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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

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".

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- 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 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

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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,

/s/

William K. Hubbard
Associate Commissioner for Policy and Planning

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