

Why Are There Drug Shortages?

by

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Risks: Underlying Causes and Needed Reforms.”

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Jenny Morrill, a Kinston, New York, mother and former arts administrator, had been battling ovarian cancer since 2007. When she went for her chemotherapy treatment in June 2011, the nurse greeted her with good news and bad news. The good news: she was responding well to the drug Doxil. The bad news: the hospital had no more Doxil to give her. Morrill was not alone. By November 2011, the plant that produced the drug completely shut down, leaving 7,000 US patients without access to its life-saving properties.²

Doxil is not the only drug that patients have faced trouble getting. The problem has been escalating for many years. (See the Figure below.) Some patients have died as a result.³ Others are trying to get by on inferior substitute therapies.

¹ Dr. Goodman is president of the Goodman Institute for Public Policy Research.

² Roni Caryn Rabin, "Drug Scarcity's Dire Cost, and Some Ways to Cope," *New York Times*, December 12, 2011, <http://www.nytimes.com/2011/12/13/health/policy/the-personal-price-paid-for-shortages-of-doxil-and-other-drugs.html>.

³ See for example, Andrew M. Seaman, "Drug Shortage in 2011 Tied to Increased Deaths," *Reuters Health*, March 21, 2017,

Nearly all thirty of the most frequently used emergency department drugs experienced shortages from 2006-2019, exacerbating patient harm “due to the time-sensitive nature of acute care.”⁴

Today, between 186 and 308 drugs have shortages.⁵ 2022 shortages include saline, a drug potentially needed by almost every patient who gets admitted to the hospital.⁶ Almost all of the drugs in short supply, by the way, are generics.

Reacting to shortages of key medications for the flu, ear infections and sore throats during the wake of COVID-19, pediatric infectious disease specialist Dr. Stacene Maroushek of Hennepin Healthcare in Minnesota said: “In my 25 years of being a pediatrician, I’ve never seen anything like this. I have seen families who just aren’t getting a break. They have one

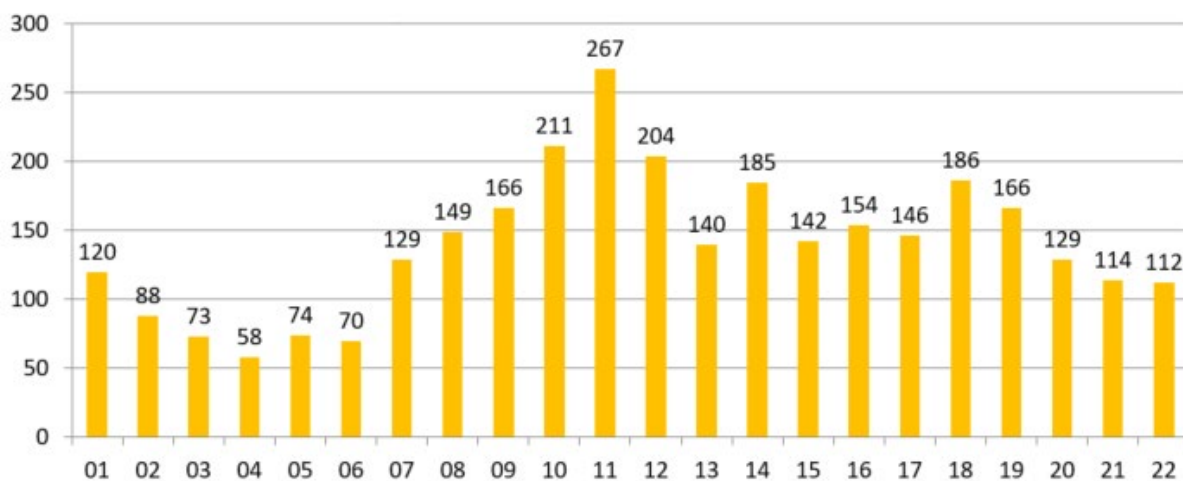
⁴ Lin MP, Vargas-Torres C, Shin-Kim J, Tin J, Fox E. “Nearly all thirty most frequently used emergency department drugs experienced shortages from 2006-2019.” *Am J Emerg Med.* 2022 Mar;53:135-139. doi: 10.1016/j.ajem.2021.12.064.

⁵ The number depends on how you count them. See Drugs.com “Current Drug Shortages,” <https://www.drugs.com/drug-shortages/and> Food and Drug Administration, “Current and Resolved Drug Shortages and Discontinuations Reported to FDA,” <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>,” (accessed November 23, 2022). See also David R. Henderson and Charles L. Hooper, “Are Some Drug Prices Too Low?” *Goodman Institute Brief Analysis No. 133*, January 13, 2020, <https://www.goodmaninstitute.org/wp-content/uploads/2020/10/BA-133-Are-Some-Drug-Prices-Too-Low-1-13-20web.pdf>.

⁶ Judy Packer-Tursman, “U.S. Drug Shortages Put People With Life-Threatening Illness At Risk,” *United Press International*, September 16, 2022, https://www.upi.com/Health_News/2022/09/16/drug-shortages-lorazepam-cancer/6681663190912/.

viral illness after another. And now there's the secondary effect of ear infections and pneumonia that are prompting amoxicillin shortages."⁷

Reported Drug Shortages



Source: American Society of Health-System Pharmacists, "Drug Shortages Statistics," <https://www.ashp.org/drug-shortages/shortage-resources/drug-shortages-statistics> (accessed November 23, 2022)

Note: Each column represents the number of new shortages identified during that year.

In one 2011 survey, nine in ten anesthesiologists reported

⁷ Brenda Goodman and Raenu Charles, "Shortages of antivirals, antibiotics compound stress of a rough season for viral illnesses in kids," CNN, November 22, 2022, <https://www.cnn.com/2022/11/22/health/drug-shortages-tamiflu-amoxicillin-albuterol>.

experiencing a shortage of at least one anesthesia drug.⁸ Another survey found that more than 40 percent of the thirty-four generic oncology drugs on the market were in short supply.⁹ There are no reliable substitutes for most of these drugs. Most are generic injectable medications that have been on the market a long time and are commonly used in hospitals, emergency rooms, and cancer treatment centers. The American Hospital Association reported in 2011 that virtually all the community hospitals it surveyed had experienced a drug shortage in the previous six months. Two-thirds of hospitals had experienced a shortage of cancer drugs; 88 percent were short on pain medications; and 95 percent were lacking anesthesia drugs needed for surgery.¹⁰

Hospitals respond in a variety of ways, including delaying treatment, giving patients less effective drugs, and providing a different course of treatment than the one recommended.

⁸ “Survey Reveals 90 Percent of Anesthesiologists Experiencing Drug Shortages of Anesthetics,” Press Release, American Society of Anesthesiologists, May 9, 2011, <http://www.asahq.org/For-the-Public-and-Media/Press-Room/ASA-News/Survey-Reveals-90-Percent-of-Anesthesiologists-Experiencing-Drug-Shortages-of-Anesthetics.aspx>.

⁹ Ezekiel Emanuel, “Shortchanging Cancer Patients,” *New York Times*, August 6, 2011, <http://www.nytimes.com/2011/08/07/opinion/sunday/ezekiel-emanuel-cancer-patients.html>.

¹⁰ Scott Gottlieb, “Drug Shortages: Why They Happen and What They Mean” (Statement before the Senate Finance Committee, United States Senate), December 7, 2011. See also Edmund Haislmaier, Ensuring Americans’ Access to Pharmaceuticals: A Primer and Road Map for Policymakers, *The Heritage Foundation Background No. 3545*, October 20, 2020, <https://www.heritage.org/sites/default/files/2020-10/BG3545.pdf>.

Indeed, about 82 percent of hospitals surveyed reported at least occasionally delaying a treatment because of a drug in short supply.

According to Ezekiel Emanuel in 2011 (who in addition to being White House adviser was also an oncologist), only about 10 percent of shortages were due to a lack of raw materials needed to manufacture the drugs. A more important source of the problem is government policy.

Problem: Unwise Output Regulations: The Food and Drug Administration (FDA) attempts to ensure that drug manufacturing processes and facilities meet its quality standards by instituting a zero-tolerance policy. By way of enforcement, the agency levies fines and forces manufacturers to retool both domestic and foreign facilities. They use a binary (pass/fail) system that does not reward companies that exceed minimum required standards, nor accounts for whether a facility is using best practices to anticipate and minimize the occurrence of production problems. Regulations not only slow the production at particular facilities, they make it difficult for competitors to take up the slack. If a shortage develops because the FDA shuts down a competitor's plant, for example, a manufacturer must seek FDA approval to increase output and alter its production timetable. This slows down adjustments in production.

Problem: Medicare Part B Price Controls. Some drugs that are administered by physicians—such as chemotherapy drugs or anesthesia during surgery—are paid for through Medicare Part B. Government price controls prevent the prices of these drugs from adjusting in response to shortages, increases in manufacturing costs, or increases in demand. Normally, the market price of a product rises when it is in short supply, attracting competing manufacturers. However, Medicare discourages this response.

Medicare Part B allows health care providers, such as doctors and hospitals, to charge a small percent over the drug’s “average selling price” to cover the cost of administering the drug. However, that “average selling price” is calculated across all manufacturers and is based on historical prices.

So, if one manufacturer sees a shortage developing, that manufacturer can legally raise the price of its drug. But since the health care providers that purchase it will purchase it at a loss, they won’t want to purchase it. As a result, the shortage won’t be averted.¹¹

Problem: Inability To Compete on Any Product Dimension Other Than Price. Regulations also limit the ability of drug makers to communicate improvements in safety, reliability or

¹¹ Gottlieb, “Drug Shortages.” See also David R. Henderson and Charles L. Hooper, “Are Some Drug Prices Too Low?” *Goodman Institute Brief Analysis No. 133*, January 13, 2020, <https://www.goodmaninstitute.org/wp-content/uploads/2020/10/BA-133-Are-Some-Drug-Prices-Too-Low-1-13-20web.pdf>.

efficacy to potential customers. These regulations remove the economic incentives to solve problems the way they would be solved in any normal market. As a result of these and other regulations, firms cannot recoup investments they make, including improving the reliability of supply.¹²

At the same time, the pharmacists who fill the prescriptions are implicitly or explicitly required to fill them with the generic that has the lowest price. The result: There is no competition on any other product feature other than price.

When buyers and sellers are forced to compete on price alone, there will be a race to the bottom on every other product dimension.

Contrast what happens in the market for regulated generics with what happens in the largely unregulated market for aspirin. Because aspirin is sold directly to consumers (rather than through a pharmacist middleman), there can be different prices for different brands and producer reputation matters to many consumers.

I can't remember when there has been a shortage of aspirin or any other over-the-counter pain relief drug.

¹² Gottlieb, "Drug Shortages." See also David R. Henderson and Charles L. Hooper, "Sometimes Drug Prices Are Too Low," *The Wall Street Journal*, October 31, 2019, https://www.wsj.com/articles/sometimes-drug-prices-are-too-low-11572561325?mod=article_inline.

Problem: 340B Price Controls. The federal 340B drug rebate program also contributes to shortages. This program allows hospitals and clinics treating low-income and uninsured patients to dispense drugs purchased at a discount from drug manufacturers but still receive reimbursement from the federal government at full prices. According to one analysis:

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.

As a *New York Times* expose explains:¹³

Thanks to 340B, Richmond Community Hospital can buy a vial of Keytruda, a cancer drug, at the discounted price of \$3,444... But the hospital charges the private insurer Blue Cross Blue Shield more than seven times that price — \$25,425, according to a price list that hospitals are required to publish. That is nearly \$22,000 profit on a single vial.

How is that done? A nonprofit chain (Bon Secours) links a hospital in a poor neighborhood (to qualify for the program) with clinics in wealthier neighborhoods, where patients with generous private insurance receive expensive drugs.

¹³ Katie Thomas and Jessica Silver-Greenberg, “How a Hospital Chain Used a Poor Neighborhood to Turn Huge Profits,” *New York Times*, Updated Sept. 27, 2022

Meanwhile, services provided in the poor neighborhood have deteriorated over time.

As the years passed, Bon Secours began stripping the hospital's services, including the I.C.U. The unit had only five beds.... Ringed by public housing projects, Richmond Community consists of little more than a strapped emergency room and a psychiatric ward. It does not have kidney or lung specialists, or a maternity ward. Its magnetic resonance imaging machine frequently breaks... Standard tools like an otoscope, a device used to inspect the ear canal, are often hard to come by.

Hospitals and clinics have gained from these discounts – \$6 billion in 2015. 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.” 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.¹⁴

¹⁴ David R. Henderson and Charles L. Hooper, “Are Some Drug Prices Too Low?” *Goodman Institute Brief Analysis No. 133*, January 13, 2020, <https://www.goodmaninstitute.org/wp-content/uploads/2020/10/BA-133-Are-Some-Drug-Prices-Too-Low-1-13-20web.pdf>.

Additional resources:

David R. Henderson and Charles L. Hooper, *Are Some Drug Prices Too Low?* Goodman Institute Brief Analyses No. 133, January 13, 2020. <https://www.goodmaninstitute.org/wp-content/uploads/2020/01/BA-133-Are-Some-Drug-Prices-Too-Low-1-13-20.pdf>

David R. Henderson and Charles L. Hooper, *Why Are Drug Prices So High?* Goodman Institute Brief Analyses No. 117, January 10, 2017. <https://www.goodmaninstitute.org/wp-content/uploads/2017/01/BA-117.pdf>
