HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

December 8, 2023

The Honorable Gary Peters
Chairman
Committee on Homeland Security
and Governmental Affairs
United States Senate
Washington, DC 20510

The Honorable Rand Paul, M.D.
Ranking Member
Committee on Homeland Security
and Governmental Affairs
United States Senate
Washington, DC 20510

The Honorable Sherrod Brown
Member
United States Senate
Washington, DC 20510

The Honorable Marsha Blackburn
Member
United States Senate
Washington, DC 20510

Re: "*The Rolling Active Pharmaceutical Ingredient and Drug (RAPID) Reserve Act*" (S. 2510)

Dear Chairman Peters, Ranking Member Paul, Senator Brown, and Senator Blackburn:

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 comments on "*The Rolling Active Pharmaceutical Ingredient and Drug (RAPID) Reserve Act*" (S. 2510). HSCA supports your continued efforts to address this pressing problem, and we look forward to working 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 secure high-quality medical products at fair prices for the benefit of 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 smaller healthcare 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 is voluntary, flexible, and clinically driven. GPOs work in close collaboration with 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

[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.

the competitive price offered, but also the quality, reliability, and stability of supply. GPOs recognize that market conditions change, and when they do, GPOs work with suppliers to adjust contracts. GPOs work diligently to ensure member hospitals and providers can select the products they need to care for their communities and patients most effectively and provide clinical resources across their network of providers.

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 drug 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 we are leaders in working to prevent and mitigate drug shortages. Every HSCA member GPO has innovative programs that are operating effectively 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 comments to the Committee regarding the RAPID Reserve Act (S. 2510):

Re: Awarding contracts or cooperative agreements to eligible entities with respect to drugs and active pharmaceutical ingredients of such drugs that the Secretary determines to be critical and to have vulnerable supply chains.

The definition of eligible entities in section C of S. 2510 includes organizations that are distributors or wholesalers of an eligible drug, either in partnership with holders of abbreviated new drug applications

(ANDA) per subsection (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21. U.S.C. 355)[3] or in partnership with entities that hold regulated biologics licenses per subsection (k) of section 351 of the Public Health Service Act (42 U.S.C. 262)[4] for eligible drugs.

HSCA supports the Secretary of Health and Human Services (HHS) awarding contracts to eligible entities with respect to drugs and API. **However, to further strengthen the resiliency of the supply chain, HSCA recommends that GPOs be included as "eligible entities" for contracts or agreements. GPOs have shortage mitigation programs in place to ensure that manufacturers and suppliers can deliver critical medications to their healthcare provider members.**

To ensure the buffer inventory is aligned with the contracts and programs GPOs have in place, **HSCA recommends that the following be added as a new section: Section e(5)(D) (Eligible Entities), which comes directly from 42 CFR § 1001.952 (j)(2)[5]:**

> "*Group Purchasing Organization," means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity). Group Purchasing Organization is contracted with a manufacturer, distributor, or wholesaler for an eligible drug, in partnership with an entity that meets the requirements of subparagraph (A).*

Re: Ensuring that reserves of critical drugs and API are maintained to prevent supply disruptions in the event of drug shortages or public health emergencies.

Developing reserves of critical drugs and API sources is essential to preventing and mitigating drug shortages across the country. **HSCA recommends investing in quality and building secondary supply lines.** By not only incentivizing production, but also incentivizing the investment in quality and capacity, including the additions of secondary supply lines and having backup API sources, suppliers and manufacturers can increase long-term access to generic medications.

HSCA supports HHS awarding contracts to appropriate manufacturers to ensure there is a buffer inventory of critical medications. **HSCA suggests that there be greater transparency within the supply chain to ensure that these buffer inventories do not duplicate and overstock on medications, which may exacerbate the drug shortage crisis instead of providing auxiliary supply as intended. Supply chain stakeholders, both public and private, should communicate with each other to determine if certain APIs are in short supply and how that may impact inventories.**

HSCA further recommends that HHS engage in fair share allocation with buffer inventories, so some entities are not taking more supply than necessary, or available. Additionally, HHS should enforce

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[3] "21 U.S.C." *U.S.C. Title 21 - Food and Drugs*, www.govinfo.gov/content/pkg/USCODE-2010-title21/html/USCODE-2010-title21-chap9-subchapV-partA-sec355.htm.

[4] "42 USC 262: Regulation of Biological Products." *42 USC 262: Regulation of Biological Products*, uscode.house.gov/view.xhtml?req=%28title%3A42+section%3A262+edition%3Aprelim%29.

[5] "42 CFR 1001.952 -- Exceptions." Www.ecfr.gov, www.ecfr.gov/current/title-42/chapter-V/subchapter-B/part-1001/subpart-C/section-1001.952.

penalties – whether financial or otherwise – on organizations that take more than their fair share of supply.

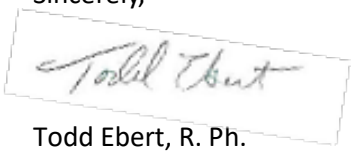
Re: The HHS Secretary publishing the list of critical and essential drugs and active pharmaceutical ingredients of such drugs.

HSCA supports the HHS Secretary publishing list of critical and essential medications and the API required to make those drugs, as healthcare providers should be aware of what medication is in short supply, so they may determine alternatives to treat their patients.

HSCA recommends that the HHS Secretary also publish criteria for this list to determine why certain medications and API are listed as critical compared to others. The HHS Secretary should consider manufacturing quality, whether products and API are adequately distributed, and if suppliers are having difficulty delivering products in the market when compiling and publishing this list. Using established standards will help the HHS Secretary determine if drugs and API should be included in this list, or if there are alternate ways to source medications and API without listing them as critical.

We appreciate the opportunity to provide the Committee with our comments and 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,



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