July 7, 2023

The Honorable Cathy McMorris Rodgers
Chair
Committee on Energy and Commerce
United States House of Representatives
Washington, DC 20515

The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

Re: Congressional Drug Shortages Request for Information (RFI)

Dear Chair McMorris Rodgers and Ranking Member Crapo,

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 comment on the joint committee drug shortages request for information (RFI). HSCA applauds your efforts to examine this pressing problem and we look forward to working with you to prevent and mitigate drug shortages and preserve access to high-quality care.

As the sourcing and contracting partners to virtually all of America's 7,000+ hospitals and the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers, GPOs lower costs for patients, providers, Medicare and Medicaid, and taxpayers. An analysis found that GPOs save the U.S. healthcare system $34.1 billion annually and up to $456.6 billion over ten years, with Medicare savings of up to $116.3 billion and Medicaid savings of up to $90.2 billion over the same period.[1] These savings are particularly important for small and rural hospitals, and independent physician offices that often lack the purchasing power to access competitive pricing for essential supplies. Traditional healthcare GPOs allow smaller providers to obtain critical supplies at the same value as large providers. GPOs allow all healthcare providers and physicians to focus on their core mission: providing first-class patient care.

The GPO model is voluntary, flexible, and member driven. GPOs take a comprehensive approach to sourcing and contracting that not only accounts for the competitive price offered, but also the quality, reliability, and stability of supply. 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 quality while encouraging a healthy market, which generally includes at least three manufacturers (with at least one domestic manufacturer). GPOs continue to work with suppliers to map out entire product supply chains and encourage manufacturers to identify alternative sources of active pharmaceutical ingredients (API) and raw materials.

GPOs work diligently to ensure a robust, competitive market for drugs and healthcare products. We recognize that price fluctuations occur. When they do, GPOs work with suppliers to adjust contracts, as we saw recently in the wake of natural disasters and the COVID-19 pandemic. GPOs also work to expand the overall number of suppliers, with a focus on encouraging new domestic manufacturers to enter the market.

HSCA and its member GPOs respectfully offer the following responses to those RFI questions where our unique position in the supply chain has given us relevant insight:

[1] 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.

Re: Questions 1 and 1b. How would you define the scope and impact of the recent and ongoing U.S. drug shortages? What are the impacts of recent and recurring shortages of generics and other critical medicines on patient care?

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 and to ensure that patients and providers have consistent access to the drugs, products, and devices they need.

Despite some limitations on existing data, 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. When shortages do occur, GPOs identify and support alternative sources and clinically appropriate substitutes.

HSCA member GPOs recognize the role that reliability and predictability play for manufacturers in the product development process. That is why GPOs work with generic drug manufacturers on contracts that provide the certainty and predictable demand they need to remain in the market.

Re: Question 2. What market and economic conditions undermine pharmaceutical supply chains or the availability of drugs? Please discuss any specific barriers in public payment programs.

Both high and low drug prices can precipitate drug shortages, and shortages occur with both brand-name and generic medications.

Following a supply disruption, the cost of acquiring products in shortage may increase due to a variety of factors. These cost increases can create an additional burden for many providers and patients, who then must identify alternative sources of the medication or alternative medications. In addition, because provider payment rates are set prospectively, drug price increases are not immediately recognized by payers and providers are forced to absorb the financial and operational burdens associated with shortages.

Although there is regular demand for low-cost, commonly used drugs, as with any industry, profitability often drives business decisions for generic drug manufacturers. Should lower profitability reduce manufacturer motivation to remain in the market for older prescription drugs, **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 API sources, to support long-term access to generic medications.**

Moreover, last year's Fiscal Year Consolidated Appropriations Act (P.L. 117-328) authorized the Strategic National Stockpile (SNS) to enter into vendor contracts to assist with the rotation of soon-to-be expired products. Given the ability of GPOs to anticipate certain shortages, such as regional shortages and

shortages pertaining to special populations (e.g., pediatric versus adult), **HSCA encourages Congress to refine this authority so supply chain stakeholders can work collaboratively with agency officials to help identify when and where product should be released.**

Re: Question 4. How can federal agencies, such as Centers of Medicare and Medicaid (CMS), better address the economic forces driving shortages? Are these agencies using their current authorities effectively?

With timely and sufficient stakeholder input, federal agencies have an opportunity to help address the economic forces driving drug and product shortages.

During the COVID-19 pandemic, for example, foreign export restrictions and production shutdowns threatened U.S. supply of N95 respirators and other personal protective equipment. Recognizing that 1) hospitals would need to be able to rely on domestic manufacturers of N95s in the event of future pandemics, and 2) hospitals were likely to incur additional costs when purchasing domestic N95s, CMS proposed payment adjustments to offset the additional marginal costs of domestic procurement. CMS could take similar steps for certain drugs that are frequently in shortage.

HSCA recommends that CMS consider payment adjustments for essential generic medications, including generic sterile injectables (GSI), that are frequently in shortage. Payment adjustments could be contingent on manufacturer adherence to certain supply chain mitigation and resiliency requirements, including participation in the FDA's quality management maturity (QMM) rating system.

GPOs may require manufacturers to keep a safety stock (generally three to six months of volume) of drugs and products deemed essential as buffer inventory within the U.S. As a result, there are more than 130 million units of additional drug inventory stored in the U.S. today, and more than 1.8 million units of additional inventory were accessed in the last 12 months. **To increase access to critical 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. Further, 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.**

Re: Question 6. Given that supply chain issues can trigger manufacturing delays and disruptions that result in shortages, are further incentives necessary to address manufacturing issues?

Manufacturing incentives for low-cost generic drugs – including for domestic manufacturers – would create resiliency in the supply chain that could help prevent shortages. Increasing incentives for domestic pharmaceutical production specifically would also allow the FDA to conduct more inspections, which would help avert supply disruptions and shortages. At production sites in the U.S., the FDA can inspect facilities without advance notice. For diplomatic reasons, the FDA must give as much as two weeks advance notice of an inspection at foreign production sites.

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 quality products being made *and* sold in the U.S.

Re: Question 12. How has consolidation among Group Purchasing Organizations and Prescription Drug Wholesalers led to less redundancy in the drug supply chain? Has this consolidation contributed to drug shortages, especially among generic drugs? Have business practices, such as just-in-time deliveries and limited-source contracts contributed to the drug shortage issue we are seeing?

GPOs operate in a vigorously competitive market and competition among GPOs is essential to preventing shortages. There are hundreds of traditional healthcare GPOs in the United States. Definitive Healthcare reports data on 150 GPOs, which is likely a conservative estimate. Eighty of them are considered regional GPOs, or "regional purchasing coalitions," and seventy are national GPOs. The market share percentage of total spend through the contract portfolios of the seven largest GPOs in 2020 was between 54.1% and 60.5%, while the share of the three largest GPOs was 41.5%. Many healthcare providers maintain membership with more than one GPO at a time and can shift their purchasing from one GPO contract portfolio to another. GPO contracts with healthcare providers are voluntary. Providers can shift to new areas, customers, or product focus, which helps maintain vigorous competition among GPOs. Providers expect their GPOs to keep up with the market and maintain a competitive product and service portfolio.

Not only do shortages threaten the ability of providers to care for their patients and delay critical patient care, but they are also antithetical to the GPO model. GPOs are unable to provide their services without sufficient products, suppliers, or competition. Working with a GPO allows suppliers to have increased certainty in product demand, which provides both predictability and stability as they navigate supply. This information can also help suppliers make sure that they will achieve a sufficient profit margin to continue producing supply in the long term.

GPOs help create a fair, open, and competitive marketplace and compete for business based on a variety of factors including, but not limited to, supplier product pricing, strength of GPO supplier contract terms, breadth of contract portfolio, supply chain and clinical analytical assistance, and customer service. Additionally, GPOs also encourage competition among suppliers, working to expand the number of suppliers in the market and incentivizing them to continue producing essential products and life-saving medications. By providing a platform for new and innovative competitors, particularly small companies without significant market capability, GPOs allow suppliers to access a large number of buyers.

It is worth noting that traditional healthcare GPOs are distinct entities from pharmacy benefit managers (PBMs) and large retail buying groups such as wholesalers/distributors. Traditional healthcare GPOs serve healthcare providers, do not take title to product, and are net-price driven and pass manufacturer rebates through to their members. Flexibility for providers and manufacturers is integral to the GPO business model, and actual purchases are made by GPO member providers, not GPOs. Pharmacy benefit managers (PBMs) work primarily in the retail prescription market with insurance and plan sponsors, and PBM-operated GPOs aggregate rebates.

Re: Question 14. Are there any other issues leading to drug shortages that we have not considered in this RFI?

Pandemics, other public health emergencies, and natural disasters place enormous stress on the entire healthcare system. Healthcare GPOs have played a critical role in supporting COVID-19 response efforts, working closely with all stakeholders, including federal, state, and local health and emergency management agencies to ensure that providers have the products, drugs, and devices necessary to safeguard patient care. GPOs have taken a number of innovative steps to combat the COVID-19 pandemic, including adding new and non-traditional suppliers and manufacturers to shore up domestic manufacturing; proactively communicating patient volumes and product demand surges to help expand manufacturing capacity for PPE and other vital supplies; harnessing data and cutting-edge technology to provide supply chain insights and improve care; and protect healthcare providers from counterfeit or inferior products.

HSCA and its member GPOs respectfully offer the additional recommendations for your consideration:

FDA-designated 503B compounding pharmacies play an important role in bringing sterile drugs to market. Currently, however, the FDA restricts compounders to only being able to compound a product when that

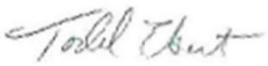
product is already in active shortage. To mitigate further product delays, **Congress should encourage FDA to provide outsourcing facilities with more flexibility to meet provider demand and loosen restrictions to allow compounders to make certain high-risk products in anticipation of a potential shortage, rather than only in response to an existing shortage.**

The FDA's quality management maturity (QMM) program, through which the agency will assess and rate facilities manufacturing drug products and active pharmaceutical ingredients, has the potential to prevent drug shortages by increasing supply chain transparency and informing purchasing decisions. **HSCA recommends that Congress fully fund FDA's 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.**

The FDA recently issued an import alert for Intas, a manufacturer of important oncology products based in India. While the alert restricts the import of some products, it allows the company to continue to supply 24 products from their Ahmedabad manufacturing site that are considered in short supply in the U.S. **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 suppliers and drug product manufacturers.**

We appreciate the opportunity to offer our perspective and look forward to continuing to serve as a resource to Congress and all stakeholders to continue improving the healthcare continuum. Please do not hesitate to contact me directly if HSCA can be a resource moving forward. I can be reached at (202) 629-5833 and tebert@supplychainassociation.org.

Sincerely,



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