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Director
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket #2004N-0115

Dear Director:

The issue of pharmaceutical prices, price controls, and importation from Canada is a critical issue that policymakers cannot afford to get wrong.

As an economist, I often find myself in the unenviable position of advising people that well-intentioned and seemingly clever solutions won't, in practice, achieve the desired results. I'm afraid that's exactly the case with efforts to import pharmaceuticals from Canada. The proposed policies cannot deliver the promised less expensive drugs for any sustained period of time.

The reason pharmaceutical are less expensive in Canada is because of government price controls. If U.S. policymakers want Canadian prices on pharmaceuticals, it makes little sense to import them. They should declare that the government is better able to price these important products than the individual companies that develop and produce them, and implement and take responsibility for domestically set price controls.

However, experiences with price controls are not generally happy—they produce shortages, extinguish new investment and product development, kill jobs, and push people to alternate, illicit sources of supply. So our politicians prefer to frame the issue as one of free trade.

Basic math shows policymakers can't import price controls through the back door. Canadians consumed roughly $14 billion in pharmaceuticals in 2003. In 2003, U.S. residents consumed $216 billion in pharmaceuticals. Asking Canadian pharmacies to supply the California market is equivalent to asking Lake Mead to supply the entire nation's water supply.

The effects would be the same: shortages of a necessary product and sky-high effective prices. In the case of pharmaceuticals, U.S. residents would be forced to enter illicit markets to secure needed drugs. After studying the issue, the Congressional Budget

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Office concluded in April of this year that "the reduction in drug spending from importation would be small."

This basic supply imbalance holds many implications. In so far as the pharmaceuticals shipped south are indeed Canadian in origin, the now illicit trade puts pressure on the domestic market in Canada. That's a concern of the Canadian Association of Pharmacists, which recently conducted a survey in which three in four respondents reported that supply problems in Canada are increasing.

It's also a concern of the Canadian International Pharmacy Association, which represents the burgeoning industry of Internet pharmacists that earn handsome profits buying north of the U.S. border and selling south. The association's president, David McKay, has informed state and municipal officials seeking to relieve pressure from state budget deficits and Medicaid budgets that Canada simply can't provide the supply for their pharmaceutical needs. California's public sector alone could purchase nearly half of Canada's total supply of pharmaceuticals.

Perhaps even more worrisome would be the situation in which significant quantities of pharmaceuticals were imported from Canada with no effect on the Canadian market. This would indicate that the drugs were not sourced in Canada, and therefore subject to the standards of Canadian inspectors, but merely transshipped through our northern neighbor from some other country such as China, Pakistan, South Africa, Iran, just to name a few.

The information recently compiled by Giuliani Partners is instructive. In its interim findings, it reports that as much as 10 percent of the world's pharmaceutical supply is counterfeit, according to the World Health Organization. It also reports, based on information from the Canadian government, that pharmaceutical imports to Canada have increased significantly from 2002 to 2003. Imports from China are up 43 percent, Iran 2,753 percent, and South Africa 84 percent.

Policymakers need to consider the effects of their actions on the future, not only the present. This principle was described by philosopher Frederic Bastiat in his famous 1850 essay, "That which is seen and that which is not seen." What will be seen is, of course, lower sticker prices for some pharmaceutical products. (Generics are already less expensive in the U.S. than patented drugs in Canada, also a result of the Canadian price controls on patented medicines.)

But there are many unseen effects. Pharmaceutical products, which on balance reduce overall health expenditures, take years and hundreds of millions of dollars to develop and produce. Price controls, whether imported or mandated, will reduce industry revenues and sap profits, which will result in significantly decreased levels of R&D spending and decreased employment.

Capital and talent migrate to where they are welcome. European price controls drove the pharmaceutical industry to our shores with a tremendous benefit to U.S. consumers, scientists, and the communities that were fortunate enough to house the industry. The U.S. should be careful not to repeat the same mistake and drive its world-class industry to more hospitable shores.

Value in the pharmaceutical industry derives from intellectual property. Policymakers need to be aware that the Canadian government reserves the right to confiscate the intellectual property of U.S.-based companies under the guise of "compulsory licensing" if companies don't act in a way that's acceptable to the government. Given the supply and demand imbalances between the Canadian and U.S. markets, this is a real threat should importation increase to levels that put greater stress on the Canadian market.

Finally, there is the issue of safety and the ability of U.S. citizens to seek redress should they be defrauded or harmed by tainted foreign supply. There can be little doubt that much of the product shipped south will be of high quality, correspond to its labeling, and basically fit for human consumption. There can also be little doubt that human nature combined with the gold rush nature of the Canadian importation business—the industry has exploded from two guys selling nicotine patches on the Internet in 1999 to 175 firms within three years—will produce scams that prey on the pocketbooks and even health of U.S. consumers. Random FDA and U.S. Customs inspections at ports of entry in 2003 found that nearly nine in 10 packages containing pharmaceuticals from foreign countries were not in compliance with U.S. regulations.

Spending taxpayer money to facilitate and regulate the trade will only partially address this issue, even as it cuts into the total cost savings. The other means is through the courts. Unfortunately for U.S. consumers, the Canadian Medical Association, which provides malpractice insurance for Canadian physicians—the organization best equipped to assess the risk of the country's nascent export business—has declared that it will not provide insurance for doctors who write U.S.-based prescriptions. This means that U.S. residents harmed by fraudulent, mislabeled or inappropriately shipped drugs—innocent or otherwise—will have no practical recourse.

In summary, allowing imported pharmaceuticals from Canada is not a solution to the perceived problem of high U.S. pharmaceutical prices. In practical terms, it cannot significantly decrease prices paid by U.S. consumers. By opening the supply chain to outside sources, it threatens to put the health of some U.S. consumers at risk. These consumers will have no legal recourse. In so far as this policy does divert significant product from the domestic Canadian market, it threatens the intellectual property of U.S.-based companies, the property on which the future of innovation and the livelihoods of millions of U.S. residents depend.

Based on the important facts about drug importation presented above, I strongly urge the FDA to oppose any proposed legislation allowing the importation of drugs from Canada.

The U.S. pharmaceutical industry develops innovative and life-enhancing drugs that allow us to live longer and healthier lives. It is essential that we make the policy decisions today that will allow the U.S. to continue to produce such innovation for many more years to come.

Sincerely,

Sally C. Pipes
President and CEO

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