

February 28, 2014

Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Avenue NW
Washington, DC 20580

RE: Workshop on Follow-On Biologics: Project No. P131208

To Whom It May Concern:

Together, we represent patients and caregivers who face serious or life-threatening diseases every day. As such, we understand the profound impact that biological medicines have had on our lives and appreciate the Food and Drug Administration's (FDA) leadership in developing policy and guidance for the approval of biosimilars. As FDA considers guidance on the naming of biosimilar products, we ask that FDA support a system of distinguishable names for all biological medicines, in order to uphold the critical principles of transparency in healthcare and promote accurate physician-patient communication.

We believe that the decision to use a particular treatment should always lie with patients and their physicians. When there are multiple treatments available, patients and their physicians must decide on the right medicine based on each individual's medical history and treatment needs. Because biosimilar products will be similar, but not identical, to their reference products, it would be confusing for these products to share nonproprietary names. Assigning related but distinguishable nonproprietary names for all biological medicines among a similar class of product will help to ensure accurate physician-patient communication, as well as reliability in the prescription and dispensation of specific therapies.

We are excited about the biosimilar pathway and appreciate your ever-vigilant efforts to protect patient safety while promoting access to essential treatments for the conditions we face. We believe that instituting a system of distinguishable names for all biological medicines will achieve these goals, and we look forward to working with you on this important issue.

Sincerely,

National Organizations:

Alliance for Patient Access (AfPA)
Alpha-1 Association
Alpha-1 Foundation
American Autoimmune Related Diseases Association
American College of Rheumatology
Association of Black Cardiologists, Inc.
Colon Cancer Alliance
Crohn's & Colitis Foundation of America
Digestive Disease National Coalition
Global Healthy Living Foundation (GHLF)
Hispanic Federation
International Cancer Advocacy Network (ICAN)
International Institute of Human Empowerment, Inc.
Latino Commission on AIDS
Lupus Foundation of America
Lupus Research Institute
Men's Health Network
MLD Foundation
National Alliance on Mental Illness (NAMI)
Prevent Cancer Foundation
RetireSafe
Scleroderma Foundation, Inc.
Sjögren's Syndrome Foundation
The AIDS Institute
The Center for Lawful Access and Abuse Deterrence (CLAAD)
The COPD Foundation
US Pain Foundation
Veterans Health Council
Vietnam Veterans of America

State Organizations:

Lupus Alliance of Long Island / Queens
Lupus Alliance of Upstate NY
Lupus Foundation of Colorado
Lupus Foundation of Florida, Inc.
Lupus Foundation of Genesee Valley NY, Inc.
Lupus Foundation of Northern California
Lupus Foundation of Mid and Northern New York, Inc.
Lupus Foundation of Pennsylvania
Lupus Foundation of Southern California
Lupus LA
Michigan Lupus Foundation
New Yorkers for Accessible Health Coverage
NYS Rare Disease Alliance
NYS Rheumatology Society
Scleroderma Foundation / Tri-State, Inc. Chapter
S.L.E. Lupus Foundation