May 1, 2016

Leah Christl, Ph.D., Associate Director
Therapeutic Biologics and Biosimilars
Food and Drug Administration
10903 New Hampshire Ave.,
White Oak Bldg 22, Room 6426
Silver Spring, MD 20993
(via electronic delivery)

Dear Dr. Christl,

The undersigned organizations collectively represent individuals, caregivers, family members and healthcare professionals attempting to manage serious, complex, life-threatening conditions each day. As such, we understand the profound impact that biologic medicines have had on the lives of many Americans and it is our hope that as biosimilars enter the marketplace, they will provide additional treatment options by being both affordable and accessible.

It is our view as patient and provider stakeholders that all policy regarding biosimilars must recognize and reflect their unique nature. Unlike chemical generics, biosimilars are not exact copies of their reference products, but instead created from different materials and processes to mimic the therapeutic properties of the reference product. Variances will always exist between a biosimilar and its reference product, as well as between two or more biosimilars to a shared reference product, and may cause unexpected effects including immunogenic responses. A biosimilar may not be approved for all disease indications of the originator product, and approval for an indication may have been based on extrapolation, rather than on clinical research.

For these reasons, we support the FDA's leadership in creating a system of distinguishable names for all biologic medicines, including biosimilars. Distinct naming helps ensure a patient receives the intended medicine and allows for accurate designation of any adverse events to the correct product, aiding in pharmacovigilance while promoting manufacturer product accountability. Furthermore, a four-letter structure makes it potentially compatible with the WHO's Biological Qualifier system, which will extend these protections to patients worldwide.

It is our position regarding the structure of the distinguishing suffix that meaningful suffixes such as the FDA used with its first biosimilar approval, for Zarxio (filgrastim-sndz), are preferable to the random suffixes described in the FDA's Draft Guidance and used in its second approval for Inflectra (infliximab-dyyb).

Meaningful suffixes are easier for patients, providers and pharmacists to both recognize and remember, thus facilitating accurate association between adverse events and specific products. A suffix based on the manufacturer name, as was used in the Zarxio approval where '-sndz" refers to "Sandoz", also promotes manufacturer accountability. A survey of 400 prescribers of biologics revealed that they prefer meaningful suffixes over random by a six-to-one margin, and a survey of 401 US pharmacists showed 77% prefer manufacturer-based suffixes over random.

Biosimilars hold great promise for millions of individuals living with debilitating, life-altering diseases and we appreciate your ever-vigilant efforts to promote access to these treatments. We believe that by the FDA instituting a distinguishable naming system for biological medicines that incorporates meaningful, memorable suffixes will achieve these goals by providing strong patient protections, critical transparency and promoting pharmacovigilance, resulting in greater provider confidence. **Please contact Kathleen Arntsen from LADA at lupuskaa@aol.com or 315-264-9101 if you have any questions and thank you for the opportunity to share our perspective on this important issue.**

Sincerely,

ASBM Steering Committee Members:
Alliance for Patient Access
American Academy of Dermatology Association
American Autoimmune Related Diseases Association (AARDA)
Association of Clinical Research Organizations
Colon Cancer Alliance
Global Colon Cancer Association
Global Healthy Living Foundation
Health HIV
Hepatitis Foundation International
ICAN, International Cancer Advocacy Network
Kidney Cancer Association
National Psoriasis Foundation
ZeroCancer

Stakeholder Groups:
1 in 9, The Long Island Breast Cancer Action Coalition
American Behcet's Disease Association (ABDA)
American College of Rheumatology (ACR)
Arizona Bioindustry Association, Inc. (AZBio)
Arizona United Rheumatology Alliance
BioNJ
Coalition for State Rheumatology Organizations (CSRO)
Dysautonomia International
Florida Society of Rheumatology
Gay Men's Health Crisis (GMHC)
GBS/CIDP Foundation International
Genetic Alliance
Global Liver Institute
Hemophilia Federation of America
Hewlett House: A Community Learning Resource Center for Cancer Concerns
Hispanic Federation
Hispanic Health Network
Immune Deficiency Foundation (IDF)
International Foundation for Autoimmune Arthritis (IFAA)

International Pain Foundation
Latino Commission on AIDS
Lupus Alliance of Long Island/Queens
Lupus Alliance of Upstate New York
Lupus and Allied Diseases Association, Inc. (LADA)
Lupus Foundation of Colorado
Lupus Foundation of Florida, Inc.
Lupus Foundation of Illinois
Lupus Foundation of New England
Lupus Foundation of Northern California
Lupus Foundation of Pennsylvania
Lupus Foundation of Southern California
Lupus LA
Michigan Lupus Foundation
MLD Foundation
Molly's Fund Fighting Lupus
National Alopecia Areata Foundation
National Infusion Center Association (NICA)
New York State Osteopathic Medical Society (NYSOMS)
New York State Rare Disease Alliance (NYSRDA)
New York State Rheumatology Society (NYSRS)
New York BIO
National Organization for Rare Disorders (NORD)
Patients for Biologics Safety and Access (PBSA)
Pennsylvania Bio
Relapsing Polychondritis Awareness and Support Foundation, Inc.
RetireSafe
Scleroderma Foundation
Scleroderma Foundation Tri-State Chapter
Sjögren's Syndrome Foundation
Society for Investigative Dermatology
Society for Women's Health Research (SWHR)
Spondylitis Association of America
The AIDS Institute
The Myositis Association
United Rheumatology, LLC
United Spinal Association
U.S. Pain Foundation