

Prescription Drug Costs

Issue

Health care costs in general have grown faster than the economy. Although still only a modest part of total health care spending in the United States (11% in 2002), the growth in pharmaceutical spending has outpaced other categories of health care services over the last few years. What, if anything, should the government do to make prescription drugs more affordable?

Background

Developments in pharmaceuticals have transformed health care over the last several decades. Today, many diseases are prevented, cured, or managed effectively for years through the use of prescription drugs. In some cases the use of prescription drugs keeps people from needing other expensive health care such as being hospitalized or having surgery.

These advances have not come without a price. In 2002, spending on prescription drugs in the U.S. grew 15 percent compared to a 9 percent increase for all health care.¹ This growth in spending on prescription drugs is due to three factors: increased use of prescription drugs in general, the higher costs for new products coming to market and replacing existing drugs, and increases in drug prices. In 2002, the average price of a retail prescription grew almost 6 percent, reflecting the influence of newer, higher priced prescription products in the market.²

The prices for prescription drugs reflect the consumer demand, or willingness to pay for medications, and the patent system, which encourages manufacturers to invest in developing new drugs. Consumer demand has been affected by the growth in private third-party payment for pharmaceutical products, which means that consumers directly see only a small part of increasing drug costs when they fill a prescription.³ Another possible factor has been the growth in direct-to-consumer marketing of pharmaceutical products, which encourages consumers to ask their doctors about new medications⁴, while increasing their knowledge about drug options.

Patents affect prices by providing manufacturers who develop new pharmaceutical products an exclusive right to sell the drug for 20 years from the date of the patent filing.⁵ The actual costs for making most prescription drug products are relatively small (although such costs may be significantly higher in some cases, such as for biotechnology products), and thus, the prices for a drug are usually considerably lower once the patent expires and generic competition enters the market. Therefore, the company that developed the drug must recoup its investment and make most of its profit on a product during the period it has the patent. Once the patent expires, the drug may be manufactured in generic versions by any number of manufacturers.⁶ Even during the patent years, other products to treat the same condition may come to market, producing price competition among therapeutic options.

Manufacturers make substantial investments in the products that they bring to market, and to be profitable, they must recoup not only the development costs of successful drugs and devices, but also, the costs for research and development for products that never make it to market. Only one in five medicines that enter the clinical testing process ever gain Food and Drug Administration (FDA) approval and enter the market.⁷ Thus far, however, drug makers have been able to make a profit. From 1995 through 2002, pharmaceutical manufacturing was the most profitable industry in the U.S. Profitability declined somewhat in 2002, and in 2003 it ranked third with profits after taxes of about 14 percent.⁸

The cost of prescription drugs has commanded considerable public attention over the last decade. People with coverage for their prescription expenses have seen their cost-sharing for brand products increase substantially as employers and health plans move to arrangements which provide financial incentives for consumers to use lower cost drugs.⁹ People without drug coverage, including many Medicare beneficiaries, often pay the highest prices for prescription medications, and must confront rapid cost increases directly. In response to concerns over the out-of-pocket cost burdens on the elderly and disabled, Congress passed a law last year that provides new Medicare outpatient prescription drug benefits that will be available beginning on January 1, 2006. While government assistance will be comprehensive for low-income beneficiaries, the benefits for others are such that many Medicare beneficiaries will still be paying large amounts out-of-pocket for their medicines.

Options for making prescription drugs more affordable

While there are a number of policy options under consideration for addressing rising drug costs, the two that are currently receiving the most political attention are reimportation and the government's role concerning drug prices in the Medicare program.

Importation. Proposals that would allow Americans to purchase drugs from other countries are referred to under the terms "importation" or "reimportation".¹⁰ It is currently illegal to import prescription drugs into the U.S. from other countries, and only the original manufacturer may reimport a pharmaceutical product, subject to meeting certain standards on how they are handled and labeled. In practice, however, the FDA, which is the federal agency responsible for overseeing pharmaceutical products, does not enforce the law banning importation in certain circumstances where drugs are imported for personal use.

The significantly lower prices available for common prescription drugs in bordering countries, Canada and Mexico, has led some Americans to import drugs from those countries and has encouraged politicians of both parties to propose lifting the import ban. Congress has passed legislation allowing for expanded importation of drugs on several occasions but the laws were never implemented because they required that the Secretary of the Department of Health and Human Services (HHS) conclude that safety could be maintained and that costs would significantly be reduced. Both HHS Secretary Shalala in the Clinton Administration, and Secretary Thompson in the Bush Administration concluded that they could not meet these standards.

A number of bills on importation have been introduced in the current Congress. The bills differ in a number of ways. Some would allow drugs to be imported only for personal use while others would allow imports for commercial purposes. The bills also differ in terms of the countries from which drugs could be imported, safety standards, regulatory requirements, and fees that would be levied to help pay the costs of increased government regulation. In addition, a number of states, including Illinois, Iowa, Michigan, Minnesota, and Ohio, as well as a number of cities, have undertaken efforts to get lower drug prices for their residents through purchase from other countries. They are doing this in order to reduce state costs for providing drug benefits to state employees, or to make it easier for their residents to import drugs. Although the FDA has not approved these efforts, it also as yet has not stopped them.

Would allowing importation result in lower prescription drug costs for American consumers?

There are varying opinions on this issue, but most experts caution that savings cannot be guaranteed, especially if importation is limited to only certain countries, such as Canada.¹¹ The Congressional Budget Office (CBO), the agency responsible for estimating the financial impact of federal policy changes, concludes that the effect would be small.¹² It acknowledges that prices for drugs still under patent protections (as opposed to generic products) are 35 percent to 55 percent lower in other countries than in the U.S. However, it cautions that responses by foreign governments and by the pharmaceutical industry to such a change in policy could erode most savings. For example, foreign governments could restrict the supply of drugs leaving their borders; or pharmaceutical manufacturers could limit the supply of drugs sold to foreign nations that facilitate sales to U.S. purchasers.

On the other hand, those who advocate in favor of allowing importation acknowledge that drug importation limited only to Canada would not be a long-term solution.¹³ They believe that if importation were legal from other countries, including the Asian and European markets, as well as from Canada, there would be enough volume to significantly affect prices in the U.S. market.¹⁴ They also believe that the potential of lower prices from foreign countries will cause U.S. pharmacies to cut their prices in order to be competitive. At the very least, they feel that the debate around importation makes people aware of the fact that prices are lower in other countries and puts continued pressure on drug makers to keep their U.S. prices in check.

Supporters of importation also argue that the safety issue can be addressed. For example, legislation which passed the U.S. House of Representatives with bipartisan support would limit reimportation to FDA-approved drugs manufactured in FDA-approved facilities in 25 countries, require the use of counterfeit-resistant packaging (or testing of each pharmaceutical shipment that does not use such packaging), and give the Secretary of Health and Human Services the power to immediately halt importation if a product violates the law.¹⁵ Opponents argue that these safeguards are not adequate. Bills on importation that have been introduced in the Senate are still awaiting action and may not be debated before Congress adjourns.

Government's role in Medicare drug prices. The second visible issue in the 2004 campaign relating to drug prices involves the appropriate role for government regarding drug prices for Medicare beneficiaries. The Medicare Modernization Act of 2003, which establishes outpatient prescription drug coverage for Medicare beneficiaries beginning in 2006, relies on competition among private health plans to make drugs available to beneficiaries at reasonable prices. Medicare beneficiaries who wish to participate in the new program will have to enroll in one of the Medicare drug plans available to them in their area of residence. Each plan will be responsible for negotiating with drug manufacturers and pharmacies to determine the prices for medicines that will apply under the plan. Because the drug benefits are limited for beneficiaries who are not low-income, many seniors will have access to lower prices, but will also still have significant out-of-pocket costs for their medicines. The law specifically prohibits the government from interfering in the negotiations between the drug plan sponsors and drug manufacturers and pharmacies. It also prohibits the government from establishing any specific list of drugs that will be covered (formulary) or imposing any price controls on drugs.

Supporters of the market-based approach in the new Medicare law believe that the competition for enrollees will cause plans to negotiate with drug manufacturers and pharmacies to offer drugs at the lowest possible prices. They believe that permitting the government to set prices for Medicare would not necessarily guarantee lower prices, may have unintended consequences on the rest of the market, and would negatively affect patients because government price controls would stifle industry incentives to invest in research and development of new therapies.

Some people argue that the current market-based tools being used by health plans and pharmaceutical benefit managers (PBMs) have not been effective, and that prices for brand pharmaceutical products are considerably higher in the U.S. than in other countries where governments take a more active role in negotiating prices and rates of return with manufacturers. It should be noted that the federal government regulates prescription drug prices in the fee-for-service Medicaid program and the veterans' health program.¹⁶ Opponents of market-based tools also suggest that in cases where manufacturers have exclusive rights for drugs with few or no competitors, competition may have little or no impact on price. They support removing from the law the ban on government interference and price setting, and granting the government the authority to directly negotiate prices with manufacturers. Some advocate that this authority not be used unless the private plans are not able to achieve lower prices. Other options include using this power only for certain drugs for which there is no competition.

Assessing Candidate Positions

While there is no clear partisan division between Republicans and Democrats on the issue of importation, candidates tend to be more divided regarding government intervention in drug pricing, aligning

themselves with those who support a market-based approach versus those who favor more government intervention. Included below are a series of questions to help evaluate candidate positions on prescription drug costs.

- Should the U.S. allow people to buy prescription drugs from other countries? Under what circumstances?
- What can be done to assure the quality and safety of prescription medicines imported into the U.S.?
- If people in the U.S. are allowed to import drugs, will drug companies invest less in research and development? If so, are there any measures the government can take to encourage companies to do research and development?
- Is a market-based system or government intervention the most effective way to control drug costs for seniors?
- If prescription medicines remain unaffordable for many seniors after the Medicare drug law goes into effect, what approach should be taken?

In the presidential election, both the Bush-Cheney and Kerry-Edwards campaigns support the importation of safe drugs. The two campaigns differ on the role of government in Medicare drug prices. The Bush-Cheney campaign opposes direct government negotiation of prices and supports relying on competition between private plans to control costs, while the Kerry-Edwards campaign supports direct government negotiation of prices.

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¹ National Health Expenditures Tables. <http://www.cms.hhs.gov/statistics/nhe/historical/t2.asp>.

² Lundy, Janet, Benjamin Finder, and Gary Claxton. Trends and Indicators in the Changing Health Care Marketplace, 2004 Update. Kaiser Family Foundation. April 2004. Exhibit 1.18.

³ The percentage of prescription drug costs paid for by private health insurance increased from 24 percent in 1990 to 47 percent in 2001. Fact Sheet: Prescription Drug Trends, Kaiser Family Foundation, May 2003. Figure 2.

⁴ Rosenthal, Meredith B., et al. Demand Effects of Recent Changes in Prescription Drug Promotion, Kaiser Family Foundation, June 2003. Direct to consumer advertising rose by 28 percent annually between 1996 and 2001. The study found that increases in direct-to-consumer advertising between 1999 and 2000 accounted for 12 percent of drug sales growth during that period.

⁵ However, the effective patent period is usually shorter because patents are obtained before the products are approved for marketing.

⁶ Often, in order to extend their favorable market situation, a company may get a new patent on a slightly different version of a drug about to go off patent.

⁷ Di Masi, Joseph A. "Success Rates for New Drugs Entering Clinical Testing in the United States," 58 *Clinical Pharmacology and Therapeutics*, 1995, p. 1-14.

⁸ Lundy, Janet, Benjamin Finder, and Gary Claxton. Trends and Indicators in the Changing Health Care Marketplace, 2004 Update. Kaiser Family Foundation. April 2004. Exhibit 1.21.

⁹ Between 2000 and 2004, copayments in multi-tier arrangements increased by 62 percent for preferred brand drugs and by 94 percent for non-preferred brand drugs. Henry J. Kaiser Family Foundation and Health Research and Educational Trust, *Employer Health Benefits Annual Survey*, 2000 and 2004.

¹⁰ Importation refers to bringing products into the U.S. from other countries, whereas reimportation means bringing back into the U.S. products that were produced here and exported to another country.

¹¹ Schuler, Kate. Weighing Promise and Perils of Drug Importation. CQ Weekly, July 24, 2004. p. 1791.

¹² CBO. Would Prescription Drug Importation Reduce U.S. Drug Spending, April 29, 2004.

<http://www.cbo.gov/showdoc.cfm?index=5406&sequence=0>

¹³ Families USA. Written testimony submitted to the U.S. Committee on Finance, Hearing on International Trade and Pharmaceuticals, April 27, 2004.

¹⁴ Schuler, Kate. Weighing Promise and Perils of Drug Importation. CQ Weekly, July 24, 2004. p. 1790.

¹⁵ See H.R. 2427 (108th Congress).

¹⁶ For example, in Medicaid, the government requires manufacturers to provide rebates to state governments for outpatient drugs, effectively reducing the price the state pays for the drug.

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