A Perspective on US Drug Reimportation

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The high cost of prescription drugs in the United States receives media attention almost daily. In the past year, one third of Americans say that they or a family member has had difficulty paying for medications.\textsuperscript{1} A similar proportion has not filled a prescription or has reduced a prescribed dosage because of high out-of-pocket costs.\textsuperscript{2} In response, Americans are turning to cheaper sources for their prescription drugs.\textsuperscript{3} Canadian pharmacies are a logical choice because, partially as a result of governmental controls, prices for many of the most widely used drugs are substantially lower in Canada.\textsuperscript{4} A recent survey of US consumers found that 7\% have purchased medications from pharmacies in Canada or another country and 16\% of individuals with annual out-of-pocket drug expenditures over $1000 have done so.\textsuperscript{5} Moreover, 73\% of Americans older than 50 years would consider buying drugs from Canada or another country if this were feasible.\textsuperscript{6}

Many of the brand-name drugs sold in Canadian pharmacies are produced by US manufacturers. When they are purchased by Americans these drugs are technically being imported back into the United States; therefore, this practice is known as “reimportation.” Municipal and state governments throughout the United States have begun establishing programs to help Americans buy drugs from Canadian sources with the expectation that these programs will result in substantial savings.\textsuperscript{7-9} For example, Minnesota’s program, which allows state employees and their dependents to obtain certain prescription drugs from Canadian sources with no out-of-pocket costs, is estimated to save the state $1.4 million by the end of 2005.\textsuperscript{10} More dramatically, if all prescriptions for participants of Illinois’ employee and retiree health benefits program were to be filled from Canadian sources, the state estimates that it could save more than $90 million annually.\textsuperscript{11}

The US Food and Drug Administration (FDA) opposes the practice of drug reimportation on the grounds that it is unable to ensure the safety of Canadian medications.\textsuperscript{12} In addition, drug companies oppose reimportation because they stand to lose profits and argue that reimportation will eliminate incentives for research and development (R\&D). Some drug companies have restricted the quantity of drugs supplied to Canadian pharmacies that sell to Americans\textsuperscript{13-15} and others have threatened to follow suit.\textsuperscript{16} While this has successfully forced some Canadian pharmacies to stop supplying US customers,\textsuperscript{17} it has also prompted a seniors’ federation in Minnesota to bring an antitrust lawsuit against 9 drug companies. The suit alleges that by restricting supplies to some Canadian pharmacies, the companies are forcing US consumers to buy drugs in the United States at unlawfully inflated prices.\textsuperscript{18}

The implications of drug company practices for Canadians are potentially profound—not only does limiting supply threaten access to drugs, it may also drive up their cost. As a result, Canadian advocacy groups have called for a ban on online pharmacies that sell drugs to Americans.\textsuperscript{19,20}

The purpose of this article is to provide a perspective on the cross-border drug debate. Our 3 specific objectives are to demonstrate that the safety concerns raised by the FDA appear to be unfounded in the case of Canadian imports; to discuss how importing drugs from Canada will not necessarily threaten R\&D because drug company profits are large; and to outline what the Canadian government’s response to reimportation might be and, thereby, to demonstrate why reimportation is a poor policy choice if America’s goal is to reduce costs.

Safety First

The FDA has been a clear opponent of the reimportation of drugs from Canada and other countries, citing concerns about its inability to ensure the safety of these products and, accordingly, to protect Americans from harm.\textsuperscript{12} Critics suggest that the FDA’s position is really a reflection of the considerable pressure it faces from US pharmaceutical companies to keep profits high.\textsuperscript{21} It is certainly the case that the FDA has a regulatory mandate to ensure drug safety. However, there are several specific reasons to suspect that the FDA’s concerns about the safety of Canadian drugs are exaggerated.

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First, the medications imported by Americans from Canadian sources are largely the same drugs that Canadians use. Canada, through its FDA counterpart the Health Products and Food Branch of Health Canada, has equivalent procedures to those used by the United States for ensuring drug safety, including a rigorous drug approval process, importation and marketing procedures, and postmarketing surveillance.32 Accordingly, a State of Illinois report found that “the Canadian regulatory system provides substantially equivalent protection for the health and safety of the public as is provided for in the State of Illinois.”31 Moreover, Health Canada and the FDA recently signed a memorandum of understanding for closer collaboration, which makes the activities of these organizations even more similar.32

There is an important regulatory loophole that may place US consumers at some risk. Section 37 of the Canadian Food and Drugs Act states that “[t]his Act does not apply to any packaged food, drug, cosmetic, or device not manufactured for consumption in Canada and not sold for consumption in Canada;”24 i.e., drugs produced in Canada but not intended for consumption by Canadians are not regulated by Canadian authorities. However, this problem could be fixed by bringing these products under US jurisdiction. Both the North American Free Trade Agreement25 and the proposed Pharmaceutical Market Access and Drug Safety Act of 200426 appear to allow for this.

Second, as evidence for the lack of safety of imported drugs, the FDA cites a series of “blitzes” it has conducted that found that “potentially hazardous” products are entering the United States.27 Examples of violations included the importation of products that have potentially serious adverse effects (eg, warfarin), that require frequent monitoring (eg, levothyroxine), or that did not meet FDA standards of labeling or packaging. While these infringements do represent potential problems, issues of labeling and packaging can be addressed and there is little evidence that they otherwise threaten patient safety any more than, for example, medications bought from legitimate US online pharmacies.

In fact, the General Accounting (now Accountability) Office recently conducted a study of online pharmacies in Canada, the United States, and other countries and found that the samples purchased from Canadian and US pharmacies had comparable chemical compositions to FDA-approved medications.28 Moreover, all 18 of the Canadian pharmacies from which purchases were made required prescriptions, while only 5 of 29 US pharmacies did.29 Health Canada found similarly high standards of safety from a sample of Canadian pharmacies that sell drugs via the Internet or distance dispensing.29 It is possible, of course, that some online pharmacies claiming to be Canadian are actually located in another country. However, at the very least, pharmacies formally endorsed by state and municipal reimportation programs are all licensed by a Canadian province, and as for online pharmacies in the United States, are accredited by Verified Internet Pharmacy Practice Sites programs.30

Third, the FDA is concerned that importing drugs from other countries may increase the number of counterfeit products to which US consumers are exposed. The uniform pricing for drugs in Canada to different groups within the healthcare system (eg, hospitals, physician offices, retail pharmacies) results in a limited secondary market, thus reducing the opportunity for the production of counterfeit products.30 In contrast, the high retail profits in the United States and the movement of drugs through multiple vendors create both incentives and opportunity for counterfeiting.31 Certainly, significant increases in the volume of drugs exported from Canada to the United States might create new incentives for Canadian resellers to produce counterfeit products. The safeguards set forth by the reimportation proposals before Congress and municipal and state programs should protect against this.

Fourth, drug companies are multinational firms that produce drugs in many countries and frequently produce all of the worldwide supplies of a given drug in one country. For example, Lipitor and Viagra are manufactured exclusively in Ireland.31 Accordingly, many brand-name drugs sold in Canada are produced by US manufacturers in FDA-approved facilities and are equally safe as drugs consumed currently by Americans.31 Moreover, the term reimportation, while technically correct, does not reflect the true nature of global drug manufacturing. This situation is really no different than that of a US shoemaker producing a given shoe line in Asia and then shipping these shoes to the United States for sale. Therefore, it is not surprising that drug companies do not cite safety concerns when discussing their opposition to drug reimportation; this would be a damnation of their own products.

**Profits or Progress?**

Drug reimportation represents a substantial departure from the existing structure of the North American pharmaceutical market. Normally, patents allow drug manufacturers to set prices, which are often well above their current production costs, without experiencing substantial reductions in sales.32 Because different countries have different price sensitivities (willingness to pay) for drugs, the prices set by drug manufacturers are not the same in different markets. “Drug arbitrage,” the purchasing of drugs in one market to sell at a profit in a higher-priced market,33 would normally take place when price differentials exist. In the case of the pharmaceutical industry, arbitrage is prevented by regulatory processes, such as those imposed by the FDA, and by industry behavior, such as selling equivalent drugs in different countries under different names, in different packaging, and in slightly different formulations.

Drug makers argue that the reimportation of drugs from Canada should be prevented because high drug prices in countries like the United States are important for the purpose of funding R&D. The position of drug companies is defended by those who agree that price controls will limit

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innovation and by economic theory, which asserts that the high fixed costs of drug development are most efficiently covered when the differential price sensitivities of buyers are exploited. Furthermore, there is evidence that drug company profits and outlays on R&D are related.  

However, the evidence linking drug prices to innovation is limited and many argue that drug prices and drug company profits could be safely reduced without removing existing incentives for innovation. Several lines of reasoning support this view. First, the cost that drug companies incur for the development of each successful new drug, commonly quoted to be approximately $800 million, is likely significantly exaggerated, and, therefore, equivalent incentives for innovation would still exist at lower levels of profits. Second, drug companies make substantial profits from new formulations and new mechanisms of delivering existing drugs that cost significantly less to develop. The reported costs of innovation fail to take these revenues into account. Third, drug companies often reap the rewards of taxpayer-funded research. The National Institutes of Health (NIH) contributed funding for the development of a majority of the most clinically significant drugs created between 1965 and 1992. More recently, the General Accountability Office estimated that NIH contributed $484 million or approximately one third of the money required for the development of Taxol, a drug for which Bristol-Myers Squibb had total worldwide sales of more than $9 billion. Fourth, drug companies are consistently among the most profitable US industries. According to the Office of Technology Assessment, “the financial rewards from R&D have more than offset its costs and risks” and the economic returns to the pharmaceutical industry as a whole exceed returns to corporations in other industries by 2% to 3% per year.  

Large institutional purchasers within the United States, such as Medicare, Medicaid, and the Veterans Health Administration (VA), already obtain substantial discounts from drug manufacturers through formulary negotiations and other mechanisms, and despite this, innovation persists. Of course, the effects of discounting drug costs to large US purchasers on R&D are not precisely known and the expected discounts obtained through reimportation programs are generally larger than the discounts that drug companies currently offer. However, discounts lead to higher volumes and, therefore, almost certainly contribute to higher drug company profits. A similar logic may follow from drug sales from Canada. A recent analysis suggests that if the share of imports of new prescriptions from Canada is reasonably high, pharmaceutical companies will be selling drugs to consumers who would otherwise not have purchased these medications.  

Eliminating drug company profits altogether would certainly also eliminate incentives for innovation. However, it does not necessarily follow that existing levels of profit and existing levels of R&D are optimal. If the presumption is correct that Americans will be hurt by price regulation, then it would seem that any barriers that currently prevent drug companies from raising prices and increasing profits should be eliminated. Why shouldn’t Americans opt for even higher drug prices to stimulate even more innovation, for example by granting drug companies longer patents? Of course, it is not clear how much benefit will be derived from additional innovation. Assuming that there is a tradeoff between sufficient profits and sufficient innovation, less innovation might be an acceptable outcome if prices on existing drugs were lowered. How do those who argue for the status quo know that the current balance is correct?  

In addition to efficiency concerns (ie, achieving the greatest amount of R&D at the lowest possible cost), the current system of drug pricing in the United States raises issues of equity. Just as with reimportation, arbitrage opportunities between buyers who obtain price discounts and those who do not is prevented by law. As a result, the price paid by individuals without drug coverage at retail pharmacies is 15% higher, on average, than the prices paid by third-party payers on behalf of those with drug coverage. These calculations do not include rebates from manufacturers and, therefore, disparities are likely to be even greater. The result is that individuals with the least insurance and the greatest drug needs, who are often unemployed or employed in low-paying jobs, pay the largest amount for drugs. As such, it is unfair that the burden of stimulating pharmaceutical company research is borne to the greatest extent by the most economically vulnerable Americans.  

Getting to the Real Problem  

Arguably, drug reimportation from Canada is safe for Americans and may not threaten new (important) drug innovation. Reimportation may be an attractive short-term solution for US consumers and politicians, and selling drugs to Americans may have short-term economic benefits for some Canadians—sales of drugs by Canadian pharmacies to Americans were estimated to have been $650 million in 2003. Nevertheless, importing drugs from Canada is not a viable long-term strategy to address America’s prescription drug problem.  

Canada accounts for only 2% of worldwide pharmaceutical sales, whereas the United States accounts for nearly 50%. If the practice of drug reimportation is adopted on a large scale, it is highly doubtful that there will be enough drugs in Canada to adequately supply the US market. In fact, since the threats by some pharmaceutical companies to limit or cut off the supply of drugs to Canadian pharmacies that sell drugs to Americans have already successfully altered the practices of these pharmacies, there appears to be little slack in the Canadian pharmaceutical market.  

It is unclear whether drug companies can be compelled to provide increasing supplies to Canadian pharmacies, although proposals before the US Senate attempt to do so. The Pharmaceutical Market Access and Drug Safety Act of 2004 proposes to explicitly prohibit drug companies from restricting supplies to entities that export drugs to the United
States. The Reliable Entry for Medicines at Everyday Discounts through Importation with Effective Safeguards Act of 2004 proposes to amend the Internal Revenue code to remove tax deductions for advertising expenditures of a drug manufacturer that does not certify that it has not taken any action to prevent authorized importation. This bill also proposes an increase in the tax credit for research activities for a drug manufacturer that makes such certification.

If adequate supplies of drugs are not available for Canadians, it is almost certain that increasing demand will cause the price of pharmaceuticals in Canada to increase. Canadian residents would have a significant incentive to sell limited supplies of drugs to the United States at a higher price than they would normally sell to Canadians. A similar phenomenon was observed when the European Union became a single market. In addition, drug companies may attempt to renegotiate the prices set by the Patented Medicine Prices Review Board in Canada. Overall, this would result in limitations on the cost savings that reimportation offers to Americans.

More likely, as has recently been suggested, the Canadian government will ban drug exportation altogether before prices in Canada increase. The governments of other countries from which drugs may be imported, such as Australia and the European Union, will likely follow suit. That would put an end to reimportation.

So what then should America do about high drug prices? Generally speaking, drug costs may be controlled either by increasing the purchasing power of consumers (eg, through formularies and purchasing cooperatives) or by imposing explicit price or profit controls. The role of price lowering strategies in the United States has been hotly debated and mirrors traditional tensions in US politics between regulatory and market-based approaches to control expenditures. Many policy experts caution that all methods of price setting are fraught with practical challenges, especially in situations where drugs are patent protected and have no substitutes and the potential exists for political abuse in times of budgetary pressures. The empirical evidence suggests that price controls have effectively constrained drug prices. Where price controls fall short is their impact on long-term drug expenditure—which has increased steadily even in jurisdictions with price controls—as lower prices may lead to higher rates of potentially inappropriate drug utilization.

In contrast, programs based on preferred drug lists and incentive-based formularies, with tiered co-payments or refills, may offer a more practical solution to deal with this problem. Opponents to reimportation argue that drugs from other countries are un

safe and will eliminate incentives for drug companies to develop new drugs. We contend that even though these concerns appear to be overstated, the responses of foreign governments will limit the benefits of arbitrage. Accordingly, difficult choices must be made to balance the competing policy objectives inherent to the prescription drug market. Fundamentally, the United States must decide how to simultaneously maintain access and innovation. Unfortunately, it is clear that reimporting drugs from Canada is not the answer.

Funding/Support: Dr Choudhry is funded by a Pharmaceutical Policy Research Fellowship from Harvard Medical School and a Canadian Institutes of Health Research postdoctoral fellowship. Neither of the authors has any financial conflicts of interest related to this article.

Role of the Sponsors: The funding agencies had no role in the conception, conduct, data collection, analysis, interpretation, writing, or approval of this article.

Acknowledgment: We are grateful to Joseph Newhouse, PhD, Robert Evans, PhD, Sujit Choudhry, LLB, LLM, Meredith A. Goldwasser, ScD, and Allen Kachalia, MD, JD, for helpful comments.

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