

Submission by the Canadian Pharmacists Association, the Ontario Pharmacists' Association, and the Best Medicines Coalition to the Subcommittee on Interstate Commerce, Trade and Tourism of the Senate Committee on Commerce, Science and Transportation regarding the *Pharmaceutical Market Access and Drug Safety Act of 2007 (S. 242).*

March 7th, 2007 Washington, D.C.

Do No Harm: Congress Should Leave Canadian Prescription Drugs Alone

Canadian pharmacists, pharmaceutical distributors and patients are extremely concerned by the proposed *Pharmaceutical Market Access and Drug Safety Act of 2007*, and its serious implications for the integrity of Canada's prescription drug supply.

We understand fully that your hearings will focus on the impact of this legislation on the United States and its citizens. As you proceed, however, we would urge you to widen your perspective to consider the repercussions of this legislation on Canadians and their healthcare system.

Our representatives would have liked to make these arguments directly to you. Your committee has however decided to invite only a few organizations to speak at the hearings, excluding any representation from Canada, the country most directly affected by this proposed legislation. Under these circumstances, we urge you to consider the issues in this written submission.

We would like to focus on three points. Allowing Canadian price-controlled medicines to be imported in bulk into the United States will have serious consequences for Canadians and will be of very little long term benefit to Americans. Not only will such a measure damage the Canadian drug supply, it will in all likelihood lead to increased drug prices for Canadians. The *Pharmaceutical Market Access and Drug Safety Act of 2007* is a quick-fix solution to a complicated issue which will not, given the differences of scale between Canada and the United States, significantly reduce the cost of prescription drugs in your country.

This proposed legislation also puts the health of Americans at risk by opening your borders to increased counterfeit drugs and criminal activity from outside North

America. Although our submission does not address this issue in detail, we fully share the deep concerns expressed by organizations such as the American Pharmacists Association on this matter.

1. A Threat To Canada's Supply

Canada's supply of prescription medicines is not limitless. It is designed for the demands of a population of 30 million, not for a market ten times that size.

Lipitor®, Zocor®, Prevacid®, Nexium® and Plavix® are among the top ten most prescribed medicines in the United States. Although widely prescribed in Canada, our domestic supply of these drugs could meet only a small fraction of U.S. demand. For example, the Canadian stock of Lipitor represents the equivalent of just 14 per cent of U.S. demand. Similarly, Plavix stocked in Canada is sufficient to meet only nine per cent of U.S. demand.

Table 1 Supply of Leading Prescriptions in the U.S. Available in Canada

Rank (by number of prescriptions filled in the U.S.)	Product	Number of prescriptions: U.S. – 2005 (millions)	Number of prescriptions: Canada - 2005 (millions)	Canadian share of U.S. demand
1	Lipitor	79, 170	11,24	14%
2	Zocor	27,839	1,77	6.4%
3	Nexium	27,341	1,94	7%
4	Prevacid	25,020	1,75	7%
8	Plavix	23,973	2,15	9%

Note: Based on 2005 figures, IMS Health

At the request of some members of Congress in 2004, Professor Marv Shepherd of the University of Texas at Austin provided a comparative analysis of the size of the pharmaceutical market in the United States and Canada. By comparing the total number of prescription drugs dispensed in Canada with the number of prescriptions filled in the United States every day, Dr. Shepherd calculated that Canada's annual supply of prescription drugs would be exhausted in 38 days if U.S. residents were to purchase all their prescriptions in Canada¹.

This scenario is obviously meant to draw out the worst-case outcome but it effectively illustrates that bulk imports by the United States will very significantly curtail the supply available to Canadians. Indeed, as Table 2 illustrates, if 10% of U.S. prescriptions were filled in Canada, this would lead to a minimal increase in the size of

¹ Marv Shepherd, *Drug Importation Analysis: Comparison of the Canadian Pharmaceutical Market Size with the U.S. and Implications for Drug Importations*, Center for Pharmacoeconomic Studies College of Pharmacy, The University of Texas at Austin, May 5, 2004, p.13, http://www.utexas.edu/pharmacy/research/institutes/pharmacoeconomics/candrugmarket.pdf.

U.S. supply while significantly reducing the amount of drugs available to Canadians.

Table 2
Projected Increase on U.S. Supply if 10% of America's Prescriptions Were Filled in Canada

Rank	Product	Number of U.S.	10% of Canadian	Projected increase
		Prescription	Supply	based on 10% of U.S.
				prescriptions filled in
				Canada
1	Lipitor	79,170,000	1,124,000	1.4%
2	Zocor	27,839,000	177,000	0.6%
3	Nexium	27,341,000	194,000	0.7%
4	Prevacid	25,020,000	175,000	0.7%
8	Plavix	23,973,000	215,000	0.9%

Note: Based on 2005 figures, IMS Health

To further illustrate the differences in size between the two pharmaceutical markets, the number of U.S. seniors is greater than the total Canadian population. To supply just half of U.S. seniors, Canada would have to increase its total annual prescription drug supply by 2.5 times, an increase that pharmaceutical companies would not be capable of achieving.

Shortages of prescription drugs are already on the rise in Canada. The Canadian Pharmacists Association reported in 2004 that 80% of pharmacists had experienced one or more drug shortages weekly. Pharmacists surveyed also stated that shortages were becoming more frequent. Shortages are caused by a variety of factors ranging from issues with the manufacturing process to shortages of raw materials and also exports to the Unites States through internet pharmacies. It is clear, however, that actively seeking bulk purchases from Canada would seriously compound an existing problem with the Canadian supply.

2. A Threat to the Integrity of Canada's Price-Control Regimen

If passed, the *Pharmaceutical Market Access and Drug Safety Act of 2007* will, in effect, distort and disrupt the Canadian pharmaceutical market. It will do so by providing a strong incentive to big-box retailers present in Canada (either American owned or not) to re-route their stock of price-controlled pharmaceutical products for sale at a higher margin in their U.S. stores. This practice, known as 'arbitrage,' would completely corrupt Canada's price-control regimen.

The resulting shortages will unavoidably lead to higher prices in Canada, negating the intended benefit of this legislation to the U.S.

² Canadian Pharmacists Association, *Administrative Burden on Canadian Pharmacists Due to Drug Shortages*, November 2004,

 $http://www.pharmacists.ca/content/hcp/resource_centre/practice_resources/pdf/DrugShortageReport-Final.pdf\\$

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Canadian provinces already face tremendous pressure to keep the costs of healthcare manageable. This bill could seriously compromise the various measures put in place in Canada to negotiate lower prices for prescription medication. Not only would this legislation lead to shortages for Canadians, it could possibly force provincial governments to further limit the number of drugs placed on their formularies, thereby further penalizing Canadian patients by limiting their therapeutic options.

3. Limited Benefit to the United States

Although the impacts of bulk importation on Canada's domestic drug supply and on Canadian patients is real, what is less clear is the net benefit the legalization of bulk imports would have on America's supply and American consumers.

Given the small size of the Canadian market, it comes as no surprise that the U.S. Department of Health and Human Services concluded in December 2004 that "total savings to drug buyers from legalized commercial importation would be one to two percent of total drug spending and much less than international price comparisons might suggest. The savings going directly to individuals would be less than one percent of total spending. Most of the savings would likely go to third party payers, such as insurance companies and HMOs."

Conclusion

Canada's drug supply and price control systems were intended to meet the health care needs of Canadians, not to provide Americans with a quick fix or a band-aid solution to the cost of prescription drugs in your country. The real purpose of this bill is not the importation of cheaper prescription drugs, but rather the importation into the United States of Canadian price controls. The United States should not be cherry picking parts of Canada's healthcare system.

Once U.S. demand depletes Canadian stocks, prices will almost certainly rise, narrowing or possibly even eliminating the difference between U.S. and Canadian pharmaceutical prices. In short, there is no long-term advantage to be gained in raiding Canada's regulated market. Further, there is always the likelihood that the Canadian Parliament would simply ban bulk exports of prescription drug to the United States. The undersigned organizations have called on the government of Canada to institute such a ban, immediately, in order to protect the Canadian drug supply and pricing system and to protect Canadian patients. In fact, Canada's Health Minister has recently indicated to our organizations a willingness to pass legislation that would do exactly this.

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³ Department of Health and Human Services, *Report On Prescription Drug Importation*, December 2004, p. 65, http://www.hhs.gov/importtaskforce/Report1220.pdf

The *Pharmaceutical Market Access and Drug Safety Act of 2007* is deeply flawed. It will not solve the problems of high drug costs in the U.S. but will certainly increase prices paid by Canadians and restrict the number and quantity of prescription drugs available to Canadian patients.

If adopted, it is clear that this proposed legislation will strain Canada-U.S. relations. We urge Members of Congress to consider this possibility. We call upon you to see beyond the narrow scope of domestic issues, and to consider the full range of consequences that would attend the passage of this legislation.

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