Op-Ed

The Drug Price Controversy Nobody Notices

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THE COST OF PRESCRIPTION DRUGS HAS GOTTEN A LOT OF attention recently. One reason is the high-profile controversy over Martin Shkreli, the bombastic pharmaceutical executive whose company acquired a special anti-infection drug and jacked up the price 5,500%. Another reason is the introduction of Sovaldi, a miracle cure for hepatitis C that costs \$85,000 per regimen and is already putting a major financial strain on public and private insurance programs.

But there is another story about prescription drugs that should get attention. It doesn't involve a sleazy entrepreneur or a breakthrough drug that costs more than a luxury car. It is not even a new story.

Even so, it reveals a great deal about how the pharmaceutical industry operates—and whether its practices really line up with the public interest.

The story is about Nexium, a popular treatment for acid reflux—and how much Medicare Part D, the program that covers prescriptions for seniors, is spending on it. In 2014, according to federal data, Nexium accounted for \$2.66 billion in total Medicare spending. That was the second-highest total for any drug. The federal government picked up most of that cost, with individual Medicare beneficiaries responsible for the rest as out-of-pocket costs. That \$2.66 billion figure represents a significant number in the context of the federal budget. It'd be more than enough to put 200,000 additional kids in Head Start, for example.

Sometimes the benefits of a drug justify the enormous sums government, insurers, and individuals spend on them. They treat or cure a disease that would be debilitating and require ongoing, expensive treatments, or they relieve symptoms without the usual side effects, making them clearly superior to their predecessors.

Is Nexium one of those cases? Here it helps to know the drug's backstory, which books like Merrill Goozner's *The \$800 Million Pill* lay out.¹ Acid indigestion and heartburn are occasional and short-lived problems for most Americans. But they are chronic problems for some

and can lead to painful, dangerous conditions like ulcers, acid reflux, erosion of the esophagus, and even esophageal cancer. In the 1970s, the drug industry started developing breakthrough drugs that could reduce the stomach's secretion of hydrochloric acid, rather than merely neutralize it, with a new agent that blocks the histamine receptors in the gastric glands. In 1989 a Swedish-based manufacturer won approval to sell a new drug called Prilosec in the United States. The company, which later became AstraZeneca, promoted the "purple pill" heavily, and by the late 1990s it had become the world's best-selling medication.

But by then AstraZeneca was already thinking about the future—specifically, 2001, when its patent on Prilosec was set to expire. Once that happened, generic manufacturers would produce their own versions, forcing down the price and cutting significantly into AstraZeneca's revenue stream. As Gardiner Harris, then a reporter with the *Wall Street Journal*, later recounted, AstraZeneca's executives convened a working group to find ways of replacing the lost revenue. They named the project "Shark Fin" because a graph of the income from the drug would look like a shark fin—sales sharply increasing, and then decreasing with the loss of the patent—if AstraZeneca didn't do something.²

AstraZeneca's solution was Nexium—the "new purple pill," as the company called it. But AstraZeneca hadn't really invented a new drug. Instead, it had taken advantage of the fact that Prilosec, like many drugs, is actually composed of 2 "isomers"—roughly speaking, 2 molecules that are mirror images of one another. AstraZeneca cleaved the isomers from each other and marketed one as Nexium.

It's a common strategy in drug development, and sometimes it actually yields a better drug because one isomer turns out to produce substantially better results than the other. But after the company commissioned 4 studies of Nexium's effectiveness relative to Prilosec, only one comparing Prilosec and Nexium at comparable dosages showed improved results for Nexium. It was for one particular condition, erosive esophagitis, which affects only a fraction of patients who have acid reflux disease. And the difference was marginal.

Thomas Scully, who in 2002 was running Medicare and Medicaid for the Bush administration, gave multiple speeches blasting Nexium as wasteful—and urging state Medicaid directors not to cover it. "I just got pissed off that Medicaid was covering a drug with no new benefit," Scully later said. "Any doctor that prescribes Nexium should be ashamed of himself."³ In the private sector, officials at organizations

like Group Health of Puget Sound and Kaiser Permanente, which pay close attention to cost-effectiveness, said they wouldn't make Nexium part of their regular formularies. (Formularies are lists of drugs that an insurer will cover.)

Confronted with such arguments, AstraZeneca maintained that the drug offered clear advantages—a position a company spokesperson reiterated to me when I recently inquired about the controversy: “AstraZeneca believes doctors need a range of options as they seek an appropriate treatment for individual patients, because they recognize a one-size-fits-all approach to treating people with GERD is not appropriate.” Apparently that argument carried the day. Thanks to a massive marketing campaign that included direct-to-consumer advertising and free samples of Nexium for people already taking Prilosec, millions of patients went looking for the new drug, doctors prescribed it, and insurers—public and private—paid for it.

Spending on Nexium won't be such an issue in the future, since its own patent just expired in 2015. But many public health experts believe it's high time the federal government gave new drugs more scrutiny. One possibility would be to manage Medicare Part D formularies more aggressively—perhaps by assigning higher copayments to drugs with more ambiguous benefits, unless patients and physicians can demonstrate a medical rationale. This is essentially what happens at places like Group Health and Kaiser Permanente now. Another remedy would be to place new restrictions on the kinds of claims that drug companies can make with direct-to-consumer advertising. Or, of course, the government could simply take a more assertive and direct role in setting drug prices. That's what the governments of most developed countries do.

Sadly, the more aggressive government interventions run into strong resistance from conservatives, who oppose government regulation on principle. And even steps like limiting government formularies to drugs with clear clinical value generate intense opposition from the powerful pharmaceutical lobby. As the drug companies tell it, such efforts would end up dampening innovation by making it harder for them to recoup the expense of developing drugs.

Many public health experts disagree, and they have a lot of data to back up their views. But it's the drug companies' claims that usually prevail. Employers, the government, and, eventually, individual Americans are left picking up the check.

References

1. Goozner M. *The \$800 Million Pill*. Berkeley: University of California Press; 2004.
2. Harris G. Prilosec's maker switches users to Nexium, thwarting generics. *Wall Street Journal*. June 6, 2002. <http://www.wsj.com/articles/SB1023326369679910840>. Accessed March 11, 2016.
3. Whelan D. Little pricey pill. *Forbes*. March 25, 2010. <http://www.forbes.com/forbes/2010/0412/opinions-healthcare-nexium-hmo-prescriptions-heads-up.html>. Accessed March 12, 2016.

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