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Before the

Subcommittee on Health
House Committee on Energy and Commerce
U.S. House of Representatives

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“Legislative Proposals to Prevent and Respond to Generic Drug Shortages”

Summary of Testimony

The Healthcare Distribution Alliance (HDA) appreciates the committee's focus on drug shortages. Distributors are the supply chain's logistics experts, who work daily to connect manufacturers to [330,000 sites of care](#). Because of this, we understand the impact of supply- and demand-driven drug shortages and work daily to mitigate them.

Distributors maintain capabilities to mitigate and manage drug shortages — such as demand forecasting, supply chain monitoring and fair-share allocation. HDA distributor members are the backbone of the pharmaceutical supply chain, handling approximately [94 percent](#) of medicines that are dispensed or administered in the United States. HDA and its members believe that while it is crucial to address existing drug shortages, it is also important to note the success of the healthcare supply chain, in part due to the supplier diversification, competition and resilience it possesses. We caution against actions that may disrupt the efficiency and continuity of the supply chain.

We encourage recommendations that maintain competition and continuity of supply and can mitigate the potential for additional or worsening existing shortages. HDA and our members support the proposals on Medicaid Drug Rebate Program rebate cap on generic drugs in shortage and the proposal to enhance domestic medicines production. We caution against the proposed narrowing of the definition of bona fide service fees, which could have the unintended consequence of exacerbating drug shortages.

We applaud the Energy and Commerce Health Subcommittee for their efforts to act on drug shortages and caution against policy proposals that would create unintended disruptions to the supply chain. Our industry remains committed to working with you to identify solutions to the problems you seek to address.

Statement for the Record – Healthcare Distribution Alliance

Good morning, Chairman Guthrie, Ranking Member Eshoo and esteemed Members of the committee. My name is Chip Davis, and I am the President and CEO of the Healthcare Distribution Alliance (HDA). On behalf of HDA and our 35 distributor member companies, we thank you for the opportunity to provide an overview of the pharmaceutical distribution industry and to share our perspective on drug shortages.

We applaud your efforts to examine the issue of drug shortages, and their impact on patients and the pharmaceutical supply chain. We agree that drug shortages deserve attention, and we support changes that will allow us to preserve the strength and efficiency of the pharmaceutical supply chain while tackling this issue.

In my remarks, I will provide an overview of the role and value of the pharmaceutical distribution industry, a description of drug shortages from the distributor perspective, our takeaways from the discussion draft shared last month by the committee and recommendations to address drug shortages.

Overview of Pharmaceutical Distributors

HDA distributor members are the backbone of the pharmaceutical supply chain, handling approximately [94 percent](#)¹ of medicines that are dispensed or administered in the United States. Distributors find [the safest and most efficient ways to get products where patients need them, in a continuous and reliable manner](#).² Distributors work

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. "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>.

diligently to deliver products to customers daily, sometimes multiple times a day. Distributors are the supply chain's logistics experts, who work each day to [connect approximately 1,400 manufacturers to 330,000 sites of care](#).³ Distributors ensure a streamlined supply chain by coordinating the delivery of medical products across the United States, while also maintaining a [0.6 percent net profit margin](#) (after taxes).⁴ In the supply chain, distributors offer logistics expertise that allows for the safe storage and delivery of up to approximately 11 million products.

[Without distributor services](#)⁵, those manufacturers would need to independently connect to 330,000 sites of care multiple times a week to ensure daily access to medical products through delivery in a complex transportation network. That scenario also would place a burden on hospitals and pharmacies, creating a logistical challenge and administrative hardship, requiring each facility to set up and maintain individual connections to each manufacturer.

The conversation about supply chain resilience has been ongoing for the last decade, with an increased focus over the last few years. The attention on supply chain resilience has been in part to ensure that the pharmaceutical supply chain is agile and robust enough to respond to surges that might increase the demand for medicines. We appreciate the importance of this discussion's impact on public health. While today we focus on drug shortages, we must remember that resilience encompasses the mitigation and

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

⁴ HDA Research Foundation. *93rd Edition HDA Factbook: The Facts, Figures and Trends in Healthcare*. Published 2022. <https://www.hda.org/publications/93rd-edition-hda-factbook-the-facts,-figures-and-trends-in-healthcare/>.

⁵ Healthcare Distribution Alliance. "How Do Medicines Get to Where They Need to Go?" Published 2023. <https://hda.org/getmedia/ee0c6753-3549-4fd6-a58d-8ffaed19936d/hda-factsheet-howdomedicinesgettowheretheyneedtogo-2023.pdf>.

management of drug shortages, but also other aspects of supply chain continuity. And we believe it is in the best interest of public health to ensure that the capabilities that exist in the supply chain are preserved, while we work together to add capacity where we could build resilience.

Pharmaceutical distributors' capabilities were on full display during the COVID-19 pandemic, when the healthcare response to the pandemic and need to maintain continuity of care required a robust and stable supply chain that balanced the needs of chronic care patients and those with acute needs. Distributors demonstrated their capabilities to deliver medical products to sites of care, expand capacity to support specialized requests, and partner with their pharmacy and hospital customers as they prioritized patient needs. All distributors stepped up to serve our communities, patients and our country by working collaboratively to ensure the safe, effective and efficient distribution of critical medications and supplies. When considering policy proposals or program investments, HDA cautions against actions that may disrupt the continuity of the supply chain. Any investments made into the healthcare supply chain should be considered carefully so that this capacity is upheld.

Drug Shortages: Supply and Demand Driven

Put simply, drug shortages occur because the available supply does not meet the demand for certain products. However, there is no single definition of what constitutes a drug shortage. We align with the U.S. Food and Drug Administration (FDA) definition of a drug shortage — a period when the demand or projected demand of all versions of a

commercially available drug exceeds the supply.⁶ The driving factors behind shortages differ widely. From our perspective, there is no single solution that will resolve or prevent drug shortages.

Due to our unique vantage point in the supply chain, we see the issue of drug shortages as highly nuanced and dynamic — categorized by both manufacturer supply-driven and demand-driven shortages. Supply-driven shortages occur due to upstream disruptions to manufacturing or raw materials supply availability. These can be attributed to scenarios such as raw materials and active pharmaceutical ingredient (API) shortages, manufacturer disruptions, or quality issues and regulatory enforcement actions. Demand-driven shortages are caused by sudden medical surges or other increases in demand for which demand outpaces the supply. We consider these each to be distinct categories of drug shortages, as the causes and potential solutions are very different.

While reviewing the scope, impact and root causes of recent drug shortages, we find that they can be varied, depending on the manufacturer and type of product. Upon review of the shortages from the last year, the root causes vary significantly and are impacted by several factors, such as the drug type, the manufacturers involved and the reason for the shortage. For example, the recent supply-driven shortages of albuterol sulfate inhalation solution and oncology treatments were triggered by partial manufacturing shutdowns limiting the total supply available.⁷ With limited global manufacturers, there are few immediate pathways to alleviate access challenges. Demand-driven shortages (such as the flu and

⁶ US Food and Drug Administration. “Drug Shortages: Root Causes and Potential Solutions.” Published 2019. Updated February 21, 2020.” <https://www.fda.gov/media/131130/download>.

⁷ 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>.

RSV season of 2022) were the result of a surge in flu and RSV cases, which exceeded projected demand.⁸ There are instances when a drug shortage has multiple root causes, such as the demand-based shortage of Adderall, which was driven by a significant increase in demand, in this case, increased telehealth-based prescribing. That said, Adderall also could be characterized as a supply-driven shortage —because suppliers could not keep up with additional manufacturing volumes, which would have required an increase of regulatory quotas to address access hurdles.

So, to summarize, from the perspective of the distribution sector, you could say that not all drug shortages are created equal. We seek to work together — with industry leaders and policymakers alike — to find ways to categorize drug shortages based on key factors that may help us think about how to better understand, and hopefully, mitigate them.

Resilience Practices of Distributors

HDA and its members support overall [supply chain resilience](#)⁹ as enhanced resilience across the entire system creates the ability for the healthcare ecosystem to manage shocks, such as drug shortages, without significant disruption to patient care. When shortages occur, be they supply- or demand-driven, distributors employ multiple systems to mitigate the disruption and equitably distribute products in conjunction with manufacturers. Demand forecasting and constant monitoring of supply help distributors

⁸ Centers for Disease Control and Prevention. Centers for Preparedness and Response. Flu, RSV, COVID-19 and other Respiratory Threats this Fall and Winter. Presented November 29, 2022. https://emergency.cdc.gov/epic/pdf/2022/112922_slides.pdf.

⁹ Healthcare Distribution Alliance. “Healthcare Supply Chain Resilience and Data Illumination.” Published Spring 2023. <https://www.hda.org/getmedia/38b4ad3e-1164-4ef5-9516-963f7dbfb048/HDA-Data-Illumination-Report.pdf>.

maintain inventories to meet expected demand. When prolonged shortages, such as generic sterile injectables, become evident distributors immediately look for alternative sources of products to meet demand. If demand begins to outpace supply, distributors employ [fair-share allocation](#) programs¹⁰ [to ensure that all downstream customers have equitable access to available products](#) based on historical purchasing patterns while taking into account unique demand-surge needs. [This helps to forestall potential hoarding or panic buying.](#)

In addition, some distributors maintain a national network of distribution centers. In the event of a natural disaster or public health emergency, distributors can coordinate with federal and state officials to direct resources to where they are most needed.

Strength of the Industry

While some supply chain stakeholders have suggested that pharmaceutical wholesalers conduct sole-source procurement for generic medicines, this is not standard practice for the distribution industry. Customers frequently have a variety of choices for the exact same drug. Distributors stock and distribute the same drug from multiple generic manufacturers for many reasons. Distributors prioritize supplier redundancy, diversification and stable contracting relationships with manufacturers to help ensure a reliable supply of generic medicines. If one supplier is suddenly unable to supply a drug, distributors often

¹⁰ Healthcare Distribution Alliance. "Drug and Medical Product Availability: Distributors Promote a Resilient Supply Chain." <https://www.hda.org/getmedia/45f48c39-69e6-4ff8-8919-af1c4cfb7432/Drug-and-Medical-Supply-Shortages.pdf>.

have working relationships with other manufacturers and frequently already have stock of that same drug from another supplier.

The drug distribution business is highly competitive. Distributors must provide high service levels, stock the products their customers need and offer a competitive price. Ultimately, distributors procure the products that customers want to buy at the price customers are willing to pay. By maintaining a diversified supplier set, distributors are maintaining both competition and redundancy in the market, while also working to provide generic manufacturers with the assurance of meaningful market share for awarded products.

Finally, the ordering patterns of customers can be highly variable. So, inventory held by distributors can act as a buffer thereby minimizing variability in ordering patterns to the manufacturer, which in turn assists in production planning. This is a benefit offered to manufacturers because of their partnership with pharmaceutical distributors.

Drug Shortages

It is important to note that the generic medicines industry operates in a commoditized market, which means that standard market forces are the primary driver of price and market stability. The pharmaceutical supply chain has been and continues to be under pressure to decrease the cost of medicines. A wide array of stakeholders – including employers, providers, healthcare systems, patients and consumers, state and federal policymakers and government agencies regularly and routinely put pressure on the pharmaceutical supply chain to control pricing and costs. That impetus continues to be front and center in the

debate over drug prices today. The current dynamics of the generics market have focused on a resilient supply of quality, FDA-approved, low-cost generic medicines to patients.

HDA and its members believe that while it is crucial to address existing drug shortages, it is also important to note the success of the healthcare supply chain, in part due to the supplier diversification, competition and resilience maintained, as stated above. In the United States, 90.2 percent of prescriptions dispensed were generic drugs (2022 data).¹¹ Factors that drive shortages in our country are consistent with the global trends and drug shortages observed in other countries, which suggests that some factors are driven by the global market. [The European Union \(EU\) issued a report¹²](#) citing the drivers of shortages to be increased demand, manufacturing and quality problems, factory closures and supply-chain bottlenecks.

We want to note that there are currently tremendous successes in the efficiency of the healthcare supply chain. We caution against actions that may disrupt the efficiency and continuity of the supply chain. Any investments made into the healthcare supply chain should be considered carefully to avoid disrupting the competition and continuity of the supply chain. HDA and our members advocate for increased supply chain resilience, which includes addressing drug shortages. We align with many of the recommendations published earlier this year by the Association for Accessible Medicines on specific solutions that would

¹¹ IQVIA. Long, Doug. US Pharmaceutical Trends, Issues & Outlook for HDA. Presented March 13, 2023.

¹² *Politico*. "Non-Paper – Improving the security of medicines supply in Europe – (BE, AT, NL, LU, HU, CZ, ES, FR, DE, EE, SI, RO, LV, LT, EL, MT, PL, IT, PT)." Published May 2, 2023. <https://www.politico.eu/wp-content/uploads/2023/05/02/Non-paper-security-of-medicines-supply-02.05.23.pdf>.

help address supply-driven drug shortages.¹³ We were pleased to see some of these proposals included in the discussion draft.

Discussion Draft Feedback

The committee's discussion draft released last month included thoughtful policies that aim to address different factors that touch supply-driven shortages. HDA and its members support recommendations that encourage and maintain competition and continuity of the supply chain, but at the same time mitigate the potential for additional or worsening existing shortages.

We support the proposed Medicaid Drug Rebate Program rebate cap for specified generic drugs (Sec. 101), recognizing that this policy would help generic manufacturers who are working to avoid or get out of a drug shortage to do so without additional pressures. We appreciate the committee's recognition that generic drugs and certain sterile injectable products would benefit from this policy.

We also support the provision to offer incentives for shelf-life extension studies (Sec. 502), specifically for generic sterile injectables. We encourage the committee to direct CMS to give preferred formulary position to new generics and biosimilars, such as generic sterile injectables. These efforts would expand access for patients, help reduce expenditures and open additional markets for manufacturers of these products.

¹³ Association for Accessible Medicines. "Drug Shortages: Causes & Solutions." Published 2023. https://accessiblemeds.org/sites/default/files/2023-06/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf.

We also support the proposal to enhance domestic production and provide incentives for U.S.-based manufacturers to address challenges such as continuous manufacturing and increasing domestic production. While the discussion draft did not focus on this, we do want to raise the importance of incorporating a thoughtful regionally based stockpile program into the proposals. We are aware of several legislative proposals that would leverage market dynamics to build a sustainable stockpile of essential medicines, and we ask the committee to consider these policies in their review.

While there are multiple positive policy recommendations in the discussion draft, we do want to point out an area of real concern. The proposed narrowing of the definition of bona fide services fees (or BFSF, Sec. 307) may have unintended consequences that could exacerbate existing shortages and destabilize our healthcare system. Ultimately, a transition to flat-based fees will not prevent manufacturers from having to pay service fees to distribute their products.

The bona fide service fees manufacturers pay distributors underwrite the products' physical movement through the supply chain. These fees cover services such as the safe and secure storage and handling of tens of thousands of products, costs associated with cold chain storage and delivery, automated inventory management systems that process orders and select and package shipments, documenting and reporting requirements for regulatory agencies (Drug Enforcement Administration/Food and Drug Administration), and the cost of transporting more than 11 million products every day to the nation's 330,000 sites of care. Distributors take on significant tasks on behalf of manufacturers and the fee structure enables them to perform these activities and ensure that healthcare facilities receive product deliveries securely and on time.

The service fee rates are based on the product size, turn rate, cold chain requirements, controlled substance handling, Risk Evaluation and Mitigation Strategy (REMS) protocol and security of high-cost product. Bona fide service fees can vary based on the product type and the complexity of logistics to move the product. For medicines to be transported from the manufacturer to the provider (and ultimately, the patient), these services would have to be fulfilled. By providing core and value-added services that streamline the supply chain, distributors save the healthcare system up to \$63 billion annually. If manufacturers had to handle all these distribution services, costs would increase.

When evaluating the impact of narrowing the definition of what constitutes bona fide service fees paid to a distributor, it is important to understand that this could exacerbate drug shortages. This provision would destabilize the supply chain, and by reducing provider reimbursement, it could also further deflate prices for sterile injectables reimbursed under Medicare Part B, driving additional manufacturer suppliers out of the market.

Although the revised definition of bona fide service fees shows up only in the context of products with an Average Sales Price (ASP), we believe manufacturers will have to implement this definition in all instances where the concept of bona fide services fees apply (such as products with an Average Manufacturer Price [AMP]). Manufacturers must maintain robust policies, procedures and IT systems to ensure reporting of AMP, ASP, Best Price and other government price reporting requirements are accurate. HDA does not believe these systems can operate properly with different definitions of bona fide service fees.

Moreover, the changed definition for BFSF is not necessary. By definition, bona fide service fees are already required to be fair market value to qualify as a bona fide service fee under federal law.

A shift in service fee structure is likely to result in a shift in costs from brand manufacturers to generic manufacturers. This is likely to result in increased costs for many products, destabilizing the pharmaceutical supply chain. This provision would result in reduced access to products and even more downward pressure on generic manufacturers.

For these reasons, we feel this provision should not be considered in whatever vehicle the Committee decides to move forward. Respectfully, we ask why a BFSF provision, which as we have stated may exacerbate drug shortages, is being considered in discussion draft designed to mitigate shortages? BFSFs have nothing to do with the underlying fundamentals that are contributing to drug shortages.

Recommendations

In addition to the changes proposed in the discussion draft, we wanted to share a few recommendations that we believe could strengthen our nation's ability to mitigate and manage drug shortages.

Regarding the role of the federal government, HDA would welcome studies and reviews that examine the partnerships that could be leveraged to address shortages, as well as authorities that would increase market access. We welcome a study from the U.S. Government Accountability Office to explore potential solutions and partnerships, specifically with the FDA, Department of Health and Human Services and the Administration for

Strategic Preparedness and Response, to reduce potential drug shortages or lessen the impacts of current supply- and demand-driven shortages.

We recommend that the FDA work with the private sector to conduct a focused review of the challenges that affect specific classes of products. Recognizing that some classes of drugs have a higher frequency of shortages, it may be valuable to review the relationship between the number of Abbreviated New Drug Applications and the number of suppliers currently in the market, specifically for products at high risk of shortage.

Distributors support a policy that would increase access to generics and biosimilars on Medicare formularies. We support the Centers for Medicare and Medicaid (CMS) giving [preferred formulary position](#)¹⁴ to new generics and biosimilars.

Finally, to ensure that changes in the upstream supply chain are sustainable (including the increased domestic production), we welcome an examination by Congress and the FDA to explore financial incentives and operational considerations for strategically investing in product development, capacity and working with distributors to build targeted safety stock and/or buffer inventory.

Conclusion

HDA and its members recognize the challenges drug shortages pose to the healthcare system, and that is why we work with manufacturers to mitigate and manage them when they occur. We applaud the Committee for the admirable efforts to act on drug

¹⁴ Association for Accessible Medicines. "Drug Shortages: Causes & Solutions." Published 2023. https://accessiblemeds.org/sites/default/files/2023-06/AAM_White_Paper_on_Drug_Shortages-06-22-2023.pdf.

shortages but caution against policy proposals that would create unintended disruptions to the supply chain, such as changes to bona fide services fees. We remain committed to working with you to identify solutions to the problems you seek to address.

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.