

Understanding Drug Shortages: An Overview and Recommendations

Introduction

During the COVID-19 pandemic, a surge in patient demand and limitations on manufacturing and distributing medicines and healthcare products raised the visibility of and increased interest in healthcare [supply chain resilience](#) — particularly the issue of [drug shortages](#). Drug shortages are not a new phenomenon. In 2011, a peak year, more than 250 drugs experienced shortages.¹ Recently, Congress has shown an increased interest in understanding and acting to mitigate drug shortages by holding committee hearings², publishing committee reports³, opening a Request for Information (RFI) on shortages⁴ and introducing legislation.⁵

The Healthcare Distribution Alliance (HDA) and its pharmaceutical distributor members recognize the challenges that drug shortages pose to the healthcare system and patients. In fact, the distribution industry works to mitigate and manage shortages at both ends of the supply chain to enhance resilience. Given HDA members' central position in the healthcare supply chain, our industry has a unique perspective on the types and drivers of drug shortages as well as recommendations to reduce these events.



What Is a Drug Shortage?

No matter the driver, drug shortages occur because there is a lack of supply to meet current demand. HDA and its members align with the [FDA definition](#), which states that a shortage occurs when the total commercially available supply of a medical product is not able to meet the current demand.⁶ According to the FDA, there are currently [138 drugs in shortage](#).⁷

1. U.S. Food and Drug Administration. "Tenth Annual Report on Drug Shortages for Calendar Year 2022." 2023. <https://www.fda.gov/media/169302/download>.
2. United States House Committee on Energy and Commerce Subcommittee on Oversight and Investigations. "Examining the Root Causes of Drug Shortages: Challenges in Pharmaceutical Drug Supply Chains." May 11, 2023. <https://energycommerce.house.gov/events/oversight-and-investigations-subcommittee-hearing-examining-the-root-causes-of-drug-shortages-challenges-in-pharmaceutical-drug-supply-chains>.
3. United States Senate Committee on Homeland Security & Governmental Affairs. "Short Supply. The Health and National Security Risks of Drug Shortages." March 2023. <https://www.hsgac.senate.gov/wp-content/uploads/2023-03-20-HSGAC-Majority-Draft-Drug-Shortages-Report.pdf>.
4. United States House Committee on Energy and Commerce. "Chair Rodgers, Ranking Member Grapo Issue Request for Information to Inform Policymaking on Drug Shortages." June 12, 2023. <https://energycommerce.house.gov/posts/chair-rodgers-ranking-member-grapo-issue-request-for-information-to-inform-policymaking-on-drug-shortages>.
5. United States House Committee on Energy and Commerce. "Chair Rodgers Unveils Proposal to Address Root Cause of Drug Shortages Facing American Patients." July 28, 2023. <https://energycommerce.house.gov/posts/chair-rodgers-unveils-proposal-to-address-root-cause-of-drug-shortages-facing-american-patients>.
6. U.S. Food and Drug Administration. "Drug Shortages: Root Causes and Potential Solutions." Last Updated February 21, 2020." <https://www.fda.gov/media/131130/download>.
7. U.S. Food and Drug Administration. "FDA Drug Shortages, Current and Resolved Drug Shortages and Discontinuations Reported to the FDA." Accessed July 27, 2023. <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

However, it is important to note that the drug shortages discussion often references different numbers of products in shortage, based on the varying definitions outside of the FDA definition of drug shortages. Other entities may use broader definitions of drug shortages, which qualify products on [fair-share allocation](#) (receiving a partial fulfillment of a requested order) or stockouts (temporary inability to receive a product) as “in shortage.” When addressing drug shortages, it is essential to accurately represent the number of drugs in shortage, as multiple definitions can obfuscate the issue. Drug shortages are a complex and dynamic issue, which is why it is critical to rely on a single definition for a drug shortage in policy discussions.

What Causes Drug Shortages?

Shortages typically fall into two categories: supply-driven shortages and demand-driven shortages. Supply-driven shortages⁸ are characterized by limited availability of a drug caused by manufacturing disruptions or a change in the availability of raw materials.⁹ Demand-driven shortages occur when disaster-related or non-disaster-related medical surges create a sudden uptick in orders.¹⁰ The causes of supply-driven and demand-driven shortages differ significantly.



Supply-Driven Shortages

Supply-driven shortages are often rooted in upstream disruptions to manufacturing processes, quality issues and raw material or active pharmaceutical ingredient (API) shortages. Disruptions to the manufacturing process may result from manufacturing quality issues and market access challenges.

Manufacturers experience challenges that impact supply, including raw material and API shortages, disruptions in manufacturing and quality issues. Moreover, manufacturing quality issues are frequently related to the need for greater investment in robust manufacturing processes and resilience practices to mitigate possible issues, such as contamination. Drug shortages may plague a specific product class, such as generic sterile injectables, due to quality and contamination issues that result from a lack of robust manufacturing processes and investments in resilience practices.¹¹ The recent COVID-19 pandemic exposed the global nature of the supply chain, particularly U.S.-based businesses that rely on raw materials and medical products from other countries.¹²



Demand-Driven Shortages

Demand-driven shortages often result from legitimate demand or “hoarding” practices related to disaster or non-disaster-related medical surges. Disasters and public health emergencies like pandemics, hurricanes and flu season can cause medical surges. Typically, distributors can use public health data to forecast demand and scale up for medical surges from events like the seasonal flu. However, complex disasters and events are less predictable. For example, the December 2022 polycrisis phenomenon of COVID-19, respiratory syncytial and flu viruses exceeded projections¹³, resulting in a shortage of antivirals and pediatric acetaminophen.¹⁴

The drivers of non-disaster-related demand shortages include increased patient demand, hoarding practices or provider overprescribing. For example, off-label prescribing practices and unprecedented social media popularity contributed to a surge in patient demand for Ozempic®.¹⁵ Distributors cannot easily project demand-driven shortages, which vary greatly based on the cause and supply of products available.

8. Healthcare Distribution Alliance. “HDA RFI Submission on Drug Shortages.” July 2023. <https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf>.

9. Ibid.

10. Ibid.

11. Ibid.

12. Healthcare Distribution Alliance. “Bolstering Disaster Preparedness and Operational Resilience in the Healthcare Supply Chain.” 2023. <https://www.hda.org/getmedia/f13bb354-88eb-494e-81ca-2456ea4d795c/Bolstering-Disaster-Preparedness-and-Operational-Resilience-in-the-Healthcare-Supply-Chain.pdf>.

13. IQVIA. Long, Doug. U.S. Pharmaceutical Trends, Issues & Outlook for HDA. Presented March 13, 2023.

14. U.S. Food and Drug Administration. “FDA Drug Shortages. Current and Resolved Drug Shortages and Discontinuations Reported to FDA.” Accessed July 25, 2023. <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>

15. IQVIA. Long, Doug. U.S. Pharmaceutical Trends, Issues & Outlook for HDA. Presented March 13, 2023.

Recommendations for Mitigating and Managing Drug Shortages

The distribution industry business model uses redundancy to deliver products to patients continuously and reliably. Distributors reliably connect [1,500 manufacturers to 330,000 sites of care](#)¹⁶ while maintaining a [0.4 percent net profit margin \(after taxes\)](#).¹⁷ Distributors' business practices are built on maintaining supply chain and operational resilience. Accordingly, distributors can help industry partners understand the scope and duration of a drug shortage by communicating about product availability. Moreover, distributors can leverage their business model and unique lens into the supply chain to understand the causes of drug shortages occurring upstream (manufacturing processes) and downstream (consumer use patterns).

HDA and its members work with regulators, policymakers and other healthcare supply chain stakeholders to ensure the availability of safe and effective medicines.¹⁸ To mitigate drug shortages, HDA and its members recommend the federal government take the following actions:

Challenge

Pharmacy benefit managers place a higher-priced product on a Tier 1 formulary, making it very difficult for lower-cost products, including generics and biosimilars, to gain traction in the marketplace.¹⁹ This practice may contribute to drug shortages, because it can stifle investment into additional generic and biosimilar medicines, and ultimately, result in fewer manufacturers and less redundancy.

- **Recommendation:** The Centers for Medicare & Medicaid Services should give preferred formulary positions to new generics and biosimilars.

Challenge

Adopting broader resilience practices, like creating additional production or buffer stock, may carry the risk of financial insolvency. A lack of broader resilience practices makes the pharmaceutical supply chain more vulnerable to disruptions like drug shortages.

- **Recommendation:** Congress and the FDA should examine financial incentives and operational considerations for strategically investing in product development and capacity and work with distributors to build targeted safety stock/buffer inventory.



Challenge

Some product classes, such as sterile injectables, experience chronic drug shortages due to the need for greater investment in robust supply chain resilience practices. Investing in resilience practices may prevent manufacturing quality issues, such as contamination.

- **Recommendation:** The FDA should work with the private sector to conduct a focused review of the challenges affecting specific product classes.

16. Healthcare Distribution Alliance. "Delivering Value Across Healthcare." 2023. <https://hda.org/getmedia/807f7717-3a3a-4e8a-9011-2c8a91502dec/hda-factsheetdeliveringvalueacrosshealthcare-2023.pdf>.

17. HDA Foundation. "94th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare." 2023. <https://www.hda.org/publications/94th-edition-hda-factbook-the-facts-figures-and-trends-in-healthcare/>.

18. Healthcare Distribution Alliance. "Pharmaceutical Traceability." Accessed July 31, 2023. <https://www.hda.org/pharmaceutical-traceability/>.

19. Healthcare Distribution Alliance. "HDA RFI Submission on Drug Shortages."

Challenge

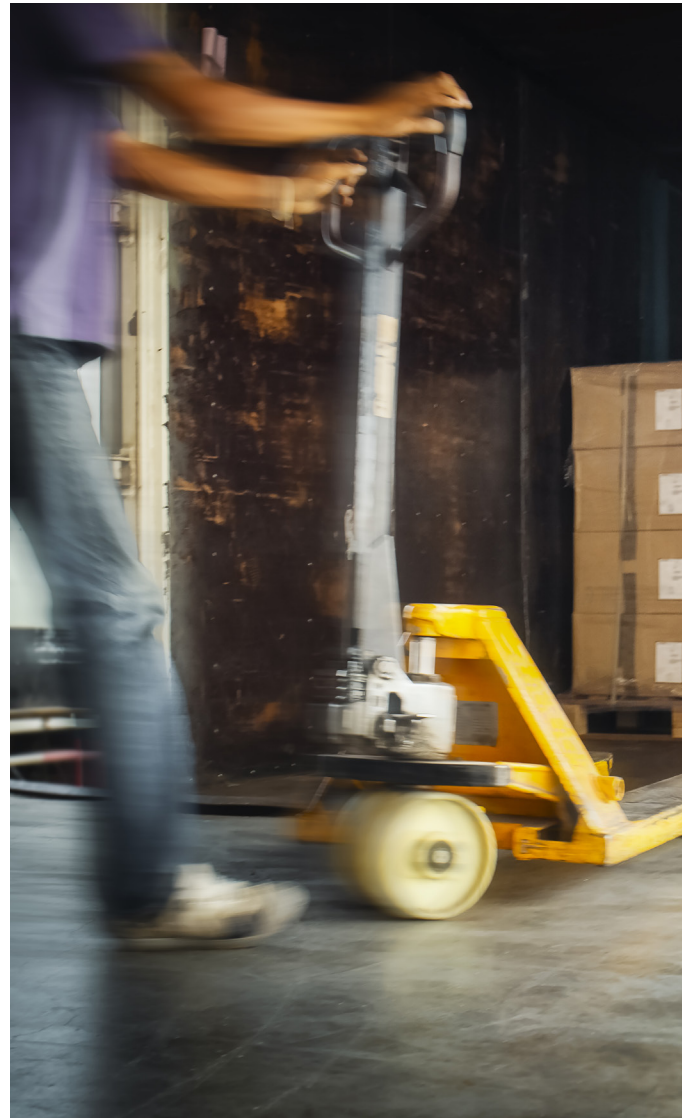
A record number of Abbreviated New Drug Applications (ANDAs) have been approved for generic medicines in the last five years. However, 16 percent of total ANDAs went unlaunched in 2022.²⁰ Unlaunched ANDAs creates a situation where there is less redundancy in the market for certain products, some of which may be vulnerable to drug shortages.

- **Recommendation:** The FDA should review the relationship between the number of ANDAs and the number of suppliers currently in the market, specifically for products at high risk of shortage.

Challenge

There is the potential for partnerships between the public and private sectors to enhance supply chain resilience and mitigate drug shortages. Public-private partnerships can help reduce potential drug shortages and lessen the effects of ongoing drug shortages.

- **Recommendation:** Congress should direct the U.S. Government Accountability Office to conduct a study to explore additional solutions and partnerships, specifically with the FDA, Department of Health and Human Services and the Administration for Strategic Preparedness and Response. These solutions and partnerships could reduce potential drug shortages and lessen the effects of current shortages.



Conclusion

Mitigating and managing drug shortages²¹ is critical to enhancing supply chain resilience and maintaining operational resilience. Drug shortages are highly nuanced, complex and unique events. Actions to address drug shortages should address both supply-driven and demand-driven shortages while building additional resilience in the healthcare supply chain. Distributors' unique position in the healthcare supply chain allows the industry to successfully mitigate and manage drug shortages, recognizing the need to maintain continuity of care for millions of patients daily.

20. 3 IQVIA. Long, Doug. U.S. Pharmaceutical Trends, Issues & Outlook for HDA. Presented March 13, 2023.

21. Healthcare Distribution Alliance. "Mitigating and Managing Drug Shortages: The Role of Healthcare Distributors." 2023. <https://www.hda.org/Accelerator/media/PDFs/Policy/Issue%20Briefs/Mitigating-and-Managing-Drug-Shortages.pdf>.

About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.