



Healthcare Distribution Alliance

**Statement for the Record
House Committee on Ways and Means
U.S. House of Representatives**

February 20, 2024

“Examining Chronic Drug Shortages in the United States”

Statement for the Record – Healthcare Distribution Alliance

On behalf of the Healthcare Distribution Alliance (HDA), we thank you for the opportunity to provide an overview of the pharmaceutical distribution industry and share our perspective on drug shortages. We applaud the Committee's efforts to examine the issue of drug shortages and the impact shortages have on patients and the pharmaceutical supply chain. We agree that drug shortages deserve attention, and we support changes that will preserve the strength and efficiency of the pharmaceutical supply chain, along with patient access, while tackling this challenging issue.

Overview of Pharmaceutical Distributors

HDA's 37 distributor members form the backbone of the U.S. pharmaceutical supply chain, handling approximately [95 percent of medicines](#) dispensed or administered in the United States.¹ We understand the risk that drug shortages pose, and distributors work to address them daily. Distributors [mitigate and manage drug shortages](#) as a core part of their business operations. Distributors ensure supplier diversity and maintain regular communication with supply chain partners. These partners include the manufacturers of brand, specialty, and generic medicines. Partners also include more than [330,000 downstream customers](#) distributors serve every day, including hospitals, clinics, physician offices, and pharmacies in every state in the country.

Overview of Drug Shortages

The issue of drug shortages is highly nuanced and dynamic. Distributors' unique role in the supply chain provides a perspective on the upstream availability of products and the downstream needs of the provider community. Distributors can look to historical drug shortage trends to gauge potential shortages in the future.

The drivers of drug shortages vary significantly, and as a result, there is no single or simple solution to prevent drug shortages. Essentially, drug shortages can be divided into two categories: [supply-driven shortages](#) and [demand-driven shortages](#). Supply-driven shortages occur because of upstream disruptions to manufacturing capacity or due to a natural disaster or geopolitical unrest.² Demand-driven shortages occur when available supply is outstripped by unforeseen situations, such as medical surges resulting from a natural disaster or potentially a disease outbreak.³

Unfortunately, our nation faces challenging drug shortages driven by supply and demand issues affecting the availability of certain medicines. Federal agencies, Congressional committees, and the Administration have made solving drug shortages a national priority. Solutions being considered to address drug shortages include increasing domestic manufacturing capacity, extending the shelf-life of drugs, increasing stockpiling or buffer inventory, and adjusting reimbursement for certain generic drugs.

¹ Healthcare Distribution Alliance. Delivering Pharmaceuticals and Value to Healthcare. Published 2023. https://www.hda.org/getmedia/4e490d25-762b-433a-aea4-9622e6b7d826/hda-factsheet_delivering-pharmaceuticals-and-value-to-healthcare-v7.pdf.

² Healthcare Distribution Alliance. Understanding Supply-Driven Shortages. Published 2023. <https://www.hda.org/getmedia/dada514b-7d2d-4d15-8c91-ed6f05c48443/HDA-Understanding-Supply-Driven-Drug-Shortages-Factsheet.pdf>.

³ Healthcare Distribution Alliance. Understanding Demand-Driven Drug Shortages. Published 2023. <https://www.hda.org/getmedia/f2d7f204-ea19-434b-a8a4-c0bc5610f08f/HDA-Understanding-Demand-Driven-Drug-Shortages-Factsheet.pdf>.

How Distributors Mitigate Drug Shortages

HDA and our members understand the critical impact of drug shortages on patients and providers. Distributors work to [mitigate shortages](#) by building redundancy into their sourcing programs and everyday business practices. They do this by purchasing medicines from numerous suppliers in multiple regions of the world.⁴ Distributors also work to forecast demand and anticipate demand surges.⁵ Specifically, distributors use demand forecasting to inform anticipatory purchasing decisions, such as preparing for seasonal demand spikes for cold and flu season.⁶

How Distributors Manage Drug Shortages

When drug shortages occur, distributors [manage](#) them to ensure consistent and reliable access to available prescription medicines. Distributors use tools such as fair-share allocation, which ensures product availability to as many customers as possible.⁷ Fair-share allocation is beneficial to facilities that do not have the financial resources or physical capability to hold large inventories of drugs.⁸

Generic Drug Shortages

The passage of [Hatch-Waxman](#) created today's generic drug industry. This law was intended to lower the price of medicines by increasing generic competition. Since the passage of this law in 1984, thousands of generic medicines have entered the marketplace, resulting in [trillions of dollars of savings](#)⁹ for payers and consumers. While generic drug prices have come down, in many cases, they have come down so far that generic manufacturers cannot remain in the market or are forced to operate on unsustainable margins.

How Distributors Support Generic Stability and Reliability

The generics industry has adapted to the realities of today's payer-driven marketplace, including prices from government-funded programs such as Medicare and Medicaid. In almost all cases, Medicare and Medicaid demand that the lowest-priced, clinically effective product be made available to beneficiaries.

Distributors recognize the economic reality of the generics marketplace, and as a result, they focus on creating stability and reliability for both upstream manufacturers and downstream customers. When partnering with manufacturers, distributors focus on the ability of the manufacturer to produce a reliable supply at a sustainable price. To promote stability with the manufacturer, distributors often partner with manufacturers on a long-term basis.¹⁰

⁴ Healthcare Distribution Alliance. Mitigating and Managing Drug Shortages: The Role of Healthcare Distributors. Published 2023. <https://www.hda.org/getmedia/984131d4-5163-411a-b74b-f3467113146b/Mitigating-and-Managing-Drug-Shortages.pdf>.

⁵ Healthcare Distribution Alliance. HDA RFI Submission Drug Shortages. Published 2023. <https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf>.

⁶ Ibid.

⁷ Healthcare Distribution Alliance. HDA Letter to Pharmacy Organizations on Inventory Management. Published 2020. <https://www.hda.org/getmedia/20a92a62-7f72-408b-ad6b-c5bb42e2ceba/2020-04-27-HDA-Letter-to-Pharmacy-Organizations.pdf>.

⁸ Healthcare Distribution Alliance. Insights and Recommendations From the National Academies' Report on Building Resilience in the Nation's Medical Product Supply Chain. Published 2023. <https://www.hda.org/getmedia/7290a259-5893-4fbb-9391-d8a91aa3eb85/Insights-and-Recommendations-From-the-National-Academies-Supply-Chain-Report.pdf>.

⁹ Association of Accessible Medicines. The U.S. Generic & Biosimilar Medicines Savings Report. Published 2023. <https://accessiblemeds.org/sites/default/files/2023-09/AAM-2023-Generic-Biosimilar-Medicines-Savings-Report-web.pdf>.

¹⁰ Healthcare Distribution Alliance. HDA RFI Submission Drug Shortages. Published 2023. <https://www.hda.org/getmedia/cc3658b0-cebe-47cd-a944-0af2504ece9a/HDA-RFI-Submission-Drug-Shortages.pdf>.

Economic Dynamics That Affect Provider Reimbursement

Each stakeholder in the pharmaceutical supply chain has faced pressure to lower drug prices for the last 40 years. This financial pressure has resulted in stakeholders often operating in a constrained marketplace. Distributors must source products not only from reliable and dependable manufacturers, but at prices that the downstream payer-driven market demands.

Healthcare providers, including but not limited to pharmacists, often face financial pressures from payers through low reimbursement rates, particularly for generic medicines. As a result, providers often look for the lowest-priced drugs when they order from their distributors.

HDA Solutions to Prevent Drug Shortages

While some financial pressures confronting generic manufacturers are direct byproducts of the free market system, HDA and its members want to share a few recommendations that could help combat drug shortages.

Federal Coordination – Given the unique position distributors have in the supply chain, we are willing to work collaboratively with our downstream trading partners to share information with government officials when we experience demand surges that have the potential to strain available supply. Partnerships with the federal government and trading partners may increase transparency and visibility throughout the supply chain to better assess vulnerabilities. Increased transparency efforts must include confidentiality agreements, so information is not pre-maturely shared, thus creating potential disruptive purchasing behaviors.

Strategic Investment - The federal government should invest in domestic manufacturing capabilities to address drug shortages. These federal investments should be strategically focused to reshape production capacity for active pharmaceutical ingredients, key source materials, and finished dose formulations for medicines vulnerable to drug shortages.

Stabilizing the Generic Supply Chain - We suggest implementing the following two policies to address market failures in the generic marketplace.

1. We recommend reviewing the outcomes of Hatch-Waxman, which aims to lower drug prices and increase the number of generic medicines in the market. A National Academy of Medicine study should be conducted to review the impact of Hatch-Waxman and Generic Drug User Fee Amendments (GDUFA) policies to determine if they are currently sustainable in today's healthcare marketplace. In addition, determine if the FDA has the necessary resources to conduct foreign inspections.
2. We also recommend that CMS and the FDA coordinate to review the number of suppliers for a given product over five years to determine if the deflation experienced is sustainable to avoid market failure. This review should also determine whether the number of ANDA approvals for each respective national drug code (NDC) losing patent exclusivity precipitates product "dumping" and forces generic companies to exit the market.

Reimbursement Policy – We also recommend adjusting reimbursement policies to increase pharmacy and provider reimbursement for generic medicines. Economic approaches to address drug shortages must acknowledge the financial strain and complex reimbursement providers face.

Conclusion

HDA and its members recognize the challenges drug shortages pose to our nation's healthcare systems and patients. We are committed to working with manufacturers and providers to mitigate and manage them when they occur. We applaud the Committee for its efforts to act on drug shortages.

HDA and its members stand ready to provide our continuing perspective and insight on behalf of the pharmaceutical distribution industry and partner with you on real solutions to this complicated challenge.