Op-Ed

Prescription Drug Pricing Is Not Just an Election Issue

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IT IS HARDLY SURPRISING THAT RISING PRESCRIPTION DRUG pricing found its way into the 2016 election. Prescription drug costs frequently get more attention than their share of the health care dollar would suggest—approximately 10% of total spending on health care (although it's more than 16% if both retail drugs and non-retail drug spending such as hospital spending is considered relative to personal health spending).¹

Two reasons help explain the disproportionate focus on prescription drugs.

First, insurance coverage for prescription drugs has typically been less extensive than the coverage for physician and hospital care. As a result, many people are more aware of pricing changes in prescription drugs because they are more likely to experience some portion of the cost change.

Second, spending growth for prescription drugs periodically spikes and focuses attention on drug pricing. This happened from 2000 to 2003 and again in 2014. The former was driven by the release of a large number of new, branded products that replaced older, less expensive drugs. The spending spike in 2014 came after several years of unusually low prescription drug spending growth (a rate slower even than the rest of health care spending, which was also growing relatively slowly). The primary reason for this spike was the introduction of several new biologic or specialty drugs. Most attention went to new drugs treating the hepatitis C virus (HCV)—Gilead's Sovaldi, which was the highest-selling drug in 2014 at \$7.9 billion—along with several specialty drugs introduced for cancer, diabetes, and multiple sclerosis.

More recently, we saw huge price jumps for two older drugs with expired patents. In 2015, Turing Pharmaceuticals increased the price of Daraprim, an old drug used to treat protozoal and malarial infections, to \$750 a pill. In 2016, Mylan raised the price of the EpiPen, a delivery

device for epinephrine, which is used to treat severe allergic responses, from about \$100 to \$600.

Many people think prescription drug costs are unreasonable, even if they are able to pay for them, and believe that Congress and the president should address the issue.² Since 2003, when Medicare Part D was enacted, Democrats have pushed for Medicare to be able to “negotiate” drug prices, an idea that has wide public support. At the same time, the Congressional Budget Office has estimated that no savings would result if Medicare was allowed to use administrative pricing for Part D drugs the way it does for other parts of Medicare. The reason I place quotation marks around “negotiate” is that neither the Centers for Medicare & Medicaid Services (CMS) nor the Department of Health and Human Services (HHS) negotiates prices in Medicare (they are set administratively), and both CMS and HHS have no experience in negotiating prices the way insurers or pharmacy benefit managers (PBMs) do.

During the 2016 presidential campaign, both Hillary Clinton and Bernie Sanders supported the right for Medicare to negotiate drug prices. Clinton also supported the creation of a government oversight panel that could impose penalties for “unjustified” price increases for older treatments that were off-patent and would allow importation of alternative treatments, an idea that did not gain much traction during the election period. Donald Trump also supported the right for Medicare to negotiate drug prices early in the primary season but stopped mentioning it after his estimated savings were ridiculed.

Ideology influenced adopting the choice of competitive private plans to deliver Medicare Part D prescription drugs, rather than relying on administrative pricing strategies. That said, there are several reasons why administrative pricing is regarded as more complicated for prescription drugs than for other health care areas. If administrative pricing “misprices” reimbursement for hospital or physician services, there will likely be some pushback in the first few years and adjustments will be made. This happened after the 1997 Balanced Budget Act was passed, reducing the reimbursement for most providers other than physicians and was followed by legislation that “gave back” some of the reductions, such as the Balanced Budget Refinement Act in 1999. Congress was also reluctant to implement the legislated reductions in physician payments under Medicare because of concerns that access problems might result and only reduced them once in 2003 although the sustainable growth rate legislation would have reduced them every year for a decade.

The problem with prescription drug administrative pricing is that the effects of errors may not be felt for several years because once a drug is on the market, the actual production costs are relatively small. Unlike other health care areas, most of the costs for new drugs occur up front as part of research and development (including the many drugs that fail in the development process), during clinical trials, or in getting the drug to market.

Patents can further complicate matters. Protecting intellectual property is necessary to encourage investments in innovative drugs and medical devices. Without these protections, many companies will be hesitant to invest. The appropriate length of a patent is a policy decision for which there is no right answer and is something that can and should be discussed. However, the nature of a patent is that it confers monopoly rights on the patent's holder. The more unique the product, the more effective the patent, although pricing beyond certain levels will usually lower profits for the patent holder because it negatively affects demand for the product.

So what should and can be done? We have seen the effect aggressive PBMs have on negotiating lower prices when competitive products come on the market. Express Scripts obtained a substantial price reduction once AbbVie's HCV products came on the market to challenge the Gilead drugs Solvadi and Harvoni.

The role of PBMs has raised some questions about how they behave, regarding their lack of transparency in the prices negotiated with manufacturers and the receipt of manufacturer rebates. Such savings help the "plan sponsors" (ie, employers and insurance companies) but only indirectly benefit consumers through lower premiums and co-pays.

Nonetheless, PBMs are potentially effective bargainers—with 3 PBMs covering 80% of the population—provided there are alternative, effective therapies available. This potential for PBMs suggests the value of expediting Federal Drug Administration review for alternatives to expensive branded therapies. It also reinforces the importance of reducing the generic approval backlog. As of July 2016, more than 4,000 generics were awaiting approval.

Ascertaining the value of new, expensive drugs, especially in oncology, is being discussed, as well. The American Society of Clinical Oncology (ASCO) is developing a Value in Cancer Care framework to provide a user-friendly software tool for shared decision making with patients.³

Sloan-Kettering developed a Drug Abacus to help decision-making by integrating objective information on cancer drugs.⁴ Whether patients and physicians will become comfortable using these tools remains to be seen.

What is clear is that the questions about prescription drug pricing and the value new drugs provide are not likely to go away anytime soon.

References

1. Department of Health and Human Services. *ASPE Issue Brief: Observations on Trends in Prescription Drug Spending*. aspe.hhs.gov/sites/default/files/pdf/187586/Drugspending.pdf. Published March 8, 2016. Accessed September 23, 2016.
2. Cubanski J, Neuman T. Searching for savings in Medicare drug price negotiations. Kaiser Family Foundation. kff.org/medicare/issue-brief/searching-for-savings-in-medicare-drug-price-negotiations. Published February 9, 2016. Accessed September 23, 2016.
3. Statement by ASCO President Julie M. Vose, ASCO Value Framework Update [press release]. Alexandria, VA: American Society of Clinical Oncology; May 31, 2016. www.asco.org/about-asco/press-center/news-releases/asco-value-framework-update. Accessed September 23, 2016.
4. Bach PB. A new way to define value in drug pricing. *Harv Bus Rev*. hbr.org/2015/10/a-new-way-to-define-value-in-drug-pricing. Published October 6, 2015. Accessed September 23, 2016.

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