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Prescription Drug Reimportation: The Law & Its Problems

The new Medicare law does little to lower U.S. drug prices and thus prevent Americans from seeking less-expensive drugs from Canada. Yet, the law allows the Secretary of Health and Human Services to block efforts to implement safe systems for reimporting less expensive, FDA-approved, U.S.-made drugs.

WHAT THE LAW DOES

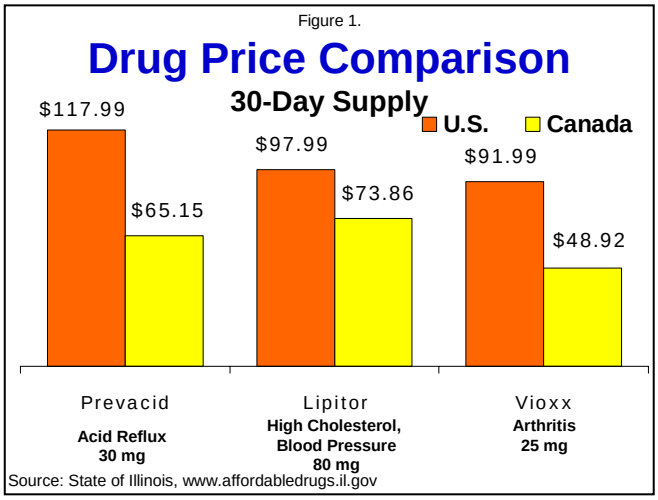
The new Medicare law allows the importation of drugs from Canada -- but only if the Administration permits it. Specifically, the Secretary of Health and Human Services must certify to Congress that importation "will pose no additional risk to the public's health and safety; and result in a significant reduction in the cost of covered products to the American consumer."[1] If this certification is given, the Secretary must issue regulations that allow pharmacists and wholesalers (called "importers") to import certain drugs from Canada. These regulations must, among other conditions, include safeguards to ensure that each drug imported is safe and effective for the drug's intended use. They also must require importers to submit information and records on imported drugs and have in place a system for testing drugs.[2] The law also includes a waiver authority to allow individuals, under certain circumstances, to import Canadian drugs. Even if importation is permitted, the Secretary has the right to end it after implementation if he or she certifies that the harm outweighs the benefits. The Secretary must conduct a study on importation and report the findings to Congress by December.

CONCERNS ABOUT THE LAW

Empty promise. Congress authorized reimportation but gave the Secretary of Health and Human Services "veto" authority over its implementation. The Secretary can block reimportation of U.S-made drugs, and, to date, has done so. At a U.S. Senate Budget Committee hearing on February 12, Secretary Thompson stated, "The law requires me to certify that drugs coming in from another country are safe. This is a hurdle I can't meet." The Commissioner of the Food and Drug Administration (FDA), in reference to Members of Congress supporting reimportation, stated, "…these members are out of touch with the realities of keeping our drug supply safe, and the clear and present dangers to America's drug supply that their bills would create."[3] On February 17, the FDA launched statewide consumer information campaigns to discourage state and local governments from purchasing prescription drugs from Canada. Thus, the promise of the new law is far from being fulfilled.

Prevents significant savings. Prescription drugs are a major factor in the rapid rise of health care costs in the nation. Drug prices do not just affect seniors and other consumers. They drive up costs for responsible businesses who offer workplace health benefits. They also exacerbate state budget problems. Even the harshest critics of reimportation acknowledge that Canadian prices are lower. One study found that consumers would save $38 billion annually if they could buy prescriptions at Canadian prices.[4] For individual drugs, the savings can be significant (see Figure 1). While reimportation will not solve the drug cost problem, it allows for immediate relief from prescription drug cost growth and creates pressure for broader policies to drive prices down.

Figure 1.



Source: State of Illinois, www.affordabledrugs.il.gov

Falsely claims that safely importing drugs is impossible. Public officials at the federal, state and local levels all agree that ensuring the safety of any imported drug is critical. A number of ideas have emerged on how to screen out counterfeit drugs, ensure correct dosages, guarantee accurate labeling, and generally improve consumers protections (see table 1). Yet, it appears that the Administration will not permit implementation or even testing of these policies. The governors of Iowa, Illinois, Minnesota, New Hampshire, and Wisconsin have approached the Administration seeking, at a minimum, waivers to conduct pilot programs. Action is pending in 25 states in total.[5] The mayors of Springfield, MA and Montgomery, AL have already begun programs. The Administration has not responded and, in fact, has threatened legal action against states or cities that implement such programs.[6]

Leaves consumers at risk. As long as drug prices remain higher in the U.S. than Canada, desperate citizens will use the internet and cross borders to obtain affordable medicines. Prescription drugs reimported from Canada doubled between 2002 and 2003, and millions of Americans already buy their drugs from Canada on a regular basis.[7] The Administration actually promotes personal importation by saying it will not enforce the law,[8] even though this practice is much more dangerous than the state pilot programs that have been proposed. As such, the failure to act forces citizens to choose between risking importation of unsafe drugs or not being able to afford needed medicines.

Table 1. Ideas On Ensuring The Safety Of Imported Prescription Drugs

Safety Policy	State	Policy
Prevent counterfeit or tampering	MN, IL	Ship only in manufacturer's original, sealed containers in dose-appropriate amounts
	HR 2427	Use anti-counterfeiting packaging similar to the technology used by the U.S. Department of Treasury
	MN, IL	Contract with qualified, licensed Canadian pharmacies
	MN	Required inspections by state officials of participating Canadian pharmacies and wholesalers
	MN, WI, NH	Use website ordering to access qualified Canadian pharmacies. See www.mnrxconnect.com, www.drugsavings.wi.gov
	IL	Use a state-based mail-order facility to handle the distribution
Prevent "black market"	IL, MN	Limit to prescriptions that have already been filled in a state pharmacy
	IL	Subject prescriptions to additional verification processes
Monitor	IL, IA	Promote coordination and monitoring of reimported drugs through Primary Care Pharmacist model
	IL	Implement monitoring program to evaluate the safety / efficacy of drugs received by plan participants from all sources
Test on small group	IL, IA, NH	State employees and retirees
	NH	Prisoners
	NH	Mental health systems
Test on subset of drugs	IL, HR 2427	Limit to FDA-approved drugs in FDA-approved dosages
	MN, HR 2427	Limit to drugs produced in FDA-approved manufacturing facilities
	MN	Limit to maintenance drugs
	IL	Limit to brand-name drugs for long-term usage for which cost-effectiveness can be demonstrated

[1] Sec. 1121, in Sec. 804(l)(1).
[2] Sec. 1121, in Sec. 804(c).
[3] M. McClellan, FDA Commissioner. (October 20, 2003). Fifth Annual David A. Winston Lecture, National Press Club.
[4] A. Sagar. (2001). A Prescription Drug Peace Treaty. Boston University School of Public Health. http://dcc2.bumc.bu.edu/hs/sager/Peace%20Treaty%2028%20Sept%2000.pdf
[5] S. Rich. (February 23, 2004). "States Pushing Drug Reimportation Plans." *Congress Daily*.
[6] Associated Press. (January 11, 2004). "FDA chief says he may prosecute cities that import drugs from Canada."
[7] L. Loyd. (February 18, 2004). "Value of reimported drugs soars," *Philadelphia Inquirer*. http://www.philly.com/mld/inquirer/business/7976550.htm?template=contentModules/printstory.jsp
[8] T. McGinnis, FDA. (December 2, 2003). Ask the Experts: Importing Drugs. http://www.kaisernetwork.org/health_cast/hcast_index.cfm?display=detail&hc=1026