

Are Some Drug Prices Too Low?

When people think about drug pricing in the United States, they tend to think of the sky-high prices of some newer drugs. High prices do cause real problems. Some people in need may go without.

People may also go without needed drugs because prices are too low.

In an unfettered free market, prices contain information that buyers and sellers use to balance supply and demand. Producers and sellers “communicate” that they “need” a certain price to produce a given volume. Buyers and consumers “communicate” that they “need” a certain price to purchase a given volume. Once there’s a match between buyers and sellers, the market clears. People who are willing to pay the market price get the goods and people who are willing to accept the market price get to sell. Prices are an efficient way for buyers and sellers to communicate with each other and this causes the market to function efficiently.

When prices are artificially set, however, market distortions and misallocations usually result. Prices can be manipulated when a government directly sets prices or when a government artificially alters either supply or demand.

In the United States, the federal

government has manipulated drug prices directly with the Medicaid “best price” law, the 340B hospital drug pricing program, and Medicare Part B’s cost-plus pricing arrangement. It has manipulated them indirectly with the Hatch-Waxman Act.

The Medicaid Best-Price Law and 340B Hospital Pricing

Before 1990, drug companies gave discounts to clinics and hospitals that were treating a large number of low-income and uninsured patients. When the Medicaid “best price” law of 1990 was enacted, it stated that Medicaid would pay only the “best price” (that is, the lowest price) offered to any other customer. The law created a dilemma. If clinics and hospitals continued to receive discounts, drug companies would need to give the same discounts to the whole of Medicaid, a very large program. So, predictably, pharmaceutical firms stopped offering such discounts, causing

Because some prices are too low to give pharmaceutical companies a reason to develop and improve medications, Americans are being denied needed drugs.



David R. Henderson, research fellow, Hoover Institution, and emeritus economics professor, Naval Postgraduate School



Charles L. Hooper, president of Objective Insights

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prices to increase by more than 30% at some hospitals and clinics.

The so-called Medicare 340B hospital pricing law of 1992 was designed to fix this problem. The 340B program, created under the Veterans Health Care Act of 1992, allows hospitals and clinics to dispense drugs that were acquired at a discount from drug manufacturers but still receive reimbursement from the federal government at full prices.

Hospitals love this profitable arrangement. But the 340B hospital pricing law relies on self-policing. A Government Accountability Office audit found that the rules are so unclear that hospitals must use their own judgment about whether they qualify for full reimbursement. In principle, that means that *any hospital* can apply for the discounts.

Hospitals and clinics have gained from these discounts – \$6 billion in 2015¹. But there appears to be no gain for either patients or taxpayers. According to a study in the *New England Journal of Medicine*, there is no clear evidence of “expanded care or lower mortality among low-income patients.”² Taxpayers haven’t gained, because the government still pays the full price for the drugs. Effectively, there’s a financial transfer from drug companies to hospitals and clinics with little benefit to anyone else.

Long term, however, we all lose. Because both

the 340B program and the Medicaid best-price law keep prices lower than otherwise, drug companies underinvest in the next generation of hospital outpatient and Medicaid recipient-focused drugs.

Medicare Part B Cost-Plus Pricing

Under Part B, Medicare reimburses health care providers that administer drugs in a doctor’s

office or a hospital. The facility that administers one of these drugs can charge an administration fee and receive an additional 4.3% of the drug’s “average selling price.”³ If a drug company raises a price it charges

doctors and hospitals, the providers can’t apply the 4.3% to the new, higher price. The 4.3% must apply to the industry average across all manufacturers. This means a doctor or hospital could be forced to sell the drug at a loss.

If a doctor has a drug that costs \$100 and has a few patients a day who need it, she can stock and replenish this drug each day, making a return of \$4.30 plus an administration fee on each patient. That makes financial sense. But what if the drug costs \$10,000, demand is sporadic, and the shelf life is limited? To dispense this expensive drug, the doctor must purchase and stock it in the hope that an occasional patient will buy it. The doctor might respond by not stocking the drug.

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¹“What Is 304B?” 340B Health Partners, https://www.340bhealth.org/files/340B_AtAGlance.pdf.

²Sunita Desai and J. Michael McWilliams, “Consequences of the 340B Drug Pricing Program,” *New England Journal of Medicine* 378 (Feb 8, 2018): 539-548.

³The amount is normally ASP+6%, but the 6% was reduced to 4.3% as part of the Budget Control Act of 2011 and has now been extended through 2024.



When doctors underinvest in such drugs, patients who need immediate treatment might not get it.

The fixed 4.3% margin is not a typical price control. Instead, it is a result of the government using its monopsony power (its power as the sole buyer) to decide how much it will pay to providers. In the health care arena, government is the 800-pound gorilla. Whether you cheer for or jeer at what the monopsonist does, remember that health care providers and pharmaceutical companies respond to whatever the government does.

The drug they don't develop and the drug you aren't administered might have been the one that got you out of the hospital a day earlier or even saved your life.

If prices are artificially low, consumers may not be able to get the quality or quantity they would like.

From a taxpayer point of view, Medicare costs could be lower if patients received better treatment and had lower morbidity or shorter hospital stays, or avoided the hospital completely.

Hatch-Waxman and Generic Drugs

When competition breaks down, consumers can be harmed in one of two ways. On the one hand, monopoly power will cause consumers to face prices that are artificially high. On the other hand, if prices are artificially low, consumers may not be able to get the quality or quantity they would like.

An example of the second problem happens with the generic drugs that make up 89% of

all U.S. prescriptions.⁴ With most products, customers face a tradeoff between cost and quality and they are often willing to pay more for higher quality. But the Food and Drug Administration has prevented consumers from becoming aware of this tradeoff in the market for generic drugs. Specifically, the FDA prohibits generic producers that make better versions of a drug from communicating that quality improvement to customers. Why make it better if you can't claim that it's better? The result is a race to the bottom in both manufacturing

costs and quality. If that kind of perverse competition drives manufacturers out of the market, there may be shortages in the supply of the drugs.

Complicating this race to the bottom, in 1984 the Hatch-

Waxman Act waived the requirement that all small-molecule, or "regular," generic drugs be clinically tested for safety and efficacy. With the new rules, generic drug manufacturers simply needed to show that their generic drugs were, as far as could be determined, equivalent to the original drugs. Further, via the Hatch-Waxman system, generic drugs have been aided by widespread substitution of generics for brand drugs by pharmacists. They generally do so without the doctor's approval and are often rewarded by more lucrative dispensing fees.

Consider Merck's Mevacor, now sold generically as lovastatin. In 2018, there were seven manufacturers of generic lovastatin⁵

⁴"7 Fast Facts about Generic Drugs," Optum, Inc., <https://www.optum.com/resources/library/7-fast-facts-generic-drugs.html>.

⁵Karl Matuszewski et al., "Variation in Generic Drug Manufacturers' Product Characteristics," *P&T Community* 43, no. 8 (August 2018), www.ptcommunity.com/journal/article/full/2018/8/485/variation-generic-drug-manufacturers-product-characteristics.

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and Merck had long since stopped selling branded Mevacor. A pharmacist is free to provide the cheapest version of lovastatin when a prescription comes written for Mevacor or lovastatin.

As long as manufacturers can produce a drug that meets the minimum standards of “lovastatin,” they can stay in the market and have their product seem to be as good as other manufacturers’ lovastatin. The FDA has effectively banned incentives to make lovastatin better, to make guarantees of safety or reliability, to discover new uses for it, or even to do something as simple as developing new tablet sizes. As soon as lovastatin goes generic, it dies, so to speak. The FDA would consider a better version of lovastatin to be a new product that would need to be developed, reviewed, and then marketed on its own, separate from the regular generic versions.⁶

Generic companies make most of their money on newly generic products when the number of competitors is few. Once the generic has been available for a year or two, more companies are selling it, and profit margins are quite low. Then, when companies have manufacturing problems or an FDA inspection reveals some

issue, or when the financial return is lower than other opportunities provide, they may cease manufacturing that product. As the number of manufacturers declines, the amount supplied may, at times, be less than the amount demanded.

Currently, 114 to 260 drugs are unavailable or in short supply. Which number is correct depends on how they are counted.^{7,8}

These supply problems persist in the face of widespread attention and government attempts to address them. The issue is not new. In 2011, President Obama released an executive order directing the FDA to resolve and prevent critical shortages of vital medicines and prevent future ones. “The president’s action is a recognition of the fact that this is a serious problem, and we can and should do more to help solve it,” said an anonymous administration official. “We can’t wait anymore.”⁹ Unfortunately, yes we can. We’re still waiting.

Risks for Patients

Patients are dying. A 2011 shortage of norepinephrine hampered hospitals’ ability to treat septic shock, and a study published in the *Journal of the American Medical Association*

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⁶Such a product would be subject to the FDA’s 505(b)(2) regulations, which are less stringent regulations designed for products that are based on existing products, <https://www.pharmacytimes.com/contributor/ryan-chandanais-ms-cphd/2017/11/505-b2-regulatory-pathway-for-new-drug-approvals->

⁷“Drug Shortages,” Drugs.com (Drugsite Trust), <https://www.drugs.com/drug-shortages/>

⁸“FDA Drug Shortages,” U.S. Food and Drug Administration, <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

⁹Tracy Stanton, “Obama to Order New FDA Action on Drug Shortages,” FiercePharma, October 31, 2011.



concluded: “Patients admitted to these hospitals during times of shortage had higher in-hospital mortality.”¹⁰

Morphine was developed between 1805 and 1816 and became popular after the hypodermic needle was perfected in 1853. Morphine is still, today, the standard analgesic for use in hospitals. Who would imagine that, two hundred years later, we’d have trouble manufacturing enough morphine? But we do. Right now, hospitals and ambulatory surgery centers are grappling with a shortage.

Citing shortages such as these, the Federal Aviation Administration has exempted airlines from requirements that their airplanes stock five key drugs.¹¹ Those drugs form the core of an emergency medical kit for use during flights. Their absence on airplanes has made air travel more dangerous. Dr. Sherif Badawy, who has published several studies of in-flight medical emergencies, said, “To think you could fly without epinephrine is crazy.”

Consider the Bacillus Calmette–Guérin (BCG) vaccine that is a key bladder cancer treatment. Merck became the only manufacturer of BCG after its competitor Sanofi halted production in 2017 following a mold infestation at its manufacturing plant.¹² Demand for BCG has

increased, BCG is tricky to manufacture, and Merck has had some manufacturing problems of its own. For these reasons, the supply of BCG has been limited for some time.¹³ Urologists are forced to make tough choices about which patients receive treatment and, undoubtedly, there are needless bladder removals and even deaths of bladder cancer patients as a result.¹⁴

There are two obvious solutions – at least in theory. First, Merck could boost the manufacture of BCG and substantially increase the price

to compensate for the additional costs stemming from the difficulty of manufacturing the drug. However, Merck has chosen not to do that, perhaps from fear of potential customer backlash. Second, a generics

company could manufacture BCG at a price premium and advertise itself as a reliable, high-quality provider of BCG – providing quality that is worth the higher price. But as we have seen, federal regulations prevent that from happening.

Companies work hard to improve their manufacturing processes. Improvements that reduce costs flow directly to the bottom line. Improvements that boost reliability – such as enhanced safety stock – and quality – from extra levels of testing – increase costs and make sense only if customers can be convinced that the

Airlines no longer have to stock five key drugs in emergency medical kits, making air travel more dangerous.

¹⁰E. Vail et al., “Association between U.S. Norepinephrine Shortage and Mortality among Patients with Septic Shock,” *Journal of the American Medical Association* 317, no. 14 (April 11, 2017) 1433-1442. doi: 10.1001/jama.2017.2841.

¹¹Roni Caryn Rabin, “Why Lifesaving Drugs May Be Missing on Your Next Flight,” *New York Times*, October 3, 2019.

¹²Peter Loftus, “Sanofi to Stop Production of Bladder-Cancer Drug BCG,” *Wall Street Journal*, November 18, 2016, <https://www.wsj.com/articles/sanofi-to-stop-production-of-bladder-cancer-drug-bcg-1479484412>.

¹³“BCG Shortage Info,” American Urological Association, <https://www.auanet.org/about-us/bcg-shortage-info>.

¹⁴Meghan Keshavan, “With One Manufacturer and Little Money to Be Made, Suppliers of a Critical Cancer Drug Are Dwindling,” *STAT* (Boston Globe Media), February 20, 2019. <https://www.statnews.com/2019/02/20/supplies-bladder-cancer-drug-bcg-dwindling/>.

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benefit is worth the cost. Generics companies are prohibited from advertising such benefits and, if customers are implicitly told that all generics are identical, customers will be unlikely to understand and to act on the cost/benefit tradeoff.

Given these factors, there is a general underinvestment in generic drugs and the supply of some drugs is precarious. If a mold issue befalls Merck, as it did Sanofi, the bladder cancer patients who rely on BCG will be the next victims.

Consider something as seemingly insignificant as a new tablet strength for a generic drug. Ketorolac is a non-opioid analgesic with the power of an opioid, but without the potential for abuse. The patent for the branded version of ketorolac, Toradol, expired years ago. At the time, the only approved oral tablets of ketorolac had a strength of 10 mg. A compelling case can be made that there should be a stronger version of ketorolac oral. After all, the usual dose for ketorolac is 30 to 60 mg. It would be very reasonable for a company to develop a 30 mg oral ketorolac tablet, benefiting patients

and doctors. The product would be identical to existing versions of ketorolac except for the strength of the tablets: 30 mg versus 10 mg.

Unfortunately, the FDA views a higher strength table for ketorolac as a new product.¹⁵ To develop and launch such a product, a drug company would need to spend millions of dollars to show that 30 mg pills are safe and effective—never mind the fact that 30 mg doses of ketorolac are given to patients every day. And then, if this company succeeded, other companies that didn't invest the time and money could produce generic versions in a few years and drive the price down. The net result? We don't have and are unlikely to benefit from a new tablet strength of ketorolac.

We are witnessing a race to the bottom. Companies that can't effectively price and promote the advantages of their products, wisely don't make products with advantages. Americans are being denied needed drugs because some prices are too low.

¹⁵For the reasons why, please see footnote 6.



6335 W Northwest Hwy - #2111 • Dallas, TX 75225 • email: info@goodmaninstitute.org • +1 214 302.0406

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