



October 2, 2020

Lisa R. Barton
Secretary to the Commission
U.S. International Trade Commission
500 E Street SW
Washington, DC 20436

**Re: COVID-19 Related Goods: The U.S. Industry, Market, Trade, and Supply Chain Challenges
[Investigation No. 332-580]**

Dear Members of the Commission:

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments to the U.S. International Trade Commission (USITC) regarding supply chain challenges related to COVID-19 and critical medical products. HSCA appreciates the Commission’s leadership and efforts to-date to help identify COVID-related materials and goods and increase access to these essential supplies. Through collaboration and efforts to further strengthen supply chain resilience, we can best support our nation’s healthcare providers and overall preparedness. HSCA is committed to supporting patient care and ensuring healthcare providers are equipped to respond to emergencies and public health crises like the COVID-19 pandemic.

HSCA represents the nation’s leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America’s 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. GPOs work with healthcare providers to negotiate competitive prices and support a safe and reliable supply of products. In 2017, former U.S. Federal Trade Commission Chairman Jon Leibowitz [examined](#) the GPO market and determined that GPOs operate in a highly competitive environment and that the GPO model supports lower costs and increased competition. GPOs are particularly critical to smaller and rural hospitals who often lack the purchasing power on their own to procure the supplies they need at an affordable price. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

GPOs have a unique line of sight over the healthcare supply chain, which allows us to work across the supply chain with providers, suppliers, distributors and the federal government in emergency preparedness and disaster response and develop innovative solutions to our nation’s healthcare challenges.

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GPOs Drive Stability, Competition, and Quality Throughout the Supply Chain

GPOs work to advance quality and reliability throughout the healthcare system. GPOs are committed to increasing competition and bringing new domestic suppliers to market to ensure continued access to critical medicines and products. For example, during the COVID-19 pandemic, an HSCA member GPO leveraged its relationship with an Ohio-based textile manufacturer to assist in converting manufacturing lines to create more than 2 million reusable isolation gowns and 700,000 reusable surgical masks and reusable face shields. Another GPO partnered with several of its hospital members to invest in a domestic manufacturer of face masks to help shore up domestic manufacturing of critical products during the pandemic. GPOs also advocate for common-sense, innovative, market-based solutions to help prevent and mitigate drug shortages and increase competition in the drug marketplace. HSCA successfully advocated for expedited FDA review and approval of abbreviated new drug applications (ANDAs) for products where there were three or fewer manufacturers, a provision that ultimately became law as part of the FDA Reauthorization Act of 2017.

GPOs are supply chain leaders in quality assurance and take a comprehensive approach to purchasing that considers not only the competitive pricing offered, but also the quality of the manufacturer and the reliability and stability of supply as well as key FDA inspections and Current Good manufacturing practices (cGMP) as part of the contracting process. GPOs' fierce commitment to quality helped to protect member hospitals from purchasing counterfeit or inferior goods during the COVID-19 pandemic, working around the clock to field thousands of inquiries and vet new manufacturers for compliance with standards set by the FDA and National Institute for Occupational Safety and Health (NIOSH) and ensure safeguards for product quality.

GPO contracts provide predictability and stability to both hospitals and suppliers and are voluntary, openly and competitively negotiated. Suppliers are not required to contract with GPOs, and hospitals and other providers are similarly not obligated to use GPOs and are free to purchase outside of their GPO arrangement. GPOs also ensure their contracts are flexible and work with suppliers when they experience raw materials shortages or disruptions to production. GPOs also include contract provisions to control price variations, in cases where there is a surge in demand. These pricing provisions helped to protect GPO hospital members against price gouging and drastic price spikes during the COVID-19 pandemic.

GPO Efforts Help Support Access to Critical Supplies During COVID-19

Health crises like coronavirus place enormous stress on hospitals, other healthcare providers and the communities they serve. GPOs have played a critical role in supporting emergency response and public health efforts and have taken a number of innovative steps to support COVID-19 response efforts, including supply coordination efforts to help medical teams obtain much needed supplies and support surge capacity, adding new manufacturers to contracts to rapidly increase supplies, and working with non-traditional and adjacent industries to fill supply gaps for essential products such as hand sanitizer,

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isolation gowns, and surgical caps. As an industry with a proven track record of providing critical support during emergencies like Hurricane Harvey, the California wildfires and the Ebola outbreak, GPOs are committed to helping America’s healthcare providers and public authorities confront difficult challenges to support patient care.

As the United States continues to address the spread of the coronavirus, strengthening the healthcare supply chain is more important than ever before. HSCA has long advocated for measures to support supply chain resiliency. The healthcare supply chain is global and complex, and we must consider overall capacity for our nation’s readiness in times of crisis. COVID-19 has brought these issues to the forefront. A multifaceted approach is needed to strengthen the healthcare supply chain and invest in a comprehensive plan for the longer term for our nation’s public health and national security. Increasing supply chain resiliency, enhancing competition, leveraging public-private collaborations and supporting the Strategic National Stockpile are all critical to safeguarding continued patient access to high quality, affordable healthcare. HSCA supports measures like those included in the CARES Act, which strengthened reporting requirements for manufacturers, including certain information about active pharmaceutical ingredients and other raw materials, to better prevent, assess, and address shortages of medical products needed for patient care in the U.S. As part of our efforts, HSCA also issued a series of [principles and recommendations](#) to further strengthen supply chain resiliency and enable an effective response to public health crises.

HSCA respectfully submits the following recommendations to help strengthen the resiliency of the supply chain and support current and future response efforts:

Increase Supply Chain Collaboration and Communication Among Public and Private Stakeholders

Increased collaboration and communication among all stakeholders are critical during national emergencies. Public-private partnerships can help form a connection between the government and industry stakeholders, allowing stakeholders to coordinate emergency response plans, identify potential areas of vulnerability, and create lines of communication. GPOs collaborate with stakeholders to help identify key areas of need and surge capacity and support supply coordination efforts across all distribution channels to help meet provider needs. Policymakers should continue to encourage public and private stakeholders to coordinate and engage in appropriate information-sharing to help support response efforts and enable a comprehensive, holistic response.

Promote Data Standardization and Integration Throughout the Supply Chain

GPOs are fierce proponents of using data to help their provider partners and public authorities prepare for, and respond to, public health threats and emergencies. Timely information-sharing and leveraging data to gain insights are essential to facilitating an effective and efficient response effort. GPOs work in partnership with providers regarding inventory levels to inform purchasing decisions, anticipate

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potential shortages, and pinpoint hotspots. To further support data integration and critical information in the supply chain, HSCA, its Committee for Healthcare eStandards (CHeS) and its GPO members are working with healthcare organizations to promote the use of data standards in the healthcare supply chain to enable solutions that increase traceability in the supply chain. Doing so would help enhance patient safety and quality of care, unlock supply chain efficiencies, and strengthen cybersecurity.

Explore Private Sector Incentives to Increase Domestic Manufacturing

Strengthening domestic manufacturing in the United States is critical for fostering supply chain resiliency. GPOs have helped bring new or expanded products to market with U.S. manufacturers through committed volume to help support manufacturer investment and long-term marketplace sustainability. In order to increase domestic manufacturing, policymakers should explore manufacturing incentives such as public-private partnerships, regulatory flexibility, long-term commitments, and additional tax incentives and capital investment to support domestic manufacturing of finished products as well as key raw materials.

Support Capacity Through Increased Supply Chain Diversification

Supply chain diversification is essential for helping the United States avoid overreliance on any particular region or location. The global nature of the supply chain should be leveraged to build in redundancies, shoring up domestic manufacturing as well as sourcing in various geographical locations to help prevent supply disruptions for raw materials or finished products. Previous shortages due to manufacturing issues or natural disasters like Hurricane Maria make it clear that it is important to have sourcing and manufacturing capabilities both domestically and globally to help ensure multiple suppliers and ability to scale up as needed. Increased redundancy will also reduce the risk of bottlenecks and severe disruption in the case of regional events or other issues impacting manufacturing.

Enhance Upstream Visibility to Strengthen Supply Chain Resiliency in Advance of Emergencies

Access to accurate information and data in advance of an emergency is critical to strengthening supply chain resiliency. HSCA and its member GPOs continue to support policy solutions that not only enable FDA and other authorities to have greater visibility into the source and location of manufacturing of medical products, but also permit access to that information in advance of a public health emergency. This will enable FDA and other supply chain stakeholders to plan for and identify potential shortages, consider backup supply, and take measures to help mitigate and respond to shortages before they occur. HSCA supports policy provisions like those included in the CARES Act that strengthen reporting requirements for manufacturers to better prevent, access, and address shortages of medical products and their key components needed for patient care in the U.S.

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Explore Dynamic Allocation Models to Support Efficient Effective Distribution of Critical Products

While traditional allocation models and “just in time” manufacturing are typically appropriate and effective, pandemics and national emergencies require new thinking about government stockpile accumulation and allocation processes. GPOs understand the importance of making informed sourcing decisions aligned to current and anticipated needs. Public and private supply chain stakeholders need to collaborate on dynamic allocation processes to reduce strain on supply and ensure products are directed to where they are needed most in a timely manner.

Support Federal and State Emergency Stock and Ensure the Strategic National Stockpile is Equipped with Adequate Resources

The Strategic National Stockpile (SNS) plays a critical role as a partner in response efforts, serving as a stopgap in crises like the coronavirus pandemic. HSCA supports efforts by SNS and other authorities to partner with entities that comprise the private healthcare infrastructure to increase manufacturing capacity for critical products. Both state and federal stockpiling efforts should continue to engage private stakeholders in maintaining reserves of critical supplies and replenishing efforts, including making key stockpiled products available to the private sector prior to expiration and rotating in new products in order for efficient distribution as appropriate.

Safeguard the Supply Chain from Counterfeit Products

As public and private stakeholders work to provide critical supplies to help providers during the COVID-19 pandemic, ensuring the integrity of the supply chain and the quality of products is vital. HSCA and its member GPOs are committed to protecting patients from counterfeit drugs or devices that could cause serious harm. We support policy solutions like the Safeguarding Therapeutics Act, which enhances FDA’s authority to destroy counterfeit drugs and medical devices at American ports of entry, preventing such products from entering the supply chain and helping to ensure a safe and reliable supply of products.

Continue to Provide Tariff Relief for Critical Medical Products During the COVID-19 Pandemic

Healthcare providers are working to meet the needs of COVID-19 patients and researchers and medical product innovators are working to develop treatments and a vaccine. They are relying on critical drugs, devices and other supplies to effectively treat COVID-19 patients and fight this pandemic. Tariffs on medical goods needed to treat and prevent the spread of the coronavirus can create additional barriers to provider access to essential supplies and adversely impact patient care. As the United States works to address the COVID-19 pandemic, continued exclusion of these critical medical products during this time of unprecedented demand is an important step to ensure continued patient and provider access to products essential to our fight against COVID-19.

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We appreciate the opportunity to provide our perspective to the Commission, and we look forward to continuing to work with policymakers and all federal agencies to ensure patient and provider access to essential healthcare supplies. Please do not hesitate to contact me directly if HSCA can be a resource on this issue going forward. I can be reached at (202) 629-5833 or info@supplychainassociation.org.

Sincerely,

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