Competitive Enterprise Institute
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Advancing Liberty – From the Economy to Ecology

April 24, 2008 **No. 136**

Drug Reimportation's Dangerous Allure

A Misguided Cost-Control Measure Guaranteed to Harm Patient Care

By Gregory Conko*

Despite the heated rhetoric emanating from the Democratic and Republican presidential campaigns, all three major party candidates seem to agree on one thing: that the prices of innovative new pharmaceuticals are unfairly high, and that costs could be controlled if only Congress would legalize the large-scale reimportation of drugs from countries like Canada, Britain, and elsewhere, where price controls make drugs more affordable.

However, such an approach is short-sighted, and implementing it as policy would have serious negative consequences for American consumers. Although reimportation would, in the short run, result in lower prices for drugs already on the market, in the long run it would reduce the capital available for drug research and, in turn, reduce the flow of new drugs developed and entering the marketplace each year. As Nobel Prize winner Milton Friedman and over 160 other economists have argued, "American consumers would get the short-term windfall of lower prices, but they would end up unnecessarily suffering and living shorter lives—because promising new therapies would be delayed or not even developed."[1]

High Development Costs. For many Americans, drug reimportation appears to hold the tantalizing promise of relief from high pharmaceutical costs. A lot of them are already purchasing drugs online from pharmacies purportedly in Canada—many of which are actually located in less developed countries and sell counterfeit knock-offs of dubious quality. Still, reimportation supporters believe the process is simple and cost-free. And the alleged ease of legalizing reimportation adds to its attractiveness. All that is supposedly necessary is a simple change in the law, making legal an activity in which thousands of Americans already engage. Doing so would allow American consumers to take advantage of the price controls instituted in other countries.

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Unfortunately, the solution to high drug costs is not so simple. Creating, testing, receiving regulatory approval for, and manufacturing pharmaceuticals are all hugely expensive. Economists Joseph DeMasi of Tufts University, Ronald Hansen of the University of Rochester, and Henry Grabowski of Duke University found, in 2003, that the average cost of developing a new drug totals roughly $802 million.[2] In 2006, economists at the U.S. Federal Trade Commission (FTC), skeptical that the price was really that high, conducted their own study of drug costs and arrived at an even higher estimate—between $839 and $868 million.[3]

Importantly, the FTC study also indicates that drug development costs are substantially affected by FDA overregulation. The FTC economists found, for example, that the average cost of developing a treatment for HIV/AIDS is around $479 million—much lower than the average for all drugs—in part because AIDS drugs have been regulated less severely than other drugs. That, in turn, results in substantially lower costs and faster times to market, with obvious benefits for patients.

Even though some new drugs eventually make billions of dollars for their manufacturers, most pharmaceuticals fail in laboratory tests or clinical trials before ever making it to market. When the expenditures on failed products and other capital costs of research and development are added in, the profitability of the pharmaceutical industry is not significantly greater than that of other comparable research-intensive industries.

In 2005, pharmaceutical firms in the Fortune 500 placed ninth out of the 50 industries ranked by return on assets, 12th in 2004, and second in 2003.[4] That gives ammunition to drug maker critics who accuse the industry of being unduly profitable. But, as the Congressional Budget Office (CBO) points out, "those figures misrepresent the industry's actual profits." Standard accounting measures overstate profitability for R&D-intensive industries by treating most research spending as an expense rather than as a capitalized investment that increases the company's value. "Not accounting for that value overstates a firm's true return on its assets,"[5] notes the CBO.

Ultimately, the high retail prices of pharmaceuticals reflect the vast expense of developing those products and getting them approved for sale. Without correspondingly high prices to enable the recoupment of those costs, few investors would willingly take the risks inherent in supplying capital to the pharmaceutical industry. The result would be fewer and fewer lifesaving medicines.

Danger of Importing Price Controls. Reimportation advocates ask: If this is so, why do pharmaceutical manufacturers sell their products at much lower prices in other countries? Clearly, they suggest, it is possible to sell drugs at lower prices and remain profitable. But this argument misses one important point: Because the United States is the only major country that does not impose drug price controls, the pharmaceutical industry can only remain profitable by charging uncapped prices here. In effect, American consumers are subsidizing consumers in countries that impose price controls by paying the full cost of drug industry research and development.

Some reimportation supporters acknowledge this conundrum. Indeed, they admit that reimportation does not offer a tradeoff-free cost-cutting option; it would eliminate this subsidy to foreign purchasers by forcing drug firms to cut off the supply of pharmaceuticals to countries that impose price caps.[6] Thus, since it is well known that free trade improves consumer well-being, they insist, it only makes sense to permit reimportation.

The ban on reimporting pharmaceuticals does appear, at first, to violate our national commitment to free trade. Several key factors, however, make this a unique controversy: pharmaceutical patent rights face serious threats internationally, and the pharmaceutical industry's ability to defend these rights is itself hampered by domestic law. Under these circumstances, the reimportation ban essentially functions as a government substitute for contractual terms and other market mechanisms that, in a more perfect world, would be negotiated by drug companies themselves.

Indeed, free market advocates of reimportation are partly correct on one point: Import restrictions would be preposterous if not for three facts unique to this controversy:

1) The up front cost of developing a new drug totals hundreds of millions of dollars, but each additional dose costs only pennies to make, so pharmaceutical manufacturers—like companies in other research intensive industries—rely on patent rights expressly provided for in the U.S. Constitution to spread the R&D costs across every sale over several years;

2) International treaties and foreign nations' sovereign status severely weaken drug makers' ability to negotiate with foreign governments, because they run the risk of having their patents unilaterally broken; and

3) The ability of drug makers to collaborate with one another when negotiating with foreign governments—which could alleviate some of the asymmetry of power between the producers on the one hand and monopsony drug purchasers on the other—is strictly prohibited by U.S. antitrust laws.

As these factors demonstrate, drug reimportation cannot be straightforwardly analyzed simply in free market terms. If drug companies could freely negotiate contracts abroad and have those contracts enforced, their agreements with foreign distributors could restrict reimportation to preserve their ability to recover the huge research and development costs entailed in launching new drugs. In effect, the reimportation ban functions as a government-assisted substitute for that missing contractual freedom. It may be an imperfect substitute, but the legal and political restrictions on the drug industry make it the best available solution.

Conclusion. Optimal policy decisions, at least in the short term, occasionally call for second-best solutions. In fact, this approach has been formalized by several economists into what is known as "the theory of the second best,"[7] under which piecemeal reforms to correct a regulatory distortion in one market for a product could be harmful if distortions

persist in other markets for that product. The "theory of the second best" as applied to the drug reimportation debate suggests that removing the reimportation ban may harm overall consumer welfare because of the way in which insecure patent rights, international treaties, and antitrust laws already distort the market.

In the short term, there is one unmistakable fact—when we reimport drugs from foreign countries, we import those countries' price controls, with the attendant destruction of future productivity and innovation that price controls always bring. This effect is always harmful, but in the field of medicine that harm would be incomparable. For American patients, this cost-cutting choice threatens life and limb.

Notes

[1] Milton Friedman et al, "Economists Warn of Dangers of Drug Importation, Price Controls," *Health Care News*, February 1, 2004, (reprinted with permission of *Tech Central Station*), http://www.heartland.org/Article.cfm?artId=14308.
[2] Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The price of innovation: new estimates of drug development costs," *Journal of Health Economics,* Vol. 22 (2003), pp. 151–185.
[3] Christopher P. Adams and Van V. Brantner, "Estimating the Cost of New Drug Development: Is It Really $802 Million?" *Health Affairs*, Vol. 25 (2006), pp. 420-428.
[4] Congressional Budget Office, *Research and Development in the Pharmaceutical Industry*, Washington, DC: October 2006, p. 43.
[5] Ibid.
[6] See, e.g., Roger Pilon, "Drug Reimportation: The Free Market Solution," Cato Institute Policy Analysis No. 521, Washington, DC: August 4, 2004, http://www.cato.org/pubs/pas/pa521.pdf.
[7] See Richard G. Lipsey and Kelvin Lancaster, "The General Theory of Second Best," *The Review of Economic Studies*, Vol. 241 (1957), pp. 11-32.