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Summary: *Consumer groups and the media are putting pressure on public officials to allow U.S. citizens to reimport drugs from foreign countries like Canada. This report concludes reimportation programs or price controls would have a dramatic negative impact on drug development in the United States and, because it is home to a significant research center, on the economy of Massachusetts.*

The Impact of Drug Reimportation and Price Controls:

The U.S. and Massachusetts

By David G. Tuerck, John Barrett, Douglas Giuffre, and Zaur Rzakhanov

Motivated by the price difference between Canadian and U.S. pharmaceuticals, U.S. consumer groups and the media have been pressuring legislators both at the state and federal levels to lower domestic drug prices.

The most politically appealing approach so far has been some form of drug reimportation policy, in which brand name prescription drugs that are made in the United States and sold and shipped to other countries—usually at lower prices than U.S. citizens pay—are then sold and shipped (i.e., reimported) back to U.S. consumers.

Since reimportation is simply a way to import price controls from other countries without explicitly adopting them in the United States, the economic consequences of reimportation are roughly the same as directly imposing price controls.

Reimportation or price controls, while yielding lower drug prices in the short run, could have a significant negative impact on drug development and innovation, as well as on the regional economies in which the pharmaceutical and biotechnology industries play an important role, such as Massachusetts.

Drug price controls and reimportation schemes would shrink the pipeline for new prescription drugs by reducing the ability of companies to recover their investment in research and development. We estimate that, in the 12 years following the implementation of a price control policy:

- R&D spending by pharmaceutical and biotechnology firms would fall by $14.8 billion, in net present value terms.
- Price control policies would lead to the abandonment of an additional 262 drugs for economic reasons.

- Under a price control policy, only nine new drugs would likely be approved in a year—a decrease of more than 70 percent from the current average of 31.

In Massachusetts, where nearly 10 percent of the nation's pharmaceutical and biotech R&D dollars are spent:

- Price controls would destroy 3,957 jobs over the first six years.
- By 2010, the loss in economic activity (as measured by value-added) in Massachusetts would total $247 million (in 2000 dollars).

Moreover, there are concerns about the quality and safety of reimported drugs. While many patients assume that re-imported drugs are of U.S. origin, manufactured under the FDA's safety guidelines, a recent report by Giuliani Partners, LLC indicates that in many cases drugs purchased from Canada are manufactured in Pakistan, China, Iran, Singapore or elsewhere. The report points out that "there is significant evidence that patients have received drugs through the Internet that are past their expiration date, are sub-potent (or, in some cases, more potent than indicated), are contaminated or clearly counterfeited, are not properly stored or shipped."

Recent Attempts to Impose Reimportation and Price Controls

The United States forbids the reimportation of drugs except when the Secretary of Health and Human Services is willing to certify the safety and significant cost savings of the drug(s) to be reimported. Neither the current secretary, Tommy Thompson, nor the secretary during the Clinton administration, Donna Shalala, provided that certification. Nevertheless, consumer groups (and their elected representatives) wishing to reduce drug prices are actively attempting to bypass this obstacle.

Several cities and states are considering ways to permit or facilitate access to reimported drugs.

Springfield, Massachusetts is already importing drugs from Canada for city employees. The Springfield model could spread to other cities and even states, should the Food and Drug Administration continue to decline to intervene legally.

The governor and attorney general of Vermont have filed suit against the FDA for rejecting their plan to allow Vermont employees to reimport drugs from Canada. Iowa is considering joining the suit.

The governor of Illinois is moving forward with a plan to allow citizens of the state to reimport drugs from Canada, the United Kingdom and other countries—abandoning any pretext at restricting the drug sources to Canada. The mayor of Boston has indicated that he would like to adopt a similar policy.

Republican Senator Charles Grassley of Iowa introduced reimportation legislation in April 2004. Massachusetts Senator Edward M. Kennedy has sponsored a bill that would allow imports of prescription drugs from Canada, and Democratic presidential candidate John Kerry has called for legalizing reimportation. Even President Bush now agrees that, "If it's safe, then it makes sense."

Responses to Drug Reimportation and Price Controls

A possible response to reimportation is action by foreign governments, themselves eager to provide an abundant supply of price-controlled drugs to their own populations. One can hardly expect Canadian health care administrators to be complacent about growing shortages of drugs in Canada due to reimportation by Americans. Indeed, some Canadian officials are already looking for ways to curb exports to the United States.

Other possible responses are as follows:

- Price controls may encourage the development of gray or black markets in drugs, especially if certain states successfully impose price controls while others do not. To the extent that prices vary across regions, intermediaries will have an incentive to engage in spatial arbitrage—buying in a price-controlled state and selling in a non-price-controlled state.
- Pharmaceutical and biotech firms may respond to the lower relative price of drugs in the United States by selling less in the United States and more in other developed countries with no price controls (such as the United Kingdom and Germany), and to search for new markets where price controls are not present.
- Reimportation leads to the launch delay of major new drugs. A firm about to launch a new drug would do so promptly everywhere, if it could charge different prices in different national markets (taking into account levels of income, regulations and willingness to pay on the part of consumers). A 2003 National Bureau of Economic Research study points out that a firm's response to reimportation would be to "accept delay, and in the limit, forego launch entirely, rather than agree to a relatively low price in one country, particularly in a country that is small and prone to parallel exports to other, potentially higher-price markets." The authors found that countries with lower expected prices or smaller expected market size within the European Union experience longer delays in new drug access.

The Impact of Reimportation and Price Controls On Drug Innovation and R&D Expenditures

The cost of drug development has risen tremendously from slightly over $100 million per successful drug in the 1980s to about $800 million in 2003. The high cost of drug development is in part due to the high failure rate. Although only one in five projects makes it to consumers, all projects, both successes and failures, require a constant flow of cash, adding to the final cost of successful projects. Funds spent on the development of drugs that eventually fail safety or efficacy tests or prove to be potentially money losing are legitimate costs that successful drugs must recoup. Not being able to recoup all expenses (including those of eventual failures) would deprive companies of necessary funds to finance the search for new therapies.

Drug development projects are often abandoned for economic reasons (when the drug is no longer perceived to earn enough profits in the future).

According to the baseline assumptions in our model, a cohort reaching clinical trials, consisting on average of 130 drugs, could be expected to yield 31 new drugs. Under a reimportation or price control policy, this same cohort can be expected to yield only nine new drugs, a decrease of over 70 percent—suggesting the new policy could have severe consequences for drug innovation rates.

What is the effect of such a policy on the number of drugs abandoned after 2004? In Table 1, columns two and three indicate the number of drugs abandoned for economic reasons, per cohort, under the baseline conditions and with price controls for the period 2005-2016. For cohorts entering clinical trials from 1998 through 2016 under the baseline conditions, 323 drugs would have been abandoned. Under the new price control policy, approximately 585 drugs would be abandoned during this same period. Thus, during the first 12 years of the price control policy, an additional 262 drugs would be abandoned for economic reasons.

A drug abandoned for economic reasons due to the price control policy in the fourth year of clinical trials represents a loss of four drug years of R&D spending. Table 2 illustrates this difference by year and the associated difference in R&D spending. The key result of this exercise is that lost R&D spending, while moderate in the first year of a price control or reimportation policy, becomes substantial very quickly, as the cumulative effect of abandoned drug years grows with each new cohort entering development. In the 12 years following the implementation of a price control policy, R&D spending by pharmaceutical and biotechnology firms would fall by $14.8 billion in net present value terms.

Table 1 Drugs Abandoned for Economics Reasons, 2005–2016, by Cohort

Cohort Entering Clinical Trials	Baseline	Price Controls
1998	1.1	2.0
1999	2.2	3.9
2000	4.5	8.1
2001	7.6	13.8
2002	12.1	21.9
2003	20.7	37.4
2004	24.6	44.5
2005	26.9	48.7
2006	26.9	48.7
2007	26.9	48.7
2008	26.9	48.7
2009	26.9	48.7
2010	25.8	46.8
2011	24.8	44.8
2012	22.4	40.6
2013	19.3	35.0
2014	14.8	26.9
2015	6.2	11.3
2016	2.3	4.2
Total	**322.9**	**584.7**

Table 2 Annual Loss in Research and Development Spending, 2005–2016

Year	Total Lost Drug Years of R&D Spending	Lost R&D Spending *(millions, 2000$)*
2005	21.8	$310.85
2006	42.9	$645.56
2007	62.9	$986.82
2008	81.8	$1,297.07
2009	99.7	$1,578.04
2010	116.5	$1,828.98
2011	123.7	$2,245.96
2012	128.5	$2,396.30
2013	128.5	$2,554.11
2014	128.5	$2,554.11
2015	128.5	$2,554.11
2016	128.5	$2,554.11
Total	**1,191.8**	**$14,750.17***

*Net Present Value (5%)

Consequences of Reimportation and Price Control Policies for Consumers

Patent protection is a statutory monopoly granted by the state to encourage innovation. Without it generic drug manufacturers that invested nothing in discovery would offer the drug to consumers at deeply discounted prices immediately after its introduction.

Reimportation and price controls would have the same effect as eliminating patent protection because brand name drug companies would be forced to sell at prices equal (or close) to the manufacturing cost of a drug. Lower prices would decrease profits available for R&D investment and drastically lower the innovation rate.

The adverse long-run effects on consumers are twofold:

- All consumers would have fewer new drugs and therapies.
- Consumers who live in states housing a substantial number of pharmaceutical and biotechnology firms would be affected by lower investment in pharmaceutical R&D. Massachusetts is one such state.

The Impact of Drug Reimportation and Price Controls on R&D in Massachusetts

Massachusetts has effectively utilized its outstanding universities and academic medical centers to fuel its rapid growth in the biotechnology industry. Today the state is home to 280 biotech companies (including three of the nation's 10 largest) employing over 30,000 people. In 2001, R&D spending by biotech firms in Massachusetts totaled approximately $2.3 billion.

For every direct job created in the biotech industry, an additional two jobs are created throughout the rest of the economy. Based on this estimate, the total employment attributable to the Massachusetts biotech industry is on the order of 90,000 jobs.

Table 3 summarizes the cumulative impact on the state economy through the first six years of a price control policy.

Table 3 Economic Impact (Direct, Indirect and Induced) of Reduced R&D Spending in Massachusetts, 2005–2010

	Lost R&D Spending in Massachusetts (millions, 2000$)	Lost Value-Added (millions, 2000$)	Employment Loss in Scientific R&D Industries	Loss in Employment
2005	$30.42	$46.51	354	745
2006	$63.18	$94.53	720	1,515
2007	$96.57	$141.51	1,078	2,268
2008	$126.94	$182.21	1,388	2,921
2009	$154.43	$217.26	1,655	3,482
2010	$178.99	$246.89	1,881	3,957

The loss of R&D investment in Massachusetts has overarching ripple effects on the state's economy. The cumulative loss in employment for the period 2005-2010 is 3,957 jobs, many of these (1,881) in high-paying research positions. The lost R&D spending further results in a cumulative loss of $247 million in regional value-added.

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