

Canadian Pharmacies Continue to Violate State Agreement

Second and third reports continue to disappoint

by Justin Pacult

The July/August 2004 issue of *JPSW* included an article that described violations with the state's prescription drug importation Web site. The Web site, www.drugsavings.wi.gov, was established to assist in the importation of less expensive prescription drugs to Wisconsin residents from pre-selected Canadian pharmacies. A signed agreement with these Canadian pharmacies placed restrictions on which medications could be dispensed to ensure safe use for Wisconsinites. The first month's report confirmed the Pharmacy Society of Wisconsin's concerns for safety of use when 295 or 39% of the prescriptions filled were in violation of the agreement. These violations consisted of medications not listed on the Web site, non-U.S. Food and Drug Administration (FDA) approved generics and drug products, and even some refrigerated products.

For the last few months, PSW has monitored the traffic on the Doyle Administration's state sponsored Web site to determine whether these violations are still occurring. The Canadian pharmacies have violated the state agreements for the third time in as many reports. In the second report, 285 prescriptions were mailed to consumers using this service, down significantly from the 765 prescriptions of the first report. Upon inspection of the April report, PSW found that 71 or 25% of the medications sold to Wisconsin consumers were in violation of the agreements. Of the 71 prescriptions, 32 were medications that were not approved in the United States and not approved by the FDA. Some examples of these potentially unsafe, non-approved drugs were generic versions of Warfarin[®], Zocor[®], Zoloft[®], and Lamictal[®]. The other 39 violations involved medications that were

“The noncompliance rates found by PSW prior to your Warning letter [sent April 27, 2004] were alarming, but even more alarming is that the non-compliance 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 . . . 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.”

From a July 22 letter to Governor Jim Doyle from William Hubbard, Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration

mailed even though they were not included in the Wisconsin Web site eligibility list.

Despite a warning letter sent on April 27, 2004 by the Doyle Administration to the Canadian pharmacies, these violations continued to occur in May. PSW's review of the May report found that 10 of the 185 prescriptions shipped to Wisconsin consumers violated the agreements, even

though a memorandum from the state official responsible for managing the Web site had indicated that no shipments occurred that were not allowed by the state agreements. Of these ten violations, eight of the medications were not listed on the Web site and two medications were for generic drugs not approved by the FDA.

Also disturbing was a discovery in the April and May reports provided by one of the Canadian pharmacies, Total Care Pharmacy, that showed an apparent alteration in information. PSW found some inconsistencies from the online report provided by the Canadian pharmacy and the report provided by the Doyle Administration. Information that was included in the online report referenced a category called “other” prescription drugs dispensed. It appears to be a category of prescription medications that were shipped to Wisconsin consumers but deleted from the publicly released report. PSW suspects the Canadian pharmacy is diverting Wisconsin consumers to a new or different Web site or business line to deliver the medications that are not allowed through the Wisconsin Web site. These Web sites have even less regulation and could be a dangerous trap door for some trusting Wisconsin consumers.

The Web site set up by the Doyle Administration states that these selected pharmacies are “safe, reputable and reliable.” The agreements made were supposed to ensure the medications received by Wisconsinites were safe for use. For three months these violations have been occurring, with no repercussions to the offending pharmacies. The continued violations with the state agreements and the dispensing of drugs neither approved by the FDA nor available in the United States illustrates that the businesses are neither

AGREEMENT VIOLATIONS FOR THREE-MONTH PERIOD: MARCH TO MAY 2004

VIOLATION TYPE	1 st Report	2 nd Report	3 rd Report	Total	% Total
Drugs not listed on Web site	193	39	8	240	19.4
Non-FDA approved generics	94	30	2	126	10.2
Non-FDA approved drug products	2	2	0	4	0.3
Refrigerated items	6	0	0	6	0.5
Total violations	295 of 765	71 of 285	10 of 185	376 of 1235	30.4

reputable nor reliable. The safety of such unregulated practices is suspect at best.

FDA'S CONCERNS

A second letter addressed to Governor Doyle on July 22 from William Hubbard, associate policy and planning commissioner for the FDA, reaffirmed the FDA's concerns with the Web site set up by the state. Hubbard stated that it is clear from the state's monthly reports and PSW's reviews of the Web site that the drugs being purchased through the state program are not of the same high quality that the FDA approved for sale in

the United States. The letter restates the FDA's concerns for patient safety directed toward the Web site that were brought to Governor Doyle's attention in a previous letter on March 18, 2004.

Further confirming the safety concerns expressed by PSW, the FDA's Chicago District Office recently conducted an evaluation of incoming packages from the three Canadian pharmacies participating in the Wisconsin Web site. Over a five-day period in late June to early

July, the FDA sting continually found shipments from these participating pharmacies that violated the agreements each

pharmacy has with the state of Wisconsin. The FDA found that 55 of the 79 parcels originating from these Canadian pharmacies participating in the Wisconsin pharmacy program contained either generic medications for which there is no approved FDA generic or drugs the FDA considers high risk because they have been counterfeited in the past.

The FDA communicated to Governor Doyle that these violations pose potentially dangerous safety issues for the Wisconsin public. The alarming noncompliance rates found after the state's warning letter sent in April to the Canadian pharmacies points out that the State of Wisconsin is not able to control the quality or safety of these foreign medications being dispensed to its residents. Hubbard stated in the letter that, "Your actions [Governor Doyle's] in facilitating the sale of foreign, unapproved drugs, outside the regulatory system Congress has created to protect public health, puts Wisconsin residents at risk." Given the health risk and continuous violations of the agreements that Wisconsin made with the Canadian pharmacies, the FDA urged the Doyle Administration to reconsider the continuation of the Web site.

The FDA has offered to work with the Doyle Administration and PSW to provide Wisconsin's citizens with alternative, legal and broader access to safe and effective drugs. PSW's Executive Vice President Chris Decker has also requested a meeting with key state and federal officials to address the problems associated with unregulated importation and the violations of the Wisconsin Web site in particular. ●



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