HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

January 11, 2019

U.S. Food and Drug Administration
Attention: Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, Maryland 20852

Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA Request for Comments on Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions [Docket No. FDA-2018-N-3272]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) on the causes of critical prescription drug shortages and potential solutions.

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. We help our healthcare provider partners leverage their purchasing volume to negotiate competitive prices on healthcare products and services. Former FTC Chair Jon Leibowitz recently studied GPOs and found that they operate in a vigorously competitive environment and reduce healthcare costs for patients, hospitals, payers, Medicare and Medicaid, and taxpayers. One report estimated that between 2013 and 2022, GPOs will reduce healthcare spending by up to $864 billion and a 2018 study by the Wharton School and the American Hospital Association found that hospitals are overwhelmingly satisfied with their GPOs and the cost-savings they deliver. The value that GPOs deliver allows healthcare providers to focus on their core mission: providing first-class patient care.

HSCA, its member GPOs, and our member healthcare providers are committed to preventing and mitigating prescription drug shortages and ensuring continued patient access to essential medications. We applaud the FDA for having taken steps to address drug shortages, including forming a drug shortage task force. As FDA has previously noted, drug shortages are a complex issue caused by quality problems, manufacturing delays, and capacity difficulties and one that requires a multi-stakeholder solution. A 2018 study conducted by Alex Brill at Global Matrix Advisors echoed FDA's findings on drug shortages and also emphasized the need for a multi-stakeholder solution. In pursuit of finding a multi-stakeholder solution, HSCA participates in a drug shortage working group composed of leading healthcare provider organizations – including hospitals, health-system pharmacists, physicians, GPOs, and other supply chain stakeholders – to develop policy proposals to help prevent and address drug shortages in a comprehensive manner. A number of those policy ideas are reflected in HSCA's recommendations below.

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GPOs play a crucial role in helping hospitals and other healthcare providers prevent and mitigate drug shortages. GPOs work 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 help hospitals source and safely migrate to alternate products when shortages arise, track data on potential shortages, communicate with suppliers about product demand, evaluate supplier reliability when awarding contracts, and negotiate fair, volume-based prices with suppliers to enable cost-effective production. To help lessen hospital exposure to drug shortages, GPOs evaluate manufacturer reliability when sourcing and awarding contracts, and help providers establish best-practice purchasing procedures. And they work with suppliers to communicate provider needs in advance, so that manufacturers can plan their production capacity and avoid shortage situations.

GPOs 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. HSCA provided feedback to the Drug Enforcement Administration (DEA) regarding a proposed rule on annual opioid production limits**.** HSCA urged the DEA to differentiate between outpatient/oral narcotics and inpatient/injectable opioids, many of which are currently already in shortage and are an essential element of treatment for inpatient post-surgical and medical pain management. HSCA also urged FDA not to significantly reduce the list of approved bulk substances for 503B compounding, which could lead to suppliers exiting the market and exacerbate drug shortages. HSCA also provided feedback to the Department of Health and Human Services (HHS) on HHS' blueprint to lower drug prices and reduce out-of-pocket costs. Most recently, HSCA provided recommendations to FDA to promote the swift uptake of biosimilar products.

Given our unique line of sight over all aspects of the healthcare supply chain, HSCA respectfully makes the following recommendations that expand on the important work that FDA is already doing, and provide FDA the necessary authority, resources, and flexibility to comprehensively address drug shortages:

FDA Should Encourage Early Drug Shortage Alerts and Ongoing Multi-Stakeholder Communications

FDA should encourage all stakeholders in the market, including providers, manufacturers, wholesalers, GPOs, and others to communicate with the FDA as soon as a potential shortage situation is identified, and continue to share information as available. FDA and others should continue working to improve inter-agency communication and cross-agency coordination in shortage situations like the injectable narcotic shortage that occurred earlier this year, which required involvement of both the FDA and the Drug Enforcement Administration (DEA). Encouraging early and ongoing communication is critical for mitigating risk and reducing the likelihood of shortage situations.

FDA Should Enhance Transparency Requirements for Drug Shortage Information

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FDA should require the reporting of accurate and timely information regarding shortages, including anticipated duration, supplier information about what drugs are manufactured at which plants and where those plants are located, and other disclosures, to ensure that all stakeholders take the most effective steps toward addressing drug shortages and ensuring uninterrupted, quality care for patients. The goal for policy solutions should be to ensure that all parties operate under good, complete and timely information.

FDA Should Strengthen Drug Shortage Disclosures

Title X of the Food and Drug Administration Safety and Innovation Act (FDASIA) should be strengthened to require notifications to include disclosure of the problem causing the interruption, the extent of the shortage, and the expected duration of the shortage. Failure to provide timely notice of a drug shortage should result in a monetary penalty for the manufacturer. Also, manufacturers should be required to report current or anticipated supply concerns, including issues pertaining to the production or acquisition of raw materials. The information provided should be collated and organized by the FDA into a source on its website and easily accessible by the public.

FDA Should Improve and Standardize Review Processes for Manufacturers

FDA should improve the regulatory violation process for current good manufacturing practices (cGMP) by shortening turnaround times and improving and standardizing processes of FDA reviews to identify problems prior to shutting down facilities. More rapid review of corrective actions taken by manufacturers would help moderate fluctuations.

FDA Should Require Manufacturers to Develop Drug Shortage Action Plans

FDA should require manufacturers to develop current drug shortage action plans that would help prevent, identify, and actively respond to drug shortage situations. These remediation plans should be completed annually.

FDA Should Expand Its Drug Shortage List

The FDA should expand its list of drug shortages to incorporate shortages included on other lists – such as the drug shortage list maintained by American Society of Health-System Pharmacists (ASHP) – to ensure a comprehensive and current list of drug shortages is being used. A more complete list can be used to help determine appropriate prioritization and will include more information that is needed to mitigate shortages – e.g., information on 503B compounders. The FDA's list fails to take into account drugs that are in shortage based on their administration form and dosage, and does not include drugs that are experiencing significant regional shortages. An expanded list would enable feedback from providers that are on the front line.

We appreciate the opportunity to provide our perspective, and we look forward to continuing to work with FDA to address prescription drug shortages. HSCA and its member GPOs can be a resource for FDA

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on drug shortages. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833.

Sincerely,

Todd Ebert

Todd Ebert, R.Ph.
President and CEO
Healthcare Supply Chain Association

HSCA MEMBER COMPANIES

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