

Prescription Drug Importation Legislation: Is it the Solution?

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Introduction: The Problem

Healthcare spending is at a record high. Policymakers, physicians, and patients are concerned costs will continue to rise, and quality and access to medical care will be compromised. The rapid growth of prescription drug expenditures has outpaced all other categories of healthcare, prompting policymakers to focus on new ways to reduce this figure.

Americans pay 30 to 300 percent more than other industrialized nations for the same medications. Currently, 18% of those 65 years old or over, and 32% of those under 65 skip medicinal treatments because of cost. Some argue that costs could be reduced, and access could be improved by legally re-importing drugs distributed in foreign countries. While importation is financially sound for the consumer, the Food and Drug Administration, President Bush, Health and Human Services (HHS), and pharmaceutical companies have expressed concern about the inability to guarantee the safety and efficacy of drugs purchased via this unregulated practice.

Re-importation Legislation

The Proposed Solution

The solution must decrease cost while maintaining quality and improving access to prescription medication. The two main proposals under review in the House and Senate address the regulation of the importation of patented prescription drugs:

- **Pharmaceutical Market Access Act of 2005** would change current law in four ways:

Expand the list of countries from which drugs can be imported;

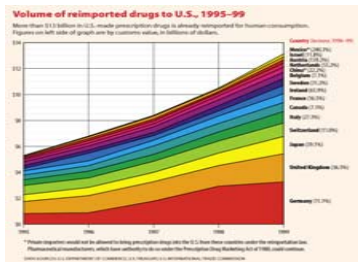
Allow individuals as well as wholesalers and pharmacists to import drugs;

Make multiple provisions to ensure safety;

Give HHS the responsibility for assigning a fee schedule, which is capped.

- **Pharmaceutical Market Access and Drug Safety Act (PMDSA)** would waive the limitation on importation of prescription drugs exported from the US, would establish registration conditions for importers and exporters, and would regulate the importation of qualifying drugs different from US label drugs.

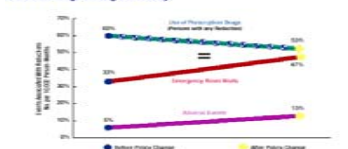
Re-Importation Legislation: Effect on Volume of Imported Medication



Re-importation legislation will increase volume of imported drugs, but quality and access issues may persist

Importance of Access to Medication

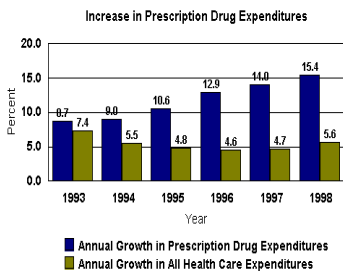
Adverse Outcomes Associated With Higher Prescription Cost-Sharing for Essential Drugs among the Elderly



Source: Robert Blendon et al., "The Impact of Prescription Cost-Sharing on the Access of Elderly Patients to Essential Medications," *Health Affairs*, vol. 24, no. 10, pp. 2400-2408, 2005.

Increased adverse events and emergent health access seen with decreased access to medication

Increasing Cost of Medications



Source: General Accounting Office

Cost of Medications: US and Canada



Americans pay 30-300 percent more for most medications compared with neighboring countries

Stakeholders

Proponents

The American Medical Association (AMA) recently changed its vote in support of re-importation of prescription drugs by wholesalers and pharmacies, but only if certain conditions are met to ensure patient safety.

The American Alliance of Retired Persons cites increased access and decreased costs.

Opponents

The Food and Drug Administration (FDA) risks re-importation of counterfeit, contaminated, and other risky medicines in the current, unregulated market.

The Pharmaceutical Research and Manufacturers of America (PhRMA) cite real risks to the patient, and provides no guarantee of cost savings

The American Osteopathic Association (AOA) cites safety concerns.

Canadian International Pharmacy Association changed its vote in opposition, and is restricting the supply of inexpensive prescription drugs mailed to the US each year, citing the possibility of a resultant shortage for Canadian consumers.

Safety Issues with Drug Re-Importation

Table 2-13

Findings from Drug Interceptions

- ✓ Unapproved drugs (eg, anti-azathioprine, human growth hormone)
- ✓ Controlled substances (>25 brands, including narcotics and anabolic steroids)
- ✓ Animal drugs not approved for humans (eg, clenbuterol)
- ✓ Drugs under restrictive distribution (eg, isotretinoin)
- ✓ Counterfeit lifesaving medications (eg, HIV antivirals, epoetin, antibiotics, antimalarials)
- ✓ Inadequately labeled drugs (eg, missing dosage, non-English labeling)

Safety is a key factor in opposition of drug re-importation.

Recommendations

The purpose of drug re-importation is to increase safe access to medications for more Americans at a decreased cost. Unfortunately, drug re-importation does not guarantee cost savings, increased access, nor safety.

HHS and the Congressional Budget Office conducted separate studies which concluded the current system of drug re-importation regulation has been effective in protecting the public and legalized commercial importation would decrease only a small fraction of total drug spending overall, but would greatly increase liability concerns and costs.

Although there will be increased volume of drugs imported with such legislation, it will not guarantee increased access, especially for those least able to afford these medications. Additionally, the FDA, AMA, AOA, PhRMA, President, and HHS have voiced safety concerns with drug re-importation.

Re-importation legislation would not decrease healthcare costs significantly, would decrease global access to pharmaceutical products, and would undermine the quality of pharmaceutical products consumed in the US.

References

1. Guido R. Zanni, PhD. Rx Reimportation and Importation: Panacea or Prelude to Disaster?, www.pharmacymimes.com/article.cfm?id=...
2. Reclaim Democracy.org. U.S. Health Care Spending Reaches All-Time High: 15% of GDP. www.reclaimdemocracy.org/articles_2004/us_recordhigh_thealthcare_spending.html
3. Thomas: Legislative Information on the Internet. **Pharmaceutical Market Access Act of 2005 (Introduced in House)**. Available at: www.thomas.loc.gov/cgi-...