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

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Good afternoon. My name is Philip Schneider. I am a professor of pharmacy at the Ohio State University. I also currently serve as Chair of the Advisory Board for the Alliance for Safe Biologic Medicines. Since its founding in 2010, ASBM has sought to empirically document the perspectives of healthcare providers around the world regarding biosimilars.

Today, I'd like to focus my comments on addressing what we at ASBM believe to be incorrect assumptions underlying these proceedings today - that biosimilar uptake in the U.S. is strongly linked to low physician confidence levels in biosimilars, and physician confidence has been depressed because of anti-competitive practices. First, we are unaware of either negative physician sentiment, or any anticompetitive practices. Second, we know that physicians have confidence in biosimilars.

Last year ASBM conducted a survey of 579 physicians in 6 Western European countries - France, Germany, Italy, Spain, Switzerland, and the UK. We surveyed physicians in 10 different areas of practice including rheumatology, gastroenterology, oncology, dermatology, and neurology. All of these physicians prescribe biologics in their practice.

What we found was that these physicians were very familiar with and confident in biosimilars. This is perhaps not surprising since European physicians have had 13 years of experience with biosimilars. Depending on country, between 82% and 93% of prescribers considered themselves familiar or very familiar with biosimilars. Between 80% and 99% would feel comfortable prescribing a biosimilar to a new treatment-naïve patient. Between 46-76% would be

comfortable switching a patient from a reference product to a biosimilar, even if they're stable on their current medicine.

But, if the premise behind today's proceedings is valid - that biosimilar uptake is strongly tied to physician confidence, the high physician confidence in biosimilars across the board should correlate with a consistently high uptake across the board.

Yet if we look at the biosimilar market shares across the six countries we surveyed, there is a very wide variation, and variation among biosimilars in different product classes. For example, market share for the Epoetin biosimilar ranged from 6-84%. There are similar ranges for other biosimilars.

Clearly there are other factors besides physician confidence, which is uniformly high across the countries. These factors likely include differences between each country's payer policies, differences in the length of time a biosimilar has been on the market, the number of biosimilars in a given product class, the discount of each product relative to the originator product, and other factors.

ASBM has identified six policy requirements that we consider "must have" to create a sustainable biosimilar market. Two of them include:

(1) **Procurement practices must provide for multiple suppliers.** Competition creates downward pressure on prices, and greater savings for the health system. We are beginning to see this happen here in the US when we get multiple biosimilars in a given product class.

(2) **Policies with a potential to undermine sustainability, such as measures which induce biosimilar uptake or promote preferential treatment, thereby limiting physician choice, should be avoided.** There should be an even playing field that fosters

competition among both reference products and biosimilars.

Healthcare professionals here in the US, as in Europe, are not anti-biosimilar. It is inaccurate to suggest that negative perceptions are holding up biosimilar development and commercialization. We are enthusiastic about biosimilars and want to see more of them as much as anyone, and we are pleased at how far the US has come in a few short years. We urge the FDA and FTC to continue their work to build a strong and sustainable biosimilar market.

Thank you for the opportunity to comment.