For 7/13/2017 FDA AC morning session to start 10:15 to 11:15 am

On behalf of USP, I would like to thank the Agency for the opportunity to comment on the approval application for the proposed biosimilar to Avastin (bevacizumab).

USP is an independent, scientific, nonprofit organization dedicated to protecting and improving public health. We collaborate with FDA and other stakeholders to develop public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP shares FDA's goal of advancing and promoting patient safety across all medicines, and we support efforts to broaden access to safe and effective biosimilar products. Better access to biosimilar products will facilitate the availability of life-saving therapies, while helping to ensure costs to patients and the health care system remain affordable and sustainable, and upholding FDA's standard for evidence-based, science-based regulation.

The biologic drug Avastin has been used by numerous patients in the U.S. since it was first approved in 2004, and is currently FDA approved in six cancer types. Biologic medicines such as Avastin have transformed quality of life for patients with chronic conditions including rheumatoid arthritis, psoriasis, and cancer. As more biosimilar products gain approval and enter the market, increased competition will provide more treatment options and better patient access to life-sustaining and life-altering medicines. This situation is similar in some ways to the advent of generics for small-molecule drugs.

USP recognizes and applauds FDA's substantial work to advance the successful implementation of the Biologics Price Competition and Innovation Act (BPCIA). We support FDA's efforts to develop the regulatory pathway while simultaneously addressing very complex scientific issues and implementation challenges. This regulatory pathway, created in collaboration with industry and other stakeholders, provides confidence to healthcare providers, patients, caregivers, and the public that an approved biosimilar is a quality medicine that delivers benefits consistent with the originator product.

USP remains committed to working collaboratively with the Agency and other stakeholders to fulfill BPCIA's promise. While USP has a longstanding program in biologics standards development, we are now focusing on a paradigm that will primarily emphasize development of raw material and performance standards to keep pace with this dynamic product development landscape.

Performance standards are physical reference standards that support biologics analytical testing for quality specifications throughout the product lifecycle. These standards are used to ensure and demonstrate method effectiveness and process functioning throughout various steps in investigational work, process development, and manufacturing operations. The standards are broadly applicable to product families or classes as opposed to a specific drug substance or drug product. Performance standards are also known as "platform" or "system suitability" standards.

USP is dedicated to working with FDA and industry to ensure that performance standards support product quality throughout a biologic's lifecycle. At the time when stakeholders reach a

consensus that a new product-specific standard is needed, USP will stand ready to address the need in conjunction with FDA and industry.

Ultimately, patients and the public will benefit greatly from the availability of safe, effective, quality biosimilars on the market. For many patients, access to biosimilars could bring the opportunity to delay disease progression or even achieve a cure, depending on the medical condition and other factors. In order to bring biosimilar medicines to the patients who need them, USP is committed to collaborating effectively with FDA and stakeholders, bringing to the table our scientific standard-setting process and the great responsibility imparted by our statutory recognition for quality standards.

Thank you
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USP