

February 3, 2014

The Honorable Edith Ramirez  
Federal Trade Commission  
Chairperson  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Dear Commissioner Ramirez:

As organizations advocating for greater patient and provider access to more affordable FDA-approved biologic medicines, we applaud the FTC's decision to hold hearings to examine issues of market access and competition for products that will be approved by the FDA through this new pathway. Biosimilars can be of value to patients only if they are accessible and affordable. However, there is a third focus that is as important as the other two, namely patient safety and consumer protection. We hope the FTC will give this concern the important weight and priority it deserves.

This is particularly pertinent in an area that the FTC has chosen to address at the upcoming hearings: the naming of biosimilars products. Before approving the first biosimilars in the U.S., the FDA will first need to establish a naming policy for all biologic products, including biosimilars. Given the vast differences between chemical compounds and biologics/biosimilars, we are among those urging the FDA to adopt unique names for biologic products including biosimilars rather than requiring biosimilars and their innovative reference product to share the same name.

There is room for reasonable disagreements about whether use of a single name for multiple products is pro- or anti-competitive. However, we are united in believing the threshold issue is patient safety and not competition. It is our view that patients across the nation will be best served if distinguishable names are required for all biologics. By providing clarity of information dating back to the point of prescription, distinguishable names facilitate the process of determining the cause of an adverse event by creating a more expeditious route back to the origin of the problem. Some problems that may be particular to a specific biological product may even be entirely untraceable without distinguishable names or other distinct identifiers.

Accordingly, through the way it sets naming policy, the FDA can provide the best possible protection for other patients also using similar products, while simultaneously ensuring the highest credibility for biosimilars as they enter the marketplace. We urge the FTC to give broad

exposure to this viewpoint and to adopt it as the agency's conclusion and recommendation to the FDA.

Sincerely,

[AIDS Foundation of Chicago](#)

[Alliance for Patient Access \(AfPA\)](#)

[Alliance for Patient Advocacy](#)

[California Healthcare Institute \(CHI\)](#)

[Hemophilia Federation of America \(HFA\)](#)

[Immune Deficiency Foundation \(IDF\)](#)

[International Cancer Advocacy Network \(ICAN\)](#)

[Institute for Safe Medication Practices \(ISMP\)](#)

[National Alliance on Mental Illness \(NAMI\)](#)

[National Comprehensive Cancer Network \(NCCN\)](#)

[National Patient Safety Foundation \(NPSF\)](#)

[RetireSafe](#)

[Rheumatoid Patient Foundation](#)

[The Wall Las Memorias](#)

[Women Against Prostate Cancer](#)

Cc:

Margaret Hamburg, MD, Commissioner of the U.S. Food and Drug Administration

Janet Woodcock, MD, Director of the Center for Drug Evaluation and Research, U.S. Food and Drug Administration