



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

July 22, 2004

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 continued concern that we read the reports sent to the State of Wisconsin by the Canadian internet pharmacies participating in your Prescription Drug Resource Center program that show that the drugs being purchased through your program are not the same high quality drugs that are FDA approved for sale in the United States. It is increasingly clear that the participating pharmacies continue to sell drugs to Wisconsin citizens that are in violation of the standards you have established in an attempt to assure the quality and safety of such medications and despite your Warning Letters of April 27, 2004 to these pharmacies.

As you will recall, in our March 18 letter, we brought to your attention several safety concerns with your newly created website. These safety concerns included:

- The number of Canadian pharmacies that have been found lacking in safe pharmacy practices even in pre-announced initial inspections by state inspectors from Minnesota and have not been inspected by appropriate U.S. regulatory authorities.
- The Canadian pharmacies listed on your website that sell drugs that have not been manufactured, shipped or held within FDA oversight, and to our knowledge the State of Wisconsin has not even attempted to inspect these pharmacies to assess their safety practices.
- The drugs listed on your website have less expensive FDA approved, generic versions available in the United States. Consequently, Wisconsin citizens, on your recommendation, may pay more for foreign drugs than they could pay in the United States for a FDA-approved generic version.
- The fact that your website continues to include disclaimers that place the "sole responsibility for any purchase from the Canadian pharmacies listed" on Wisconsin citizens using the website, while the State "expressly disclaims any and all liability from such importation." Your disclaimer stands in stark contrast to our current U.S. prescription drug regulatory system that assures the safety and efficacy of all FDA approved drugs.

Subsequent to our March letter to you, we also noted and reviewed the concerns raised by the Pharmacy Society of Wisconsin (PSW) (available at: <http://www.pswi.org>) regarding violations of the contracts Wisconsin entered into with the three Canadian pharmacies. The State of Wisconsin Pharmacy Agreement (Agreement), signed by the participating pharmacies prior to the launch of the Wisconsin website, states, in pertinent parts, that the participating pharmacies would sell only prescription medications "listed" on your website. The Agreement further states that the participating pharmacies "shall not" provide:

- "Medications for which there is no equivalent approved for sale in the United States by the Food and Drug Administration of the United States Department of Health and Human Services;" (Section II, A (2)(b))
- "Generic medications for which there is no equivalent approved by the U.S. Food and Drug Administration for sale in the United States;" (Section II, A (2)(c)) and
- "Medications which require refrigeration or any medications that cannot be safely shipped via mail order" (Section II, A (2)(d))

In the first monthly report for March 2004 provided by the Canadian pharmacies to Wisconsin's Department of Health and Family Services, PSW found that, of the 765 prescriptions distributed, 316 violated the Agreement. Specifically, PSW found that 127 drugs dispensed were not FDA approved and had no approved version available in the United States. PSW also found that 189 prescriptions were dispensed using drugs that were not listed as available on the Wisconsin Prescription Drug Resource Center program that lists 119 medications currently available under the website's program. In the April report, PSW found that "almost one out of every five prescriptions dispensed through the website violated the terms of the agreement with the state." Specifically, PSW found that 35 of the 285 prescriptions dispensed were not FDA approved products and had no FDA approved version available in the United States and that 16 were not listed on the website. PSW noted that, contrary to the statements by Wisconsin officials, the participating pharmacies continued to violate the Agreement.¹ Once again, in the May report, PSW discovered violations of the Agreement, including the distribution of unapproved drugs and that have no FDA approved version available in the United States and drugs not even listed on the website.

We are also concerned about the April 27 Warning Letters from Administrator Sue Reinardy of the Wisconsin Department of Health and Family Services sent to the three participating pharmacies citing violations of the Agreement and clarifying the terms set forth in the original Agreement. Specifically, Ms. Reinardy wrote that all three pharmacies dispensed generic medications for products with no equivalent generic FDA approved version. Additionally, Ms. Reinardy noted that insulin, a refrigerated item, was dispensed.² As discussed above, the

¹ In its press release on the second report, PSW wrote: "Despite claims by the administration that initial problems with the site were corrected, the Canadian pharmacies continue to dispense unapproved drugs, including many not even listed on the Web site."

² In the April 27, 2004 letter to CanadaDrugs.com, Ms. Reinardy wrote: "Upon receipt of this letter, CanadaDrugs.com must stop dispensing refrigerated items. CanadaDrugs.com must also stop providing generic versions of brand medications on Wisconsin's list where there is no current FDA approved generic available in the United States." Similar letters were sent to both Granville Pharmacy and Total Care Pharmacy.

Agreement Wisconsin originally entered into with these participating pharmacies clearly prohibits the dispensing of these violative products.

We have grown ever more concerned that after the issuance of these Warning Letters, PSW continued to find additional violations of the contract in reviewing the monthly reports submitted by the participating pharmacies (available at <http://www.pswi.org>). We share PSW's concern that, on review of the third report, Wisconsin's own administrator failed to find violations of the Agreement, while PSW found ten.³

In an effort to further confirm the safety issues found by PSW and by Ms. Reinardy, FDA's Chicago District Office recently conducted its own assessment of incoming packages from all three participating Canadian pharmacies. Over a five-day period in late June and July, FDA observed that the participating pharmacies were continuing to violate the Agreement. Specifically, FDA found that 55 of 79 parcels originating from the Canadian pharmacies participating in the Wisconsin pharmacy program contained either generic medications for which there is no equivalent approved by the FDA for sale in the U.S.; or drugs that FDA considers high risk because they have been counterfeited in the past or pose potential safety concerns. These violations continue to present ongoing safety concerns for Wisconsin residents who are led to believe they will get foreign drugs that are identical to or the same as FDA approved products, while leaving them with very limited recourse when in fact they receive drugs that are unapproved foreign versions that violate the State agreement and are not what they ordered. The non-compliance rates found by PSW prior to your Warning letter was alarming, but even more alarming is that the noncompliance rates found after your letter and independently confirmed by our own assessment indicate that the State is not able to control the quality of foreign drugs being dispensed through this program to its residents. For example, TARO-Warfarin, an unapproved version of Warfarin, was one of the products discovered during the five-day blitz. Warfarin is used to prevent blood clotting and its potency may vary depending on how it is manufactured. Because it can cause serious, life-threatening bleeding if not administered appropriately, it requires careful monitoring by a health care provider of a patient's blood count during treatment. Our assessment confirms PSW's concerns regarding continued violations by participating pharmacies as well as the fact that Wisconsin residents are purchasing unapproved drugs as well as generic products that are actually less expensive in the United States.⁴

FDA shares with public officials and others the great concern for senior citizens and other patients who have difficulty paying for prescription drugs and we understand the need to find solutions to this problem so that all American citizens will have affordable access to safe, effective, FDA-approved medications. However, these must be reliable solutions that offer our citizens the public health protections they deserve and expect. Consumers are exposed to a

³ In her July 1, 2004 Memorandum regarding the May monthly report, Administrator Sue Reinardy stated: "There were no shipments of prescriptions not allowed in the Wisconsin agreement." In its press release on this monthly report, PSW wrote: "Despite a state memorandum stating otherwise, independent analysis by the Pharmacy Society of Wisconsin found the administration's latest report from the Canadian pharmacies showed continued violation of the contractual agreement between the pharmacies and the state of Wisconsin.... The fact that the state did not recognize violations of its own agreement points to the complexity of the business and the need for legitimate regulation."

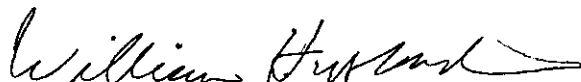
⁴ See FDA White Paper on the cost of generic drugs at <http://www.fda.gov/oc/whitepapers/drugprices.html>.

number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws. Patients are at risk because there is no certainty about what they are getting when they purchase some of these drugs. Consumers may unknowingly receive counterfeit copies of drugs that contain only inert ingredients, legitimate drugs that are outdated and have been diverted to unscrupulous resellers, or dangerous sub-potent or super-potent products that were improperly manufactured.

It is often assumed that a drug sold by a Canadian pharmacy is the same or very similar to American drugs, since Canada has a regulatory system analogous to our own. However, it is important to note that drug products must be made with great care and to exact specifications, without which drugs containing the same active ingredients may vary significantly. In fact FDA has gone to great lengths to ensure that the generic version of a drug is the same--is absorbed into the body, enters the blood stream, and has the same therapeutic effect--as the brand name drug. We know from experience that, for some drugs, even a seemingly minor deviation in the manufacturing process can make a significant, therapeutic difference. For foreign drugs that are manufactured outside of FDA's regulatory regime and/or in facilities that have not been deemed acceptable by FDA, FDA has no way of assuring that such drugs will be the "same," even if they contain the same active ingredient, and thus, such drugs may be unsafe in a number of ways.

Given the continuing violations by the participating Canadian pharmacies of the Agreement with Wisconsin, FDA urges you to reconsider your website program. Your actions in facilitating the sale of foreign unapproved drugs, outside the regulatory system Congress created to protect the public health, put Wisconsin residents at risk. We strongly believe that the endorsement of the practice of purchasing foreign drugs over the internet by a public official such as yourself undermines one of our nation's key consumer protection statutes. I want to emphasize that we are ready to work with you to provide Wisconsin's citizens with alternative, legal and broader access to safe and effective drugs. As public servants entrusted with consumer protection, it is our duty to provide them with more than a link to a foreign website with the hope that they will be successful in obtaining safe and effective medications. Moreover, it is imperative for WI citizens to have confidence in the fact that their health is our number one priority.

Sincerely,



William K. Hubbard

Associate Commissioner for Policy and Planning