



March 9, 2020

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

**Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA Request for Comments on the Importation of Prescription Drugs [Docket No. FDA-2019-N-5711]**

Dear Commissioner Hahn:

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) regarding the importation of prescription drugs from Canada. HSCA is dedicated to ensuring patient access to affordable healthcare, and we applaud FDA for taking steps to reduce prescription drug costs, support greater competition, and ensure patient safety.

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 healthcare products. We play a critical role in helping to 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 \$34.1 billion annually and up to \$456.6 billion over the next ten years. The value that GPOs deliver allows healthcare providers and physicians to focus on their core mission: providing first-class patient care.

HSCA, its member GPOs, and our member healthcare providers are committed to lowering costs, increasing competition, and promoting quality throughout the healthcare system. GPOs advocate for common-sense, innovative, market-based solutions to help providers confront the myriad challenges facing the healthcare supply chain. We support policy approaches like the CREATES Act that foster competition and innovation in the drug marketplace. HSCA provided [feedback](#) to the Department of Health and Human Services (HHS) on HHS's blueprint to lower drug prices and reduce out-of-pocket costs. HSCA also provided [recommendations](#) to FDA to promote the swift uptake of biosimilar products. Most recently, HSCA joined other leading healthcare organizations in [support](#) of a robust biosimilars market and FDA efforts to expedite the approval pathway for biosimilar insulin.

HSCA MEMBERS



Given our unique line of sight over all aspects of the healthcare supply chain, HSCA respectfully shares the following recommendations as FDA continues to weigh its importation proposal:

**FDA Should Consider Expanding the Scope of Drugs Eligible for Importation**

While we understand the initial scope of eligibility may be limited, we note the list of eligible drugs in the proposed rule does not currently include some categories, such as injectable drugs and biologic products like insulin. Many of these drugs are essential medications that are currently in shortage, have a limited number of manufacturers, or have high price tags, creating hardships for patients and providers alike. As a result, we encourage FDA to consider expanding the list of eligible drugs in order to reduce costs, increase supply, and strengthen competition for drugs that acutely need it.

**FDA Should Examine the Effects of Implementation and Delivery of Overall Cost Savings**

Due to the number of new and important safety and labeling requirements for importation, we note states and relevant stakeholders interested in importing drugs would likely incur a number of compliance and importation costs, including which could limit or reduce the cost savings being generated. Furthermore, care should be taken to ensure there is not inflating of drug prices by parties in the import process, which would be counter to the objectives of the proposal. HSCA therefore encourages FDA to take into account the implementation costs and related considerations when assessing overall cost savings and costs of operationalizing the proposal to meet needs.

**FDA Should Ensure the Security and Integrity of the Supply Chain**

Strengthening competition in the drug marketplace is essential for reducing drug prices, but the quality and safety of those medications must not be sacrificed. The proposed rule exempts certain transactions with foreign entities from the Drug Supply Chain Security Act (DSCSA). While requirements to adapt and maintain certain DSCSA requirements are included in the proposed rule, it is critical that we maintain the integrity of the supply chain and not expose patients to unsafe or counterfeit medications. We note the potential benefits of DSCSA to the supply chain would be depleted under the proposed rule's framework. As FDA continues to explore potential avenues for importation, we urge FDA to pursue solutions that address this safety concern and ensure the security and integrity of the healthcare supply chain.

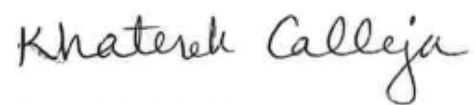
**FDA Should Engage with Supply Chain Stakeholders on Efforts to Reduce Drug Prices Through Importation**

As FDA continues to take steps to reduce drug prices through importation, the Agency should engage with healthcare stakeholders and seek their feedback on importation, offer solutions to safeguard the supply chain, and explore additional solutions to reduce drug prices. HSCA stands ready to provide additional expertise as would be helpful in this process.

We commend the Administration's efforts to increase access to affordable drugs for U.S. patients. These efforts align with HSCA and its member GPOs and their member healthcare providers' mission of advancing quality and value in healthcare. We appreciate the Agency's efforts to work with stakeholders on this priority to find ways to increase competition and curb high drug prices.

We thank you for the opportunity to provide our comments, and we look forward to continuing to work with FDA to advance competition and reduce drug prices. We believe HSCA and its members GPOs can be a resource for FDA. Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833 or [info@supplychainassociation.org](mailto:info@supplychainassociation.org).

Sincerely,

A handwritten signature in black ink that reads "Khatereh Calleja". The signature is written in a cursive, flowing style.

Khatereh Calleja, J.D.  
President & CEO  
Healthcare Supply Chain Association