

Causes and Non-Causes of Drug Shortages

By Alex Brill

JANUARY 2017

EXECUTIVE SUMMARY

In recent years, a number of high-profile drugs, particularly generic sterile injectable drugs, have been in short supply in the United States. Overall, the number of new drug shortages rose from 64 in 2006 to a peak of 257 in 2011.

The surge in shortages led to media attention, Congressional inquiries, and an executive order by President Obama in 2011 directing the Food and Drug Administration (FDA) to take action. Some experts and Members of Congress further expressed frustration with the FDA for its role in causing or exacerbating shortages. Congressional inquiry into remedies for shortages led to the enactment of the FDA Safety and Innovation Act of 2012 (FDASIA), which granted the FDA the authority to require early notification from drug manufacturers of any developments that could lead to a shortage.

Since 2012 there has been a substantial reduction in new drug shortages. In 2015, the number of new shortages dropped to 136. Ongoing shortages, however, have skyrocketed – from 40 in 2007 to 291 in 2015. Addressing persistent shortages will require a thorough understanding of what dynamics or elements in the pharmaceutical supply chain drive drug shortages.

A variety of factors contribute to drug shortages, principally quality control concerns in manufacturing and capacity constraints generally. According to the Government Accountability Office, from January 1, 2011, through June 30, 2013, 40 percent of reported

shortages were attributable to issues with manufacturing quality, and 30 percent were attributable to manufacturing delays and capacity issues. Other lesser causes of drug shortages include manufacturers discontinuing certain drugs, unavailability of active pharmaceutical ingredients or other components, and spikes in demand.

In examining the underlying causes of the recent increase in drug shortages, this report debunks claims that health care group purchasing organizations (GPOs) are a contributing factor, as some have argued. GPOs represent hospitals, long-term care providers, surgery centers, clinics, home health agencies, and other buyers to reduce transaction costs and negotiate with manufacturers for more competitive prices. The Federal Trade Commission, in charge of policing anticompetitive behavior, has repeatedly examined health care GPOs and has found no cause to invoke its enforcement authority.

In looking for additional remedies to ongoing shortages, policymakers should recognize three points. First, economic realities mean that it is impossible to avoid all drug shortages. Second, the FDA must continually strive to resolve problems before they turn into shortages. And finally, while GPOs play a role in reducing transaction costs and negotiating for lower prices of many pharmaceuticals, they are not a contributing factor to the recent shortages that have occurred.

INTRODUCTION

In recent years, a number of high-profile drugs have been in short supply in the United States, leading to media attention, Congressional inquiries, and an executive order by President Obama. This report provides an overview of the topic, from the dynamics of pharmaceutical supply and demand to the trends in and causes of recent drug shortages to policymaker and industry responses. In reviewing existing evidence of the underlying causes of shortages, the report debunks claims that group purchasing organizations (GPOs) are a contributing factor, as some have claimed. Rather, a variety of factors – principally quality control concerns in manufacturing and capacity constraints generally – caused the recent spike in drug shortages.

Unique Dynamics of Pharmaceutical Supply and Demand

Unlike typical consumer goods, demand for prescription drugs is relatively insensitive to price increases, in part due to the fact that third-party payors cover much of the cost of most medicines and in part due to the medical necessity of most drugs. As the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation (ASPE) explains, “These drugs are, by definition, medically necessary, implying that they have few substitutes and consumption cannot generally be shifted over time.”¹

On the supply side, given the complexity and expense involved in producing drugs, particularly sterile injectable medicines, which comprise a large share of shortages, “it will

generally take a long time – years – for the industry to increase capacity in response to an increase in prices. If the increase in prices is expected to be temporary (as would be expected in the case of a shortage due to a production line disruption), investments in increased capacity are unlikely to occur.”²

The nature of pharmaceutical supply and demand means that drug shortages can be expected to occur periodically. In light of this, the Food and Drug Administration (FDA) has had a drug shortages program since 1999.³ Shortages, which the FDA defines as “a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug,”⁴ have historically been very limited, affecting roughly 0.5 percent of drugs a year.⁵ But in the last decade, shortages have increased dramatically.

Recent Trends in and Responses to Drug Shortages

From 2006 to 2007, the number of reported drug shortages nearly doubled, from 64 to 114.⁶ In subsequent years, shortages climbed steadily, peaking at 257 in 2011 – a 300 percentage point increase from 2006.⁷ (See **Chart 1.**) Particularly affected were generic sterile injectable drugs, which constituted roughly half of all shortages from 2009 to 2013.⁸

This surge in shortages generated substantial media and policymaker attention and concern.⁹ In the fall of 2011, four Congressional committees held hearings on the issue.¹⁰ Of particular focus was how the FDA could help alleviate shortages. Some experts and Members of Congress expressed frustration with the FDA for its role in causing or exacerbating shortages. For example, at a

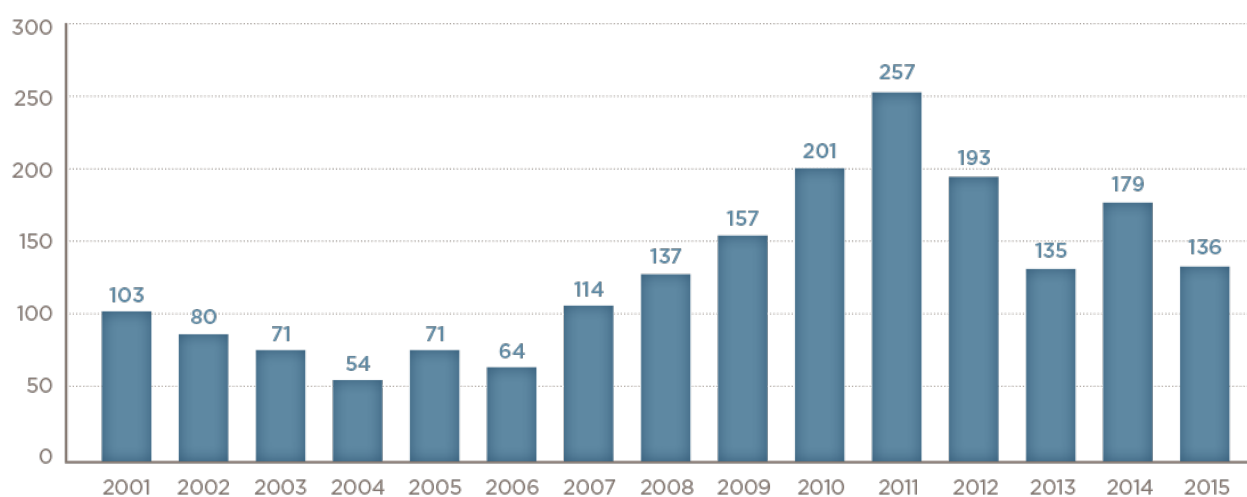
Congressional hearing in November 2011, Scott Gottlieb, a former FDA Deputy Commissioner, recommended making the agency’s oversight of drug manufacturing more efficient:

Manufacturers have long complained that these policies are outdated and at times inflexible. Another regulatory issue that plays in these shortages relates to the backlog that FDA currently has for generic drug manufacturing supplements. The backlog in reviewing manufacturing supplements can add as much as a several-year delay to the approval of manufacturing changes.¹¹

At the same hearing, Congressman Paul Gosar (R-AZ) declared, “We have problems with the FDA,” and suggested that part of the solution is “making the FDA . . . a little bit more nimble.”¹²

According to the FDA, however, the problem did not stem from lack of flexibility.

CHART 1. NEW DRUG SHORTAGES, 2001-2015



Source: GAO 2011, 2014, and 2016 drug shortage reports.

At a hearing in September 2011, Sandra Kweder, Deputy Director of FDA's Office of New Drugs, testified:

There absolutely is flexibility, and we do [expedite review and inspections] routinely when we are aware that, say, a new facility is needed or a new supplier is needed and when there is a circumstance that might lead to a potential shortage of an important medical product. We do it routinely. We can often turn things around in a matter of weeks.¹³

The problem, FDA maintained, arose when manufacturers did not notify the agency of potential shortages. In October 2011, the FDA released a report reviewing the agency's approach to shortages. Many of the immediate actions the FDA identified centered on early notification by drug manufacturers, something the agency did not have the regulatory authority to require.¹⁴

Also released in October 2011 were the ASPE economic analysis of the factors contributing to drug shortages discussed above,¹⁵ and, at the request of the Senate Committee on Health, Education, Labor, and Pensions, a Government Accountability Office (GAO) report on drug shortages.¹⁶ The flurry of shortage-related activity in the fall of 2011 culminated in an Executive Order issued by President Obama on October 31, 2011, directing FDA to "take steps that will help to prevent and reduce current and future disruptions in the supply of lifesaving medicines."¹⁷ In response to the Executive Order, FDA issued an interim rule in December 2011 that was intended to

encourage early notification of possible shortages.¹⁸ Six months later, Congress passed the FDA Safety and Innovation Act (FDASIA), which granted the FDA the authority to require early notification from drug manufacturers. President Obama signed FDASIA into law in July 2012.

In implementing FDASIA's provisions related to drug shortages, FDA detailed manufacturer requirements in a Proposed Rule issued in November 2013 that went into effect in September 2015.¹⁹ Receiving early warning of developments in the pharmaceutical supply chain that could lead to shortages allows the FDA to take actions – such as expediting review of applications – to prevent shortages from occurring.²⁰ From January 2010 through July 2014, FDA expedited review of 383 applications and supplements related to shortages.²¹ According to the FDA, the agency prevented 128 shortages in the first nine months of 2015.²²

In addition to responses by policymakers to the drug shortage crisis, others involved in the pharmaceutical supply chain were working to address shortages. For example, the Generic Pharmaceutical Association created the "Accelerated Recovery Initiative," a tool to facilitate cooperation and communication among drug supply chain members.²³ GPOs worked to improve contracts with pharmaceutical manufacturers, increase access to API with limited supply, and seek and source new market entrants.²⁴ And in 2010, 2013, and 2014, Drug Shortages Summits were convened in Washington, DC, where representatives from hospitals, providers, government, GPOs, and

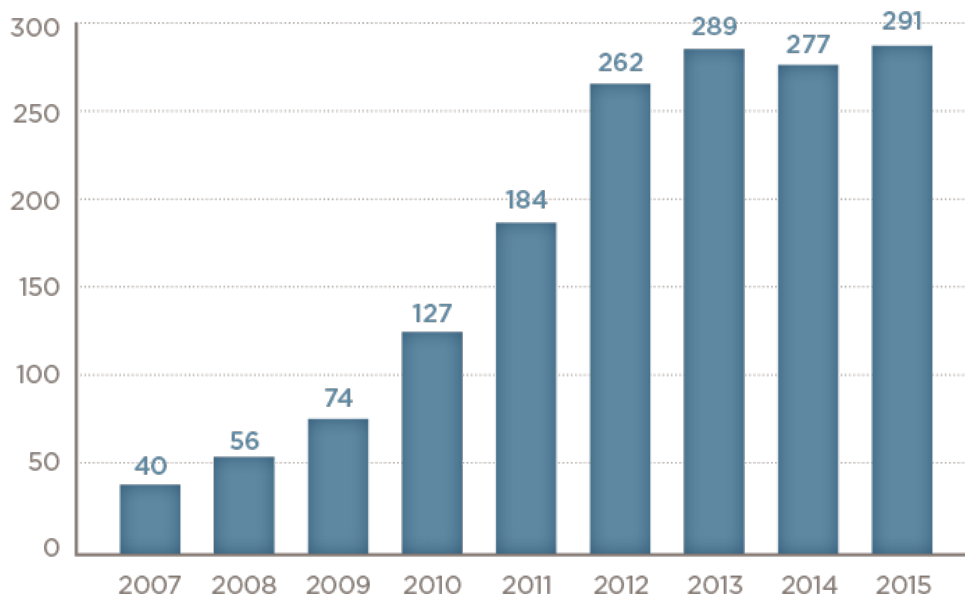
pharmaceutical manufacturers discussed causes and potential solutions to shortages.²⁵

These efforts seem to have substantially reduced the number of new shortages, as Chart 1 shows. In 2015, there were 136 new shortages, compared to 257 in 2011.²⁶ The number of ongoing shortages, however, has skyrocketed – from 40 in 2007 to 291 in 2015.²⁷ (See **Chart 2.**) And the duration of ongoing shortages is troubling. Of the 291 ongoing shortages in 2015, nearly 60 percent (171 shortages) had already lasted more than two years.²⁸ This shift from new to ongoing shortages indicates that the next issue for policymakers to address will be resolving

persistent shortages. For example, the FDA has a large backlog of generic drug applications to process—more than 4,000 as of September 2016.²⁹ Clearing this backlog would allow more generic manufacturers to enter the market, thereby potentially increasing supply and helping to alleviate ongoing shortages. Clearing the backlog could also mitigate the risk or severity of future shortages.

Addressing persistent shortages will require a thorough understanding of what dynamics or elements in the pharmaceutical supply chain drive drug shortages. Fortunately, there is a wealth of literature on this topic that can be drawn on to formulate policy.

CHART 2. ONGOING DRUG SHORTAGES, 2007-2015



Source: GAO 2014 and 2016 drug shortage reports.

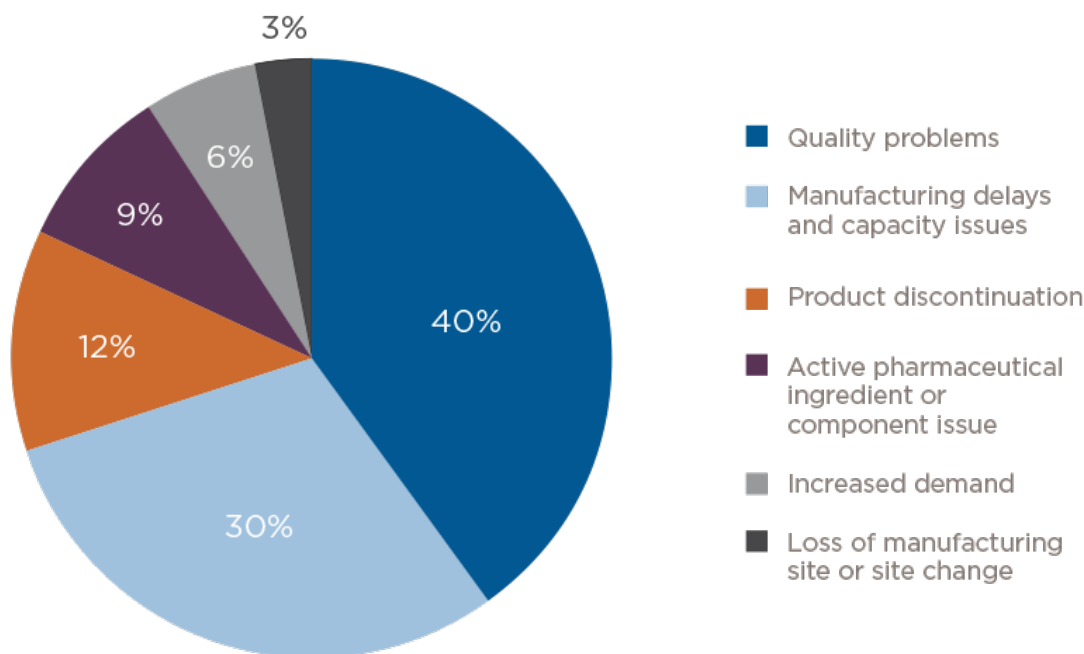
Known Causes of Drug Shortages

To address the question of what causes drug shortages, GAO in 2014 performed an extensive literature review and interviews of key players in the drug supply chain.³⁰ See **Chart 3** for a breakdown of the causes of drug shortages as reported to the FDA by manufacturers. Of the identified causes, the most prominent are serious quality concerns and poor manufacturing practices – for example, bacterial contamination – that led manufacturers to stop or reduce production and caused a supply disruption. According to GAO, from January 1, 2011, through June 30, 2013, 40 percent of

reported shortages were attributable to issues with manufacturing quality.³¹ Some blamed the FDA’s warning letters for causing drug shortages by forcing manufacturing facilities to stop production, but FDA officials have pointed out that warning letters do not require the cessation of production.³²

Supply disruptions of this nature would not be as significant if other manufacturers could quickly step in to meet demand. But there are relatively few manufacturers making many of the sterile injectable drugs for which shortages are reported, and this compounds the problem. GAO points to a 2013 study published in *Clinical*

CHART 3. REPORTED CAUSES OF DRUG SHORTAGES



Note: As reported to FDA by manufacturers, January 2011 through June 2013.

Source: GAO 2014 drug shortage report.

Pharmacology & Therapeutics for evidence of this industry concentration.³³

[The] study found that seven manufacturers dominate the generic sterile injectable market overall and also found that this market is even further concentrated for specific therapeutic classes. Specifically, this analysis indicated that in 2008, three manufacturers produced 71 percent of all generic sterile injectable oncology drugs and that three manufacturers held 91 percent of the market share of generic sterile injectable nutrients and supplements.³⁴

Further compounding this problem is limited manufacturing capacity and the potential for a long lead time and high fixed cost associated with adding new capacity. The presence of only a few suppliers does not necessarily mean that a shortage is inevitable should one manufacturer cease or slow production. But oftentimes, remaining manufacturers – particularly of sterile injectable drugs – do not have excess manufacturing capacity, nor can they easily scale up.

Other lesser causes of shortages that GAO identifies include manufacturers discontinuing certain drugs, the unavailability of active pharmaceutical ingredients or other components such as vials, the loss of manufacturing sites from natural disasters, and spikes in demand.³⁵ In addition, a 2011 study on drug shortages identified causes ranging from labor disruptions to voluntary recalls and shifts in clinical practices.³⁶ Still others have called attention to global triggers of shortages such as fragile supply chains.³⁷

Role of Group Purchasing Organizations

Some observers have pointed at group purchasing organizations (GPOs) as contributors to the increased prevalence of drug shortages,³⁸ while others, including ASPE, view GPOs as potential allies in the effort to mitigate the risk of shortages.³⁹

GPOs represent multiple buyers in an industry to reduce transaction costs and negotiate with manufacturers for more competitive prices. GPOs, which exist in other industries, including food and agriculture, are prevalent in the health care industry and negotiate contracts for hospitals, long-term care providers, surgery centers, clinics, home health agencies, and other buyers for the purchase of drugs and supplies.

Because of their function in aggregating buyers to achieve lower prices for their members, GPOs have been accused of what is known as oligopsony, which describes a market with only a few buyers (or sometimes monopsony, a market with one buyer). The argument is that GPOs, in exerting oligopsony power, drive manufacturers out of certain markets, causing drug shortages. Specifically, as GAO identified in its literature review on drug shortages, some have argued that not winning a GPO contract can force a generic manufacturer to stop producing a product, while others have argued that generic manufacturers may leave a market because GPOs create prohibitively low profit margins.⁴⁰ These accusations are unfounded.

The first argument – that not winning a GPO contract drives or keeps generic manufacturers out of the market – is inaccurate because there are many potential buyers. As competition

policy experts Roger D. Blair and Christine Piette Durrance explained in a recent article on GPOs and antitrust issues, “A rival that is excluded from the market must strike out everywhere.”⁴¹ While some health care GPOs and other purchasers (such as the Department of Veterans Affairs and the Department of Defense) are large, there is a plethora of health care GPOs in the United States.⁴² And, while nearly all hospitals engage in group purchasing, GPO contracts comprise only 72 percent of hospital purchases.⁴³ Hospitals can – and do – negotiate directly with manufacturers.⁴⁴

The second argument – that GPOs drive profit margins so low that manufacturers are forced out of a market – merely describes the nature of competition. Generic drug prices are low because competition is robust, not because GPOs exert some special control over prices. In fact, the Federal Trade Commission (FTC), in charge of policing anticompetitive behavior, would take action if there were an antitrust issue. The FTC’s longstanding Statements of Antitrust Enforcement Policy in Health Care (issued jointly with the Department of Justice) identify a 35 percent market share as the trigger for antitrust concerns for health care group purchasing arrangements.⁴⁵ No GPO has a market share that reaches this threshold.

In March 2016, FTC Chairwoman Ramirez was asked about anticompetitive behavior by GPOs in questions for the record following a Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy, and Consumer Rights hearing. Chairwoman Ramirez responded:

The FTC is aware of the concerns raised about the conduct of GPOs and has on a

number of occasions examined complaints about GPO conduct. Determining whether any specific conduct is anticompetitive is a fact-specific inquiry requiring a careful examination of market circumstances. Evaluating claims that a particular GPO has market power involves more than just an assessment of the sales volume made through GPOs. Moreover, possession of market power alone is not an antitrust violation. Rather, the key question is whether market power has been obtained, or is being maintained, through improper means. To date, the Commission has not charged a GPO with a violation of the antitrust laws.⁴⁶

To understand more fully how the FTC reached this conclusion, it is worth revisiting a previous FTC investigation of a non-GPO acquisition, wherein FTC analysts explained the difference between monopsony/oligopsony power and buyer concentration:

It is important not to equate market concentration on the buyer side with [monopsony or oligopsony] power. For example, a shift in purchases from an existing source to a lower-cost, more efficient source is not an exercise of monopsony power. Nor do competition and consumers suffer when the increased bargaining power of large buyers allows them to obtain lower input prices without decreasing overall input purchases. This bargaining power is procompetitive when it allows the buyer to reduce its costs and decrease prices to its customers. A buyer has monopsony power – or a group of buyers has oligopsony power – when it can

profitably reduce prices in a market below competitive levels by curtailing purchases of the relevant product or service.⁴⁷

In the case of the drugs that GPOs are accused of driving into shortage, GPOs may have negotiated low prices – prices willingly offered by competing manufacturers in arms-length agreements – but they did not decrease purchases, as demand for health care is

relatively inelastic. Moreover, because there are many GPOs, not to mention hospitals and other buyers, a single GPO cannot exert sufficient power over generic drug manufacturers to force them from the market. Rather, manufacturers can compete for GPO, hospital, and other contracts as they do in the rest of the market while also maintaining their sales through distributors.

CONCLUSION

A disruption to the delivery of quality health care caused by a drug shortage is potentially serious. While steps taken by manufacturers and the FDA in the last five years have resulted in a significant decline in the number of new shortages, persistent shortages remain elevated. Despite progress, policymakers rightly remain concerned. In looking for additional remedies, lawmakers and regulators should recognize three points.

First, economic realities such as the time and cost associated with building a new manufacturing facility and the sometimes unpredictable nature of shifts in demand mean that it will never be possible to avoid all drug shortages. Second, while the FDA should be commended for the progress it has made, the agency must continually strive to accelerate review times and work cooperatively with manufacturers to resolve potential problems before they materialize into shortages. And finally, while GPOs play an important role in reducing transaction costs and negotiating for lower prices of many pharmaceuticals, including sterile injectables that have been in shortage, there is no evidence that they are a contributing factor to the shortages that have occurred.

ABOUT THE AUTHOR

Alex Brill is the CEO of Matrix Global Advisors, an economic policy consulting firm. He is also a research fellow at the American Enterprise Institute. Previously, he was chief economist and policy director to the House Ways and Means Committee. Prior to his time on the Hill, he served on the staff of the President's Council of Economic Advisers.

This report was sponsored by Healthcare Supply Chain Association. The author is solely responsible for the content. Any views expressed here represent only the views of the author.

NOTES

- ¹ Office of the Assistant Secretary for Planning and Evaluation (ASPE), “Economic Analysis of the Causes of Drug Shortages,” *ASPE Issue Brief*, October 2011, available at <https://aspe.hhs.gov/sites/default/files/pdf/108986/ib.pdf>.
- ² Ibid.
- ³ Food and Drug Administration (FDA), “U.S. Drug Shortages,” available at www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM273360.pdf
- ⁴ Government Accountability Office (GAO), “Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge,” July 2016, available at www.gao.gov/assets/680/678281.pdf.
- ⁵ ASPE, “Economic Analysis of the Causes of Drug Shortages,” *ASPE Issue Brief*, October 2011.
- ⁶ GAO, “Drug Shortages: FDA’s Ability to Respond Should Be Strengthened,” November 2011, available at www.gao.gov/assets/590/587000.pdf.
- ⁷ GAO, “Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge,” July 2016.
- ⁸ GAO, “Drug Shortages: FDA’s Ability to Respond Should Be Strengthened,” November 2011; and GAO, “Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability,” February 2014, available at www.gao.gov/assets/670/660785.pdf.
- ⁹ See, for example, Sheri Fink, “Drug Shortages Forcing Hard Decisions on Rationing Treatments,” *New York Times*, January 29, 2016.
- ¹⁰ Cheryl A. Thompson, “Drug Shortages – Congress Listens, FDA Acts,” *American Journal of Health-System Pharmacy* 69, no. 2 (January 15, 2012): 90–91.
- ¹¹ “Drug Shortage Crisis: Lives Are in the Balance,” hearing before the Subcommittee on Health Care, District of Columbia, Census and the National Archives of the Committee on Oversight and Government Reform, 112th Congress, 1st sess., November 30, 2011, transcript available at www.gpo.gov/fdsys/pkg/CHRG-112hhrg72804/pdf/CHRG-112hhrg72804.pdf.
- ¹² Ibid.
- ¹³ “Examining the Increase in Drug Shortages,” hearing before the Subcommittee on Health of the Committee on Energy and Commerce, September 23, 2011, transcript available at www.gpo.gov/fdsys/pkg/CHRG-112hhrg77032/html/CHRG-112hhrg77032.htm.
- ¹⁴ See FDA, “Executive Summary: A Review of FDA’s Approach to Medical Product Shortages,” available at www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm277744.htm
- ¹⁵ See ASPE, “Economic Analysis of the Causes of Drug Shortages,” *ASPE Issue Brief*, October 2011. The ASPE report was released in conjunction with the FDA’s report.
- ¹⁶ GAO, “Drug Shortages: FDA’s Ability to Respond Should Be Strengthened,” November 2011. GAO released follow up reports on the issue in 2014 and 2016. See GAO, “Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability,” February 2014; and GAO, “Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge,” July 2016.
- ¹⁷ Executive Order No. 13588, “Reducing Prescription Drug Shortages,” 76 *Fed. Reg.* 68295 (November 3, 2011), available at www.gpo.gov/fdsys/pkg/FR-2011-11-03/pdf/2011-28728.pdf.
- ¹⁸ FDA, “Applications for Food and Drug Administration Approval to Market a New Drug; Revision of Postmarketing Reporting Requirements – Discontinuance,” 76 *Fed. Reg.* 78530 (December 19, 2011), available at www.gpo.gov/fdsys/pkg/FR-2011-12-19/pdf/2011-32354.pdf.
- ¹⁹ FDA, “Permanent Discontinuance or Interruption in Manufacturing of Certain Drug or Biological Products,” 80 *Fed. Reg.* 38915 (July 8, 2015), available at www.gpo.gov/fdsys/pkg/FR-2015-07-08/pdf/2015-16659.pdf.
- ²⁰ Ibid.
- ²¹ GAO, “Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge,” July 2016.
- ²² FDA, “Third Annual Report on Drug Shortages for Calendar Year 2015,” *Report to Congress*, available at www.fda.gov/downloads/Drugs/DrugSafety/DrugShortages/UCM488353.pdf.
- ²³ Generic Pharmaceutical Association, “GPhA Reveals the Accelerated Recovery Initiative: An Unprecedented Multi-Stakeholder Proposal to Address Drug Shortages,” news release, December 15, 2011, available at www.gphaonline.org/gpha-media/press/gpha-reveals-the-accelerated-recovery-initiative-an-unprecedented-multi-stakeholder-proposal-to-address-drug-shortages.
- ²⁴ Adam Rubenfire, “Surmounting Shortages: GPOs Work Creatively with Manufacturers to Avert Drug Shortfalls,” *Modern Healthcare*, October 24, 2015, available at www.modernhealthcare.com/article/20151024/MAGAZINE/310249987.
- ²⁵ See *2014 Drug Shortages Summit*, August 1, 2014, available at www.ismp.org/pressroom/2014-Drug-Shortages-Summit.pdf.
- ²⁶ GAO, “Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge,” July 2016.
- ²⁷ Ibid.; and GAO, “Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability,” February 2014.
- ²⁸ GAO, “Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge,” July 2016.

-
- ²⁹ Zachary Brennan, "GDUFA II: FDA Looks to Speed Up Generic Drug Approval Process," *Regulatory Focus*, September 26, 2016, available at www.raps.org/Regulatory-Focus/News/2016/09/26/25898/GDUFA-II-FDA-Looks-to-Speed-Up-Generic-Drug-Approval-Process.
- ³⁰ GAO, "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," February 2014.
- ³¹ *Ibid.*
- ³² GAO, "Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge," July 2016.
- ³³ See J. Woodcock and M. Wosinska, "Economic and Technological Drivers of Generic Sterile Injectable Drug Shortages," *Clinical Pharmacology & Therapeutics* 93, no. 2 (February 2013): 170–76.
- ³⁴ GAO, "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," February 2014.
- ³⁵ *Ibid.*
- ³⁶ Anna Gu, Albert I. Wertheimer, Bernard Brown, and Fadia T. Shaya, "Drug Shortages in the US – Causes, Impact, and Strategies," *Innovations in Pharmacy* 2, no. 4, article 60 (2011).
- ³⁷ See, for example, C. Lee Ventola, "The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies," *P&T* 36, no. 11 (November 2011); and International Society for Pharmaceutical Engineering, "Report on the ISPE Drug Shortages Survey," June 2013.
- ³⁸ See, for example, House Oversight Staff Report, "FDA's Contribution to the Drug Shortage Crisis," June 15, 2012, p. 4; and Phillip L. Zweig and Robert A. Campbell, "How to Stop Generic Drug Shortages: End Hospital Group Purchasing Kickbacks," *Fortune*, January 30, 2015.
- ³⁹ ASPE, "Economic Analysis of the Causes of Drug Shortages," *ASPE Issue Brief*, October 2011.
- ⁴⁰ GAO, "Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability," February 2014.
- ⁴¹ Roger D. Blair and Christine Piette Durrance, "Group Purchasing Organizations, Monopsony, and Antitrust Policy," *Managerial and Decision Economics* 35, no. 7 (October 2014): 433–43.
- ⁴² ASPE, "Economic Analysis of the Causes of Drug Shortages," *ASPE Issue Brief*, October 2011.
- ⁴³ Healthcare Supply Chain Association, "A Primer on Group Purchasing Organizations: Questions and Answers," available at www.supplychainassociation.org/resource/resmgr/research/gpo_primer.pdf.
- ⁴⁴ ASPE, "Economic Analysis of the Causes of Drug Shortages," *ASPE Issue Brief*, October 2011.
- ⁴⁵ Department of Justice and FTC, "Statements of Antitrust Enforcement Policy in Health Care," August 1996, available at www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf.
- ⁴⁶ Federal Trade Commission (FTC), "Responses of Federal Trade Commission Chairwoman Edith Ramirez to Questions Submitted for the Record," Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy, and Consumer Rights hearing on "Oversight of the Enforcement of the Antitrust Laws," March 9, 2016, available at www.judiciary.senate.gov/imo/media/doc/Ramirez%20Responses%20to%20QFRs.pdf.
- ⁴⁷ FTC, "Statement of the Federal Trade Commission In the Matter of Caremark Rx, Inc./AdvancePCS," File No. 031 0239, available at www.ftc.gov/sites/default/files/documents/cases/2004/02/040211ftcstatement0310239.pdf.