Drug reimportation practices in the United States

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Background: Drug reimportation is perceived as a costs-cutting strategy by Americans. Nonetheless, issues such as drug safety and efficacy prevent legalization of the practice. With the contradictory views from supporters and opponents, debate on drug reimportation continues to snowball. The objective of this commentary is to discuss issues regarding drug reimportation practices in the United States (US). It also examines policy implications and potential solutions of the controversy.

Findings: Comparatively inexpensive drugs available across the border help Americans relieve the burden of medication costs. Consequently, the volume of reimported drugs entering the US has considerably increased. However, these practices are illegal and legalization of drug reimportation is a political debate. While safety is the most important barrier for legalization, this concern does not seem to affect growing number of Americans who are getting their prescriptions filled from across the border. Canadians oppose legalization of reimportation in the US as it could exacerbate the problem of medication shortage in Canada.

Summary: Currently, legalization of dug reimportation has wedged between the arguments by different groups. Until the US government finds a solution to reduce medication costs, it seems to be impossible to stop Americans from buying the comparatively inexpensive medications available across the border.

Keywords: drug reimportation, drug importation, prescription drug costs, drugs from Canada

Background

The increasing expenditure on prescription medications is a big concern for consumers in the United States (US). Due to the increasing burden of medication costs, Americans, especially elderly and the uninsured, avoid taking medications or skip doses. According to a study, 22% of seniors do not fill their prescriptions because they cannot afford the cost of their medications (Safran et al 2002). The percentages are higher (32%) for uninsured population, which account for approximately 10% to 15% of the US population (Safran et al 2002).

Consequently, a growing number of Americans choose to buy comparatively inexpensive medications available in other countries such as Canada and Mexico. Several internet pharmacies help consumers obtain medications from other countries without requiring them to travel across the borders. Even though these drugs are often manufactured in the US, the drug price control acts in countries like Canada keep the prices of prescription medications lower than the US market prices (Wagner and McCarthy 2004). The practice of importing back to the US prescription drugs that were originally manufactured in the US and exported for sale in another country is referred as 'drug reimportation'. Estimates indicate that buying medicines from a certified Canadian pharmacy can save Americans 20%–80% on brand name drugs (Vivian 2003). However, economists argue that these estimates could be dubious and are overestimated considering the complications involved in comparing medication prices across different nations (Danzon and Kim 1998; Wagner and McCarthy 2004).

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Many concerns restrict drug reimportation from being a legal practice in the US. These include safety, efficacy, and therapeutic equivalency of reimported drugs. While these drugs are manufactured in the US, the storage and packaging conditions in countries where drugs were exported cannot be monitored by the US Food and Drug Administration (FDA) (Meadows 2002). In addition, inappropriate storage conditions while reimporting medications back to the US may degrade the quality of drugs. The most important issue is distinguishing between drugs that are manufactured in the US from those which were manufactured elsewhere. Although technically 'reimportation' involves importing back drugs manufactured in the US, there are no means to check the originality of drugs. Similarly, it is difficult to determine whether the drugs purchased from other countries have the same dosage form, potency, and amount of active ingredient as the prescribed medication. The FDA contends that legalizing reimportation would increase the entry of counterfeit medications in the US drug supply chain (Meadows 2002). The pharmaceutical industry criticizes the reimportation practice due to the potential harm to the recovery of the research and development (R&D) costs required for new drugs (Danzon 1998; Danzon and Kim 1998). While these opponents prevent the legalization of drug reimportation, various consumer advocacy groups support the practice.

The legalization of drug reimportation remains a controversial issue in the US. While important, limited work has been done on briefing the legislative history and current status of drug reimportation. This commentary tries to explore the perspectives of different groups, emphasizing the role of healthcare professionals in drug reimportation practices. In addition, the paper also discusses policy implications of the drug reimportation practice.

Key findings

US prescription drug expenditure and drug reimportation

The cost of prescription drugs is the fastest growing sector of US healthcare costs. In 1980, US prescription drug expenditures were $12 billion, accounting for 4.9 % of total healthcare spending. By 2003, it had escalated to $184.1 billion or 11.0% of total healthcare expenditures (CMS 2005). The increased volume of prescription medications have also driven the overall costs of pharmaceuticals. The increasing number of prescription uilization was responsible for 42% of the overall increase in prescription spending from 1997–2002 (KFF 2004) (Figure 1).

On the other hand, measures such as drug price control acts in other countries such as Canada significantly reduce the prices of prescription as compared with the US. Thus in most cases, Americans can buy the same medication at significantly lower prices from countries like Canada and Mexico. For instance, the antiretroviral drug ritonavir (Norvir®, Abbott Laboratories), which is a part of many HIV/AIDS treatments costs as low as $700/per year in Canada as opposed to $7800/per year in the US (Nelson 2004). According to the Patented Medicine Review Prices Board of Canada (PMPRB), factory drug prices in the US exceeded seven nations including Canada and European countries in the year 2000. Consequently, the volume of reimported drug entering the US has significantly increased over the past decade (Dalzell 2000)

Legislative history

Various bills allowing reimportation of drugs have been proposed, but none of them have been implemented as legislation yet. The practice of reimportation is illegal in

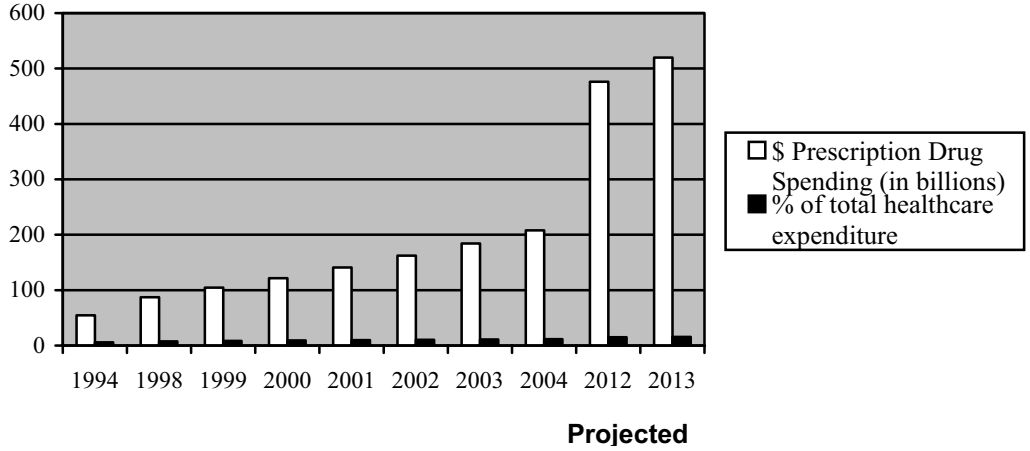

Figure 1 Prescription drug expenditure and % of total healthcare expenditure for 1998–2013 (CMS 2005).

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the US (the legal exceptions are those drugs which are manufactured in the US, and may be reimported by the original manufacturer or if the prescription drug is required for 'emergency medical care') (Creech 2001). The FDA also allows 90-day supply of reimported drugs for personal use (Reichertz and Friend 2000). In 2000, the Medicine Equity and Drug Safety Act of 2000 (MEDS act) was passed to allow pharmacists and wholesalers to reimport US manufactured, FDA approved drugs, previously exported to foreign countries, back into the US to sell them to Americans at cheaper prices. However due to lack of the congressionally required certification by the Department of Health and Human Services (HHS), the MEDS act was terminated at the end of December 2000 (Vogel and Joish, 2000). Before the proposal of this act, the Prescription Drug Marketing Act of 1988 (PDMA) allowed manufacturers to reimport drugs under FDA regulation (Creech 2001). Several times since 2000, both the US House of Representatives and the Senate have continuously discussed this issue in an effort to legalize reimportation practices. On July 25, 2003, the Pharmaceutical Market Access Act of 2003 (H.R. 2427) passed in the House had provisions to allow drug reimportation from 25 countries, including Canada, Australia, Japan, South Africa, and the European Union. A different version of this bill was passed in the Senate in June 2003 that allowed reimportation of FDA-approved drugs only from Canada (Moskowitz 2000). As a safety measure, this legislation required that the packaging of prescription drugs incorporate counterfeit-resistant technology. It also entailed a certification from the Secretary of Department of Health and Human Services that the prescription drugs do not expose consumers to any additional risks.

Currently the debate on drug reimportation practice continues to snowball although its status is still illegal. The legal status of reimportation may be misinterpreted by the consumers due to the ambiguous nature of different amendments and bills. A survey by IMS Health Inc in 2003 revealed that 45% of the respondents perceived reimportation practices to be legal, and 33% were unsure (Saatsoglou 2004). These results indicate consumers' unawareness regarding legality of drug reimportation practices.

Perspective of the US FDA

The arguments about safety and legitimacy of reimported drugs restrict the legalization of the practice. The FDA has consistently denied guaranteeing the safety, efficacy and legitimacy of reimported prescription drugs. The FDA claims that there are no means to detect the origin of the drugs despite the fact they are manufactured in the US (Meadows 2002). The FDA argues that they do not have sufficient financial as well as technological resources to assure the safety and authenticity of drugs coming from across the border (Thompson 2000). Following are some of the key findings (FDA 2003, 2004; FDA Consumer 2003; Rudolf and Bernstein 2004) that support FDA's positions on drug reimportation practices:

- The FDA and the Customs and Border Protection carried out a series of "blitz" examinations of 1982 drug packages mailed or shipped to individual recipients from abroad. Approximately 90% of these products were found to be unapproved and to present potentially severe health risks. The examined imports included drugs that had been withdrawn from the US market as unsafe; drugs with restricted distribution programs; drugs requiring initial screening and periodic monitoring of patients to ensure safe use; controlled substances such as codeine; animal drugs sold for human use; and drugs that might cause dangerous drug–drug interactions.
- The majority of the drugs had unknown quality and originated from Third World countries.
- The labeling and packaging of the reimported drugs may not be according to the FDA standards. Some medications with labels and inserts in different languages were found during the FDA inspection.
- In another case, FDA officials examined drugs ordered from a supposed Canadian pharmacy. These drugs, (including insulin) arrived in the regular mail and at room temperature (Insulin loses effectiveness at higher temperatures and is supposed to be shipped overnight to ensure it remains chilled) (Vogel 2002).
- The World Health Organization anticipated that in 2000 about 8% of bulk drugs imported to the US were counterfeit, unapproved, or substandard.
- The FDA claims that the number of counterfeit drugs investigated per year have increased to 20 since 2000 after averaging 5 per year in late 90s.

Drug reimportation is considered as a threat to recover the costs required for the new drug discovery. The pharmaceutical industry depends on patents to fund the R&D costs for new drug products. Pharmaceutical price controls reduces the amount of profit available for further R&D, which in turn affects the innovation (Vogel 2002). The average cost of bringing a new drug to market is estimated at almost $800 million (DiMasi et al 2003). These costs

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could be recovered through branded medications since the prices of generic and over-the counter medications need to be set according the market competition. To recover the costs of innovation and to gain profit, companies set prices according to the different levels of demand and price sensitivity across the different markets (Danzon 1998; Danzon and Kim 1998).

Perspective of US consumers on drug reimportation

While reimportation remains a controversial issue, these concerns do not seem to affect growing number of Americans who chose to buy their prescription medications from across the border. Currently the estimates available indicate that 1 to 10 million of Americans purchase drugs from Canada alone, and spend more than $1.1 billion on these prescription drugs in 2003 (Finkelstein 2003). Survey results from various organizations reveal some interesting results. A national survey by researchers at Stony Brook University revealed that around 58% of the consumers perceive Canadian drugs to be safe or somewhat safe and 68% think that the practice should be legalized (SBU 2003). According to a survey by Kaiser Family Foundation (KFF), 63% consumers support drug reimportation and believe that the federal government should make it easier for Americans to get access to Canadian drugs (KFF 2003).

Canadian perspective on US drug reimportation

It is important to consider the drug reimportation issue from the Canadian perspective as well. A few US drug companies have already cut off drug supplies to the Canadian pharmacies that sell prescription drugs to US consumers (Elliott 2003). This has led to serious drug shortages at these pharmacies. Also, Canada's drug supply is very limited and cannot service the need of the whole American population (Graham 2003). Considering the lucrative nature of the drug reimportation business, there is a high possibility that in fulfilling the increased demand of US consumers, Canadian pharmacists might order drugs from other countries such as India, Thailand, and Africa where the rate of drug counterfeiting could be higher. Nonetheless, various Canadian pharmacies available on the internet could be bogus and ordering medications from such online pharmacies could be dangerous (Mulligan 2003).

Is reimportation really a cost beneficial strategy?

While international price comparisons of medications show the comparatively higher prices in US, economists argue that international comparisons must be viewed with skepticism (Danzon 1998). Medication prices in other countries generally reflect the lower incomes in some states and the highly politicized nature of most foreign healthcare systems. Exchange rate variations also play a role in setting medication prices. The US has a relatively strong dollar in comparison with other countries, which could have made medications in some other countries seem particularly inexpensive. Research by Danzon and Kim (1998) studied the issues of patent protection, price controls, and continuing availability of prescription drugs without prescriptions. After adjusting for such factors as well as the role of generic equivalents, volume discounts, and frequency of use, they found that the average US consumer would have paid 3% more in Canada, 27% more in Germany, 30% less in France, 9% less in Italy, 8% less in Japan, 44% more in Switzerland, 9% more in Sweden, and 24% less in the UK.

Practices such as reference pricing and parallel trade, which are allowed in European Union (EU), may erode above-normal profits of the pharmaceutical industry if allowed in the US. While the concept of parallel trade is attractive, economic analyses showed that differential pricing is in fact beneficial for recovering costs of R&D of new drugs (Vogel and Joish 2001).

The medication costs issues in the US are mainly associated with brand name drugs. According to a new study by the FDA, Americans who buy drugs in Canada in hopes of saving money could pay significantly more for certain prescription drugs than if they had purchased generic versions of these drugs in the US. This study found that out of seven top-selling prescription drugs for chronic disease, six generic US versions cost significantly less than their Canadian equivalents (FDA 2003). A Canadian study of 27 top-selling generic prescription drugs concluded that three-fourths of those drugs cost less in the US, and Canadians could save millions by access to the US versions (D'Angelo 2002). These findings are asserted by another study, which found that US, on average, had higher prices for new originator products, but had the lowest generic prices compared with countries including Canada, Chile, France, Germany, Italy, Japan, Mexico, and the UK. The US also had the lowest over-the-counter drug prices (Danzon and Kim 1998).

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Costs involved in legalization of drug reimportation should not be neglected as well. The major emphasis for legalizing the practice of reimportation in the US has been the cost savings it offers. However, based on the estimates by Congressional Budget Office (CBO), enactment of the H.R. 2427 bill that allows reimporting drugs into the US would reduce total prescription drug spending by only about 1% or US$40 billion in the next decade (CBO 2003). Few economists and researchers have concurred that drug reimportation might not be a panacea for the soaring drug costs (Thompson 2004). To ensure the safety and authenticity of reimported/imported drugs, researchers have proposed using anti-counterfeiting technology for medication packages to avoid the entry of spurious prescription drugs in the US. According to the FDA estimates, this anti-counterfeiting technology would cost approximately $2 billion.

Policy implications and suggested potential solutions

Legalizing the reimportation practices might not solve the problem of growing prescription medication costs. Drug reimportation certainly involves potential threat of counterfeit drugs, which could result in additional costs to the healthcare system. The problem of high drug costs should be solved using the combination of most safe and appropriate treatment strategies wherever possible. One such strategy may be to promote use of FDA-approved generic drugs. Policymakers should promote policies allowing easy market entry of generic drugs and increasing awareness of Americans regarding costs-savings due to generic drug use.

The Medicare Part D, an enhancement of the Medicare Prescription Drug, Improvement and Modernization Act of 2003, will be implemented in January 2006. This outpatient prescription drug benefit plan has a potential to transform American healthcare delivery by significantly reducing the costs of prescription drugs along with increasing access to medicines. A transitional drug discount card program that has been ongoing since mid-2004 may be useful for elderly consumers to manage their prescription drug expenditures.

The major challenge for the US policymakers is to provide an access to affordable and safe medications to consumers without diminishing revenues available for pharmaceutical R&D. Although few solutions are suggested in the literature, an in-depth analysis and effectiveness of these solutions is required to solve the prescription drug problem. Until then, drug reimportation will continue to be a conundrum for US policymakers.

Conclusions

From its inception, the two main objections against reimporting prescription drugs from across the border have been the safety and authenticity of these drugs that could jeopardize public health, and that the profits of drug companies which is used for R&D of new drugs would be seriously hurt. Views on reimportation are extremely polarized among supporters and opponents with each trying to justify their own interests. The legislative and administrative bodies do not take the responsibility of the reimported drugs. On the other hand, various consumer groups and organizations continue to support the drug reimportation. The motive for consumers is the direct cost-savings offered by purchasing drugs from across the border. Increasing support from consumers might push legislatives to closely ponder over the issue of legality of drug reimportation practices.

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