HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators In Evidence-Based Sourcing

September 21, 2018

Scott Gottlieb, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA-2018-N-2689; Facilitating Competition and Innovation in the Biological Products Marketplace

On behalf of the Healthcare Supply Chain Association (HSCA), thank you for the opportunity to provide comments on the U.S. Food and Drug Administration's (FDA) "Facilitating Competition and Innovation in the Biological Products Marketplace."

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 deliver critical cost savings that allow healthcare providers to focus on their core mission: providing first-class patient care.

The ability to safely substitute FDA-approved biosimilars for reference biologics will be critical to realizing the full cost-savings potential of biosimilars and will ensure that patients have timely access to safe, less-costly therapies. HSCA and its member healthcare group purchasing organizations are committed to lowering costs through increased competition and innovation in the healthcare marketplace and have consistently advocated for policies to ensure a pathway to market for biosimilars that prioritizes patient safety and cost savings.

We applaud the FDA for recognizing the value of a competitive and innovative biosimilars marketplace and respectfully offer the following recommendations to promote the swift uptake of biosimilar products:

Revise Naming Guidance to Require the Same INN for Biosimilars as the Reference Product

As HSCA has publicly 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. The FDA has proposed unique suffixes for biosimilars; however, we are concerned that suffixes might lead to clinician confusion and hinder adoption of biosimilars by creating the mistaken impression

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that a biosimilar product will behave differently than its originator. 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 rescind the current naming guidance and reissue guidance that uses the same INN for biosimilars as the biologic reference product.

Amend Draft Interchangeability Guidance to Enable the Use of Foreign Originator Products in Switching Studies

The ability to use data comparing a biosimilar to a non-U.S. licensed originator product is a scientifically justified cost-savings mechanism that has been used in most approvals to date. However, the interchangeability guidance specifically precludes the use of foreign originator products in switching studies, due to concerns about subtle differences between the proposed interchangeable biologic and the non-U.S. licensed comparator. Furthermore, the draft guidance did not specifically identify what subtle differences have been recognized as areas of concern. This unwarranted prohibition will increase the cost of developing biosimilar products, potentially limiting the number of developers willing to enter the market. This makes interpretation of exclusion guidance difficult and contributes to the notion that non-interchangeable biosimilars carry a greater risk of use. We urge the FDA to revise this requirement when issuing final interchangeability guidance.

Close Loopholes and Prevent Abuses in Risk Evaluation and Mitigation Strategies (REMS) Program

Some brand name drug manufacturers are exploiting a loophole in the FDA's Risk Evaluation Mitigation Strategies (REMS) program to prevent generic and biosimilar manufacturers from accessing the product samples they need to obtain FDA approval and market entry. HSCA supports policy solutions that provide generic and biosimilar drug manufacturers with a clear and efficient pathway to obtain samples and to combat these anticompetitive practices and empower courts to award damages to the affected generic and biosimilar manufacturers.

Monitor Rebate/Payer Arrangements that Prevent the Adoption and Usage of Biosimilars

Despite an increasing number of biosimilars coming to market, some payer arrangements with brand manufacturers may be preventing patients from realizing the full cost savings potential of biosimilars. Some payers are opting to align behind branded products that provide them with the largest rebate 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 other organizations to address rebate/payer arrangements that prevent the adoption of biosimilars products.

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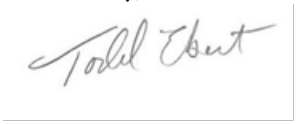
Biosimilars have the potential to increase patient access to life-saving medications and to reduce costs for the entire healthcare system. HSCA and its members look forward to continuing to work with FDA to help ensure a pathway to market for biosimilars that prioritizes patient safety and encourages development and uptake of these less-costly therapies.

Please do not hesitate to contact me directly should you have any questions. I can be reached at (202) 629-5833 or tebert@supplychainassociation.org.

Sincerely,



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