



February 20, 2024

The Honorable Jason Smith
Chairman
Committee on Ways & Means
United States House of Representatives
Washington, DC 20515

Re: Statement for the Record on the House Ways & Means Committee's "Examining Chronic Drug Shortages in the United States" Hearing on February 6, 2024

Dear Chairman Smith:

On behalf of the Healthcare Supply Chain Association (HSCA), which represents the nation's leading healthcare group purchasing organizations (GPOs), we appreciate the opportunity to provide a statement for the record regarding the February 6, 2024, hearing examining chronic drug shortages in the United States. HSCA supports your continued efforts to address this pressing problem, and we look forward to continuing to work with you to determine long-term solutions to prevent and mitigate drug shortages and preserve access to high-quality care.

Healthcare providers initially formed GPOs in the early 1900s as an efficient means to aggregate purchasing volume, drive competition among suppliers, and reduce healthcare costs. Today, traditional healthcare GPOs serve as the sourcing and contracting partners to hospitals, long-term care facilities, surgery centers, clinics, and other healthcare providers across the country. GPOs help secure access to critical medical products, providing savings for patients, providers, Medicare, Medicaid, and taxpayers. Both independent and industry funded [studies](#) confirm the effectiveness and tremendous value of GPOs, finding that GPOs deliver annual cost savings of 12-18%.^{1 2} GPOs allow rural providers to obtain critical supplies at the same value as large providers while allowing all healthcare providers to focus on their core mission: providing first-class patient care.

The GPO Business Model and Value Proposition.

The GPO business model is voluntary, flexible, and clinically driven. We work in close collaboration with our member hospitals and healthcare providers to develop sourcing policies and contract award decisions. GPOs take a comprehensive approach to sourcing and contracting that not only accounts for the competitive price offered, but also the reliability and stability of supply. We recognize that market conditions change, and when they do, GPOs work with suppliers to adjust contracts. GPOs work

¹ Burns, Lawton R, and J Andrew Lee. "Hospital purchasing alliances: utilization, services, and performance." *Health care management review* vol. 33, no. 3, 2008, pp.203-15 2008: 203-15. doi:10.1097/01.HMR.0000324906.04025.33

² Dobson, Allen, and Joan DaVanzo, "A 2018 Update of Cost Savings and Marketplace Analysis of the Health Care Group Purchasing Industry," Dobson DaVanzo & Associates, LLC, Apr. 2019.

diligently to ensure member hospitals and providers can access the products they need to care for their patients most effectively.

American hospitals, particularly those in rural areas, are facing ongoing financial challenges that threaten their ability to stay open. GPOs allow small and rural healthcare providers who often lack the negotiating power to access competitive pricing for essential supplies to utilize the same efficiencies and discounts as large healthcare providers, enabling them to focus on providing necessary care to their communities.

Health systems and independent physician offices often depend on GPOs for much more than their ability to collectively aggregate purchasing power. GPOs provide a range of services, including broad clinical feedback and providing supply chain analytics, which are especially important in rural and underserved areas. Individual practices and community hospitals often do not have the resources, scale, and expertise to perform this themselves.

The Scope and Impact of Drug Shortages.

Drug shortages place significant strain on hospitals, health systems, healthcare providers, and their patients. In 2022, the University of Utah Drug Information Service (UUDIS) [identified](#) a total of 160 national drug shortages. This figure is likely an underestimate, however, as many shortages go unreported and may occur in smaller geographic areas. A survey of manufacturers by UUDIS offered insight into the causes of drug shortages. More than half of those surveyed (56%) either did not know the cause of the shortage or would not provide this information. Those manufacturers that did respond [cited](#) supply/demand (19%), manufacturing (18%), business decisions (5%), regulatory issues (1%), and raw material issues (1%) as reasons behind shortages.

The U.S. Food and Drug Administration (FDA) [identifies](#) manufacturing quality control issues as the primary cause of drug shortages, along with production delays, lack of raw materials, and manufacturer business decisions to discontinue products. HSCA and its member GPOs are committed to collaborating with healthcare providers and suppliers to bolster the resiliency of the healthcare supply chain so that patients and providers have consistent access to the drugs, products, and devices they need.

GPOs Take Steps to Prevent and Mitigate Drug Shortages.

GPOs track all available data on shortages and raw materials, including active pharmaceutical ingredients (API). GPOs track this data on a global scale to anticipate possible supply disruptions and to provide suppliers with notice to plan for production capability. GPOs also identify and help bring to market additional manufacturers of at-risk drugs, ensuring that there are auxiliary suppliers of essential medications and products.

GPOs routinely evaluate drug suppliers on the consistency of product availability, fill rates, recall frequency and management, disaster preparedness, secondary supply lines, and manufacturing transparency. GPOs recognize and reward reliability while encouraging a healthy market, and when shortages do occur, GPOs identify and support alternative sources and clinically appropriate substitutes.

GPOs recognize the cost and impact of drug shortages on their member hospitals and the patients they serve, and are leaders in working to prevent and mitigate drug shortages. Every HSCA member GPO has innovative programs that work to prevent and minimize the impact of shortages. The GPO business model creates a vigorously competitive and healthy market among GPOs and suppliers, and competition

among GPOs is essential to preventing drug shortages. Shortages are antithetical to the GPO model, as without sufficient products, suppliers, or competition, GPOs are unable to provide their services.

Given our unique line of sight into the healthcare supply chain, HSCA and its member GPOs respectfully offer the following recommendations to the Committee:

Invest in quality and building secondary supply lines. HSCA recommends incentivizing not just production, but also investment in quality and capacity, including the addition of secondary supply lines and having alternate or backup sources of API, to support long-term access to generic medications.

Create incentives to increase domestic manufacturing. HSCA recommends that if Congress elects to create incentives related to domestic manufacturing that the incentives be tied to quality and the amount of product sold in the U.S. For incentives to tangibly impact pricing dynamics, they must align with the quality products being made *and* sold in the U.S.

Refine authority related to the Strategic National Stockpile's (SNS) ability to enter into vendor contracts. HSCA encourages congress to refine the authority pertaining to the Fiscal year Consolidated Appropriations Act (P.L. 117-328), which authorized the Strategic National Stockpile (SNS) to enter into contracts to assist with the rotation of soon-to-be expired products so supply chain stakeholders can work collaboratively with agency officials to help identify when and where product should be released.

Maintain and/or require buffer inventory. To increase critical access to drugs, HSCA recommends that the federal government, through the Administration for Strategic Preparedness and Response (ASPR) and SNS, create, maintain, and/or require buffer inventory for critical medications and devices.

Increase transparency. HSCA recommends transparency regarding buffer inventories and that input from GPOs and other private industry stakeholders be used to determine which drugs, and if possible, which products, should be considered for buffer inventory.

Fund and implement FDA's Quality Management Maturity (QMM) program. HSCA recommends that Congress fully fund FDA's quality management maturity (QMM) program and require manufacturer participation and implementation as soon as possible. HSCA further recommends that FDA share its QMM ratings with appropriate supply chain stakeholders, including GPOs, to best inform purchasing decisions.


Increase ongoing visibility into manufacturing locations and API sources. HSCA recommends Congress require manufacturers to include on their package inserts and boxes the finished product manufacturing location, including for contract manufacturers, and API source(s) on all products.

Increase facility inspections. HSCA recommends that Congress increase funding for and encourage the FDA to increase the number of inspections. HSCA further recommends that Congress encourage FDA to begin unannounced foreign inspections for API supplies and drug product manufacturers.

We appreciate the opportunity to provide you with our comments and recommendations and appreciate the subcommittee's willingness to learn about the GPO industry, our role in the healthcare supply chain, and how we work to prevent and mitigate drug shortages. We look forward to continuing to serve as a resource to Congress and all stakeholders as we all work to continue improving the healthcare system.

Please do not hesitate to contact me directly if HSCA can be a resource on this issue moving forward. I can be reached at (202) 629-5833 and tebert@supplychainassociation.org.

Sincerely,

A handwritten signature in cursive script that reads "Todd Ebert". The signature is written in dark ink on a light-colored, slightly textured background.

Todd Ebert, R. Ph.
President & CEO
Healthcare Supply Chain Association (HSCA)