DRAFT REMARKS- March 9, 2020 FDA/FTC Workshop on A Competitive Biosimilar Marketplace

Testimony by Madelaine Feldman, MD, FACR; Chair, Alliance for Safe Biologic Medicines.

Good afternoon. My name is Madelaine Feldman. I am a rheumatologist in private practice in New Orleans, Louisiana. I am also President of the Coalition of State Rheumatology Organizations, founder of the Rheumatology Alliance of Louisiana, and Chair of Alliance for Safe Biologic Medicines.

ASBM is an organization composed of more than 140 patient advocacy groups and physician societies. Since 2010 we've worked to make sure that patients remain at the center of policy discussions regarding biosimilars. This work includes sharing the perspectives of patients, physicians, and pharmacists with regulators and other policymakers at the state, national and international level.

Today I'd like to speak to some issues that occur in discussions about biosimilars. The first is that "misinformation" continues to be spread affecting the objectivity of prescribers and creating an anti-biosimilar bias among physicians, slowing the uptake of the biosimilar market. In a meeting I ran last week with rheumatologists from around the country, when asked if anyone felt that biosimilars were in anyway inferior to originators, not one person raised their hand.

The reality is - It takes time for confidence to emerge among health care professionals, including physicians, with any new drug… including when generics were first introduced.

The Hippocratic Oath states: "First Do No Harm." By nature, clinicians are generally more cautious and conservative regarding starting new treatments and are hesitant to change without sufficient experience, clinical data and independent recommendations. This is particularly true when physicians are asked to switch medications on a stable patient. It can take years to adequately control the disease activity in a rheumatoid arthritis patient. And rheumatologists have been sensitized to non-medical switching by payers wherein we are told that the medicine that finally stabilized our patient… will no longer be paid for.

By changing formularies payers can legally switch our patients medications every 6 months. This could involve switching back and forth not only among various biosimilars but even

switching patients to an entirely different biologics. So yes, physicians are leery of The Great American switching experiment..

ASBM disagrees with procurement practices and payer policies giving advantage to one product over another through incentives that benefit the physician monetarily. These do nothing to help the patient afford the drug and could actually undermine patient's trust and confidence in their physician. Consequently if there are to be incentives they should be directed to cost considerations for the patient.

And finally considering the perception, that the US is somehow "behind" the advanced countries in Europe with respect to building our biosimilars market, it should be noted that our biosimilars pathway, the BPCIA, was adopted well after the EU began creating its own process for approving biosimilars.

Five years after the EMA approved its first biosimilar, it had approved 11 products. In the 5 years since the US' first biosimilar approval we have 26 biosimilars approved; and keep in mind that this total actually understates the growth in our biosimilar market. Many of the products counted as "biosimilars" in Europe are on the market here as well, but currently they are classified as "follow-on biologics" because they predate the BPCIA.

The FDA deserves credit their support in building of a biosimilar market so quickly, and without compromising on safety and efficacy standards. Physicians are enthusiastic about biosimilars and the benefits they can bring in terms of therapeutic choices that can offer cost savings to our patients and to the larger health system.

The most important strategies to continue this process in the US are strong FDA educational programs for health care professionals and patients along with pharmacovigilance programs, *particularly in light of payers ability to so frequently switch our patient's medications through formulary changes.* This will allow clinicians the opportunity to learn from the real world experience with biosimilars- and continue to gain confidence in using them.

Thank you for the opportunity to comment.