



Prescription Drug Importation Presents Key Challenges and Demands for It Are Symptoms 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.

A recent poll by the Kaiser Family Foundation found increasing public support for commercial importation. A majority (77%) of the American public supports the idea of legalizing the purchase of prescription drugs from pharmacies in Canada. Seventy percent (70%) of adults feel that importation would not sacrifice safety or quality.¹

According to a recent 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 2003.² 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.

The 2003 Medicare Prescription Drug, Improvement, and Modernization Act permits prescription drug importation into the U.S. only 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 proposing prescription drug importation from Canada and other countries.

Position: The National Business Group on Health (the Business Group), 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

¹ Kaiser Family Foundation, *Kaiser HealthPoll Report*, March/April 2005 Edition.

² Health and Human Services Task Force on Drug Importation, *Report on Prescription Drug Importation*, 2004.

of prescription drugs.

The Business Group believes that:

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.

However, 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. The end result may be different than what we would expect. 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 US market. The extent of these increases in risk is unknown.

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 US, would go a long way toward keeping prescription drugs affordable.

Fair market competition on a global basis will also do its part in keeping U.S. prescription drug prices reasonable. A recent U.S. Department of Commerce study concluded that other countries generally rely on some form of pharmaceutical price controls.³ A system where U.S. drug companies, subject to price controls, compete 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

³ 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

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.
- 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.
- 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.