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EMPTY PROMISES: THE REALITY OF PRESCRIPTION DRUG IMPORTATION FOR MARYLAND

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Policymakers in Maryland are jumping on the bandwagon in support of prescription drug importation. Recently introduced legislation would have Maryland follow other state efforts to import prescription drugs from Canada.¹ However, such policy recommendations are full of empty promises. First, the safety and economic consequences of drug importation are clearly legitimate reasons for concern. Second, federal and state efforts to prevent drug importation have all but failed. Maryland policymakers should take heed, recognizing that the prescription drug importation is a backdoor effort to import price controls and a slippery slope towards a Canadian-style health care system.

THE CONSEQUENCES OF PRESCRIPTION DRUG IMPORTATION

While prescription drug importation sounds superficially reasonable and politically attractive, it

is not the 'quick fix' proponents purport. There are some serious implications to the proposal.

SAFETY

The federal 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.² The FDA has also devoted a web page to educate the public and highlight the dangers of importation.³ These safety concerns are not just a partisan issue. Both the Bush and Clinton Administrations have been cautious regarding the safety concerns brought about by prescription drug importation.

The emergence of the counterfeit drug market is another major problem with prescription drug

1. See Maryland Senate Bill 568 at <http://mlis.state.md.us/2006rs/billfiles/sb0568.htm>.
2. See William Hubbard, Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration, testimony before the Committee on the Judiciary, U.S. Senate, July 14, 2004, at www.fda.gov/ola/2004/importeddrugs0714.html and John M. Taylor, III, Associate Commissioner for Regulatory Affairs, U.S. Food and Drug Administration, testimony before the Permanent Subcommittee on Investigations, Committee on Government Reform, U.S. Senate, July 22, 2004, at www.hhs.gov/asl/testify/t040722a.html.
3. For detailed information from the FDA on drug importation see www.fda.gov/importeddrugs.

importation. Efforts are already underway by the FDA to bolster protection against counterfeits appearing in the U.S. market, a legitimate responsibility under its authority. However, in recent testimony on FDA efforts to combat counterfeiting, Randall W. Lutter, Acting Associate Commissioner for Policy and Planning, reiterated, "FDA cannot, however, offer the same assurance to the public about the safety and quality of drugs purchased from sources that are outside the U.S. regulatory system."⁴

In a recent FDA operation, investigators found that 43 percent of the 4,000 packages examined were purchased through so-called Canadian internet "pharmacies." Yet, 85 percent of those products purporting to be from Canada were actually manufactured in 27 other countries, falsely claiming Canadian origin.⁵ The World Health Organization estimates that counterfeit drugs account for approximately 10 percent of the world market, and sales of counterfeit drugs will account for \$75 billion globally by 2010.⁶ Counterfeiting is very profitable and counterfeiters will continue to look for new opportunities to exploit the delivery system, and prescription drug importation will only exacerbate those dangers.

Finally, there is the liability question. Just as the FDA regulates the domestic market for pharmaceuticals, Canada has a structure to ensure the safe distribution of drugs for its domestic markets, not foreign distribution. Thus, there is no clear government authority responsible for the importation of prescription drugs. Many "pharmacies" on the Internet absolve themselves from providing any warranties. Even state and local municipalities that

promote importation to their citizens or employees disclaim any responsibility for authenticating the safety of an imported drug. For example, even though the I-SaveRx effort, started by Governor Blagojevich (D-IL), claims "it is safe," it also states in its "Terms of Agreement and Warning Statement," that, "Nevertheless, the State of Illinois cannot guarantee the safety of any particular prescription drug purchase."⁷

ECONOMIC

There are also economic fallacies put forth by proponents of prescription drug importation. The Congressional Budget Office concluded that allowing prescription drug importation would have "negligible" impact on prescription drug spending.⁸ Furthermore, the Health and Human Services Taskforce on Re-importation found that generic drugs, of which U.S. consumers are large users, are typically far more affordable within the U.S. than in Canada.⁹ Moreover, as seen from research of importation in other countries, called parallel trade, the real winners are not the consumers, but the wholesalers.¹⁰ These middlemen are able to buy drugs at lower prices, but do not necessarily pass those savings on to their customers.

Finally, there can be long-term ramifications of prescription drug importation for the overall health of the economy. If importation were to become law, prescription drug manufacturers would be faced with two choices: either accept the lowest regulated price abroad or withhold its products and risk being exploited of their intellectual property rights. Regardless of the choice, there could be a serious downward spiral of pharmaceutical research and

4. Randall W. Lutter, Acting Associate Commissioner for Policy and Planning, U.S. Food and Drug Administration, testimony before the Subcommittee on Criminal Justice, Drug Policy, and Human Resources, Committee on Government Reform, U.S. House of Representatives, November 1, 2005, at www.hhs.gov/asl/testify/t051101.html.
5. "FDA Operation Reveals Many Drugs Promoted as "Canadian" Products Really Originate from Other Countries," FDA News, U.S. Food and Drug Administration, December 16, 2005, at www.fda.gov/bbs/topics/NEWS/2005/NEW01277.html.
6. "Counterfeit Medicines," Fact Sheet No. 275, World Health Organization, February 2006, at www.who.int/mediacentre/factsheets/fs275/en/print.html.
7. See "Terms of Agreement and Warning Statement," at www.i-saverx.net/print_form.htm. The I-SaveRx effort allows individuals from Illinois, Wisconsin, Kansas, Missouri, and Vermont to participate.
8. "Would Prescription Drug Importation Reduce U.S. Drug Spending?" *Economic and Budget Issue Brief*, Congressional Budget Office, April 29, 2004, at www.cbo.gov/showdoc.cfm?index=5406&sequence=0.
9. "Report on Prescription Drug Importation," HHS Task Force on Drug Importation, Department of Health and Human Services, December 2004, p. 70. at www.hhs.gov/importtaskforce/Report1220.pdf.
10. *Ibid.*, p. 69.

development. With less incentive for investment, fewer drugs will appear on the market.

In Maryland, where biotechnology is seen as a major source of economic development, the impact on new research and development investment for the state could be dramatic. As Douglas Giuffre of the Beacon Hill Institute calculates, nearly \$120 million in private research and development spending could be lost in the first five years as a result of prescription drug importation.¹¹ Thus, in reality, prescription drug importation is an economic 'lose-lose' for Maryland.

FAILED FEDERAL EFFORTS

Current law prohibits the importation of prescription drugs into the United States with few exceptions.¹² However, some federal policymakers want to change this long-standing FDA policy with the intention of providing Americans with access to lower-cost prescription drugs.

Federal proponents have tried numerous times and through different administrations, unsuccessfully, to change this law. In 2000, the Medicine Equity and Drug Safety Act was signed into law allowing for the importation of prescription drugs from abroad.¹³ However, the law also requires that the Secretary of Health and Human Services to deem the process safe and cost-effective. The requirement faced both Administrations—Secretary Donna Shalala under Clinton and Secretary Tommy Thompson and now-Secretary Michael Leavitt under Bush—and neither Administration has approved the process to go forward.

Since then, variations of prescription drug importation have been introduced at the federal level. However, most have failed or reinforced the safety requirement. Most recently, a provision was included in the Commerce, Justice, and State Departments Appropriations bill, signed into law

by President Bush in November, that would prohibit the U.S. Trade Department from negotiating trade agreements that would ban prescription drug importation from other countries.¹⁴ However, the Administration has indicated that it interprets the provision as a recommendation by Congress, not a requirement.¹⁵

Overall, however, federal efforts to legalize prescription drug importation have begun to lose momentum. One of the major target groups for importation has been senior citizens. Passage of the Medicare Modernization Act, which added a prescription drug benefit to Medicare, has diluted much of the appeal. Although not retracting their support of prescription drug importation, even the AARP observes that “many who choose the least expensive Medicare drug plan in their area that covers all their drugs could pay less this year than getting those same drugs from Canada,” and that Medicare, unlike importation, offers seniors true insurance against catastrophic prescription drug costs.¹⁶

UNSUCCESSFUL STATE AND LOCAL EFFORTS

The federal government is not the only place where policymakers are debating the legitimacy of prescription drug importation. States and local authorities have been actively promoting importation as a solution for rising health care costs. Like the federal efforts, many of the state and local efforts have fallen short as well.

The FDA has been clear and consistent in standing behind its mission to protect U.S. consumers from unregulated foreign sources of prescription drugs. The FDA has sent states and local municipalities detailed arguments for upholding the prohibition on prescription drug importation and pointing out the illegality of such efforts.¹⁷

11. Douglas Giuffre, “Drug Importation and R&D Spending: The Economic Impact on Maryland’s Economy,” Institute for Policy Innovation Issue Brief, March 10, 2005, p. 2, at www.ipi.org.
12. See “Coverage of Personal Importation,” Office of Regulatory Affairs, U.S. Food and Drug Administration, at www.fda.gov/ora/compliance_ref/rpm_new2/ch9pers.html.
13. Public Law 106-387, at http://rs9.loc.gov:7778/pls/glnp/Display_abstract1?cookie=0&Abstract_id=106245
14. Jonathan Katz, “Questions Remain about Provision Changing Drug Importation Rules,” Business News, *The Associated Press*, November 24, 2005, at www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=33961.
15. *Ibid.*
16. Patricia Barry, “The New Math: Cheaper than Canada? The Drug Benefit May be the Better Deal,” AARP Bulletin, January 2006, at www.aarp.org/bulletin/medicare/new_math.html.

However, some states and localities have considered directly challenging the FDA's authority in the courts. Montgomery County, Maryland has indicated it will file suit against the FDA for its denial of a prescription drug importation waiver.¹⁸ Vermont tried a similar suit, but took heed and dropped its battle after a federal judge dismissed the case.¹⁹ Even state attorneys general are cautious to proceed. Texas and Nevada had their importation proposals reviewed by their state attorneys general who found legal problems with their approaches.²⁰

CONCLUSION

While an open, worldwide market for prescription 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. Thus, importation is not a 'quick fix' and would certainly require an interna-

tional effort, not a state or local approach to implement.

Maryland state policymakers looking for lower-priced prescription drugs should focus their attention on promoting existing state and private sector assistance programs for those in need. Moreover, state policymakers should improve access to private health insurance for all Marylanders by advancing a robust and competitive marketplace for health insurance in the state.²¹ Private insurers and managed care providers have significant market clout and experience to deliver lower-cost drugs to their consumers, and this is a far better approach than importing a price-controlled regime into Maryland.

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17. See "Letters to State and Local Officials," U.S. Food and Drug Administration, at www.fda.gov/importeddrugs.

18. Tim Craig, "Montgomery to Sue FDA on Drug Imports," *The Washington Post*, November 11, 2005, B-6, at www.washingtonpost.com.

19. "State Decides Not to Appeal over Prescription Drug Case," Associated Press, *The Boston Globe*, November 2, 2005 at www.boston.com/news/local/vermont/articles/2005/11/02/state_decides_not_to_appeal_over_prescription_drug_case.

20. Clay Robison, "Texas Won't Allow Canadian Drugs After All," *The Houston Chronicle*, December 22, 2005, p. A-1 at www.chron.com/CDA/archives/archive.mpl?id=2005_4030342 and Anjeanette Damon, "AG Calls Drug Plan Unfeasible," *Reno Gazette-Journal*, December 28, 2005 at www.rgj.com.

21. See Maryland Senate Bill 530 introduced by State Senator E.J. Pipkin to establish a Health Insurance Exchange at <http://mlis.state.md.us/2006rs/billfile/sb0530.htm>.