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Do Drug Makers Lose Money on Canadian Imports?

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Summary

Drug makers and others persistently assert that importing prescription drugs from Canada would damage drug makers' profits and their capacity to finance research. This view is widely accepted. Importing proponents have not generally questioned this view but instead focus attention on the clinical and financial benefits of lower drug prices.

But what if importing drugs from Canada does not harm drug makers' profits? This data brief questions and explores the premise that importing necessarily means lower profits.

Lower Canadian prices let some Americans fill prescriptions that otherwise go unfilled. We find that if new prescriptions' share of imports is 44.53 percent or more, importing actually increases drug makers' profits. This is the point at which the profit lost by drug makers when patients fill existing prescriptions at lower Canadian prices is exactly offset by the profit drug makers gain by selling new prescriptions through Canada. That share is not yet known empirically, but should be ascertained. New prescriptions' share of imports may be high enough today to prevent a loss of profits owing to importation.

This finding offers reason to hope that a combination of lower drug prices and higher volumes could address patients' and payers' needs for affordable prescription drugs while satisfying drug makers' needs for adequate profits and research financing.

Introduction

In response to rising drug costs, many Americans are filling their prescriptions in Canada. Manufacturers sell the same prescription drugs, often from the same factories, for much lower prices in other nations. In 2002, brand name drugs sold in Canada cost 40 percent less, on average, than did brand name drugs sold in the U.S.¹

A growing number of local and state governments support importation from Canada. Springfield, Massachusetts and Montgomery, Alabama help municipal employees and retirees import prescription drugs. Minnesota, Wisconsin, and New Hampshire have established web sites to help citizens import from Canada.² Illinois has petitioned the Food and Drug Administration to allow wholesalers and pharmacists to import.³

As a political response to high drug prices here, Congress authorized large-scale re-importing of U.S.-manufactured prescription drugs from Canada in October 2000.⁴ This law has been viewed by some, including President Clinton, as a ploy by a Republican Congress to neutralize the issue of high-cost prescription drugs just before the November 2000 election. The statute was attached to a large appropriations bill and was signed by President Clinton despite his belief that it was “an empty promise.”⁵ Indeed, such re-importing has never been allowed.⁶

The two main objections to buying more drugs from Canada have been that unsafe drugs will harm/endanger patients, and that drug makers and research will be seriously hurt by the loss of much revenue and profit.

Most of the attention has focused on the first objection, but little on the second. Indeed, although it has been taken for granted that drug makers lose money on imports from Canada, this has apparently never been examined empirically.

Background: The Problem of Rising Spending on Drugs in the U.S.A.

Spending on prescription drugs in the United States will approach \$250 billion in 2004.

It has doubled every five years since 1994, rising more than twice as fast as the rest of health spending during decade from 1994 to 2004.⁷

During these years, prescription drug spending has grown 4.5 times as fast as the economy as a whole.⁸

The U.S. provided the world's drug makers with roughly one-half of their world-wide revenue in 2002, up from about one-third in 1996.⁹

Medications Become Unaffordable for Many

Roughly one-quarter of Americans have no insurance for prescription drugs, and this share appears to be growing.¹⁰

Rising drug prices have for several years been associated with the erosion of prescription drug coverage under employers' retiree health programs—and even with the elimination of coverage under such programs.¹¹

Many Americans cannot afford to pay for the rising cost of their medications. Many do not ask for prescriptions, fail to fill prescriptions they receive, or take drugs less often than prescribed.¹²

According to a recent survey, one-third of Americans report that paying for medications is a problem.¹³

In a recent four-day period, two striking instances of cuts in private or public prescription drug programs were announced. Both cuts were said to be caused wholly or partly by high drug costs.

- Rising drug prices were implicated in placing some 800 AIDS patients in the U.S. on waiting lists for vital medications.¹⁴
- Two New Hampshire hospitals ended their program of subsidized drug purchases. They blamed a combination of low reimbursement rates and the rising cost of prescription drugs.¹⁵

Suffering ensues when patients are not able to afford valuable medications.

A Solution: Buying Drugs in Canada

As noted in the Introduction, many Americans have begun to buy medications in Canada and Congress voted in October 2000 to allow re-importation of U.S.-manufactured drugs from Canada if the FDA certified that it was safe and would save money. Such certifications have not been forthcoming.

Yet the savings are clear: This year alone, we estimate, Americans would save some \$59.7 billion by paying Canadian prices for brand name drugs.¹⁶

Those who oppose importing drugs from Canada make much of the issue of safety.¹⁷ But little evidence shows that importing would be unsafe.¹⁸ Rather, the evidence on importing's safety and clinical benefits to patients seems clear.¹⁹

In the face of both the massive dollar savings and the clinical benefits associated with importing, why does the FDA refuse to act to certify that importing is safe?

The reason seems to lie in fear of harm to drug makers' research financing or profits, not in direct risk to patients. FDA Associate Commissioner Peter Pitts said on 17 February

2004 that importing drugs from Canada would “undermine the innovation” of the U.S. drug industry. He said “We must keep the pump primed for research and development.” He added, “We depend on the cutting edge medicines produced by the companies that make the investment in science. These companies are in the business of improving health care, but they are also in the business of making profits.”²⁰

To estimate the possible financial harm to drug makers from importing, it is helpful to begin with estimated drug-buying from Canada.

How much will Americans spend this year to buy drugs from Canada?

Initially, drugs were bought by individuals traveling to Canada or Mexico. Subsequently, fax and internet purchases have become more common. Recently, drug importing from Canada, from all sources combined, has begun to grow rapidly.²¹ IMS Health estimated 2002 purchases by Americans from Canada at \$414 million and 2003 purchases at \$695 million, only one-third by individuals actually traveling there.²² These estimates are probably fairly crude, but the trend is clear.

And these figures may well be conservative. Another estimate for 2003 is that Canadian web and mail-order pharmacies alone sold \$1.4 billion to U.S. customers in 2003.²³

It is therefore reasonable to expect that U.S. residents will buy at least \$1 billion worth of drugs in Canada in 2004, and perhaps as much as \$2 billion or even \$3 billion.²⁴ In all likelihood, these will be overwhelmingly brand name drugs, not generics.

Even so, total purchases from Canada by U.S. residents will probably equal no more than one percent of prescription drug purchases within in the United States.²⁵ This suggests that drug makers’ concern stems not from the current level of importing, but rather from expected rises.

Will Importing Drugs from Canada Deprive Drug Makers of Financing for Vital Research?

Three groups of Americans—drug makers, their friends, and even some FDA officials—insist that lower drug prices, resulting from price controls or from importing drugs from Canada, will undermine financing for pharmaceutical research.

In 2000, for example, Tracy Baroni, senior director of policy for the Pharmaceutical Research and Manufacturers of American (PhRMA) said that price controls for prescription drugs “deter investors and that wipes out funds for drug research and development. ‘The lights go out in the labs and there is no R&D,’ “ she testified to a New Mexico legislative committee.²⁶

James P. Pinkerton, a fellow at the New America Foundation, was even more overt—and inflammatory—when he wrote in a March 2004 *Los Angeles Times* op-ed, that drug price controls could harm research, and that this could be “a matter of life and death for millions.”²⁷

Disturbingly, drug makers insist that high U.S. drug prices are essential to finance research,²⁸ and FDA officials agree. As noted earlier, Peter Pitts, FDA Associate Commissioner, said that importing drugs from Canada would “undermine the innovation” that U.S. drug makers conduct.²⁹

Baroni, Pinkerton, Pitts, and their fellow-frighteners are wrong.

The line they are selling should be called “PhRMA’s Fog of Fear.”

Many different things determine drug makers’ investment in breakthrough research, and the success of that research. And many people might think that, other things equal, higher profits would engender more research. We and others have addressed elsewhere questions of whether or to what extent drug makers’ profits and research are linked.³⁰

We have urged the negotiation of a prescription drug peace treaty, one that lowers prices substantially while assuredly replacing drug makers’ lost revenue through a combination of higher private market demand and publicly-subsidized purchases.³¹

Complaints and worries that imports from Canada harm research rest on apparently unexamined assumptions that allowing Americans to buy imported drugs at lower prices will reduce drug makers’ profits.

Do drug makers’ profits actually fall when U.S. residents buy in Canada?

Do Drug Makers Lose Money on Canadian Imports?

The answer to this question depends mainly on six things:

1. Comparative prices of brand name prescription drugs in the U.S. and Canada

Using data compiled by the Canadian Patented Medicine Prices Review Board, we have calculated that U.S. prices for brand name drugs were 67 percent above those prevailing in Canada in 2002. This means that Canadian prices are 40 percent below those in the U.S.³² And the gap has been actually widening.³³

The focus in this brief report is on brand name drugs—drugs still under government-granted patent monopolies—because international price disparities appear far greater for brand name drugs than for generic competitors. It is therefore brand name drugs that U.S. patients appear most likely to seek at lower prices in Canada and elsewhere.

2. Sources or manufacturers of the drugs that Americans buy in Canada

Nothing appears to be known publicly about which firms manufacture drugs sold in Canada to U.S. residents, so we make the neutral assumption that the sources and market shares are the same as for the mix of drugs sold in the U.S. This would mean that U.S. manufacturers' share of the market for Canadian drugs sold to Americans is similar to their share of the market for drugs sold to Americans in the U.S.A.

3. What share of the imports represents new sales for drug makers? In other words, what is the division of prescriptions bought in Canada between

- replacements or substitutes for old prescriptions, those previously purchased in the U.S. and now bought in Canada, and
- new sales, prescriptions that patients were previously unable or unwilling to buy at the higher U.S. prices but now buy in Canada?

This division vitally influences the answer to the question before us, whether importing drugs from Canada reduces drug makers' profits. There does not yet appear to be information on how prescriptions bought in Canada by U.S. residents are divided between replacement (old) and new prescriptions. In the work that follows, therefore, we provide several alternative analyses that posit different old/new splits. (Please refer to Exhibit 2.)

4. Average prices of old and new prescriptions

We make the neutral assumption that the average manufacturers prices are the same for the replacement/old prescriptions bought in Canada and the new prescriptions bought in Canada. We see no reason to assume otherwise.

5. Retailers' (pharmacies') share of the prescription drug dollar

We make the neutral assumption that pharmacies' share of the prescription drug dollar is the same for drugs that Americans buy in the U.S. today and for drugs that Americans import from Canada today. (In the U.S., today, retailers on average retain 21.1 percent of the sums paid for prescription drugs.³⁴)

Because the sum going to drug makers in Canada is substantially lower for each prescription than in the U.S., the pharmacy cost, if all else is equal, would tend to be a larger share of the drug's retail price. One source of data on Canadian pharmacy markups estimates that dispensing fees represent about 25 percent of total prescription drug cost.³⁵

But another factor is likely to reduce pharmacy costs for the imported prescriptions. Since two-thirds of the prescription drugs bought by Americans from Canada are reported to be via web or fax, as mentioned earlier, the associated pharmacy costs can be expected to be lower than for the average retail pharmacy source in the U.S. Web-

reliant pharmacies do not need costly retail space and they might gain efficiencies through large-scale dispensing.

So we make the neutral assumption that those two factors largely offset each other, and thus that the pharmacy share of Americans' drug purchases from Canada is comparable to the pharmacy share in the U.S.

6. The incremental cost of manufacturing and distributing higher volumes of prescription drugs

It appears that the incremental cost of making more pills, once the research is done and the factories are built, is very low. We estimate it at 6.6 percent of manufacturer's price in the U.S.³⁶ We conservatively estimate the added burden on manufacturers of distributing the higher volume of medications at 3.3 percent of manufacturer's price in the U.S.³⁷ Production and distribution then sum to 9.9 percent of manufacturer's price in the U.S.

In the analysis that follows, drug purchases in Canada are valued in Canadian dollars. Revenue on new prescriptions—higher volumes of prescriptions—must therefore reflect Canadian prices. Drug makers' prices on brand name drugs in Canada are approximately 59.88 percent of those in the United States.³⁸ We therefore divided the 9.9 percent manufacturing and distributing cost, as a share of U.S. prices, by 0.5988 to obtain their share of Canadian drug makers' prices. That manufacturing and distribution share is 16.5 percent in Canada. This is the figure employed in the following analysis.

Because the costs of providing additional medications are so low, any rise in volume of sales—any new prescriptions sold—will therefore be highly profitable for drug makers.

Profit, of course, is revenue less costs. Please note that, in the following estimates, we address incremental changes in volume for drug makers. Their factories are already built and existing sales are covering their costs, including research. There is no reason to assume that incremental volume would require or prompt drug makers to proportionally increase spending on, for example, advertising, administration, lobbying—or research. In these straightforward calculations, therefore, we identify the difference between new revenue and the marginal manufacturing plus distribution costs as profit.

Another point regarding profit: We refer here to concerns raised by the industry and others that lower-priced imports might diminish drug makers' profits and thus reduce their financing for research. Although drug makers' profits and research funding are often mentioned together, it is worth recalling that the industry's high published rates of return reflect profits that remain *after* drug makers have paid for all of their expenses, including research expenses. Those reported profits are not sums that must still be tapped to finance research.

The Core Analysis

We have calculated that if 44.53 percent or more of the money spent for prescriptions bought by Americans in Canada is for new prescriptions, those not formerly purchased in the United States, the drug makers actually make more money when importation is allowed.

In other words, drug makers' profits will rise if no more than 55.47 percent of drugs bought from Canada by Americans are replacement prescriptions.

The 44.53 percent new prescription share is the point at which the added profits from selling more drugs from Canada, even at discounted Canadian prices, offsets the loss in revenue on forgone sales of high-price U.S. drugs.

If more than 44.53 percent of drugs bought by Americans from Canada are new prescriptions, drug makers' profits actually rise owing to importing.

1. It will be helpful to examine this calculation line-by-line. To illustrate the process concretely, we follow \$C1 billion (Canadian) in brand name drug purchases by Americans from Canada. The same calculations would apply for each \$C1 billion in prescription drug purchases by U.S. residents.

Line 1 in Exhibit 1 simply indicates that we will be tracking this \$C1.0 billion

2. We calculated the effect of various splits of the \$C1 billion, as will be shown later. We found that a division of 55.47 replacement/old prescriptions and 44.53 new prescriptions would exactly balance revenue loss on existing prescriptions with revenue gain on new prescriptions. We call this the break-even split.

A 55.47% share of \$C1 billion means \$C554.7 million spent in Canada by Americans on replacement prescriptions.

Line 2 simply indicates that if 55.47 percent of the prescriptions bought in Canada by Americans are replacement prescriptions, drug makers will break even when patients import drugs from Canada.

3. But, as we know, brand name drug makers' prices are, on average, 67 percent more in the U.S. than in Canada for the same drugs. So, if Americans make replacement purchases of \$C554.7 million from Canada, the drug makers would forgo \$C371.7 million (67% of \$C554.7 million equals \$C371.7 million) in revenue.

Another way to look at this is that, if the \$C554.7 million in replacement prescriptions had actually been bought in the U.S., the cost would have been \$C957.7 million. (That is \$C554.7 million multiplied by the 1.67 price differential.) The difference between \$C957.7 million and \$C554.7 million is \$C371.7 million.

This assumes that other things are equal. And it ignores, for now, the rise in sales volume that would likely result from the price cuts.

Exhibit 1

**Drug Makers Break Even on Canadian Imports—
If New Prescriptions Are 44.53 % of Imported Drugs**

<u>Item</u>	<u>Dollars or %</u>	<u>Explanation</u>
1. Imported from Canada	\$C1.0 billion	Projected for 2004, at manufacturers' prices
2. % replacement prescriptions	55.47%	Break-even replacement prescription share
3. profit loss on replacement prescriptions	\$C371.7 million	Buying in U.S. would have generated 67% more revenue (67% of \$C554.7 million = \$C 371.7 million)
4. % new prescriptions	44.53%	Break-even new prescription share
5. profit gain on new prescriptions	\$C371.7 million	\$C445.3 million in new revenue, less \$C73.6 million in costs to manufacture and distribute the additional volume of medications
6. Change in drug makers' profits	\$C0.0	Line 3 minus line 5.

Line 3 shows the results of this vital calculation. It indicates the revenue loss to manufacturers when American residents replace a prescription formerly filled in the U.S., at U.S. prices, with a prescription bought in Canada, at Canadian prices.

This revenue loss on replacement/old prescriptions is \$371.7 million. Again, it is calculated by taking 67 percent of the revenue generated by the replacement Canadian sales, \$554.7 million. The 67 percent is the additional revenue that would have been garnered on these prescriptions, had they been bought in the U.S.—since U.S. prices for brand name drugs average 67 percent higher than Canadian prices.

4. We have calculated that if 44.53 percent of the prescriptions bought in Canada are new prescriptions, drug makers will break even when patients import drugs from Canada.

This 44.53 percent figure is displayed on **line 4**. This, like line 2's 55.47 percent, is the result of an empirical analysis. This 44.53 /55.47 division is the split at which the profit lost by drug makers when patients replace old prescriptions in Canada is exactly offset by the profit gained by drug makers from selling new prescriptions through Canada. In other words, this is the point at which the profit reduction on replacement prescriptions exactly equals the profit increase on new sales to Americans.

5. When 44.53 percent of the \$C1 billion in drugs bought by Americans in Canada are new prescriptions, drug makers garner \$C371.7 in new profits.

If 44.53 percent of prescriptions sold from Canada to Americans are new prescriptions, that translates into \$C445.3 million in revenue. Against this must be offset the added or incremental cost of manufacturing the additional volume of medications, which we estimate at 6.6 percent of manufacturers' price, and the cost of distributing the additional volume of medications, which we estimate at 3.3 percent of manufacturer's price.³⁹

Together, these costs sum to 9.9 percent. Dividing 9.9 percent by 0.5988 (the ratio of Canadian prices on brand name drugs to U.S. prices) yields 16.5 percent. Taking 16.5 percent of \$C445.3 million yields \$C73.6 million.

Subtracting the \$C73.6 million in higher cost from the \$445.3 million in higher revenue yields \$C371.7 million in added profit on new prescriptions.

Line 5 shows this \$C371.7 million in drug makers' profit gain from selling new, additional prescriptions from Canada.

6. Since the profit loss of \$C371.7 million (line 3) is exactly offset by the profit gain of \$C371.7 million (line 5), drug makers break even when the new/old split in drugs is in this 44.53 / 55.47 proportion.

Line 6 displays the difference between lines 3 and 5 as \$C0.0, zero.

Contingency Table

Drug makers' gains or losses on importing from Canada depend crucially on the split between replacement/old prescriptions and new prescriptions. Exhibit 2 displays the calculated gains and losses on \$C1 billion in Americans' purchases of Canadian drugs at different splits. For example, drug makers' profits would fall by \$C670.0 million if 100 percent of prescriptions sold to Americans replaced prescriptions formerly filled in the U.S. At the other extreme, drug makers' profits would rise by some \$C834.7.0 million if 100 percent of prescriptions sold to Americans were new prescriptions.

Exhibit 2

Drug Makers' Profits Rise and Fall with the Old/New Prescription Split

Share of Americans' Purchases from		Rise or (Fall) in Drug Makers' Profits
Replacement/Old Prescriptions in Canada	New Prescriptions from Canada	in \$C Million
100%	0%	(670.0)
75%	25%	(293.6)
67%	33%	(173.5)
55.47%	44.53%	0
50%	50%	82.3
33%	67%	338.1
25%	75%	458.5
0%	100%	834.7

Learning More about the New/Old Split

The split of drugs currently bought by Americans from Canada between new prescriptions and replacement/old prescriptions is not known. It can be ascertained through surveys of patients. Then, the future split, in the event of routinized legalization of importing, can be projected. It will depend, essentially, on the extent to which American patients fill more prescriptions in response to lower prices, what economists call the price-elasticity of demand.

What is the price-elasticity of demand for prescription drugs—the percentage rise in volume in response to a certain percentage cut in price?

The RAND Health Insurance Experiment, conducted during the 1970s, estimated the price-elasticity of demand for prescription drugs at around minus 0.3.⁴⁰ This would mean

that a ten percent drop in price, for example, would result in a 3 percent rise in volume of drugs purchased.

For a number of reasons, we believe that the RAND estimate of price-elasticity of demand for prescription drugs from the 1970s is too low today.⁴¹

1. Few medications with high annual costs, that could benefit older people, were available at the time of the RAND study—as compared with those available today. Few medications that patients would use daily for many months, many years, or their entire lifetime were then widely available or prescribed. That means it was hard for most patients to spend a great deal of money on medications that provided substantial or sustained benefits. This has already changed enormously. Patients for whom prescription drugs are made more affordable have much more reason now to increase their use of medications.
2. Given the prominence of prescription drug advertising on television and other direct marketing to patients, many more patients may be more inclined to use drugs today if prices are lowered.
3. The RAND Health Insurance Experiment did not enroll anyone over age 65 or anyone with substantial disabilities—that is, no one resembling the Medicare population.
4. Economists and actuaries who try to project use of very large new programs from the experience with narrow empirical studies, extrapolation from other populations, and the like, very often miss the mark badly. Recall the explosive growth in use of hospital, physician, and nursing home services in the wake of the passage of Medicare and Medicaid in 1965—growth far beyond what the best actuaries had predicted at the time. Recall the explosive growth in use of many health services in the United Kingdom after the introduction of the National Health Service in 1947.

Further, as an Australian government evaluation has observed, Pharmaceutical Research and Manufacturers of America (PhRMA) claims that “price controls do not reduce pharmaceutical expenditure, citing studies by Redwood in 1993 and Gross in 1994 that lower prices lead to a sufficient increase in the volume of drug sales to maintain the same level of revenue.”⁴²

Specifically, in its *Industry Profile* for 2000, PhRMA wrote that “A 1993 study by Heinz Redwood and a 1994 study by David Gross comparing international pharmaceutical-spending controls across countries found that while price controls produce lower prices, they do not reduce pharmaceutical expenditures (price times volume) or contain health care costs.”⁴³

Thus, in arguing against price controls in the past, PhRMA has apparently endorsed findings that price controls will not save purchasers money because the price reductions will boost sales volume sufficiently to replace the revenue that would otherwise be lost to lower prices.

If that applies to price controls, it also applies to importing drugs from Canada, since both mechanisms achieve lower prices.

For all these reasons, price-elasticity for prescription drugs may be sufficient that access to lower Canadian prices spurs Americans to fill very substantial numbers of new prescriptions—increased volume which entails very low cost for drug makers. Further, this new volume may generate enough profit for drug makers to offset their reduction in profits from those purchases at Canadian prices that replace higher-priced old prescriptions.

If so, drug makers' profits have not suffered a decline because of importation.

Conclusions

Importing medications from Canada would allow substantial numbers of Americans to obtain prescription drugs they cannot afford today. And the financial harm to drug makers may be surprisingly low. Indeed, drug makers could even benefit. The split between new and replacement prescriptions would largely determine whether profits rise or fall.

This raises hope that it is possible to win affordable medications for all Americans at a low added cost—essentially the cost of manufacturing and distributing more pills—without harming drug makers' capacity to finance research, or even their profits.

It is worth noting that 65 percent of Americans support importing and 71 percent of Americans favor allowing the government to negotiate with drug makers for lower prices.⁴⁴

It therefore appears that what is politically popular may also be in the interests of patients, payers, and drug makers themselves.

We do not mean to suggest that importing prescription drugs from other nations is the best or most durable method of winning affordable medications for all Americans while protecting and enhancing breakthrough pharmaceutical research.

Rather, importing has succeeded in providing more affordable access to prescribed drugs for some of those in need. Its expansion is widely supported politically. It has captured the imaginations of many beleaguered patients. And—because it may not pose the presumed threat to drug makers' finances—it may help the U.S.A. make a smooth transition to lower priced pharmaceuticals.

NOTES

¹ Alan Sager and Deborah Socolar, *Lower Prescription Drug Prices Are Vital to Both Patients and Drug Makers—But Instead, U.S. Prices Have Been Rising Rapidly Relative to Those in Other Wealthy Nations*, Health Reform Program, Boston University School of Public Health, Data Brief No. 3, 24 July 2003, www.healthreformprogram.org.

Calculated from data in Patented Medicine Prices Review Board, 2002 Annual Report, Ottawa: The Board, 30 May 2003, and earlier years. For the 2002 report, please see, <http://www.pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf>, access confirmed 24 March 2004.

² See, for example, “Minnesota Officials Send Letter to FDA about Plan,” Kaiser Family Foundation Health Policy Report, 11 March 2004, www.haisernetowrk.org; Mark, Hayward, “Benson Report Finds Canadian Drugs Safe,” *Union-Leader*, 25 March 2004; Christopher Rowland, “Canadian Drug Ban Defied in N.H.: State Website Links Public to Supplier,” *Boston Globe*, 6 April 2004.

³ Rod R. Blagojevich, “Citizen Petition to Provide Certification to Congress under Section 804 (I) of the Federal Food, Drug, and Cosmetics Act, and to Authorize a Pilot Program for Importation of Prescription Drugs in the State of Illinois,” Part C, filed 8 April 2004, Amendment of 21 *CFR* § 203.10.

⁴ Medicine Equity and Food Safety Act. Otherwise, by the provisions of the 1988 Prescription Drug Marketing Act, only drug manufacturers may re-import from other nations.

⁵ Cited in Demetrios L. Kouzoukas, “Rx Reimportation: A Legislative History,” www.heartland.org/article.cfm?artId=10669, access confirmed 25 March 2004.

⁶ That is because secretaries of Health and Human Services Shalala and Thompson have refused to certify that drugs could be imported from Canada in a way that would “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.” The 2000 statute required such certification before drugs could be re-imported by entities other than the manufacturers themselves.

⁷ We calculate and project a rise of 296.7 percent in retail prescription drug spending between 1994 and 2004.

⁸ Adding a six percent rise in nominal gross domestic product to the U.S. Bureau of Economic Analysis's 2003 GDP estimate yields a 65 percent rise in nominal GDP between 1994 and 2004. $2.967/0.65 = 4.56$. For BEA GDP data, please refer to <http://www.bea.gov/bea/dn/gdplev.xls>, access confirmed 16 February 2004. Assuming continued low inflation, the six percent nominal rise is roughly in line with the Mortgage Bankers' Association of America projection of a real rise in GDP in 2004 of 4.7 percent. See "Mortgage Bankers: US GDP To Grow Over 4% Next 3 Years," Dow Jones Business News, 22 January 2004, http://biz.yahoo.com/djus/040122/1305001257_2.html, access confirmed 16 February 2004.

⁹ 1997: IMS Health, "World Review, 15 Largest Pharmaceutical Markets in the World, 1997," www.ims-global.com/insight/world_in_brief/new_yearly/largest.htm, accessed 5 May 1999.

2002: IMS Health, "IMS Reports 8 Percent Constant Dollar Growth in 2002 Audited Global Pharmaceutical Sales to \$400.6 Billion," www.imshealth.com, accessed 26 February 2003.

¹⁰ Alan Sager and Deborah Socolar, *Affordable Medications for Americans*, Report for the Prescription Drug Task Force, United States House of Representatives, 27 July 1999, www.house.gov/berry/taskforce/taskforcestudies.shtml or www.healthreformprogram.org (see U.S. Health Reform, prescription drugs, reports).

¹¹ This is not surprising, since (with Medicare covering many other costs) more than one-half of retiree health plan costs are from prescription drugs.

¹² Harris Interactive, "Higher Out-of-Pocket Costs Cause Massive Non-Compliance in the Use of Prescription Drugs," 9 December 2002, www.harrisinteractive.com

¹³ Will Lester, "Almost a Third of Americans Say Paying for Drugs Is a Problem in Their Families," Ipsos News Center, www.ipsos-na.com/news/pressrelease.cfm?id=2064, 25 February 2004.

¹⁴ Lisa Richwine, "AIDS Patients Face Drug Barriers, Activists Say," Reuters, 6 April 2004.

¹⁵ Holly Ramer, "Reimbursement Rates Halt Drug Program," *Union-Leader*, 2 April 2004.

¹⁶ In 2001 U.S. Senate testimony, one of us estimated that Americans would save some \$38.4 billion on brand name drugs if manufacturers sold in the U.S. at Canadian prices.¹⁶

See Alan Sager, *Americans Would Save \$38 Billion in 2001 If We Paid Canadian Prices for Brand Name Prescription Drugs: How to Win Those Savings and Use Them to Protect All Americans against High Drug Costs without Hurting Drug Makers or Drug Research*, Invited testimony before the U.S. Senate Commerce Committee, Subcommittee on Consumer Affairs, 5 September 2001, www.healthreformprogram.org, published in United States Senate Committee on Commerce, Science, and Transportation, Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, *Comparative Pricing of Prescription Drugs Sold in the United States and Canada, and the Effects on U.S. Consumers*, Washington: U.S. Government Printing Office, 2003, pp. 71-86, <http://commerce.senate.gov/hearings/090501Sager.pdf>.

From 2001 to 2004, we estimate that retail drug spending will rise by 55.5 percent. Applying that increase to the figures included in that 2001 testimony, we project that Americans would save some \$59.7 billion in 2004 were we to pay Canadian prices.

These are the gross savings. They assume that Americans cease buying current prescriptions at U.S. prices and start buying at Canadian prices. There is no allowance for demanding greater numbers of prescriptions in response to the lower prices.

¹⁷ See, for example, "FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments," *FDA News*, P03-73, 29 September 2003.

¹⁸ See, for example, Tony Pugh, "FDA Lacks Examples of Canadian Drugs Harming Americans," Knight-Ridder Newspapers, 26 November 2003; David Espo, "United Health to Cover Foreign Drugs," AP, 11 October 2002; "Pharmacy Complaints Show None on Canadian Imports," *Fargo (N.D.) Forum*, 22 March 2004 (Associated Press); "Minnesota Officials Send Letter to FDA about Plan," Kaiser Family Foundation Health Policy Report, 11 March 2004, www.kaisernetwork.org; Mark Hayward, "Benson Report Finds Canadian Drugs Safe," *Union-Leader*, 25 March 2004; and Christopher Rowland, "Canadian Drug Ban Defied in N.H.: State Website Links Public to Supplier," *Boston Globe*, 6 April 2004. For supporting views from U.S. consumer organizations, see Susan Heavey, "U.S. Drugs Too Costly, Consumer Groups Tell Panel," Reuters, 22 March 2004.

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²⁰ In "FDA Warns that Effort to Import Canadian Drugs Could Hurt Innovation," *Sacramento Bee*, 18 February 2004, reprinted by PhRMA, www.phrma.org, 19 February 2004.

²¹ A December 2002 Harris Poll, asking people about the previous year, found, "Five percent (5%) of Americans are making drug purchases outside of the U.S. already, and 21% of those who have spent in excess of \$2,000 per year on prescription drugs have shopped abroad to find better drug prices."
http://www.harrisinteractive.com/news/newsletters/wshealthnews/WSJOnline-HI_Health-CarePoll2002vol1_iss3005666.pdf.

²² Bob Tedeschi, "Looking to Canadian Web Pharmacies for Savings," *New York Times*, 8 March 2004.

²³ Carol Ukens, "UH-OH, CANADA! U.S. regulators target the new gold rush — prescription drug imports from across the border," *Drug Topics*, 5 May 2003, www.drugtopics.com.

²⁴ CanadaRx estimate cited in Jerry Mekler, "Business profile: CanadaRx USA opens in Sebastian," *The Sebastian [FL] Sun*, 12 March 2004, www.tcpalm.com/tcp/the_sun/ (archived).

²⁵ We estimate total sales of prescription drugs in the United States in 2004 at roughly \$250 billion. This includes retail, hospital, and nursing home use.

²⁶ Tracy Baroni, senior director of policy, Pharmaceutical Research and Manufacturers of America (PhRMA), in Deborah Baker, "Many in Southwest Lack Drug Benefits: Study Urges States to Fight High Costs," *Albuquerque Journal*, 7 September 2000.

²⁷ James P. Pinkerton, "Reining in Prescription Prices Is a Seductive Idea. But It Might Kill You," *Los Angeles Times*, 18 March 2004.

²⁸ See, for example, PhRMA, "Imports Carry Risks," www.phrma.org/publications/publications/20.08.2003.832.cfm, access confirmed 12 April 2004.

²⁹ "FDA Warns that Efforts to Import Canadian Drugs Could Hurt Innovation," *Sacramento Bee*. This article was reprinted on 19 February 2004 on PhRMA's own web site, www.phrma.org.

³⁰ For example, see Alan Sager and Deborah Socolar, *A Prescription Drug Peace Treaty: Cutting Prices to Make Prescription Drugs Affordable for All and to Protect Research*, with State-by-State Savings, Boston: Health Reform Program, Boston University School of Public Health, 5 October 2000, www.healthreformprogram.org, pp. 27-31.

³¹ Alan Sager and Deborah Socolar, *A Prescription Drug Peace Treaty: Cutting Prices to Make Prescription Drugs Affordable for All and to Protect Research*, with State-by-State Savings, Boston: Health Reform Program, Boston University School of Public Health, 5 October 2000.

³² 1.0 divided by 1.67 = 0.59880.

³³ Alan Sager and Deborah Socolar, "Lower U.S. Prescription Drug Prices Are Vital to Both Patients and Drug Makers--But Instead, U.S. Prices Have Been Rising Rapidly Relative to Those in Other Wealthy Nations," Boston: Health Reform Program, Boston University School of Public Health, 24 July 2003, www.healthreformprogram.org. Calculated from data in Patented Medicine Prices Review Board, 2002 Annual Report, Ottawa: The Board, 30 May 2003, and earlier years. For the 2002 report, please see <http://www.pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf>, access confirmed 24 March 2004.

³⁴ Estimate for 2001-2 from National Association of Chain Drug Stores, "Industry Facts-at-a-Glance: Pharmaceutical Pricing," <http://www.nacds.org/wmspage.cfm?parm1=507>, access confirmed 12 April 2004.

³⁵ "Average Dispensing Fees," *Benefits World*, http://www.benefitsworld.com/AA/Drug/Presc/Average_DispensFees-by_Prov-Update%20071701.asp

³⁶ Alan Sager and Deborah Socolar, *61 Percent of Medicare's New Prescription Drug Subsidy Is Windfall Profit to Drug Makers*, Health Reform Program, Boston University School of Public Health, 31 October 2003. In that report, we employed an estimate of marginal manufacturing cost of 5.9 percent of a discounted retail price. See also Alan Sager and Deborah Socolar, *A Prescription Drug Peace Treaty: Cutting Prices to Make Prescription Drugs Affordable for All and to Protect Research*, with State-by State Savings, Boston: Health Reform Program, Boston University School of Public Health, 5 October 2000, www.healthreformprogram.org, pp. 25-26.

³⁷ The National Association of Chain Drug Stores reports that the wholesale share of the prescription drug dollar was 3.3 percent in 2002. See National Association of Chain Drug Stores, "Industry Facts at a Glance," <http://www.nacds.org/wmspage.cfm?parm1=507>, access confirmed 12 April 2004.

This is not a cost to manufacturers in the U.S.A., but we conservatively assume it is an added cost to manufacturers in Canada. It is designed to account for any possible added costs to manufacturers associated with distributing medications in Canada, but we recognize that these costs may, in reality, not exist.

Eliminating this cost slightly reduces the break-even old/new split, to 57.05 percent old / 42.95 percent new. This is an increase of roughly one and one-half percentage points in the old share of the split at break-even.

³⁸ 1.00 divided by 1.67 = 0.5988. This is the ratio of Canadian to U.S. prices. See Alan Sager and Deborah Socolar, "Lower U.S. Prescription Drug Prices Are Vital to Both Patients and Drug Makers--But Instead, U.S. Prices Have Been Rising Rapidly Relative to Those in Other Wealthy Nations," Boston: Health Reform Program, Boston University School of Public Health, 24 July 2003, www.healthreformprogram.org. Calculated from data in Patented Medicine Prices Review Board, 2002 Annual Report, Ottawa: The Board, 30 May 2003, and earlier years. For the 2002 report, please see <http://www.pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf>, access confirmed 24 March 2004.

³⁹ We have elsewhere estimated drug makers' marginal manufacturing cost at 5.0 percent of retail. See Alan Sager and Deborah Socolar, *A Prescription Drug Peace Treaty: Cutting Prices to Make Prescription Drugs Affordable for All and to Protect Research*, with State-by State Savings, Boston: Health Reform Program, Boston University School of Public Health, 5 October 2000, www.healthreformprogram.org, pp. 25-26. Dividing 5.0 percent by the manufacturers' share (75.6 percent) of the retail price yields 6.6 percent.

The National Association of Chain Drug Stores reports that the wholesale share of the prescription drug dollar in the U.S.A. was 3.3 percent in 2002. See National Association of Chain Drug Stores, "Industry Facts at a Glance," <http://www.nacds.org/wmspage.cfm?parm1=507>, access confirmed 12 April 2004. As

noted earlier in the text, we conservatively used this figure as a proxy for possible added costs to manufacturers of distributing in Canada.

Adding the 6.6 percent marginal cost of manufacturing to the 3.3 percent wholesale share yields a 9.9 percent deduction from the revenue that manufacturers garner on medications sold to American residents through Canada.

⁴⁰ For a summary of the RAND Health Insurance Experiment, see Joseph Newhouse and others, *Free for All? Lessons from the RAND Health Insurance Experiment*, Cambridge: Harvard University Press, 1993.

⁴¹ The following discussion is excerpted from Alan Sager and Deborah Socolar, *How Much Would Drug Makers' Profits Rise under a Medicare Prescription Drug Benefit? A Response to PRI/PwC's Undocumented and Disjointed Critique of Our 31 October 2003 Report*, 2nd Edition, Boston: Health Reform Program, Boston University School of Public Health, 12 April 2004, www.healthreformprogram.org.

⁴² PhRMA (Pharmaceutical Research and Manufacturers of America) 2001, *Pharmaceutical Industry Profile 2001*, Washington DC, <http://www.phrma.org/publications/publications/profile01/chapter7.phtml>. The citation, summarizing PhRMA's viewpoint, is from Productivity Commission, Government of Australia, *Evaluation of the Pharmaceutical Industry Investment Program*, Research Report, 14 February 2003, Chapter 3, p. 16, <http://www.pc.gov.au/study/piip/finalreport.rtf>.

⁴³ PhRMA, *Industry Profile 2000*, Chapter 7, p. 91 (formerly on PhRMA's website but no longer available).

⁴⁴ Will Lester, "Almost a Third of Americans Say Paying for Drugs Is a Problem in Their Families," Ipsos News Center, www.ipsos-na.com/news/pressrelease.cfm?id=2064, 25 February 2004.