HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

August 22, 2022

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Dockets Management
Food and Drug Administration
Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

Re: Risk Management Plans to Mitigate the Potential for Drug Shortages Draft Guidance (Docket No. FDA-2022-D-0277)

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on the Food and Drug Administration's (FDA) "Risk Management Plans to Mitigate the Potential for Drug Shortages" draft guidance.

Healthcare GPOs are 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 providers to negotiate competitive prices and support a safe and reliable supply of products. GPOs lower costs for patients, providers, payers, Medicare and Medicaid, and taxpayers. One report estimated that GPOs reduce supply-related purchasing costs by 13.1 percent annually and will reduce healthcare spending by up to $456.6 billion between 2017 and 2026. GPOs are particularly critical to smaller and rural hospitals that often lack the purchasing power to procure the supplies they need. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

HSCA and its member GPOs are critical partners in averting and mitigating the impact of drug shortages – working collaboratively with hospitals, physicians, manufacturers, distributors, and government agencies to ensure that providers and patients have access to the life-saving drugs they need. GPOs track data on shortages, identify alternative suppliers, and develop other innovative solutions to safeguard access to safe, reliable, high-quality products. During the COVID-19 pandemic, GPOs helped expand capacity for critical medical supplies including PPE, test kits and swabs, and life-saving medications by adding new non-traditional suppliers and communicating about potential demand surges. Risk Management Plans (RMPs) give stakeholders and federal partners the opportunity to work together to prevent drug and product shortages and support a resilient supply chain.

Given the unique line of sight of GPOs over the entire healthcare supply chain, HSCA and its member GPOs respectfully recommend the following:

Section III. Risk Management Plans: Stakeholders and Products

A. **Stakeholders in the Manufacturing Supply Chain.** HSCA recommends that FDA define GPOs as an "Other Stakeholder" in this guidance alongside inactive ingredient manufacturers, packagers,

and distributors, while also recognizing that GPOs are distinct from these groups because they do not manufacture or take title to any product. Classifying GPOs as an "Other Stakeholder" will enable GPOs to access information included in Risk Management Plans that is crucial to portfolio development, advanced planning, and healthcare provider use. GPOs have significant visibility into the supply chain and can provide upstream and downstream information regarding drug and product supply issues to help reduce the risk of shortages. Therefore, GPOs should be engaged to ensure that all available information can be utilized in risk mitigation efforts. Proactive information allows all supply chain players to manage shortages or supply issues well before they occur.

HSCA also recommends that FDA take steps to further clarify expectations for "Other Stakeholders," including GPOs, who play a critical role in the supply chain but are not the origination point for any of the information listed as being a part of an RMP. This includes information regarding limitations for raw materials, intermediates, components, and drug product containers and closures, communications between contract manufacturing facilities and component suppliers, infrastructure and utilities weakness, equipment at manufacturing facilities, monitoring of vulnerable equipment, among various related topics. Clear differentiation of stakeholder responsibilities across the three stakeholder groups (primary, secondary, other) would be desired in future versions of this guidance.

B. **Products for Which RMPs are Required.** GPOs can provide valuable information regarding the types of products that require RMPs. HSCA and its members recommend that the medication needs of special populations be considered in the development of RMPs, including pediatrics, emergency medical services (EMS), law enforcement, jails, and prisons. There are multiple drugs and treatments considered "life-supporting" or "life-sustaining" in these settings, such as certain antipsychotics, that should have RMPs. GPOs are available to consult on these specific situations regarding which organizations beyond the manufacturer should have reserves of these medications e.g., the Strategic National Stockpile (SNS).

C. **Products for Which RMPs Are Recommended.** GPOs can also provide input into risk mitigation and sourcing strategies for products that FDA recommends - but does not require - stakeholders develop RMPs.

Section IV. RMP Framework and Development Strategy

A. **Stakeholder RMP Development Strategy.** Consistent with FDA's recommendation that the primary stakeholder share as much of its RMP as possible with secondary and other stakeholders, GPOs should have access to primary stakeholders' Risk Management Plans as an 'Other Stakeholder.' RMPs are a valuable source of information in the contracting process and GPOs will use this information and data to complete their portfolio contingency plans. GPOs could also require that a manufacturer's RMP be included in contract solicitation requests, Requests for Proposals (RFP). RMPs can be used in the development of sourcing strategies and other efforts to mitigate future risks related to drug shortages. We appreciate FDA's effort to encourage transparency without sacrificing confidentiality. Providing as much information as

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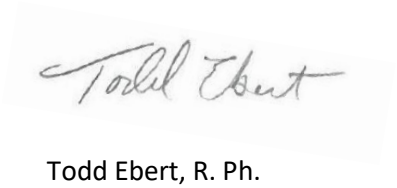
appropriate will help reduce shortages and reward quality and dependability as part of the contracting process.

We appreciate the opportunity to provide you with our perspective and we look forward to continuing to serve as a resource to our federal partners to maintain a healthy supply chain and protect access to essential drugs and products. 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,



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