IMPORTANT ISSUES FOR PATIENTS: BIOSIMILARS

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Commissioner Califf,

My name is Andrew Spiegel and I am here today as the Chair of the Digestive Disease National Coalition, but I am also the Executive Director of the Global Colon Cancer Association, a co-founder of the Colon Cancer Association, a co-founder and Steering Committee Member of the Alliance for Safe Biologic Medicines, and a Board Member of the International Alliance of Patients' Organizations. I have been a patient advocate for 20 years, following the death of my parents from Colon Cancer and Pancreatic Cancer in 1996.

One of the greatest tools patients with serious chronic conditions like CRC have is **biologic medicines.** Since my mother was diagnosed with CRC and was given 10 months to live, the life expectancy of a metastatic cancer patient has tripled- to three years- in part due to the many new therapy options. In 1998 there was one drug to treat CRC, today there are ten (?).

Biosimilars continue bring these patients new treatment options- at reduced cost. This of course affects far more than just cancer patients. It includes patients suffering from many chronic, debilitating, and difficult-to-treat diseases like Rheumatoid Arthritis, Ulcerative Colitis, Crohn's Disease, Psoriasis, and other serious conditions.

Patients want biosimilars, but we also want our physicians to have the information they need to give us informed advice when making treatment decisions. A medicine's **product label** contains approval and safety information that helps physicians choose between two or more similar medicines to select the best option for a particular patient. This also helps pharmacists give their patients informed advice.

Lack of clinical data and insufficient transparency regarding that data can be obstacles to patient and physician confidence, and thus to widespread biosimilar adoption.

Because Biosimilars, by definition, are not identical to their reference product, it is important that the FDA insist upon **high standards for safety and efficacy**

when approving biosimilars. The manufacturer must be required to demonstrate the structural, functional, and clinical similarity of their product to the innovator.

Indication Extrapolation is also an area of concern to the patient community. At a minimum, approval for each indication should be granted individually, rather than an **all-or-nothing approach.** We don't suggest that safe extrapolation is not possible, we simply think each indication should be approved individually based on solid data.

For example, In 2014, Canada approved for RA and AS indications based on data, allowed extrapolation for Psoriasis due to a similar mechanism of action, but required additional clinical data before finally approving for UC and CD two years later.

But, FDA AAC Members were only given the choice to recommend approval for ALL INDICATIONS or NONE AT ALL. Vote was 21 for, 3 against.

The FDA AAC should have more flexibility, and not be forced to approve the drug only for ALL indications or NO indications. This is constraint is not legally required, nor in the patients' best interests. This is not to suggest there is a lack of data in these approvals, but more a comment on the overall process.

Once approved, **informative and transparent labeling** that lets us make informed treatment choices, is critical to building confidence and increasing biosimilar use.

For example, we need to know whether a biosimilar was evaluated in treating our disease, or whether the approval was based on extrapolation from clinical data in other diseases. We want to know whether or not the product is a biosimilar and whether it's interchangeable with its reference product.

Comprehensive data collection on a biosimilar is also of utmost concern. Strong **post-market surveillance data** improves care and limits risks to patients. Real world data helps us better understand these medicines and promote more efficient, safer and personalized use. Strong post-approval pharmacovigilance will improve care and provide further confidence in biosimilar medications. The FDA really does have a unique opportunity to ensure new drugs on the market remain safe for patients well after approval.

Clear product identification and naming is critical to ensure safety and confidence in biologic medications. We agree with the FDA's approach in promoting distinguishable names for all biologics, including both innovator and biosimilar drugs. We continue to believe that the benefits of distinct naming would be best realized through meaningful, memorable suffixes. How long would it take you to remember your passwords if they were not memorable or meaningful to you?

For patients to realize the benefits of biosimilars, we need to be confident that our health and safety remains the primary concern, and we need to be provided full and accurate information about each medicine in order to make informed choices.

Thank you for the opportunity to comment on this issue.

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