

Economics of Reimportation and Risks Of Counterfeit Pharmaceuticals

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Historically, pharmaceutical prices have varied significantly across countries. This wide range of costs provides an incentive for arbitrage, a mechanism for sidestepping the secure supply chain and high prices that characterize some markets. Given that parallel trade in pharmaceuticals circumvents the regulatory protocols of the U.S. Food and Drug Administration, reimported drugs carry an increased risk of counterfeiting. This article examines the economic dynamics of reimportation and the risks posed by counterfeit pharmaceuticals. The analysis addresses the economic incentives, public policy ramifications, quality implications, and several policy alternatives.

Proposed solution to rising costs

The market for pharmaceuticals is characterized by sizable price differences across countries, which reflect distinct demand patterns, as well as differences in governmental regulations and health care policies. Recent events have drawn attention to the pharmaceutical price differential between the United States and Canada. In 2002, “Drug prices in the United States were 67 percent higher than in Canada” (Harris 2003). Reimportation, or parallel trade, has been proposed as a solution, allowing American consumers to purchase drugs at lower Canadian prices.¹ Under current U.S. law, it is illegal to import prescription drugs from other countries. Nevertheless, cross-border prescription drug sales have increased tremendously. Recent estimates place the value of such sales from Canada at \$650 million a year (Harris 2003). A similar trend has emerged along the U.S.-Mexican border.

To understand parallel trade, it is necessary to understand pharmaceutical price discrimination. The pharmaceutical industry is characterized by a high research and development cost that must be shared by all markets. Economic theory holds that the most efficient mechanism² for recovering this shared cost is to charge different consumers different prices, based on price sensitivity, to obtain the set of prices that generates revenue

¹ “Parallel imports are legitimately produced goods imported legally into a country without the authorization of a trademark, copyright, or patent holder. The essential purpose of such trade is arbitrage between countries with different prices” (Ganslandt 2001).

² This mechanism, known as Ramsey pricing, provides the way in which markups should vary based on elasticities of demand.

sufficient to cover the shared R&D cost as well as the highest level of consumer welfare.

Parallel trade results in unregulated distribution pipelines and weakened regulatory control of the supply chain, both of which are characteristics that facilitate counterfeiting. According to the World Health Organization, counterfeiting is facilitated when “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is a lack of effective intellectual property protection; and due regard is not paid to quality assurance” (WHO 1992). Notably, many characteristics described by the WHO are exacerbated in markets in which reimportation occurs.

Magnitude of the problem

According to the WHO, “A counterfeit medicine is one [that] is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with correct ingredients, with wrong ingredients, without active ingredients, with incorrect quantity of the active ingredient, or with fake packaging” (WHO 1997). It is a pervasive problem, affecting nations of every size and income level, and drugs of every description. Nevertheless, the magnitude of the problem is difficult to estimate. The following facts illuminate the problem’s scope:

- Counterfeit aspirin tablets containing little or no acetylsalicylic acid can be profitable, especially at open-air markets, such as those in African villages (McGregor 1997).
- In Nigeria, 80,000 children have been given fraudulent meningitis vaccines. India has been found to have some fake polio vaccines (Knox 2003).
- India accounts for 35 percent of the counterfeit drugs that are produced; Nigeria produces about 23 percent; and Pakistan, 13.3 percent (Datta 2003).
- Dora Nkem Akunyili, PhD, head of Nigeria’s institutional equivalent of the FDA, has stated that the share of counterfeit drugs in her country may be as high as 90 percent (Kontnik 2003).

While pharmaceutical counterfeiting is as profitable as the narcotics trade, it is subject to lesser criminal penalties. It also is a difficult crime to uncover, even with the availability of sophisticated tools to assist in this process. Predictably, criminal syndicates in all regions of the world have established a visible presence in the counterfeit pharmaceuticals trade.

The WHO estimates that 10 percent of the global market for pharmaceuticals comprises counterfeit products. With an estimated annual turnover of \$435 billion, the financial loss for the industry could reach \$43.5 billion per year.³ To put this figure in perspective, it is worth noting that member companies of the Pharmaceutical Research and Manufacturers of America invested \$32.1 billion in R&D in 2002 (PhRMA 2003).

Public policy ramifications

Beyond arbitrage, there are long-term consequences for pharmaceutical prices due to reimportation. In the long run, it is more likely that prices will rise in Canada rather than decrease in the United States. Evidence of this strategy already is visible in the single market of the European Union (Danzon 1998).

Alternatively, pharmaceutical manufacturers may decide to limit the supply of drugs to source countries. Considering that the U.S. market is 10 times larger than the Canadian market, many manufacturers, including GlaxoSmithKline, Pfizer, AstraZeneca, and Wyeth, are electing to limit drug sales to Canada to curb reimportation. Manufacturers now are selling their products directly to pharmacies and hospitals instead of going through wholesalers or distributors, allowing them to enforce their terms of sale more effectively.

Although prices are the driving force behind reimportation, they are only part of the problem. The economic welfare effects generated by parallel trade are ambiguous, further complicating the analysis. As with patents, parallel imports involve a tradeoff between rewarding innovation and market power. The ultimate value of the patent depends, in part, on the geographic reach of this protection. Parallel imports may reduce the patent holder's ability to capture returns to R&D, thus potentially diminishing the incentive to innovate.⁴ Ultimately, pharmaceutical reimportation may decrease global welfare.

The incentive to invest in R&D is the third public policy consideration. While estimating drug development cost is controversial, it is undeniably an expensive undertaking. According to the Tufts Center for the Study of Drug Development, the estimated cost is nearly \$900

³ Accounting for industry growth and increasing incidence of counterfeiting, this is in line with other published estimates.

⁴ Ganslandt (2001) and Danzon (1998) provide more nuanced treatments of the dynamic efficiency issues surrounding the tradeoff.

million (Tufts 2003). As such, it is not surprising that patent protection is disproportionately more important in the pharmaceutical and chemical industries than in other sectors. It ensures that the researcher appropriates the returns to R&D.⁵ Patents and other forms of protecting intellectual property rights safeguard the industry's ongoing investment in R&D. This protection is undermined by price controls that prevent innovative firms from recovering their research investments. The decline of the European pharmaceutical industry is evidence of the effects of price controls.

Finally, parallel imports preclude the FDA from guaranteeing the safety of drugs that arrive from importing nations. Without a secure supply chain, the FDA's capacity to oversee the situation is compromised and its responsibilities become unmanageable. Providing safety assurances for reimported drugs would necessitate monitoring not only the Canadian supply chain, but also the global pharmaceutical supply chain. Legalizing parallel trade in pharmaceuticals from Canada permits drugs to come from any nation or source, as long as they enter the United States through Canada.

Quality implications

Because many reimported prescription drugs are genuine, reimportation is a necessary but not sufficient condition for quality assurance. Storage and handling conditions are also concerns. Other countries may not adhere to the same rigorous standards that the FDA mandates. The strict chain of custody maintained by firms and required by the FDA may be compromised, resulting in subpotent drugs. The existing United States regulatory system safeguards not only the pharmaceutical source, but the handling conditions as well.

Although precise estimates do not exist, the use of counterfeit pharmaceuticals has resulted in prolonged illness, debilitation, and death—a phenomenon not limited to developing nations. Reimported drugs from Mexico already have been linked to several deaths in the United States (Turner 2003). Moreover, counterfeit drugs that contain a substantially reduced dose of the active constituent contribute to the great increase in global drug resistance, undermining the fight against infectious diseases.

If the U.S. market were to be opened to reimported prescription drugs, the security of the existing system could not be relied on to protect the consumer. The

⁵ Echoing earlier findings, the 1994 Carnegie-Mellon Survey found that while patents are seen as “the least effective of the appropriability mechanisms,” the drug industry regards them as more effective than other mechanisms (Cohen 1996). Several additional studies report that the protection of intellectual property is disproportionately more important to the chemical and pharmaceutical industries. For a comprehensive review of these studies, refer to Lybecker 2000.

FDA's regulatory system is based on the incentives of stakeholders⁶ who have much to lose if they fail to play by the rules. The current system, therefore, is ineffective when it comes to rogue traders who have little to lose and frequently operate at the market fringe (deKieffer 2003). The threat of rogue traders is only one risk of reimportation, which has led to widespread opposition among regulators and health care professionals.⁷ FDA opposition to pharmaceutical reimportation dates back to 1969 — 10 of the last 11 FDA Commissioners have opposed the policy. In addition, both former Health and Human Services Secretary Donna Shalala and current HHS Secretary Tommy Thompson have expressed their opposition.

Safety concerns surrounding pharmaceutical reimportation also alarm international authorities. Because the population of the United States is nearly 10 times that of Canada, Canadian officials refuse to monitor drugs shipped to the United States or to stop the huge flow of drugs moving through Canada into the United States from other nations. Moreover, legislation now under debate in Congress provides that covered products may be imported from more than 24 nations.⁸

Finally, parallel trade in pharmaceuticals generates a number of monitoring difficulties that are less apparent but significant threats to safety. With drugs entering through many source-nations, safety warnings and product recalls are more difficult to execute. In addition, product-packaging standards vary across markets, and prescription recommendations and contraindications also may differ. Differences in product packages remove the familiar packaging clues that are so important in the visual detection of counterfeits.

Policy alternatives

Consumers want access to a variety of affordable, safe, innovative prescription drugs without prohibitively high prices, counterfeit drugs, diminished R&D, or burdensome government regulation. How to ensure this access and avoid the undesirable elements is much less clear. The following four possible policy alternatives are proposed as a starting point:

- *Health insurance and prescription drug coverage.* The primary focus of the current debate has been the elderly in the population who are without prescription drug coverage. The best solution will address

⁶ Pharmaceutical manufacturers, wholesalers, distributors, physicians, and pharmacists.

⁷ The American Medical Association, the National Medical Association, and the American Osteopathic Association oppose the Pharmaceutical Market Access Act of 2003 (HR 2427) (Dingell 2003).

⁸ The complete list of importing countries may be found in the United States Code, 21 USC 382(b)(1)(A).

the underlying problem by securing an affordable health care system.

- *Manufacturer's rebates.* This alternative would require pharmaceutical manufacturers to change their pricing policies in existing low-price countries. Prices would increase to a uniform price level, but manufacturers would offer rebates that would be paid to the payer or national health system.
- *Reimportation exemptions.* Considering the economic efficiency of Ramsey pricing, reimportation should be disallowed for products such as pharmaceuticals that incur significant global shared costs. Exemptions to parallel trade laws would allow manufacturers a short period of above-marginal-cost pricing to recover the R&D investment.
- *Free market exports.* Drugs consumed domestically in low-price countries would be subject to government price controls, while exported products would be priced according to market forces. It should be possible to institute this pricing policy through contractual agreements between manufacturers and suppliers.

Price differentiation vs. safety concerns

At first glance, parallel trade in pharmaceuticals appears to be the solution to rising drug prices. Yet the price differential that characterizes neighboring markets and safety concerns actually are the most important elements of the current debate. While capitalizing on international price differences is tempting, the economic incentives involved in pharmaceutical reimportation cannot be considered without the associated risks. Before embracing reimportation, the public policy ramifications, quality implications, and potential policy alternatives should be considered. In summary, reimportation is a complicated issue that has the potential to shape both health care policy and the state of the pharmaceutical industry.

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