

Importation of Prescription Drugs

A position statement from the UW Hospital and Clinics Center for Drug Policy

by Lindsay Sutter, Susan Kleppin, RPh, and Lee C. Vermeulen, MS

Editor's note: The position statement contained within this article comes from the Center for Drug Policy at the University of Wisconsin Hospital and Clinics, and does not necessarily represent the position of the Pharmacy Society of Wisconsin, its officers or Board of Directors.

As the number of uninsured Americans reaches 44 million (approximately 15% of the United States population), access to and the cost of prescription medications has become one of our most critical public health challenges. Among the strategies currently being employed to increase access to medications and control their cost, uninsured Americans have increasingly begun purchasing their prescriptions illegally from other countries. Prescription importation is a process by which consumers have their prescriptions filled by foreign pharmacies and receive their medications by mail (most commonly in the U.S. today, from Canadian pharmacy sources). The low cost of Internet-based marketing has given rise to "international pharmacies," dispensing medications of unknown origin and integrity to consumers worldwide, often without a legitimate prescription order.

Current pharmacy regulations in the United States require a closed-loop drug supply and prescription distribution system, intended to maintain the integrity of the medication supply chain and maximize the safe provision of medications to patients. The United States Food and Drug Administration (FDA), the United States Drug Enforcement Agency (DEA), and individual states set minimum standards for these activities (ranging from good manufacturing processes to the professional practice of pharmacy) through laws, regulations and practice standards. Prescription importation poses a direct threat to these standards and the safety of American consumers.

As this public debate began, many consumers and regulators naively believed that the medications being sent to the U.S. had first been imported by Cana-

da from the U.S., to later be re-imported to American consumers. What had been described as *re-importation* is now simply known as *importation*, as it has been recognized that little of the product dispensed in this system comes initially from the U.S. The quality of the products being dispensed is of primary concern. In Canada, drugs can be imported for distribution domestically only from countries with which Canada has approved a mutual recognition agreement, guiding the quality of the imported product. Currently, Canada has these agreements with 18 countries. However, Canadian pharmacies currently import medications from over 60 countries, leading to the conclusion that Canadian pharmacy exporters are dispensing products to U.S. consumers that would be considered unsuitable for provision to Canadians.

According to the U.S. FDA, Canadian outlets have dispensed expired, subpotent, contaminated or counterfeit products. These drugs may not have been packaged or stored under appropriate conditions to avoid degradation, and are often not labeled in English. The U.S. FDA has cited numerous accounts of counterfeit drugs entering the U.S. According to a study by the Partnership for Safe Medicines, it was determined that in a sample of 1,153 imported prescriptions, 1,019 (88%) were found to contain products that were in violation of U.S. regulatory standards.

Beyond the threat to U.S. consumers posed by the unregulated direct-to-con-

sumer importation of substandard prescription medications, this practice threatens the basic relationship between pharmacists and patients that has been shown to ensure the safe, effective and efficient use of medications. Patients who take multiple medications are at particularly high risk. Unlike domestic mail order pharmacy, where patients have access to a U.S. pharmacist responsible for their care, prescriptions delivered from foreign sources may be incorrectly dispensed, inappropriate for a particular patient, unlabeled, and are often not accompanied by adequate directions for use.

American consumers are not aware of the risks involved in purchasing prescriptions from foreign sources. Information regarding these risks, including the fact that no system is in place to ensure their safety, must be provided to consumers. The University of Wisconsin Hospital and Clinics' Center for Drug Policy, located in Madison, Wisconsin (USA), works to develop, implement, maintain and monitor policies related to the use of pharmaceuticals. The Center has developed a position statement opposing this growing practice.

Lindsay Sutter is a doctor of pharmacy candidate at the UW School of Pharmacy in Madison. Susan Kleppin is deputy director for the Center for Drug Policy at the UW Hospital and Clinics in Madison. Lee Vermeulen is director for the Center for Drug Policy at the UW Hospital and Clinics in Madison and clinical associate professor at the UW School of Pharmacy in Madison.