HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

April 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 re. Ensuring a Competitive Marketplace for Biosimilars [Docket NO. FDA-2019-N-6050]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the U.S. Food and Drug Administration's (FDA) request for comments and holding of workshop on a competitive marketplace for biosimilars. HSCA is committed to increasing competition and promoting innovation in the healthcare system, and we applaud FDA for collaborating with the U.S. Federal Trade Commission (FTC) to ensure a competitive marketplace for biological products, including biosimilars and interchangeable products.

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 $456.6 billion between 2017 and 2026. The value that GPOs deliver allows healthcare providers and physicians to focus on their core mission: providing first-class patient care.

Biosimilars have the potential to increase patient access to safe, less-costly therapies while reducing costs for patients, providers and the healthcare system. As an increasing number of biosimilars come to market, ensuring robust uptake and increased competition of these therapies is critical to safeguarding patient access to life-saving treatments. HSCA and its member healthcare group purchasing organizations have consistently advocated for policies for biosimilars that prioritize patient safety in pathway to market and promote affordable access for those who need them.

We applaud the FDA for its efforts to support a robust and competitive biosimilars marketplace and respectfully offer the following recommendations to ensure timely development and swift uptake of FDA-approved biosimilars:

1341 G Street NW, Suite 600 Washington, DC 20005 Phone (202) 629-5833 Fax (202) 466-9666
Web www.SupplyChainAssociation.org Email info@SupplyChainAssociation.org

FDA Should Continue to Explore Ways to Strengthen Competition in the Biosimilars Marketplace
As demonstrated by the generic marketplace, increased competition in the drug marketplace can drive down costs. Biosimilars have that same potential to reduce costs by injecting much-needed competition into the marketplace and increasing patient access to life-savings therapies, and FDA should continue to take steps to ensure a competitive biosimilars marketplace.

FDA Should Increase Availability of Materials to Educate Patients and Providers About Biosimilars
GPOs have a track record of working to educate providers and clinicians about the safety and efficacy of biosimilars. As more biosimilars come to market, ensuring that patients and providers have access to truthful and accurate information and understand that biosimilars are equally safe and effective to their brand biologic counterpart is critical for enabling increased biosimilar uptake. A limited understanding of biosimilars or lack of provider confidence can act as a deterrent and impede successful adoption of biosimilars. HSCA therefore urges FDA to make additional materials available to help educate both patients and healthcare providers about biosimilars to encourage the appropriate uptake of biosimilars.

FDA Should Explore Opportunities to Increase Transparency and Streamline Biosimilar Requirements
FDA should continue to evaluate additional opportunities to provide transparency to biosimilar innovators and streamline biosimilar requirements where possible, including eliminating comparative effectiveness studies when scientifically appropriate. HSCA applauds FDA for taking steps to streamline regulatory requirements for biosimilar insulins by limiting unnecessary clinical data requirements, and we encourage the Agency to further streamline requirements for biosimilar and interchangeable biologics broadly.

FDA Should Require the Same International Nonproprietary Name for Biosimilars as the Reference Product
As HSCA has commented to FDA in the past, we believe that reference biologics and their biosimilars should share the same International Nonproprietary Name (INN) because they are, by definition, highly similar and have no clinically meaningful differences that would require a unique name. Creating multiple non-propriety names adds confusion among patients and providers and can hinder the adoption of biosimilars and negatively impact the healthcare system. The ability to safely substitute FDA-approved biosimilars for reference biologics will be critical to realizing the full cost-savings and access potential of biosimilars. HSCA continues to recommend that the FDA reconsider its policy and issue guidance that uses the same INN for biosimilars as the biologic reference product.

FDA Should Examine Payer Policies That May Prevent the Adoption and Usage of Biosimilars
Despite an increasing number of biosimilars coming to market, some payer policies may be a hurdle to realizing the full cost savings potential of biosimilars. Some payers are opting to align behind more expensive products (e.g., fail first policies) rather than quickly adopting a biosimilar that has been

proven to have similar safety and efficacy at a lower cost, leaving patients, providers, and employers to foot the bill. To the extent appropriate, the FDA should be aware of, monitor, and work with CMS and other relevant organizations to consider how payer policies can better incentivize the adoption of biosimilar products to the benefit of providers, patients, and the overall healthcare system.

We applaud the Agency for its commitment to advancing biosimilar competition. We appreciate the opportunity to provide our comments and we look forward to continuing to work 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. HSCA and its member GPOs can be a resource for FDA on biosimilars. 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.

Sincerely,

Khatereh Calleja

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

1341 G Street NW, Suite 600 Washington, DC 20005 Phone (202) 629-5833 Fax (202) 466-9666
Web www.SupplyChainAssociation.org Email info@SupplyChainAssociation.org