

PSW Determines Canadian Pharmacies Violate State Agreement

Initial report to the Governor unveils disturbing practices

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On February 25, 2004, three Canadian pharmacies signed a contract with the Doyle Administration to provide prescription medication reimportation for Wisconsin residents. In the contract, the Canadian pharmacies promised to honor several restrictions on the type of prescriptions that could be dispensed to consumers using this state sponsored service. Canadian pharmacies were not allowed to dispense narcotic and controlled medications, “medications for which there is no equivalent approved for sale” by the U.S. Food and Drug Administration (FDA), generic medications that have no FDA approved equivalent, and medications requiring refrigeration or other special handling. The contract also specified that prescriptions must have a valid new (not transferred) U.S. prescription, not be in excess of a 90-day supply or the amount on the prescription, and the prescription must be within a year of its issue date. According to the Doyle Administration, these requirements were to ensure the medications received by Wisconsinites were safe for use.

As also provided in the contract, the Canadian pharmacies must issue a report detailing each month of services. The first month’s report stated that 421 orders for a total of 765 prescriptions were mailed to consumers utilizing this service. Upon inspection of the report, several concerns of this service, expressed by PSW and other organizations, were confirmed. Of the drugs dispensed, 316 or 41% of prescriptions were in violation of the terms of the contract. Of the 316 prescriptions, 127 were medications that were not available in the United States and not approved by the FDA. Many of these medications were unapproved generics that are still under patent in the

United States. These generics have not undergone the strict testing of the FDA to ensure the medications are safe for use and bio-equivalent to the brand name medications with which they claim to be interchangeable. Some examples of these violations include generic versions of Zocor®, Fosamax®, Coreg®, and Zetia®.

Of the 765 prescriptions dispensed during the first month, 316 were in violation of the terms of the contract between the Canadian pharmacies and the state of Wisconsin. Of the 316 prescriptions, 127 were medications that were not available in the United States and not approved by the FDA.

According to a state response on the report, it is unclear whether the consumers requested these substitutions or the pharmacy substituted without the consumers’ consent. But in either case, the dispensed prescriptions violated the state agreement.

The other 189 violations involved medications that were dispensed even though they were not included on the Wisconsin Web site eligible product list. This Web site lists the names and prices of medications that are allowed to be dispensed. Some of these medications not

listed on the Web site, but still shipped to consumers, included some generics which are more expensive when ordered from Canada than when bought locally.

In addition to the 316 violations, six refrigerated medications were also shipped via the mail. These included insulin, calcitonin nasal spray and Xalatan® ophthalmic solution. This practice was also prohibited in the contract to prevent possible degradation of the medication during mailing.

One of the Canadian pharmacies has also advised the state that it contracted with a European supplier to help meet its difficulty in filling some prescription orders. This action prompted a warning from the state that this was outside the contract agreement. This situation further suggests that the program is not functioning as planned.

BACKGROUND

On February 20, 2004, Governor Doyle announced the state sponsored Web site, www.drugsavings.wi.gov. The Web site was created to facilitate and promote the Governor’s contract between three selected Canadian pharmacies. Although the Web site states that the selected pharmacies are “safe, reputable, and reliable,” the Web site does not explain how that was determined. It says that “regulators” inspected the pharmacies and deemed them safe. The Web site makes no mention of the fact that the Pharmacy Examining Board (PEB), the board in charge of inspecting all Wisconsin pharmacies, was left completely out of the assessment process. The PEB was not advised of the steps the Governor was taking until the news had been issued to the public.

The Pharmacy Society of Wisconsin has been alarmed by steps taken by the Doyle Administration regarding Canadian

drug importation policy. This recent report from the Canadian pharmacies seems to confirm what many have feared about the program. This first report proves the fallacy of having a safe and reliable but unregulated importation system. The state's own report verifies that trusting Wisconsin consumers were duped a staggering one-third of the time.

As of press time, the Governor's office still had not released its next report from these Canadian pharmacies, although the data was more than two weeks overdue. PSW continues to monitor this situation closely. Wisconsin pharmacists are encouraged to share the facts with consumers or organizations interested in importing prescription drugs from other countries.

PSW has not been the only one critical of this program. Both the PEB and the Federal Government have been opposed to the Wisconsin program and the actions of the Doyle Administration. William Hubbard, associate policy and plan-

ning commissioner for the FDA, told the governor, "The state's Web site encourages people to buy unapproved drugs from Canada and circumvents the FDA's inspection process."

At the same time, several members of Congress are working to create a safe and regulated system of prescription drug importation. The "Pharmaceutical Market Access and Drug Safety Act of 2004" bill forwarded by Senator Dorgan allows importation at a different level. Under Dorgan's proposal, pharmacies would be able to import drugs from select countries such as Canada, Japan and members of the European Union. This bill is unique as it allows pharmacies, rather than individual consumers, to import prescription drugs. By allowing pharmacies to import, it would bring U.S. pharmacists back into their role of dispensing and monitoring the quality of the products consumers use.

Congress has requested the development of a drug importation taskforce at the Department of Health and Human

Services. This taskforce is charged with investigating the issues surrounding the importation of drugs from other countries. The major points of concern of this taskforce include non-FDA approved drugs and counterfeit drugs entering the market. These issues will become more prominent if access to prescription drugs becomes more unregulated.

As different branches and levels of our government attempt to deal with the issue of drug importation, we should all focus on what's important — the safety and health of those who will be affected. The FDA has noted that there has been a four-fold increase in the number of counterfeit drug investigations. This number will probably rise as unregulated drug importation increases in volume. Hopefully, there will be a compromise that will provide relief to those who cannot afford their medications without sacrificing their safety in the process. ●

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