Generic Drugs: An Alternative to Drug Re-importation

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Americans spend more money on prescription drugs than do citizens of any other country. In an effort to alleviate this problem, many states have implemented drug re-importation programs whereby their citizens are able to purchase drugs from abroad. Unfortunately, obtaining drugs from foreign countries is simply a "quick fix" for the problem of exorbitant drug costs. A possible remedy to the prescription drug crisis lies in promoting expedient entry of generic drugs into the marketplace.

The cost of prescription drugs is escalating at an astronomical rate. Since 1998, drug prices have risen at a rate that is double the rate of inflation, and many Americans, especially senior citizens, are unable to keep up with the increasing cost.[1] Drug re-importation has been viewed as a potential response to this problem. Drug re-importation begins when a U.S. pharmaceutical company exports drugs, via a wholesaler, to foreign pharmacies. The foreign pharmacy then imports the drug to the American consumer at a price that is drastically lower than the price that the consumer would pay in the United States for the same drug. Countries such as Canada are able to sell prescription drugs at lower rates because the Canadian government controls the prices at which the drugs are sold.[2] In the United States, pharmaceutical companies are not subject to governmental price control and have complete control over the price of the products they sell.

Several states have enacted, or are in the process of enacting, drug re-importation programs. Illinois' "I-Save-RX" program is one of the most notable. Illinois contracts with CanaRX, a Canadian pharmacy benefit manager that monitors several online pharmacies.[3] CanaRX enables the citizens of Illinois to connect with numerous pharmacies and prescription drug wholesalers in Canada, the United Kingdom, Ireland, and more recently, Australia and New Zealand.[4] To date, four other states – Wisconsin, Missouri, Kansas and Vermont – have joined the "I-Save-RX" program.[5] Prescription drugs purchased through "I-Save-RX" are up to 50% less expensive than prescription drugs purchased through the U.S. retail market.[6] Texas[7] and Nevada[8] have recently

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[1] Danielle Deaver & Kristi E. Swartz, *Hard to Swallow Ad Costs Help Put Drug Prices Out of Reach for Some*, WINSTON-SALEM J., Apr. 27, 2003, at A1.
[2] Michele L. Creech, Comment, *Make a Run For the Border: Why the United States Government is Looking to the International Market for Affordable Prescription Drugs*, 15 EMORY INT'L L. REV. 593, 596-625 (2001).
[3] Kaiser Family Found., *Illinois, Wisconsin Add Australia, New Zealand to I-Save Rx Reimportation Program*, DAILY HEALTH POLICY REPORT, July 19, 2005, *at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=31479.
[4] *Id.*
[5] *Id.*
[6] U.S. Dept. of Health and Human Services, Health Resources and Services Administration, Pharmacy Services Support Center, *States Consider Importation Programs as Alternative Access To Lower-Cost Drugs, at* http://pssc.aphanet.org/policy/latestdevelopments.htm (last visited Dec. 5, 2005).

enacted legislation authorizing the importation of prescription drugs from Canadian pharmacies. Several cities in Massachusetts have approved measures that will allow city employees to purchase Canadian prescription drugs.[9] Florida[10] and Rhode Island[11] are currently taking steps to facilitate re-importation.

Programs such as "I-Save-RX" do offer prescription drugs at lower prices than those available on the U.S. retail market; however, for several reasons, these programs are simply a temporary solution to the high cost of prescription drugs. First, re-importation is expressly prohibited by the Federal Food, Drug and Cosmetic Act.[12] In an effort to enforce the act, the U.S. Food and Drug Administration (FDA) has blocked large quantities of prescription drug shipments that U.S. residents had purchased from Canada through "I-Save-RX,"[13] and the Department of Justice has filed suit against Canadian pharmacies that engage in drug re-importation.[14] Second, pharmaceutical companies, such as GlaxoSmithKline USA, AstraZeneca Pharmaceutical LP, Wyeth, Eli Lilly, and Pfizer, are taking steps to limit the quantity of drugs exported to Canada to an amount that is enough to cover only Canada's domestic needs.[15] Lastly, due to Canadian concern over the negative effect that re-importation may have on Canada's access to the newest drugs, efforts are underway in Canada to ban the export of Canadian drugs to the United States.[16]

To combat the problem of high drug cost, measures should be taken to expedite the entry of generic drugs into the market place. Generic drugs are just as safe and effective as brand name drugs but are sold at half of the price.[17] Furthermore, most generic drugs sold in the United States are considerably less expensive than brand-name drugs and generic drugs that are sold in countries such as Canada. An FDA study indicated that for six of seven important generic drugs (alprazolam, clonazepam, enalapril, fluoxetine, lisinopril, metformin, and metoprolol), the U.S. generic was priced less than the brand-

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[7] Texas State Board of Pharmacy, *Information on Canadian Pharmacies*, *at* http://www.tsbp.state.tx.us/SB410.htm (last visited Dec. 5, 2005).
[8] Pharmacy Services Support Center, *supra* note 6.
[9] Kaiser Family Found., *Texas Legislature Considers Measure To Allow State Residents To Purchase Prescription Drugs From Canada*, DAILY HEALTH POLICY REPORT, May 24, 2005, *at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=30283.
[10] Diane Carol Bast, *Three Strikes and More for Drug Importation*, HEALTH CARE NEWS, May 1, 2005, *available at* http://www.heartland.org/Article.cfm?artId=16861.
[11] Pharmacy Services Support Center, *supra* note 6.
[12] 21 U.S.C. § 381(d)(1) (2005).
[13] Kaiser Family Found., *FDA Seizes Some Medications from I-Save Rx Reimportation Program*, DAILY HEALTH POLICY REPORT, Mar. 10, 2005, *at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=28580.
[14] *FDA Blitzes Reimporters in Three-Pronged Assault*, DRUG INDUSTRY DAILY, Nov. 10, 2003, at 200.
[15] *Eli Lilly Fights Drug Sales from Canada*, BIOTECH WEEK, Nov. 12, 2003, at 154.
[16] *Canadian Pharmaceutical Agency Wants Ban on Exports to U.S.*, PHARMACEUTICAL & MED. DEVICE L. BULL., Dec. 12, 2003, at 5.
[17] Maria Lopez, *Is the Brand Name Drug Really Better than the Generic?*, TO YOUR HEALTH, Summer 2001, *at* http://www.pamf.org/health/toyourhealth/drug.html.

name versions in Canada, and five of the seven U.S. generic drugs are less expensive than Canadian generics.[18]

To ensure consumer access to generic drugs, federal authorities and legislators need to seal the legal loopholes that pharmaceutical companies use to extend the life of their patents. The longer the patent term, the longer it takes for generic drugs to enter the marketplace. Pharmaceutical companies use several tactics to maintain their market exclusivity. One delaying tactic involves utilizing federal legislation to extend 20-monopolies indefinitely. To compensate for the time lost during the FDA approval process, federal legislation grants patent term extensions for up to five years[19] and enables pharmaceutical companies to delay the market entry of generic drugs by up to 30 months each time a brand-name drug manufacturer files suit against a generic drug manufacturer.[20] Furthermore, because legislation does not prohibit "patent piling," pharmaceutical companies could theoretically extend their patent terms indefinitely by filing subsequent patents for a particular drug after the date of the original filing. Another delaying tactic involves participation in "sweetheart deals" in which pharmaceutical companies pay generic drug companies to keep their products off of the market.[21] To delay the introduction of generic drugs on the market, brand-name drug companies also lobby Congressional representatives to insert patent-extending provisions for a particular drug into must-pass appropriation legislation.[22]

Although prescription drug re-importation does offer temporary relief to consumers for the high cost of drugs, a more permanent solution lies in ensuring prompt proliferation of generic drugs into the marketplace. Generic drugs are significantly less expensive than brand-name drugs sold abroad, and it is vital that federal authorities remove obstacles that delay the introduction of generic drugs to the consumer. By encouraging the growth of the domestic generic drug industry, questions concerning the viability of drug re-importation can be avoided.

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[18] U.S. Food & Drug Admin., Office of Planning, GENERIC DRUG PRICES IN THE U.S. ARE LOWER THAN DRUG PRICES IN CANADA (Nov. 2003), *at* http://www.fda.gov/oc/whitepapers/drugprices.html.
[19] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2005) and 35 U.S.C. § 271(d)-(h) (2005)).
[20] 21 U.S.C. § 355(j)(5)(B)(iii) (2000).
[21] Consumers Union of U.S., *Generic Drugs: The Stalling Game*, 66 CONSUMER REPORTS 36, July 2001.
[22] *Id.*