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Would Prescription Drug Importation Reduce U.S. Drug Spending?

Summary
The rapid growth of prescription drug expenditures is prompting consumers and policymakers to look for new ways to control drug spending. Because drug prices abroad are often lower than those in the United States, some suggest that drug spending would be reduced if drug products distributed in foreign countries could be legally imported for sale in the United States. Even if this practice was made legal, however, unique aspects of the prescription drug market would limit the additional volume of prescription drugs reaching the United States. On the basis of its evaluation of recent proposals, the Congressional Budget Office (CBO) has concluded that the reduction in drug spending from importation would be small.

Introduction
In recent years, growth in prescription drug spending has outpaced that of every other category of health expenditures. Spending on prescription drugs grew at a real (inflation-adjusted) average annual rate of 14.5 percent from 1997 to 2002, reaching $162 billion in 2002.[1] That rapid growth raised prescription drug spending's share of total health expenditures to 10.5 percent in 2002, compared with 5.8 percent a decade earlier. In 1999, prescription drugs surpassed nursing homes as the third-largest category of personal health care expenditures, after hospital and physician services.

The prices of patented prescription drugs abroad are often lower than those in the United States, even for the same product. As a result, some U.S. consumers save money by purchasing prescription drugs in Canada or Mexico.[2] Many observers suggest that such savings could be extended to the whole nation if commercial importation of drugs was permitted.

In July 2003, the U.S. House of Representatives passed H.R. 2427, which would have required the Secretary of Health and Human Services (HHS) to issue regulations permitting pharmacists, wholesalers, and individuals (for personal use) to import prescription drugs from 25 industrialized countries. That bill did not become law, but the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 contains a provision permitting importation of prescription drugs from Canada contingent on the HHS Secretary's certification of the provision's safety and its prospect of significant cost savings. To date, the Secretary has not provided that certification. As Congressional debate continues, officials in several states—including Illinois, New Hampshire, Wisconsin, and Minnesota—have expressed interest in importing prescription drugs from Canada.

The Food and Drug Administration (FDA) has responded to calls for importation with warnings that the safety of imported drugs cannot be guaranteed and that patients using those products face elevated health risks. While safety issues are an important concern, this CBO analysis focuses on another important question: How much would private consumers and governments save if drug importation was permitted?

The Prescription Drug Market
Several aspects of the prescription drug market distinguish it from other markets. The first is the unusual importance of research and development (R&D) in creating new drug products. Drugmakers compete vigorously to

1. Centers for Medicare and Medicaid Services, Office of the Actuary, National Health Statistics Group. Figures were adjusted for inflation using the personal consumption expenditures chain-type price index from the Bureau of Economic Analysis.

2. This practice is generally illegal. Usually, drug products distributed in other countries are not approved for distribution in the United States, although officials rarely enforce this restriction for small amounts (up to a 90-day supply) intended for personal use.

be first on the market with breakthrough products and to introduce alternatives to existing products. Developing new drugs and getting them approved for sale is a risky, costly, and time-consuming enterprise, and drugmakers spend a higher proportion of their revenues on R&D than do firms in most other industries.[3] A decision on whether to undertake a costly clinical trial is made in the face of scientific uncertainty over the compound's clinical value, and even in successful cases the drugmaker sees no revenue for many years. One recent analysis suggests that when all relevant economic costs are taken into account, including costs from unsuccessful compounds, an average of about $800 million in R&D spending is incurred for each internally produced new compound reaching the market.[4] Most new compounds never make it to market, and research costs from the many failures are financed by sales from the few successes.

If competitors could immediately duplicate a new drug, then undertaking the long and costly development process would be unattractive. To entice drugmakers to undertake R&D, sales of new prescription drugs are protected by patents, which give drugmakers exclusive rights to make and market particular products, frequently for 10 to 14 years following FDA approval.[5] During that period, the drugmaker is the sole provider of a patented product and can charge high prices where possible and choose to make concessions in more price-sensitive markets. That ability is greatest for unique patented drugs that provide new and significant clinical benefits. Thus, while the race for innovation in drug development is highly competitive, competition in the market for existing patented drugs is limited by the fact that a given product can be distributed by only one party.[6] In many cases, however, some competitive pressure can result from the availability of one or more similar patented drugs within the same therapeutic class.

Another key distinction between the prescription drug market and other markets is the central role of regulation in determining what products may be sold. With varying degrees of stringency, the United States and most industrialized nations have regulatory standards designed to ensure the safety and clinical efficacy of commercially available drugs. Regulatory standards differ by country, and drugmakers have the opportunity to tailor marketing approaches to each country's specific circumstances. To be distributed in the United States, prescription drugs must meet the FDA's particular safety and efficacy standards and also be approved for distribution in specific forms, dosages, and strength levels. New dosages or alternative forms—capsules versus tablets, for example, or delayed versus extended release—require specific FDA approval. Finally, all products distributed in the United States must be produced in facilities registered with the FDA for production of those specific products. Much of existing worldwide sales volume does not satisfy that criterion, even drugs that otherwise meet safety and efficacy standards.

In many foreign industrialized countries, prices are also controlled or partially controlled by regulation. In the Canadian patented drug market, for example, drugmakers may not charge a price above a maximum level determined by Canada's Patented Medicine Prices Review Board (PMPRB). Drugmakers may generally set prices as they see fit in the U.S. private market, although certain restrictions apply in the case of government buyers such as Medicaid.

The Economics of Drug Importation

Recent drug importation proposals would allow drug products that were distributed in a foreign market (regardless of where the drugs were manufactured) to be diverted to consumers in the United States. Drug importation is thus a form of "parallel trade," which refers to the legal movement of products across borders without the explicit consent of the manufacturer, usually in response to price disparities.

3. Office of Technology Assessment, "Pharmaceutical R&D: Costs, Risks, and Rewards," OTA-H-522 (February 1993). For estimates of pharmaceutical R&D spending, see Pharmaceutical Research and Manufacturers of America, *Annual Report, 2003-04* (Washington, D.C.: PhRMA, October 2003).

4. Joseph A. DiMasi, Ronald W. Hansen, and Henry G. Grabowski, "The Price of Innovation: New Estimates of Drug Development Costs," *Journal of Health Economics,* vol. 22 (2003), pp. 151-185.

5. Technically, patent life is 20 years starting at the application filing date. Effective patent life is usually shorter because patents are obtained before products are approved for marketing.

6. Not all prescription drugs are under patent, but it is patented drugs that exhibit large international price disparities. The market for generic drugs, in which several firms might produce essentially the same product, is generally much more competitive and therefore produces more downward pressure on prices.

Enhanced parallel trade in prescription drugs would not necessarily significantly enhance competitive pressure and yield cost savings to consumers. One reason is that drugmakers can already take advantage of any lower-cost foreign manufacturing environments, so increased parallel trade introduces no new prospect of savings in production.[7] Furthermore, competitive pressures that generally translate lower costs into lower prices are muted in the prescription drug market because exclusive marketing rights insulate makers of patented drugs from direct competition. Thus, an expansion of parallel trade in prescription drugs differs in nature from a general expansion of free trade, which often does introduce new opportunities for production savings and enhanced competitive pressures.

When able to do so, firms charge different prices based on purchasers' willingness to pay for a particular prescription drug. International disparities in patented drug prices are, in part, a reflection of that practice. Perhaps because of lower incomes, institutional arrangements, or different consumer preferences, consumers in a foreign country may not be willing to spend as much, on average, as U.S. consumers are on a prescription drug. Instead of charging a high price and selling only a small quantity of a drug in such a foreign market segment, patented drugmakers lower their prices.

Expansion of parallel trade would make it more difficult for patent holders to charge different prices across markets. However, even if parallel trade in prescription drugs eliminated international price differences, it is not clear that the resulting global price would be substantially lower than the price initially charged in the United States. If forced to charge one price for all, a maker of patented drugs could choose a price that is higher than that currently charged in some foreign countries, even if some price-sensitive consumers are priced out of the market.

Permitting the importation of foreign-distributed drug products would not necessarily result in much additional volume reaching the United States. Many foreign governments already intervene in the patented drug market by regulating prices, and some might act to limit exports to avoid shortages. Furthermore, the possibilities of parallel trade are limited by drugmakers' ability to restrict shipments of patented drugs to markets outside the United States, effectively limiting potential imports.[8] Drugmakers could also try to stipulate in sales agreements that prices be contingent on products not being sold across borders.

Although the makers of patented drugs can exert substantial control on supply, their inability to exert comparable control over the distribution of that supply might permit some product volume to be diverted from overseas markets to the United States if restrictions on parallel trade were loosened. Any benefit to U.S. consumers from lower-priced imported drugs would be the result of that "slippage." But while an individual can fill a prescription in another country and realize savings reflecting the full difference in price, the same would not be true for the health care system as a whole. Potential overall savings would depend not just on the price difference but on the size of the parallel trade market, with greater potential savings accompanying greater potential import volume. For example, expanded parallel trade with Canada by itself would offer sharply limited prospects for aggregate savings given the small size of the drug market in Canada. Proposals to permit parallel trade with a large group of countries would offer greater potential savings.

Estimating the Effect of Parallel Trade on Drug Spending

Estimates of the potential import volume and average price differentials between the United States and other industrialized countries provide a basis for estimating the scope of potential savings.

Potential Volume of Imports into the United States

Because large-scale parallel trade in prescription drugs would be new to the United States, predicting its effects is difficult. Europe, however, has experience in this area. Recent court rulings there have established the legitimacy of parallel trade in pharmaceuticals (including patented drugs) within the European Union (EU), engendering a new industry of parallel traders. On the basis of a review of the literature on parallel trade in prescription drugs in Europe, CBO estimates that in the lower-price EU countries, roughly 5 percent to 6 percent of the volume is diverted by intermediaries for sale in higher-price EU countries. Because of institutional differences, parallel trade

7. Manufacturers may distribute foreign-made products in the United States, provided that those products comply with patent law and FDA requirements.

8. See, for example, "Pfizer Cuts Supplies to Canadian Drugstores; Sales Are Halted to Reimporters of Bargain Drugs," *Washington Post,* February 19, 2004, p. A10.

among European countries is an inexact model for parallel trade between foreign countries and the United States. Nonetheless, the pattern of drug product flow from lower-price "source" countries to higher-price "destination" countries within Europe may shed light on the volume of cheaper drug products that could become available for importation to the United States if parallel trade is expanded.

Potential savings in the United States would depend on import volume, which reflects the size of the total drug market in source countries. CBO estimates that the volume of world supply outside the United States is about twice the size of the U.S. market.[9] Assuming that volume slippage from outside the United States would resemble that from source countries within Europe, CBO estimates that the import volume would be in the range of about 10 percent to 15 percent of the U.S. market.

How Much Cheaper Are Drugs in Other Countries?

Prescription drug prices tend to be higher in the United States than in many other countries. On the basis of a review of existing literature, including estimates from Canada's PMPRB and other sources, CBO concludes that average prices for patented drugs in other industrialized countries are 35 percent to 55 percent lower than in the United States. Because analyses often employ different methods, making sense of the evidence requires consideration of three important points.

It Matters Which Drugs Are Included. Some estimates of drug price differences include both patented and generic compounds. Others are limited to a small number of top-selling patented drugs. Including generic drugs reduces the average price difference; focusing on a few top-selling patented drugs increases the difference. For purposes of analyzing drug importation proposals in the United States, neither of those extremes is appropriate. CBO's analysis focused on the likely imports—patented prescription drugs—not just a handful of top sellers and not generic drugs.

Different U.S. Buyers Pay Different Prices. In countries with one principal payer, it is easy to identify a drug's price. In the United States, however, there are many purchasers, and they pay a variety of prices. Large private purchasers negotiate prices below those paid by persons lacking drug coverage. Regulation affects the prices paid by government programs. CBO's estimated savings from importation reflect the fact that some purchasers are already enjoying discounts and stand to gain less from the proposed policy.

Price Disparities Vary by Country. According to Canada's PMPRB, U.S. patented drug prices were 67 percent higher, on average, than those in Canada in 2002.[10] Although that figure is a reasonable starting point for analyses of proposals that would permit importation only from Canada, it would not necessarily be appropriate for analyzing other proposals that would permit importation from as many as 25 countries. CBO is aware of no analysis of U.S.-foreign differences in patented drug prices in so broad a market and therefore estimated potential savings from broad importation proposals based on available evidence in a relatively small set of industrialized countries.[11]

Other Factors Affecting Potential Savings

Savings from expanded parallel trade would not reflect the full average difference in price. A portion of any given price difference would accrue to wholesalers and other intermediaries facilitating the domestic sale of drugs diverted from foreign markets. Some of that portion would represent physical costs (most imported products would require new packaging and labeling), and some would reflect earnings retained by firms. Further eroding potential savings would be the likely refusal of drugmakers to indemnify intermediaries against damages associated with the safety and integrity of products shipped to other markets.[12] Parallel trade intermediaries would therefore probably face added liability insurance costs, which would be passed on to consumers.

9. Because the U.S. market has higher average prices than do other countries, U.S. spending on pharmaceuticals amounts to a higher proportion of world expenditures than it does world volume.

10. Patented Medicine Prices Review Board, *Annual Report* (Ottawa, Ontario: PMPRB, 2002), p. 23.

11. For examples, see Patented Medicine Prices Review Board, *Annual Report* (2002), and Patricia M. Danzon and Michael F. Furukawa, "Prices and Availability of Pharmaceuticals: Evidence from Nine Countries," *Health Affairs* Web Exclusive (October 29, 2003), pp. 521-536.

12. Manufacturers often indemnify domestic wholesalers against such damages for products intended for distribution in the United States. With no incentive and little ability to vouch for the treatment and storage of the products while overseas, manufacturers are unlikely to do so for drugs shipped outside the United States.

Furthermore, the various participants in pharmaceuticals markets—foreign governments, drugmakers, and regulators—could respond to expanded parallel trade in ways that would be likely to reduce potential savings.

Foreign Governments. Many foreign governments would have incentives to limit the volume of drugs diverted to the United States, given both their interest in preventing shortages or higher prices in their own countries and the drugmakers' ability to limit supply. Depending on domestic circumstances, governments might simply influence purchasing arrangements by agreeing to export restrictions by contract, for example, or by imposing statutory restrictions on imports.

Drugmakers. Drugmakers would have an incentive to respond so as to minimize parallel trade or to reduce its rewards. Among their options, as mentioned above, are contract restrictions between manufacturers and wholesalers prohibiting exports, and limits on the volume shipped to markets where orders appear to exceed local needs. Price hikes outside the United States would reduce the price differential and hence the incentive for parallel trade; in some circumstances, even the threat of price hikes could encourage contract restrictions.

Alternatively, drugmakers could differentiate products distributed in other countries (by altering color, size, shape, or dosage), thereby preventing their distribution as approved products in the United States. Because current U.S. regulations require that all drug products (domestic- or foreign-made) be manufactured in registered facilities, drugmakers could prevent legal distribution in the United States by shifting production to foreign facilities not specifically registered with the FDA. Furthermore, under a recent decision of the Court of Appeals for the Federal Circuit, U.S. patent law may enable the manufacturer of a drug patented in the United States and produced overseas to prevent subsequent importation, resale, or use of the product in the U.S. market.[13]

Regulators. Any major proposal is likely to grant the FDA leeway in defining approved products. Given the possible responses of drugmakers—altering products, shifting production away from registered facilities—the manner in which regulators exercise discretionary authority could greatly affect volume of prescription drugs entering the United States under parallel trade.

Conclusion

On the basis of its evaluation of proposals to date, CBO has concluded that permitting the importation of foreign-distributed prescription drugs would produce at most a modest reduction in prescription drug spending in the United States. H.R. 2427, for example, which would have permitted importation from a broad set of industrialized countries, was estimated to reduce total drug spending by $40 billion over 10 years, or by about 1 percent.[14] Permitting importation only from Canada would produce a negligible reduction in drug spending.

13. Jazz Photo Corporation v. Int'l Trade Comm'n, 264 F.3d 1094 (Fed. Cir. 2001), cert. denied, 122 S. Ct. 2644 (2002).

14. Congressional Budget Office, *H.R. 2427: The Pharmaceutical Market Access Act of 2003*, CBO Cost Estimate (November 2003).

This issue brief was prepared by Colin Baker and based on an analysis developed by him, Anna Cook, and Margaret Nowak. It and other CBO publications are available at the agency's Web site (www.cbo.gov).