

February 24, 2014

Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Dear Commissioner Hamburg,

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