with you, we and others in the Federal government are ready to work with you to implement these approaches for the people of Minnesota. These approaches include: promoting access to FDA-approved generic drugs, which are proven safe and effective, account for the majority of prescriptions filled in the U.S., and generally cost less than the generic drugs sold in Canada; disease management programs to help educate patients and practitioners about low cost ways to meet medical needs; and implementation of the new Medicare Drug Discount Program, which will become effective in June and will enable seniors who lack medical coverage to obtain medicines at reduced prices.

Meanwhile, you should also know that we are working diligently to respond to our mandate from Congress to assess whether and how foreign drugs could be imported while providing assurances of their safety and effectiveness. We intend to consider the public health questions posed by Congress in a way that is fair, public, and evidence-based. Indeed, we will soon begin a series of meetings with the various stakeholders in this important area, so that we can advise the Congress on how and whether to proceed in its deliberations on drug importation. I would be glad to discuss how you can participate in this process if you so desire.

I want to repeat that offer and hope that you are ready to work with us on meaningful, proven, legal approaches to provide broader access to safe and effective drugs for the people of Minnesota. We can do better than simply giving Minnesotans a foreign fax number and wishing them luck.

Sincerely,



William K. Hubbard
Associate Commissioner for Policy and Planning