

Drug Reimportation: Is It the Solution to the High Cost of Prescription Drugs in the US?

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In today's economy, families are often forced to choose between paying for their medical care or buying groceries.^{1,2} A recent study by researchers at the Mt. Sinai School of Medicine revealed that 25% of older adults' out-of-pocket medical expenses surpassed the total value of their assets.³ One reason is higher drug prices: Bloomberg Business Week reported a study indicating that from September 2011 to September 2012, the cost of brand-name prescription drugs rose by 13.3%.⁴

Demand in the US for less-expensive pharmaceuticals has accelerated the controversial and illegal practice of drug reimportation by entities in other countries, whereby US-manufactured drugs, having been exported, are resold back to US consumers.⁵ Although reimportation gives people the opportunity to purchase pharmaceutical products at a significantly lower cost,⁶ reimported drugs, as well as those purchased online from other countries, currently have no guarantee of safety and may actually be expired or adulterated. Legislation of one aspect of drug reimportation, which would permit individuals to obtain their personal prescriptions via US-approved online foreign pharmacies, may provide a solution to the demand for less-expensive pharmaceuticals while ensuring their quality.

Another solution to high prescription costs may lie in restriction of direct-to-consumer (DTC) advertising by the pharmaceutical industry. Implementing stronger regulations for DTC advertising, or banning the practice altogether, may result in companies charging lower rates to consumers in the US. due to lowered demand from consumers for high-end products.

The Drug Reimportation Dilemma

Pharmaceutical product prices in the US are currently the highest in the world,⁷ driving consumers to search for lower-cost sources. For example, a US-made drug that has been exported to Mexico may be purchased at a significantly lower cost in Mexico than in the US. As patients have discovered this lower-cost option, reimportation has increased. From

1995 to 1999, drug reimportation from Mexico increased by 240.3%, and 7.1% for drugs reimported from Canada.⁸ Some cancer patients have paid 10 times the amount in the US as they paid for the same drug in Canada.⁹

The Part D program of Medicare provides 90% of eligible people with prescription drug insurance. However, while the *Patient Protection and Affordable Care Act* is sure to offer relief to many with small to moderate prescription costs, patients in 2012 who had to purchase their high-cost prescription medications were responsible for 86% of the cost, even when generic drugs were obtained.¹⁰ Additionally, due to a provision that acts as a loophole, patients are responsible for 100% of costs after reaching expenditures of \$2,510. They then pay all prescription costs until reaching \$5,726. In a given year, an elderly person would potentially have to pay \$3,216 out of pocket.¹¹

Medicaid is another issue. States now have the option to decline expansion of their Medicaid programs under the healthcare reform law, per a Supreme Court opinion. Therefore, the Congressional Budget Office has estimated that 3 million people could be left uninsured by 2022.¹²

Physicians report that as a result of insurance limitations, patients may elect to take medications essential to their health maintenance every other day instead of every day as prescribed.¹³ One study indicates that 22% of seniors do not fill their prescription medications at all.¹⁴ Seniors sometimes have to choose between heat or their prescription medications during the winter.¹⁵ Serious ailments may require very expensive drugs. For example, some highly unusual health conditions require personal expenditures of \$400,000 annually.¹⁶

Elders' income typically falls significantly short of what is needed for their prescription medications. *Daily Finance* ranked the economic security gap of the elderly by state. The worst state demonstrated a \$27,048 shortfall for a single elderly renter, and the average American elderly income is approximately 28% lower than the average American household budget.¹⁷

All of these factors have driven patients of all ages and health conditions to look elsewhere for affordable medications.¹⁸ While many people who travel to Canada, Mexico and other countries bring back only the pharmaceuticals they need for themselves, economic conditions in the US have created a climate ripe for illegal drug reimportation by those interested in making a large profit.

Safety Concerns About Reimportation

The US Food and Drug Administration (FDA) currently has no way to monitor reimported drugs for safety¹⁹ and these drugs may place consumers in danger as their labels may not reflect their true ingredients.

Online pharmacies and other e-commerce sites are a common source of prescription medications from other countries. However, websites are not monitored by FDA. Reference sites such as Pharmacychecker.com attempt to provide guidance on safe websites for obtaining prescription medications online.²⁰ The American Association of Retired Persons (AARP) has advocated that should drug reimportation be legalized, FDA should be provided with appropriate resources and authority to monitor websites and other sources of reimported drugs to better protect public safety.²¹

Relabeling poses additional concerns. To be distributed in the US, a prescription drug must be approved by FDA and carry a national drug code, lot number and expiration date.²² Medications sold in other countries sometimes are relabeled with new and inaccurate expiration dates to fraudulently extend their lifespan. Such practices are nearly impossible for FDA to regulate and can pose a danger to unsuspecting US citizens.

Guidance provided by the European Medicines Agency (EMA) indicates that “falsified medicines,” a term used by the World Health Organization,²³ are on the rise. Included in the definition of “falsified medicines,” according to EMA are: pharmaceuticals containing lower levels of active ingredients than stated on the label, or active ingredients of poor quality; products that are deliberately or fraudulently mislabeled; and fake packaging or inactive ingredients. These should not be confused with “counterfeit medicines,” defined as “medicines that do not comply with intellectual-property rights or that infringe trademark law.”²⁴

The European Union (EU) has issued a new directive that introduces greater control measures including required features on the outer packaging of medicines to demonstrate

authenticity and a logo that must be placed on the websites of legally operating online pharmacies, as well as a link to official national registers.²⁵ Regulation of falsified medicines could prove challenging, especially for items purchased in other countries where FDA has little to no authority or oversight, although reinforcing current FDA regulations and penalties could provide a deterrent for reimportation of mass quantities of falsified pharmaceuticals.

Issues in Dispute

Should drug reimportation for personal, individual use be legalized?

While drug reimportation can pose dangers to health, the purchase of prescriptions via FDA-vetted online pharmacies based abroad may provide an answer. There currently is no formal policy permitting the elderly and others seeking lower costs for their personal prescriptions to purchase medications abroad except in “emergency” cases. The primary challenge to creating new legislation and policy may lie in opposition by pharmaceutical companies that stand to profit less.

Should DTC marketing be banned in the US?

DTC marketing targets patients rather than doctors and hospitals. While some argue that DTC marketing provides patients with greater choice and information, others contend it may cost patients more than they would have paid upon discussion directly with their healthcare providers.

If DTC marketing is eliminated, it may contribute to patients’ paying less for their medications, reducing the frequency of drug reimportation of personal prescriptions.

Should the current drug reimportation law and penalties be strengthened to prevent reimportation of mass quantities of pharmaceuticals?

The problem of inaccurately labeled medicines making their way to the U.S. via mass drug reimportation is likely to continue to be an issue and will require monitoring and active enforcement of the existing law to ensure consumer safety. FDA is likely to require additional resources to carry out more inspections under the *Food and Drug Administration Safety and Innovation Act (FDASIA)*.²⁶

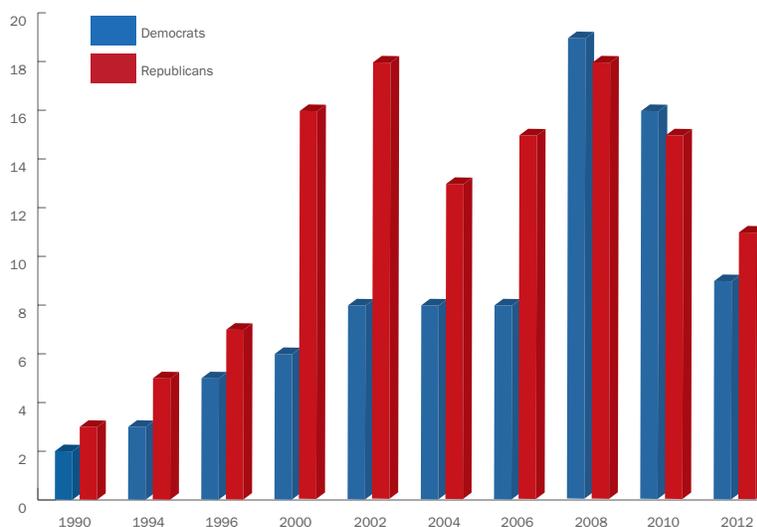
Potential Solutions

While drug reimportation is illegal under the *Federal Food, Drug, and Cosmetic Act (FD&C Act)*, the federal government has not strictly enforced it in cases of individuals purchasing prescriptions intended solely for personal use and in accordance with personal importation policy guidelines.²⁷⁻²⁹ Additionally, as of March 2011, revised subsection 801(d)(2) of the *FD&C Act* provides an exception for the reimportation of prescription drugs when authorized by the secretary of the Department of Health and Human Services (DHHS) “in the case of a medical emergency.”³⁰ For years, FDA has had an informal policy permitting individuals who acquire prescription medications abroad to bring them back into the US for personal use in cases of serious medical conditions. However, in the face of organized trips for seniors planning to buy drugs abroad and the increase in Internet-based pharmacies, the agency has indicated that it will increase its prosecutions of drug reimportation.^{31,32}

Senator Olympia Snowe introduced Senate Bill 319, the *Pharmaceutical Market Access and Drug Safety Act* of 2011, which proposed to alter the *FD&C Act* to “waive the limitation on importation of prescription drugs that have been exported from the United States”³³ and received support from AARP.³⁴ Although this bill may have been overshadowed by the debate surrounding passage of the *Patient Protection and Affordable Care Act* in 2011 and 2012, President Obama stated in an interview in 2011 that he was supportive of revisiting drug reimportation as a possible means of reducing the problem of high drug costs in the US.³⁵

In April 2012, the Senate Committee on Health, Education, Labor and Pensions (HELP) met to review *FDASIA*, which was signed into law in July 2012.³⁶ This statute amended several areas of the *FD&C Act* relevant to drug importation. For instance, Section 708 (“Destruction of Adulterated, Misbranded, or Counterfeit Drugs Offered for Import”) now gives power to the DHHS secretary to destroy pharmaceuticals valued at \$2,500 or

Figure 1. Party Split 1990-2012: Federal Campaign Contributions from Pharmaceutical Industry in Millions⁵⁰



less.³⁷ A number of amendments originally were proposed prior to the passage of *FDASIA*. One would have allowed individuals to purchase personal prescription medications from established, reputable, accredited companies in Canada. The amendment, which did not pass, would have required DHHS to publish references of Internet sites that had been vetted. Opponents to the amendment expressed concerns about the ability of the US to oversee the safety of international products, and pointed out that Internet sites selling unsafe medicines could be designed to look legitimate, thus undermining public safety.

Legislators supporting the legalization of vetted Internet sites for US pharmaceutical customers likely will face additional obstacles as pharmaceutical companies object to the possibility of decreased profits due to competition from these sources.

However, with cheaper prescription drugs available for purchase over the Internet via legalized drug reimportation for personal prescription medications, consumer demand for pharmaceuticals will trend down and will necessitate a decrease in the cost of prescription drugs in the US. Some estimates have indicated that with legalization of drug reimportation, prices could drop 30–40%.³⁸

Some speculate that because US pharmaceutical manufacturers can directly advertise to consumers, demand is created by consumers and higher prices result from this demand.³⁹

According to the Congressional Budget Office, the greatest promotional spending for newly approved drugs was in the DTC category. Spending on DTC was \$71 million, the highest of all promotional spending for approved drugs for 1999–2008.⁴⁰ Costs to patients may be higher with DTC marketing, as information about alternatives to prescriptions at full price typically are not included in DTC advertising; patients may be able to purchase a generic version of a drug, but may be unaware of this option. Additionally, patients may not know about a completely different drug option that would accomplish the same results at a lower cost.⁴¹ Thus, elimination of DTC advertising is likely to result in patients talking solely with their doctors about medication options, and, in the process, allow the patient to determine the existence of additional, less expensive pharmaceutical options. In one study noting increased cost due to DTC advertising, “older drugs for the treatment of schizophrenia were found to be equally effective and to cost as much as \$600 per month less than olanzapine (Zyprexa, Eli Lilly), quetiapine (Seroquel, AstraZeneca), or risperidone (Risperdal, Janssen).”⁴² The US is one of only two countries that permit DTC marketing (the other is New Zealand).⁴³

Part of the cost may be due to inefficiencies in the administrative processes for drug research and development, as well as for drug approval.⁴⁴ And, from 1963 to 2003, research and development costs for pharmaceutical companies increased 20-fold.⁴⁵ Pharmaceutical companies respond by maintaining that drugs are a cost-effective way to avoid even higher medical costs.⁴⁶

Another possible solution is a cap on drug prices, a strategy used by most other countries.⁴⁷ Legislation that defines price limits at which drugs can be sold may not be a realistic solution, considering the significant lobbying efforts by pharmaceutical companies. However, implementing stronger regulations with regard to advertising may force companies to charge lower rates to consumers in the US.

Just as they would oppose drug caps, pharmaceutical companies appear to offer the greatest resistance to legislation permitting Internet purchases of prescription medications for personal, individual use. The pharmaceutical industry is a leader in federal campaign contributions.⁴⁸ Examining contributions since 1990 reveals that just prior to the passage of the Medicare prescription drug program in 2003, both parties received significantly higher contributions.⁴⁹ Traditionally, pharmaceutical companies supported Republican candidates; however, with the predominance of Democrats in the House and Senate, the focus of campaign contributions has shifted (see **Figure 1**).⁵⁰

Money-making schemes such as resale of expensive pharmaceuticals to unsuspecting patients, doctors or pharmacies are likely to remain an ongoing problem and, therefore, the law will require diligence in reinforcement. FDA is already taxed in terms of resources to ensure that Good Manufacturing Practices are regularly monitored,⁵¹ and the use of additional resources will be necessary to best ensure the safety of consumers.

Conclusion

The most viable, immediate solution to the high cost of pharmaceuticals, as proposed in the Senate HELP committee hearing, may be to legalize Internet sales of reimported prescriptions for personal use. Concurrently, stronger laws and penalties for reimportation of mass quantities of pharmaceuticals may reduce the incentive for relabeling expired products and similar activities, which create falsified products and hazards to public health. Finally, implementing stronger regulations with regard to DTC advertising may reduce consumer demand and may result in companies' charging lower rates to consumers. An effective combination of these policy changes and reinforcements should contribute to lower rates of drug reimportation by individuals seeking lower costs for their medications, and increase the opportunity for successful oversight of FDA-recommended online pharmacies, thus improving safety.

The US might consider patterning control measures for online pharmacies after that of the EU. The challenge for legislators and FDA will be to determine how to certify that these Internet sources for prescription purchases are established, reputable and accredited. However, this challenge will pale in comparison to the advantage provided to the millions of Americans who will be better able to afford their prescription drugs.

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