RE: July 13, 2017: Meeting of the Oncologic Drugs Advisory Committee

Public Comment

Docket number: FDA-2017-N-2732

June 29, 2017

Jay R. Fajiculay, Pharm D.
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 31, Rm. 2417
Silver Spring, MD 20993-0002

Dear Dr. Fajiculay,

These comments are submitted on behalf of Fight Colorectal Cancer, a non-profit, non-partisan advocacy organization that is committed to the fight against colon and rectal cancer. Fight Colorectal Cancer (Fight CRC) is the leading colorectal cancer advocacy organization, empowering survivors to raise their voices, training advocates around the country, and educating lawmakers and pushing them for better policies. We offer support for patients, family members and caregivers, and we serve as a resource for colorectal cancer advocates, policymakers, medical professionals, and healthcare providers. Additionally, we do everything we can to move research forward — at all stages of development and for all stages of cancer.

FightCRC believes in fully disclosing conflicts of interest. We have worked with and received unrestricted funding and/or sponsorships from many companies who have an interest in biosimilars for colorectal cancer, including Amgen, Lilly Oncology, Genentech and Boehringer Ingelheim. Neither these companies nor any of our other corporate supporters have influenced our comments on this issue.

Biosimilars for treatment of colorectal cancer are getting closer to market. This is a new and complex issue for cancer patients, pharmacists, and healthcare providers. We hope that the discussion at the upcoming ODAC meeting provides clarity as to FDA’s thoughts on the review criteria used to ensure the quality, safety and efficacy of the therapies.

We all understand that biosimilars are not the same as generic drugs, due to the fact the source is biological, or living, the product may change during manufacture and no biotherapeutic product of the same category is exactly the same as another. It is therefore more difficult to make a comparison between a biosimilar and its original, than it is between chemically identical active ingredients in a fully synthesized medicine.

For that reason, we ask that the FDA make clear the way these medicines are quality-assured before they enter markets. Our primary areas of concern include:

- We believe that clinical data must demonstrate safety and efficacy prior to approval, and hope that FDA considers initiation of long-term, post-marketing studies of approved biosimilars to evaluate their impact in a real-world environment.
• We are concerned that patients and healthcare providers may become confused as several biosimilars become available for the same indication. We hope that FDA requires the use of distinct names for biosimilars. We believe that this will ensure correct prescribing and dispensing by healthcare providers, and reduce confusion for patients and their loved ones.

• Interchangeability evidence and guidance is of extreme value to our community. We ask for clear guidance by the FDA on labeling that indicates whether a biosimilar is interchangeable with the reference biologic; lists all indications for which the biosimilar is approved; and specifies whether supporting clinical data was derived from studies of the biosimilar or the reference biologic.

• We are cautious and concerned about the review of biosimilars, especially if the FDA considers approving extrapolation of biosimilar products for indications where the reference biologic has already been approved in the absence of safety data specific to the biosimilar agent and the patient population in question. Again, we believe that clinical data should be required for each indication until a biosimilar has sufficient safety and efficacy data.

• As biosimilars enter the market, we believe the decision to use a reference biologic or a biosimilar must be made jointly by patients living with colorectal cancers and their health-care provider, and that patients should be provided with all relevant information to make an informed choice. Both the healthcare prescriber and the patient should have full knowledge of the treatment of choice and consent for a substitution from the “originator”. Patients should have an opportunity to make an informed choice.

As biosimilars emerge, we are keenly aware of the need for up-to-date information to enhance and support patient understanding of biosimilars. Patients need evidence-based information that allows them to make informed decisions and choices about treatment and patient care. We trust that FDA will continue its tradition of providing clarity around these issues.

We look forward to future discussions with the FDA to build confidence in our community and to broaden industry, healthcare, and patient understanding of biosimilars in the treatment of colorectal cancer.

Thank you,

Anjelica Q. Davis, MPPA
President