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

Testimony by Andrew Spiegel, Executive Director of the Global Colon Cancer Association,

Good afternoon. My name is Andrew Spiegel, Executive Director of the Global Colon Cancer Association. Today I am proud to also represent the Alliance for Safe Biologic Medicines, an organization of which I am a founding member. ASBM is comprised of many patient and physician groups and since 2010 we have advocated for patient centered policies regarding biosimilars. To that end I have testified numerous times before the FDA in support of approving biosimilars, and before state legislatures nationwide in support of updating pharmacy practice acts to facilitate biosimilar substitution. I also recently participated in a series of three joint meetings with the FDA, Health Canada, and the World Health Organization with the goal of advancing a harmonized international standard for biologic nomenclature to improve global pharmacovigilance for all biologics and biosimilars.

It has also been my privilege to serve in leadership roles in international patient organizations including the International Association of Patients Organizations (IAPO) and the World Patients Alliance. These organizations allow the global community of patients to work together to increase our shared understanding of biosimilars, how to improve access to these treatments, and to share best practices about their use.

We know that biologic medicines have helped more than 800 million people worldwide. In the case of colorectal cancer, these medications have help triple the life expectancy of the most advanced CRC patients, and we expect biosimilars to bring tremendous benefits to U.S. patients- not only offering new treatment options, but doing so at a reduced cost, and hopefully expanding access to these therapies.

With respect to the U.S. market, first and foremost, speaking as the head of an international patient organization let me be clear that I am unaware of any attempt to undermine confidence in biosimilars- either in the minds of the public, the patient community, or among physicians. To the contrary, I am encouraged by the extremely positive reception biosimilars have had in the US thus far among patients, physicians, and other health care providers. They recognize what an important tool they can be in containing health costs. Just a few days ago, I chaired a panel at a biologics conference in San Diego which included one of the largest reference companies as well as one of the largest biosimilar manufacturers. Both agreed the US biosimilar market thus far is very much a success story and both agreed the future looks very positive.

This great enthusiasm and confidence surrounding biosimilars is due in no small part to the phenomenal work the FDA has done in approving so many biosimilars in a relatively short time, and doing so without compromising on its standards for safety and efficacy.

The U.S. health system, like that of any country, has its own unique challenges- different from those of the EU, or Canada, or Australia.

Nevertheless, there ARE things we can learn from other countries' successes- particularly those of European countries, who enjoy robust biosimilar markets.

One thing we've seen across Europe is that as more and more biosimilars are launched in a given product class, competition drives prices downward, discounts increase substantially, and biosimilar market share goes up. So we know what to expect, and what things to look for.

Thankfully we are seeing this happening in the US. Here we have a biosimilar filgrastim that launched with a relatively low 15% discount over its reference product. Today, with increased competition, that product has attained a majority share of the US market in its class with 55%. [1]

We have every reason to believe this pattern will continue as we see it becoming routine for 3, 4, or 5 biosimilars approved for a reference product, and as these come on the market, manufacturers will continue to compete on price- going from relatively low discounts, to higher discounts.

Speaking as a representative of the broader patient community, we of course want more biosimilars approved and available. But our enthusiasm is tempered by the understanding that as with anything of this scale and where people's lives and health are at stake, it's not an instantaneous process. Simply put, the system is working- if a little slower than some have hoped. But just as we don't want biosimilars or any other medicine rushed through approval, we urge our regulators to be mindful not to unnecessarily (and possibly counterproductively) interfere with a young -but steadily growing - biosimilars market right as it's getting started. We'd rather get it right than fast.

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[1] https://www.pacificresearch.org/wp-content/uploads/2019/07/BiosimilarsCompetition_F.pdf

Thank you for the opportunity to comment.