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Debunking the Myths of Drug Importation

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Despite enactment of the Medicare Modernization Act of 2003, some policymakers continue to advocate for the importation of prescription drugs into the United States. They argue that Americans, especially seniors without prescription drug coverage, need access to more affordable prescription drugs—seemingly ignoring the current Medicare discount card program and the upcoming 2006 prescription drug benefit.

The Medicare Prescription Drug Discount Card program, a temporary discount card put in place by the Medicare bill, has already proven to save participating seniors—especially lower-income seniors who are also eligible for subsidies—between 50 percent and 78 percent.[1] With such significant savings already reaching seniors, policymakers supporting drug importation should pause and consider its consequences.

While an open, worldwide market for drugs would have long-term economic and other benefits, it would require wrenching policy changes in many countries and far higher prices in many poorer countries. The issue in the current debate, however, is whether drug importation would be the "quick fix" for the United States that its advocates claim, even without the necessary changes needed in other counties. Proponents claim numerous effects that would occur as a result of importation. But when their claims are explored further, in the context of current international arrangements, they turn out to be more myth than reality.

Myth #1: Importation will lead to lower prices in the United States.

Reality: Economists, both liberal and conservative, agree that drug prices will not drop in the United States as much as they will rise abroad. The Congressional Budget Office concluded that allowing importation would reduce prescription drug spending by only about 1 percent and that importation from Canada would result in a "negligible reduction in drug spending."[2] Even if importation were to lead to lower-priced drugs, the real winners might not be consumers; wholesalers could buy drugs at lower prices but would not necessarily pass those savings on to their customers.

Myth #2: Importation will force other countries to pay their "fair" share.

Reality: Forcing other countries to pay higher prices does not mean that prices in the United States will drop. According to economist Robert Helms of the American Enterprise Institute, the segmented marketplace in pharmaceuticals allows manufacturers to sell their products to different consumers at different prices.[3] Therefore, a price increase abroad would not necessarily cause a price drop in the United States. Producers would lower their U.S. prices only if market conditions in the United States forced them to do so.

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Furthermore, the differences in drug prices between the United States and other countries are complex and not always so one-sided as importation proponents imply. To accurately assess drug prices in the United States and abroad, comparisons should not focus on a few select drugs, but the broadest range of options, including generic medications. Several studies do include such comparisons. Interestingly, these studies found that generics tend to cost less in the United States than they do in Canada and many other countries.[4]

Finally, this does not mean that foreign countries should not be encouraged to liberalize their markets. In a recent publication by the Institute for Policy Innovation, Merrill Matthews substantiates former Food and Drug Administration Commissioner Mark McClellan's argument that other countries are not paying their fair share for pharmaceutical research and development. The best way for foreign countries to pay their fair share, concludes Matthews, is for those countries to "relax their price controls and let the prices rise."[5] The Medicare Modernization Act includes provisions asking the Administration "to conduct a study and report on drug pricing practices of countries…and whether those practices utilize non-tariff barriers with respect to trade in pharmaceuticals" and develop strategies to address price controls in trade negotiations.[6] Such discussions can be an effective and positive approach to persuading these countries to change their practices.

Myth #3: Importation is free trade.

Reality: Under genuine free trade, buyers and sellers negotiate to find a mutually agreeable price to buy and sell a product. If an agreeable price is not reached, a seller has the right to withdraw the sale and still have the confidence that their property rights will be protected—that is, that a buyer will not steal the seller's product if he doesn't like the price. Unfortunately, the United States is one of the only countries left with a free market for prescription drugs.

In Canada, for example, pharmaceutical companies wanting to launch a product must first receive authorization from the Patented Medicine Prices Review Board (PMPRB), a quasi-judicial body that determines the maximum price that can be charged for a patented drug. While the PMPRB does not directly purchase drugs, it does influence the price at which they can be sold. According to the PMPRB, one of its primary roles is "to ensure that the prices charged by manufacturers of patented medicines in Canada are not excessive."[7] Other countries use different techniques to affect price and access to prescription drugs. By advocating for prescription drug importation, policymakers are indirectly promoting the importation of price controls into the United States.

It is true, of course, that in principle allowing imports from countries with price controls or subsidies would nudge the world towards freer trade. But while that may be theoretically accurate, the leading bipartisan proposal, S. 2328, introduced by Senator

1. Joseph Antos and Ximena Pinell, *Private Discounts, Public Subsidies: How the Medicare Prescription Drug Discount Card Really Works* (Washington, D.C.: AEI Press, 2004), p. 18.
2. "Would Prescription Drug Importation Reduce U.S. Drug Spending," Congressional Budget Office, April 29, 2004, at *www.cbo.gov/showdoc.cfm?index=5406&sequence=0*.
3. Robert Helms, "The Economics of Price Regulation and Innovation," *Supplement to Managed Care: Innovation and Drug Reimportation: Cost, Value, and Tradeoffs—Economic, Legal, and Public Policy Implications*, Vol. 13, No. 6 (June 2004), p. 10.
4. For more information, see "Generic Drug Prices in the U.S. Are Lower than Drug Prices in Canada," Office of Planning, U.S. Food and Drug Administration, November 2003, at *www.fda.gov/oc/whitepapers/drugprices.html*; John Graham, "Prescription Drug Price in Canada and the United States—Part 1: A Comparative Survey," Fraser Institute, September 2000, at *www.fraserinstitute.ca/shared/readmore.asp?sNav=pb&id=160*; and Patricia M. Danzon and Michael F. Furukawa, "Price and Availability of Pharmaceuticals: Evidence from Nine Countries," Health Affairs Web Exclusive, October 29, 2003, at *http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1*.
5. Merrill Matthews, "Riding on the Coattails of U.S. Patients," Institute for Policy Innovation, July 2004, at *www.ipi.org*.
6. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Conference Agreement, Title XI—Access to Affordable Pharmaceuticals, p. 384, at *http://waysandmeans.house.gov/media/pdf/hr1/hr1jtexplstate.pdf*.
7. "About the PMPRB," Patented Medicines Price Review Board, at *www.pmprb-cepmb.gc.ca/english/View.asp?x=87*.

Byron Dorgan (D-ND) and others, includes a section entitled "Restraint of Trade Regarding Prescription Drugs."[8] Among other things, this section would make it unlawful for a pharmaceutical manufacturer to charge different buyers different prices for a drug, to deny the sale of a drug to a buyer, or to limit the supply of a drug to a buyer. Such policies would not create a "freer" market for pharmaceuticals, but would regulate the market even further.

Myth #4: Importation is safe.

Reality: The Food and Drug Administration (FDA) has been vocal in its concern over the safety of imported drugs. The FDA regulates the domestic market for pharmaceuticals, but not foreign markets, and has stated on numerous occasions that it cannot guarantee the safety of drugs obtained from foreign sources.[9] Even without the legalization of prescription drug importation, the FDA battles to keep counterfeit drugs out of the United States. According to FDA Associate Commissioner for Policy and Planning William Hubbard, "FDA has seen its number of counterfeit drug investigations increase four-fold since the late 1990s."[10]

A review conducted by Giuliani Partners at the John F. Kennedy Airport Mail Facility found that of approximately 40,000 packages per day suspected to contain drugs, only about 500 to 700 are inspected. The drugs in those inspected packages came from around the world, and many were not FDA-approved. Some, for example, were past their expiration dates or inappropriately packaged.[11] Counterfeiting pharmaceuticals is very profitable. Therefore, counterfeiters will look for new opportunities to exploit the delivery system, exacerbating the dangers and the current safety problems. The Giuliani study concluded, "The limitations of our system should be addressed before it is opened to whole importation."[12]

The Canadian government has also clarified its position: it says that Canada cannot be responsible for the safety of products exported to U.S. customers.[13] While Canada regulates its domestic supply, it does not regulate exported drugs. Moreover, many "Canadian pharmacies" on the Internet require customers to sign a waiver absolving the pharmacies of any liability. States and local municipalities that promote importation to their citizens or employees also disclaim any responsibility for safety.[14]

Myth #5: Importation won't hurt research and development.

Reality: If importation forces prescription drug prices to the lowest regulated price or if it forces prices abroad to rise to levels that spur some governments to exploit intellectual property rights, there could be a downward spiral of pharmaceutical research and development. Future drug treatments and cures—whether for diabetes, cancer, Alzheimer's, or any other medical condition—would be at risk.

Some proponents of importation argue that such fears are overblown because the government, through its funding of the National Institutes of Health (NIH), spends heavily on the research and development of pharmaceuticals. While the NIH does conduct important research, a 2001 report from the NIH to Congress found that of 47 "blockbuster" drugs, NIH funding was involved in the

8. S. 2328, Pharmaceutical Market Access and Drug Safety Act of 2004, pp. 56–63, at *http://thomas.loc.gov.*
9. William Hubbard, testimony before the Subcommittee on Human Rights and Wellness, Committee on Government Reform, U.S. House of Representatives, June 12, 2003, at *www.fda.gov/ola/2003/canadian0612.html.*
10. William Hubbard, testimony before the Committee on the Judiciary, U.S. Senate, July 14, 2004, at *http://judiciary.senate.gov/testimony.cfm?id=1264&wit_id=3700.*
11. Rudolph Giuliani, *Interim Report to the U.S. Health and Human Services Taskforce on Drug Importation*, May 11, 2004, p. 6.
12. *Ibid.*, p. 13.
13. Marc Kaufman, "FDA: Canadian Drug Position Misinterpreted," *The Washington Post*, May 26, 2003, p. A11.
14. The State of Wisconsin's Prescription Drug Resource Center Web page, which enables citizens to order prescription drugs from Canada, includes a statement that "expressly disclaims any and all liability from such importation or reimportation or the use of any products so acquired." See "Click Here for Important Information About the Legality of Purchasing Medications from Canada," at *http://drugsavings.wi.gov/medicinelist.asp*.

development of only four and that much of that activity was through grants to universities.[15]

Conclusion. The current segmented market structure for pharmaceuticals, while not economically perfect, does give poorer countries access to modern medicines while ensuring that research on new drugs continues apace. Policymakers should hesitate to disrupt this balance by allowing importation without addressing its domestic and international consequences. For example, some countries may decide to restrict the sale of prescription drugs to domestic consumption only, while others, if prices were to rise, might even decide to circumvent the existing intellectual property rights of the manufacturers, undermining the incentive to invest in future research and development.

The best way to address the cost of prescription drugs in the United States is by providing access to discounts and helping individuals obtain health care coverage that integrates prescription drug coverage. Such a policy relies on the private sector and the free market instead of relying on a government to set prices. Besides the Medicare discount card, other efforts are underway to reach those who lack prescription drug coverage. Pfizer, for example, recently launched a new initiative to extend discounts on Pfizer medicines to the uninsured.16

Policymakers should resist "quick fix" policies that may sound logical but are dangerous and potentially counterproductive. In the end, if importation is approved but constituents do not see significant price reductions, some policymakers will quickly respond by calling for government-negotiated prices or directly advocating for price controls on prescription drugs in the United States, moving the United States one step closer to socializing the American health care system.

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15. "NIH Response to the Conference Report Request for a Plan to Ensure Taxpayers' Interested Are Protected," Department of Health and Human Services, National Institutes of Health, July 2001, at *www.nih.gov/news/070101wyden.htm.*

16. For more information, see *www.pfizer.com/are/news_releases/2004pr/mn_2004_0707.html.*