



Prescription Drug Importation Presents Key Challenges and Demands for it is a Symptom of a Larger Problem—The Unsustainability of Rising Health Care Costs

Issue: To deal with rising prescription drug prices in the U.S., increasing numbers of Americans, particularly senior citizens, are purchasing their prescription medications from other countries. In addition, some state and local governments have set up their own prescription drug importation programs in an effort to stem the continually increasing cost of their prescription drug programs.

According to a U.S. Department of Health and Human Services task force report, nearly 12 million prescription drug products valued at approximately \$700 million entered the U.S. from Canada in 2003.¹ The same report states that prescription drug importation can present significant safety risks, particularly for individuals who import medications on their own. In addition to presenting safety concerns, this practice also violates current U.S. Food and Drug Administration (FDA) regulations. Yet many Americans are willing to undertake these risks to reduce the price they pay for prescription drugs.

In 2006, the U.S. Customs and Border Protection Agency at the U.S. Department of Homeland Security announced that it will no longer confiscate drugs mailed to U.S. consumers from Canadian pharmacies. In addition, the 2006 Homeland Security Appropriations law began allowing people to import Food and Drug Administration (FDA)-approved drugs from Canada as long as the supply is for 90 days or fewer and they personally transport them across the border.

The 2003 Medicare Prescription Drug, Improvement, and Modernization Act permits prescription drug importation into the U.S. if the Secretary of the Department of Health and Human Services (HHS) certifies (1) that drugs imported from Canada pose no additional risk to public health and safety and (2) that such imports would provide significant cost savings to American consumers.

Congress has reviewed (and continues to review) a number of bills and amendments annually proposing prescription drug importation from Canada and other countries.

Position: The National Business Group on Health, a member organization of over 230 large employers who provide coverage for approximately 50 million Americans, believes that the increasing number of Americans resorting to prescription drug importation represents a symptom of a much larger problem that needs to be addressed – the unsustainability of rising health care costs in the U.S., including that of prescription drugs.

¹ Health and Human Services Task Force on Drug Importation, *Report on Prescription Drug Importation*, 2004.

Importation Proposals Respond To Legitimate Consumer Concerns About Costs

Many people find that needed medications are expensive. It is understandable to wonder why prices for the same medications are significantly less in many similar countries. As prices rise, consumer concern will undoubtedly rise.

Importation May Not Lead to Significantly Lower Prices in the Long Run

It is unclear that importation would lead to significantly lower prices for Americans. Prices may rise in other countries, particularly if they have inadequate supplies to satisfy the increased demand due to importation. Increasing the use of generics is both far easier and has potentially higher impact on saving money than importation.

Safety of the Prescription Drug Supply is also a Legitimate Concern

Widespread importation increases the risk of counterfeit, adulterated, expired, contaminated, substandard, and unapproved medicines on the U.S. market.

Fair Market Competition at Home and Abroad Will Help to Assure that Consumers Have Access to Affordable Medications

Robust competition among pharmaceutical companies, brand and generic, playing by fair market rules in the U.S., would go a long way toward keeping prescription drugs affordable.

Fair market competition on a global basis would also assist in keeping U.S. prescription drug prices reasonable. A U.S. Department of Commerce study concluded that other countries generally rely on some form of pharmaceutical price controls.² A system where U.S. drug companies, subject to price controls, competes with foreign manufacturers not bound by them can create an uneven playing field abroad.

Importation Poses Some Significant Challenges that Any Legislation Must Address

The safety of U.S. consumers is a paramount concern that would require substantial increases in FDA and U.S. Customs Service resources. The cost of additional U.S. resources to monitor prescription drug importation might equal or outweigh any savings achieved.

To ensure safety, a prescription drug importation program would need:

- Sufficient FDA authority and resources to approve the drugs to be imported, inspect and monitor pharmaceutical manufacturing facilities in other countries, as well as monitor the flow of imported drugs from manufacture to delivery;
- A formal FDA registration process for all foreign importers of pharmaceuticals, including accreditation and licensing by a reputable licensing board;
- Public access to the results of the FDA inspection, monitoring and registration process for each potential importer of prescription medications;

² U.S. Department of Commerce International Trade Administration, *Pharmaceutical Price Controls in OECD Countries/Implications for U.S. Consumers, Pricing, Research and Development, and Innovation*, 2004

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- Pedigree requirements that trace a drug from the point of origin to the point of dispensing, with each entity that handles the prescription drug required to maintain records as to the drug's pedigree; and
- Strong anti-tampering and anti-counterfeiting measures, such as bar codes, specialized ink, tracking numbers and restrictions on re-packaging and re-labeling to prevent potential misbranded or counterfeited drugs from reaching consumers.

With a more complex distribution chain involving foreign manufacturers and distributors, along with U.S. pharmacies and wholesalers, liability questions could arise for injuries caused by commercially imported prescription drugs. Legislative proposals would need:

- Clear liability provisions that outline responsibility should a commercially imported prescription drug cause injury.