Healthcare Distribution Alliance

HEALTH DELIVERED

THE HEALTHCARE DISTRIBUTION ALLIANCE'S PUBLIC COMMENT IN RESPONSE TO THE FEDERAL TRADE COMMISSION'S "SOLICITATION FOR PUBLIC COMMENT TO UNDERSTAND LACK OF COMPETITION AND CONTRACTING PRACTICES THAT MAY BE CONTRIBUTING TO DRUG SHORTAGES"

I. Introduction/Executive Summary

The Healthcare Distribution Alliance (HDA) appreciates the opportunity to submit this comment to the Department of Health and Human Services (HHS) and the Federal Trade Commission (FTC) in response to their "Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages."[1] HDA represents wholesale drug distributors (Distributors) that provide critical operational and logistical services to pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and other healthcare providers nationwide. Distributors help enable patient care by ensuring FDA-approved medications are available where and when prescribers and patients need them.

Today's pharmaceutical supply chain faces drug shortages, particularly for generic sterile injectables in acute care settings, among others, as further set forth herein.[2] The causes of these shortages are multifaceted and treatment specific. For example, recent shortages in certain Chronic Obstructive Pulmonary Disease (COPD) and chemotherapy medications are related to supply-side quality issues, while the Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA) assert that shortages in Attention-Deficit/Hyperactivity Disorder (ADHD) medications (as described by

[1] U.S. Dep't of Health and Human Svcs. & Fed. Trade Comm'n, Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages (Feb. 13, 2024), *available at* https://www.regulations.gov/document/FTC-2024-0018-0001.

[2] Brookings, Drug Shortages: A Guide to Policy Solutions (Mar. 13, 2024), *available at* https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/.

numerous public comments) are attributable to manufacturers only selling 70 percent of their permitted supply, despite demand for stimulants (including ADHD drugs) increasing 45.5 percent.[3] These various supply shortages do not lend themselves to a single or simple solution. Distributors help address drug shortage concerns because they promote access and have a vested interest in maintaining a consistent supply of products for their downstream customers.

To aid the FTC and HHS inquiry, our submission focuses upon the critical role that Distributors play in responding to supply chain disruptions occurring in the generic marketplace. In particular:

- **Distributors' core model helps pharmacies, hospitals, long-term care facilities, clinics, and other providers provide patients with access to all medicines.**

  Distributors provide critical operational support to the supply chain, helping to maintain supply chain safety, efficiency, continuity, and integrity, which includes handling logistics for suppliers and customers, promoting compliance with robust state and federal regulations, and sourcing products for customers.

- **While Distributors facilitate access, they are not the cause of generic supply disruptions, nor are they solely positioned to remedy those disruptions.**

  There are numerous causes of drug shortages, particularly those that are driven by dynamics in the marketplace for generic drugs, such as demand surges, reliability and quality concerns, national and global disruptions, and weather or other natural disasters.

- **Distributors look for strategies to mitigate supply chain disruptions that threaten patient access.**

  When disruptions do occur, Distributors immediately leverage capabilities that help maintain continued provider and patient access. These capabilities include facilitating the purchase of additional inventory (known as "buffer inventory") for customers, aiding customers with inventory management, identifying, sourcing, and securing product alternatives available to customers, and forecasting future demand of specific products.

While the FTC and HHS wrestle with the root causes of generic drug shortages, we believe that the prevalence of affordable generics continues to be a win for the American public. This is especially

[3] Drug Enforcement Administration & Food and Drug Administration, Joint Letter to the Public (Aug. 1, 2023), *available at* https://www.dea.gov/sites/default/files/2023-08/DEA%20and%20FDA%20Issue%20Joint%20Letter%20to%20the%20Public.pdf?utm_medium=email&utm_source=govdelivery.

true as policymakers strive to address rising drug costs in other areas of the pharmaceutical sector, including brand pharmaceuticals. HDA looks forward to working with its supply chain partners to find realistic and meaningful solutions to address drug shortages, while simultaneously supporting continued access to affordable generics.

II. Distributors' core model helps pharmacies, hospitals, long-term care facilities, clinics, and other providers provide patients with access to all medicines.

Distributors work to provide patients with medicines they need by managing the flow of products between suppliers and healthcare providers, following strict regulations, and sourcing the drugs that customers demand.

Distributors procure products from suppliers based on demand forecasts for medicines. Distributors purchase and take legal ownership of these medicines, and then manage the logistics and credit risk associated with transferring products to their downstream customers. To meet customer needs, distributors invest in programs to build inventory buffers or redundancies on items they believe susceptible to supply interruptions or that have previously experienced interruptions. Products that go through Distributors, including generic oral solids and generic sterile injectables, are dispensed at pharmacies, hospitals, long-term care facilities, and clinics.

As logistics experts, Distributors must find safe, efficient ways to store and transport products in a continuous and reliable manner, especially when there are shortages. Distributors work to connect 1,500 manufacturers to 330,000 sites of care via the daily delivery of 10 million product units, with 84 percent of customers receiving deliveries five times or more per week.[4] Distributors are compensated for providing logistical services to upstream and downstream trading partners. When there is limited

[4] HDA Foundation, 94th Edition HDA Factbook: The Facts, Figures and Trends in Healthcare (published 2023), *available at* https://www.hda.org/publications/94th-edition-hda-factbook-the-facts,-figures-and-trends-in-healthcare/.

availability of a product in the marketplace, Distributors often manage sales based on customers' historical purchasing patterns to help ensure the broadest access possible.

Distributors are highly regulated at the state and federal level. At the state level, Distributors must comply with stringent license requirements, pre-licensure and regular inspections, surety bonds, and criminal background checks, with significant penalties for noncompliance. At the federal level, Distributors interface with federal regulators and comply with regulations daily, including those from the DEA, FDA, and the Environmental Protection Agency.

Distributors are also experts in sourcing products that pharmacies, hospitals, long-term care facilities, and clinics need. Distributors consider multiple factors when sourcing products for customers, including cost, quality, supply, financial stability, patient and provider preference, and manufacturers' prior business practices. Distributors seek to mitigate supply risk by sourcing medicines from multiple manufacturers, known as "supplier diversification." This practice is designed to prevent overreliance on a single source and geographic concentration of supply. To further promote consistent supply of medicines, distributors may enter into long-term supply contracts with manufacturers. Such agreements are designed to aid manufacturers in managing their own supply chains and production schedules.

III. Despite Distributors' strategies to address supply chain disruptions, numerous factors beyond Distributors' control contribute to drug shortages.

Distributors are neither the cause of disruptions in the supply of generic drugs, nor are Distributors solely positioned to remedy those disruptions, even while they work to mitigate existing shortages. We address each point in turn.

A. Distributors are not the cause of drug shortages in the generic marketplace.

The issue of drug shortages in the generic marketplace is highly nuanced and dynamic, with multiple drivers and factors outside of Distributors' control. Shortages can often be categorized as either manufacturer/supply-driven or consumer/demand-driven. Supply-driven shortages are triggered by

unavailability of raw materials or active pharmaceutical ingredients, manufacturer disruptions, or quality issues at the manufacturer facility.[5] Recent shortages in treatments for COPD (albuterol) and certain cancers (cisplatin) are examples of supply-driven shortages caused by quality issues. In contrast, demand-driven shortages are caused by increases in demand that create a sudden uptick in ordering.[6]

i. Supply-Driven Shortages:

a. *Manufacturer Reliability Issues*. Production of generics is costly and complex, yet manufacturers face various pressures to keep prices low, including customer demands, Medicare reimbursement rates, inflation-based price caps, and state purchasing program requirements.[7] As a result, some generic companies struggle to make the investments required to support current Good Manufacturing Practice (cGMP) standards to prevent contamination, leading to a lack of consistently reliable supply in the generic marketplace. Recent shortages of albuterol (a drug for treatment of COPD and other lung conditions) and cisplatin and carboplatin (chemotherapy drugs for certain cancers) serve as stark examples of these reliability failures. In 2023, Akorn Pharmaceuticals, facing financial problems partly due to known quality control issues, exited the albuterol market altogether, which contributed to a shortage that persists even today.[8] Furthermore, a 2016 U.S. Government Accountability Office (GAO) report found that generic sterile

[5] Brookings, Drug Shortages: A Guide to Policy Solutions (Mar. 13, 2024), *available at* https://www.brookings.edu/articles/drug-shortages-a-guide-to-policy-solutions/.
[6] *Id.*
[7] *Id.*
[8] American Society of Health-System Pharmacists, Albuterol Inhalation Solution (Feb. 24, 2024), *available at* https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=820&loginreturnUrl=SSOCheckOnly.

injectables shortages are typically caused by manufacturers slowing or stopping production to address reliability concerns.[9] For example, Accord Pharmaceuticals contributed to a shortage of two generic sterile injectables—cisplatin and carboplatin—in 2024 due to an import ban following an FDA inspection revealing violations of cGMPs and data integrity concerns.[10]

b. *Economics of Generic Manufacturing.* When supply chains and market demand are both stable, manufacturers can more easily plan for operational continuity and forecast supply. On the other hand, when generic markets are unstable – due, for example, to large upticks in new generic entrants receiving authorization through the Abbreviated New Drug Application (ANDA) process, or to rival manufacturer exits – it can be much more difficult for manufacturers and their channel partners to adjust supply-side planning . As a result, some observers have noted that market volatility can have the effect of discouraging manufacturers from making long-term investments in future production capacity, or from quickly expanding production capacity during short-term periods of demand surges. Put differently, manufacturers sometimes plan their business around more predictable, long-term demand rather than over-rotating in response to short-term market conditions, which can ultimately result in supply shortfalls. IQVIA has observed this trend

[9] U.S. Government Accountability Office, Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge (published 2016), *available at* https://www.gao.gov/assets/gao-16-595.pdf.
[10] American Society of Health-System Pharmacists, Cisplatin Injection (Mar. 23, 2024), *available at* https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=903&loginreturnUrl=SSOCheckOnly.

particularly with regard to certain oncology medications that have lost exclusivity, where some manufacturers have chosen not to compete on price with low-cost generic alternatives when doing so would be inconsistent with their businesses' financial health.[11]

ii. **Demand-Driven Shortages and Regulatory Oversight Challenges**: During the COVID-19 pandemic, a surge in telemedicine prescribing for stimulants often used to treat ADHD led to a sharp spike in demand.[12] Many of the public comments in this inquiry focus on just this shortage, reflecting that there are unique and acute issues in that area. Following the spike, the FDA reported in October 2022 a shortage of immediate release formulations of amphetamine mixed salts (the ADHD drugs known as Adderall and Adderall IR).[13] Today, the FDA shortage list has extended at times to include other ADHD drugs, such as generics of Focalin, Ritalin, and Vyvanse.[14] There are also DEA-set regulatory limitations that could be relevant here.[15] Indeed, amphetamine

[11] IQVIA, Drug Shortages in the U.S. 2023, Exhibit 11 (Nov. 15, 2023), *available at* https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/drug-shortages-in-the-us-2023. "Following brand loss of exclusivity, oncology medicines with shortages have seen overall declines in price despite variable market participants and market concentration. Prices for injectable oncology shortages dropped significantly after generic entry, stabilizing at prices of less than $1.00 per extended unit in recent years. These pricing dynamics make it difficult for manufacturers to get a return on the investment needed to increase production when a shortage is ongoing, often leading to prolonged shortages."

[12] Centers for Disease Control and Prevention, Trends in Stimulant Prescription Fills Among Commercially Insured Children and Adults — United States, 2016–2021 (Mar. 31, 2023), *available at* https://www.cdc.gov/mmwr/volumes/72/wr/mm7213a1.htm.

[13] Food and Drug Administration, FDA Announces Shortage of Adderall (Aug. 1, 2023), *available at* https://www.fda.gov/drugs/drug-safety-and-availability/fda-announces-shortage-adderall.

[14] Food and Drug Administration, FDA Drug Shortages, Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Saccharate, Dextroamphetamine Sulfate Table (first posted Oct. 12, 2022), *available at* https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Amphetamine%20Aspartate%20Monohydrate,%20Amphetamine%20Sulfate,%20Dextroamphetamine%20Saccharate,%20Dextroamphetamine%20Sulfate%20Tablet&st=c.

[15] Drug Enforcement Administration & Food and Drug Administration, Joint Letter to the Public (Aug. 1, 2023), *available at* https://www.dea.gov/sites/default/files/2023-08/DEA%20and%20FDA%20Issue%20Joint%20Letter%20to%20the%20Public.pdf?utm_medium=email&utm_source=govdelivery.

products used to treat ADHD are Schedule II controlled substances and as such, the DEA imposes aggregate production quotas limiting how much a manufacturer can produce in a given year. Manufacturers are producing below these quotas – despite demand for stimulants increasing 45.5 percent between 2012 and 2021. The DEA found that manufacturers only sold approximately 70 percent of their allocated quota of amphetamine products in 2023, and that one billion more doses could have been manufactured.[16] Just last fall, the FDA and DEA placed responsibility for this shortage with the manufacturers, jointly urging manufacturers to increase production to meet their allotted DEA quotas or relinquish their 2023 remaining quota allotment.[17] The DEA, however, has wrestled with supply chain complexities, including anticipating supply chain issues, understanding time-to-market, and informing procurement quotas for commercial marketing. For example, this month, the DEA significantly revised its quota allocation policy to allow manufacturers to apply for product quotas on a semi-annual or, in some cases, annual basis, rather than a quarterly basis. These shifts in approach reflect the uncertainty and unpredictability surrounding manufacturers' supply decisions.[18]

iii. **National and Global Disruption**: A recent request for information from the Office of the United States Trade Representative (USTR) acknowledges that the entire U.S. supply chain, and not just the pharmaceutical sector, is facing disruptions ranging from the continuing fallout of the COVID–19 pandemic to

[16] *Id.*
[17] *Id.*
[18] *See, e.g.*, 89 Fed. Reg. 407 (Jan. 3, 2024); Drug Enforcement Administration, Letter to DEA-Registered Manufacturer[s], *available at* https://www.documentcloud.org/documents/24630258-dea-letter-to-manufacturers.

Russia's invasion of Ukraine.[19] The USTR states that the impacts of supply chain disruptions include "volatile prices for critical consumer goods and medical products and widespread product shortages that contribute to inflationary dynamics."[20] In addition, recent supply disruptions attributable to the factors highlighted by the USTR have exacerbated ongoing reimbursement pressure from third-party payers. These pressures strain the financial viability of pharmacies, hospitals, long-term care facilities, clinics, and other providers, often forcing them to purchase the absolute lowest cost products available – which creates upstream pressure on drug manufacturers to lower their prices. Hence, these reimbursement challenges resonate throughout the entire supply chain, contributing to shortages, gaps in patient care, product failures, and manufacturer exits.

B. While Distributors cannot remedy disruptions beyond their control, Distributors do look for strategies to mitigate shortages that threaten patient access.

To mitigate the impact of drug shortages in the supply chain, Distributors focus on maintaining operational resilience through a variety of strategies, including:

i. ***Inventory Management and Investments***: Distributors employ systems that allow providers to place orders that arrive shortly before medication is dispensed to providers/patients. By doing so, Distributors help to reduce the need for large amounts of storage space, while reducing inventory carrying costs as well as security and diversion risks of holding expensive, high-risk products. Distributors

[19] 89 Fed. Reg. 16608 (Mar. 7, 2024).
[20] *Id.*

use these systems to ensure efficiency, reduce costs, and streamline delivery of products.

ii. ***Buffer Inventory*:** To mitigate shortages and contribute to a resilient supply chain, distributors collaborate with customers in managing and maintaining buffer inventory.

iii. ***Product Alternatives*:** In times of extraordinary or unpredictable shortages, distributors help mitigate shortages by tapping into their national and regional networks to offer patients alternative medications.

iv. ***Demand Forecasting*:** By utilizing sophisticated inventory forecasting tools, Distributors can forecast demand and potential disruptions caused by events like seasonal flu outbreaks. Distributors share these forecasts with manufacturers, enabling them to predict production needs.

v. ***Equitable Allocation***: Equitable allocation programs can help provide access when supply is limited. For example, vaccine allocation strategy for COVID-19 is an important issue that affects the efficiency and control of virus spread.[21] Distributors contribute to equitable allocation programs by accounting for available supply and customer needs to meet the goals of the program.[22]

IV. Conclusion

The nation's pharmaceutical Distributors all share an important role: helping patients get the medications they need. They do this by managing the flow of products between suppliers and healthcare providers, following strict regulations, and sourcing the medicines customers require. Distributors are

[21] Kim C, Guo A, Yassanye D, Link-Gelles R, Yates K, Duggar C, Moore L, El Kalach R, Jones-Jack N, Walker C, Gibbs Scharf L, Pillai SK, Patel A. The US Federal Retail Pharmacy Program: Optimizing COVID-19 Vaccine Delivery Through a Strategic Public-Private Partnership. Public Health Rep (2023), a*vailable at* https://pubmed.ncbi.nlm.nih.gov/37503697/.
[22] *Id.*

also actively involved in finding strategies to mitigate drug shortages. That said, it is important to understand that the root causes of these shortages lie outside the control of Distributors, for supply-side and/or demand-side reasons such as quality control issues, demand surges, reimbursement challenges, and economic behavior specific to the generic market.

Distributors have a vested interest in a diverse, dependable, and resilient generic medicine marketplace, and they recognize the need for affordable generic medicines for American patients. To that end, HDA continues to advance approaches, such as those outlined in HDA's guiding principles and policy agenda, where supply chain stakeholders and the government can work together to address drug shortages.[23] These approaches include strengthening partnerships between the public and private sectors; identifying strategic federal investments in domestic manufacturing capabilities; and taking steps to support generic manufacturer partners in ensuring stable supply.[24] Distributors stand ready to support realistic and meaningful solutions to these challenges.

[23] Healthcare Distribution Alliance, HDA Policy Platform on Drug Shortages & HDA Guiding Principles for Drug Shortages, *available at* https://www.hda.org/drug-shortages/.
[24] *Id.*