

False solution:

Why Drugs From Canada Won't Cut Prices

By John Calfee

Drug prices are often cheaper in Canada, sometimes quite a bit cheaper. That is partly because Canadians are poorer, which is one reason why they also pay less for automobiles and computer software. But Canada also controls the prices of pharmaceuticals. That inspired Congress to pass a law in 2000 permitting drugs from American manufacturers to be reimported back to the U.S. from Canada at Canadian prices. That law never went into effect because the Department of Health and Human Services could not certify that mass reimportation would reduce costs without compromising safety.

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The FDA, which is part of HHS, said it would not be able to assure that reimported drugs would meet U.S. safety and labeling standards—or any other nation's standards, for that matter.

Earlier this year, the U.S. Senate passed another drug reimportation bill with even less safety protection, but the House of Representatives declined to go along. Reimportation is still an issue and a new bill will probably be introduced in 2003. In the meantime, AARP, along with some managed-care organizations and large pharmacies, have said they will tolerate or even encourage consumers to purchase drugs from Canada.

Consumers should understand how reimportation would work if it were actually put in place, because it would be a classic example of unintended consequences. In the short run, reimportation would do almost the opposite of what its

supporters expect. In the long run, reimportation could curtail the very research success that has made our pharmaceuticals the envy of the world.

There are two ways to import Canadian price controls. One is simply to require manufacturers to sell their medicines in the United States at the lower Canadian price. Most politicians do not support the idea of letting another nation dictate what prices our manufacturers can charge, however. Congress has pursued a second approach, which is to permit large-scale reimportation of drugs from Canada at Canadian prices. (This would require undoing a consumer protection law passed in 1987 to prohibit reimportation of drugs from Canada and elsewhere.) Either way, the idea is to get U.S. prices down to Canada's prices.

These plans raise four very big problems. First, drug safety could be seriously compromised, unless inordinate amounts are spent on monitoring drug imports. Second, U.S. prices would not drop to anything close to Canadian levels. Rather, Canadian prices would increase almost to U.S. levels. Hence reimportation would fail to achieve its primary goal, but it would have the side effect of upsetting our Canadian neighbors, whose health care system is perpetually in fiscal crisis. Third, frustrated congressional advocates of lower drug prices would look beyond Canada to other price-controlled nations, threatening to link our prices to theirs and triggering the same dynamics that raised Canadian prices and health care costs.

That in turn could easily lead to attempts to

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bring the U.S. health care system closer to European and Canadian systems—and their pervasive controls over drug prices. Finally, the specter of price controls would descend upon the U.S. pharmaceutical research enterprise, blunting incentives to spend the billions of dollars necessary to solve such tough problems as preventing Alzheimer's and curing cancer.

Safety. The most obvious problem with mass drug reimportation is safety. The FDA flatly says it cannot guarantee the safety of products whose precise origins and manufacturing facilities cannot be determined. Canada has a very competent drug authority, of course, along with responsible wholesalers, pharmacies, and health care providers, which is why drugs are safe in Canada. But if reimportation does what its supporters want it to do, the quantity of drugs moving through Canada will increase massively, by a factor of two or much more, because the U.S. population is nearly 10 times that of Canada. Canada has made clear that it will not monitor the huge shipments headed back to the United States, nor can it stop the movement through Canada of large quantities of drugs from other nations.

The FDA would no doubt halt these shipments unless Congress relieves it of responsibility for drug imports. Then the task of checking safety would fall to U.S. wholesalers, pharmacies, managed care, even individual patients, at a cost in terms of time and money that cannot be estimated but could be very large.

The Dynamics of Pricing. Even if safety can be assured, the real problem with reimportation remains. What would happen to drug prices? Not what reimportation supporters expect. To see why, let us suppose that reimportation legislation does what it is supposed to do, which is to cause U.S. drug prices to be the same as Canadian prices. What would those prices be? They would not be the old Canadian prices. Those prices were governed by government price ceilings, established by an arbitrary formula designed to let Canada free-ride on American research (which amounted to \$30.5 billion in 2001, vs. \$243 million in Canada).

Canada can get away with that as long as their government-controlled prices apply only to Canadian sales. Things would be different if the prices also applied to the much larger U.S. market. For example, consider the case of Vioxx, a popular arthritis pain treatment with \$2.03 billion in sales in 2001. Reimportation supporters have said that this drug sells for 43% less in Canada—i.e., at 57% of the American price. Let's assume that Canadians use about one-eighth as much of this drug as Americans do. Revenues in Canada would

then run at 57% of one-eighth of U.S. revenues, or about \$145 million.

What will the manufacturer do if it is told that its Canadian price will govern U.S. sales? If it continues to ship drugs to Canada at the old Canadian price, set by the price review board, the manufacturer will have to cut its U.S. prices by 43% and its revenues by the same proportion, about \$873 million. Or, the manufacturer could refuse to ship drugs to Canada. Then it would lose \$145 million in Canadian sales but could continue to sell in the United States at U.S. prices, thereby

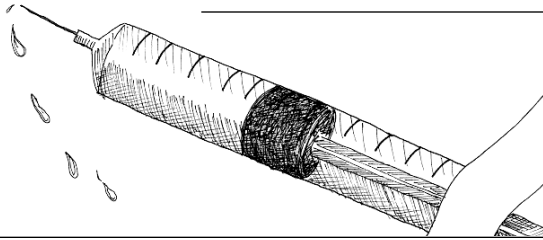
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avoiding the \$873 million reduction in U.S. revenues. The choice is clear, and Canada would find itself without cheap U.S. drugs. Canadian authorities would have no choice but to raise their price to something close to the U.S. price. The same process would apply to other drugs, of course.

The likely result: Our prices would go down very little, but Canadian prices would go up a lot. The fiscally stressed Canadian health care administrators would probably be furious at having to increase their pharmaceutical budgets. Canada would probably respond with a reimportation plan of its own, bringing in large volumes of American-origin drugs from other nations, some of which have even lower price ceilings.

This arrangement may not sound so bad for us. True, reimportation wouldn't generate lower prices, but at least it would force Canadians to pay a fairer share of R&D costs. But we would also have a very strange pharmaceutical pricing system. A large proportion of pharmaceutical prices would be governed not by the marketplace but by a price list published by Canada's Patented Medicine Price Review Board. That would bring another problem, one that seems obscure but could be quite important in practice.

Pharmaceutical firms negotiating drug prices with managed care and other bulk buyers in the United States would know that if they ever cut prices below the new, much higher Canadian prices, they could trigger renewed scrutiny of prices and a new round of negotiations if the Canadian authorities found out. That would strongly inhibit the under-the-table discounting that drives pharmaceutical price competition today. When Congress passed a law a few years ago requiring



manufacturers to give Medicaid the lowest price it gave to managed care, the result was to inhibit competition and raise prices for managed care.

The Dynamics of International Drug Politics. But that is far from the end of the story, because politics would probably introduce yet more complications. Congress would have placed its stamp of approval on the principle that controlled prices in foreign nations should trump market-driven domestic prices. Politicians, activists and consumers who had expected drastically lower pharmaceutical prices—and failed to get them—would shift their gaze to prices in Mexico and Europe. Then what? Mexico would not be a promising target because it constitutes a small market, its prices reflect the relative poverty of the nation, and drug safety does not approach the high standards of Canada.

European nations are a different story. Most of them also free-ride on American research by controlling pharmaceutical prices, and many of their prices are even lower than Canada's. Having tried and failed to cut prices through its Canadian initiative, Congress would face intense pressure to do something about the disparity between what Europeans and Americans pay. It could respond either with a broader reimportation law—which under WTO rules would have to apply equally to all European nations, including exceptionally low-price nations such as Spain and Greece—or with legislation requiring manufacturers to match their lowest European prices.

Either approach would trigger high-stakes negotiations between pharmaceutical firms and the governments of the lower-price countries. Everyone would know what had happened to Canada, and much the same would happen again. Manufacturers would refuse to sacrifice revenues in the huge U.S. market in order to satisfy the demands of price controllers in much smaller European markets. The outcome of these bitter negotiations would not only determine pharmaceutical prices in the U.S. and many European nations, but would also strongly affect the budgets of government-financed European health services, which like Canada's are always in financial crisis. It would be difficult if not impossible to separate these negotiations from international diplomacy.

These circumstances could foster a coalition consisting of Americans who advocate and expect

lower drug prices, joined by Canadian and European health officials appalled at the prospect of ballooning pharmaceutical budgets in their financially strapped health-care systems. This coalition might say—as some do now—that the United States should adopt the kinds of price controls used in Canada and Europe.

The Specter of Price Controls. An attempt to impose European-style price controls is the logical endpoint of current attempts to link U.S. and Canadian prices. Price controls would have catastrophic effects on future research. This is a necessary result of how pharmaceutical price controls work. It is only after a breakthrough drug is ready, after years of research typically costing hundreds of millions of dollars, that Canadian and European governments decide how much the inventors of the drug will be allowed to charge. With patients and health-care providers eager to use the new lifesaving treatment but far from eager to pay their share of its true cost, politicians and price regulators have little incentive to take into account the full research costs. They figure that all they have to do is set the price high enough to cover manufacturing and distribution costs, and the medicines will come to their market.

Now look at this process from the perspective of a research firm—a biotechnology firm, for example, to cite a precarious new industry that has already contributed several lifesaving therapies. How could firms trying to solve the riddle of gene therapy attract billions of dollars in venture capital, if investors know not only that most firms working on gene therapy will fail, but in addition, that the few firms that succeed will have to deal with a price-setting bureaucracy that has an overwhelming incentive to give patients cheap prices once the research has been paid for and the drug is ready for the market?

The pernicious effects of price controls are already apparent in Europe, which dominated the pharmaceutical industry before controls were adopted in most European nations in the 1980s. Between 1988 and 1998, U.S.-based manufacturers increased their share of the top 50 drugs worldwide from 19 to 33. In 1999, they sold eight of the top 10, and a well-known market research firm predicted that in 2002, European manufacturers will produce only about four of the top 25 drugs. Moreover, firms that have always been based in Europe (such as Smith-Kline-Beecham) have moved most of their operations to the United States. Our superior overall business environment must be a factor, but surely these shifts also reflect the advantages of developing new drugs in the only large market that can be expected to reward innovative pharmaceutical research solutions to our greatest health problems. 