



July 16, 2018

Department of Health and Human Services
Office of the Secretary
200 Independence Ave., SW, Rm 600E
Washington, DC 20201

Re: Comments of the Healthcare Supply Chain Association (HSCA) on the Department of Health and Human Services (HHS) Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs [Docket No. HHS-OS-2018-0010]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments to the Department of Health and Human Services (HHS) on the “Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.”

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 examined](#) 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. The value that GPOs deliver allow healthcare providers to focus on their core mission: providing first-class patient care.

GPOs are advocates of healthcare transparency, with all GPOs participating in an independent, voluntary organization called the Healthcare Group Purchasing Industry Initiative (HGPII), which was founded by the chief executives of healthcare GPOs who believed the industry should collectively demonstrate a strong commitment to ethical values. HGPII promotes the development of transparency and accountability standards, business practices, and ethics. Every year, HGPII members submit to an annual, [independent review](#) of individual company business practices and identify additional opportunities to promote transparency. In addition to HGPII, GPOs disclose all administrative fees in writing to members at least annually and any GPO fee above 3% must be included in the contract agreement. GPOs make all fee information available at the request of the Secretary of Health and Human Services, and hospitals must report GPO fee distributions as part of their Medicare cost reports.

HSCA, its member GPOs, and our member healthcare providers are committed to lowering costs and increasing competition and innovation in the healthcare marketplace. GPOs advocate for common-

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sense, innovative, market-based solutions to help providers confront the myriad challenges facing the healthcare supply chain. We are dedicated to preserving patient access to medications and reducing prescription drug prices. We applaud the Administration for having taken steps to reduce costs for patients and providers, including prioritizing review of abbreviated new drug applications (ANDAs) for drugs with fewer than three alternatives.

Given our unique line of sight over all aspects of the healthcare supply chain, HSCA respectfully makes the following recommendations to help increase access to, and reduce the costs of, prescription drugs:

I. The Administration Should Pursue Policies That Increase Competition in the Generic Drug Marketplace

Patients have long relied on generic drugs to increase access to, and reduce the costs of, essential medications. However, significant price spikes have jeopardized patient access to affordable healthcare.

Price spikes often occur when there are only a few manufacturers of a generic drug. This lack of competition among manufacturers allows high prices to go largely unchecked. A small number of manufacturers also mean that quality control problems and disruptions to manufacturing can threaten supply and give rise to drug shortages, which allow opportunistic manufacturers to further drive up the price of common generic drugs.

Increased competition in the generic drug market is critical to ensuring adequate supply and preventing significant price spikes that compromise patient access to care. HSCA and its GPO members support common-sense policy solutions that increase competition in the marketplace, reduce costs, and help to preserve patient and provider access to critical treatments. Last year, HSCA advocated for priority FDA review of abbreviated new drug applications (ANDAs) for drugs with fewer than three approved alternatives, which was subsequently included as provision in the FDA Reauthorization Act of 2017.

We believe the following additional recommendations will further increase competition in the marketplace:

HSCA Supports the “CREATES” Act (S. 974) and Policies That Close Loopholes in the Risk Evaluation and Mitigation Strategies (REMS) Program

The FDA’s Risk Evaluation and Mitigation Strategies (REMS) program serves a compelling public good by ensuring that the benefits of a drug outweigh its safety risk and by making important information available to patients and providers. However, some brand pharmaceutical manufacturers have exploited a loophole in the law to impede patient access to generic medicines and increase healthcare costs.

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HSCA supports policy initiatives like those contained in the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act,” (S. 974) which would help give generic and biosimilar manufacturers a clear and efficient pathway to market. The bill targets two forms of anticompetitive behavior: refusal to provide adequate samples to gain approval and denying generic and biosimilar access into an FDA approved single-shared REMS program. Additionally, courts would be empowered to award damages that would provide sufficient incentives to encourage good-faith dealing by brand manufacturers from the outset. While HSCA understands that passage of the CREATES Act is dependent on Congress, the Administration should encourage lawmakers to pass the legislation.

Eliminate Pay-for-Delay Tactics

Some brand name pharmaceutical manufacturers are attempting to pay the manufacturer of the first generic alternative not to enter the market – i.e., “pay for delay” – thereby allowing the brand name drug to remain the only product on the market. This lack of competition delays patient access to cheaper alternatives. **HSCA recommends the Administration support policies that eliminate the tactics that allow brand name manufacturers to prevent or delay generic manufacturers from entering the marketplace with competitor products.**

FDA Should Handle Supplemental Manufacturing Requests Separately From ANDAs

Supplemental manufacturing requests – including requests to improve, modernize, or expand manufacturing – are currently treated as ANDAs, which significantly delays their review and approval. **Supplemental manufacturing requests should be handled separately from ANDAs, and should only be evaluated on the areas that will be changed or enhanced.** By expediting these supplemental requests, manufacturers will be able to produce drugs more efficiently.

FDA Should Provide More Notice for Manufacturers of DESI Drugs

Due to the disparity in the FDA approval standards between the time period of 1938-1962 and present day, drugs approved in that time frame must be reviewed again through a process called the Drug Efficacy Study Implementation (DESI). Many of these drugs have a long history of safety and efficacy and have maintained relatively low prices due to their length of time on the market. However, manufacturers of DESI drugs are required to exit the market upon approval of a new drug application (NDA), which has led to disruptions in the marketplace and caused price spikes. **FDA should allow more notice for manufacturers and providers regarding FDA action on older drugs when immediate removal is not necessary.** Specifically, HSCA recommends that FDA announce the first NDA approval for an older medication that is currently manufactured by other companies. The FDA should also allow for 18-24 months after that notice before requiring current manufacturers to exit the market, which would allow them to engage with appropriate stakeholders and seek FDA approval for a competing drug.

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II. The Administration Should Support Policies That Reduce Critical Prescription Drug Shortages

Drug shortages not only jeopardize patient access to care, but also exacerbate price spikes as opportunistic manufacturers are able to exploit diminished supply to further drive up the price of common generic drugs. Despite a decline in new drug shortages, existing and ongoing prescription drug shortages continue to be a public health crisis and compromise patient access to essential medications. The FDA, Government Accountability Office (GAO), Congress, academia, and others, have thoroughly examined the issue of drug shortages and identified manufacturing problems, quality control issues, and barriers to getting new suppliers online as the primary causes of shortages.

GPOs are industry leaders in addressing drug shortages and are currently working collaboratively with hospitals, manufacturers, distributors, HHS, and the Food and Drug Administration (FDA) to ensure that hospitals and patients have access to the life-saving drugs they need. HSCA recently provided [feedback](#) to the 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 and its members are taking a number of innovative steps to help combat shortages. GPOs operate as an advance warning system to the supply chain with respect to drug shortages. They track data on drug shortages and strategize with their hospital members when there is potential for supply disruption. GPOs help lessen hospital exposure to shortages by evaluating manufacturer reliability when awarding contracts, and work to identify additional manufacturers who can reliably produce the needed supply. In the event of shortages, GPOs help hospitals locate, source and safely migrate to alternative products where possible. GPOs work with their supplier partners to communicate product demand so they have advance notice to plan for production capacity.

GPO contracts are voluntary, competitively negotiated, and provide predictability and stability to both hospitals and suppliers. Hospitals and other providers are always free to purchase outside of their GPO arrangement and frequently do. GPOs include failure-to-supply clauses in their supplier contracts to incentivize suppliers to produce a sufficient amount of product. At the same time, GPOs also ensure their contracts are flexible and allow suppliers to adjust contract prices when they experience raw materials shortages or shocks to production. In potential shortage situations, GPOs help guarantee purchase volume and profit margin for suppliers to ensure they have incentive to continue producing supply.

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The Administration should consider the following additional recommendations to reduce critical prescription drug shortages:

FDA Should Update its Drug Shortage List

HSCA applauds the Administration’s efforts to mitigate current drug shortages and prevent future ones. As healthcare stakeholders continue to weather numerous ongoing drug shortages, timely and accurate information-sharing between FDA and all impacted parties is essential. HHS should advise FDA to put processes in place that utilize all available information to ensure FDA has the most comprehensive and current drug shortage list. **HSCA recommends that FDA update its shortage list in conjunction with other independent drug shortage lists, such as the list maintained by the University of Utah, which provides comprehensive information related to dosage form and is updated on a timely basis.**

FDA Should Establish a Drug Shortage Navigator

The approval process for new manufacturers can be confusing and tedious, hindering the ability of manufacturers to enter the market as quickly as possible. In order to facilitate a smoother approval process, FDA should assign an FDA employee to champion assigned applications and be responsible for navigating the approval process and keeping to a timeline. In addition, HSCA recommends the establishment of a senior level navigator dedicated exclusively to reducing the shortage backlog and preventing new drug shortages.

FDA Should Make Additional Information Available About Manufacturer and 503b Compounder Quality

In shortage situations, alternative manufacturers and 503b drug compounders often step in to backfill drug shortfalls. FDA should make available additional information about the quality of those manufacturers and 503b compounders. HSCA encourages FDA to make public its findings, as well as relevant historical information and resolutions—or lack thereof—on potential quality issues.

FDA Should Ensure a Pathway to Market That Encourages Development and Swift Uptake of Biosimilars

Biosimilar drugs have the potential to increase patient access to life-saving treatments and to reduce costs for the entire healthcare system. One recent study projected that biosimilars would save the system \$250 billion over ten years. HSCA and its members are working with FDA to help ensure a pathway to market for biosimilars that prioritizes patient safety and encourages development and uptake of these less-costly therapies.

Current FDA regulations allow for a unique four-digit suffix in the naming of biosimilar products. This arbitrary suffix may lead to clinician confusion and hinder the adoption of biosimilars by creating the mistaken impression that they will behave differently than their originator. **HSCA has recommended,**

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and continues to recommend, that FDA eliminate the four-digit suffix for biosimilar products in order to better promote competition in the market and reduce the possibility of confusion for clinicians and patients.

We appreciate the opportunity to provide our perspective, and we look forward to continuing to work with HHS to ensure patient access to prescription drugs. HSCA and its member GPOs can be a resource for HHS on drug pricing. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833.

Sincerely,

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Healthcare Supply Chain Association

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