May 7, 2019

Commissioner Norman E. Sharpless, M.D.
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Comments to March 2019: “Nonproprietary Naming of Biological Products: Update”
(Docket No. FDA-2013-D-1543)

Dear Acting Commissioner Sharpless:

Thank you for the opportunity to comment on the “Nonproprietary Naming of Biological Products: Update - Guidance for Industry.” The undersigned individuals and organizations representing patients, health care providers, and manufacturers support distinguishable suffixes for all new biologics—originator, biosimilar and interchangeable products — and urge the agency to continue to implement the policy as presented in the March 2019 update.

Biologics play a significant role in treating many seriously ill people. This category of medicine is already 40% of the drug pipeline\(^1\) and that percentage is growing. Thus, getting the policy right for the long term is essential.

Patient safety must be the top priority guiding FDA policy decisions. Biologics are important and powerful medicines that warrant regulatory processes tailored to address the challenges these medicines present. Biologics are manufactured using living cells that are sensitive to the manufacturing process. The resulting medicines are made of very large molecules that are difficult to fully characterize and can cause unwanted immune reactions in patients.

The naming policy designed by FDA effectively addresses the need to distinctly identify each biologic product. A unique suffix attached to the core nonproprietary name enables biologics to be prescribed, dispensed and tracked with specificity. Biologics are important but sensitive medicines that can change over time. This risk applies to interchangeable biologics as much as it does to all other biologics. Thus, distinct suffixes must be assigned to interchangeable products.

FDA’s decision to refrain from assigning suffixes to products already approved and marketed without a distinct suffix is a practical means of achieving the best possible safety framework for biologics. Over time, the vast majority of biological products will have a suffix. Ideally, the suffix policy would have been in place before the first biologic was approved and every product

would have a suffix. FDA’s policy of assigning suffixes for new products but not products already on the market makes the best of a difficult situation. In practice, relatively few biologics will have multiple versions by different manufacturers on the market. Attention must be paid to those products to ensure accurate prescribing, dispensing and adverse event reporting.

The pharmacovigilance system in place for vaccines appears to be working well as it exists. There is no need to add suffixes because these products are already effectively recorded with specificity.

Sincerely,
The Undersigned

**Patient Advocacy Organizations (56)**
Alliance for Safe Biologic Medicines (ASBM) on behalf of its 29 US member organizations.
Alaska Rheumatology Alliance
America Autoimmune Disease Association (AARDA)
American Arthritis and Rheumatology Associates
American Behcet’s Disease Association (ABDA)
Arizona Arthritis and Rheumatology Associates, PC
Arizona United Rheumatology Alliance
Arthritis Associates, PLLC
Association of Women in Rheumatology
BioNJ
Canna-Patient Resource Connection
Caring for Lupus
Children's Hospital of Michigan
Coalition of State Rheumatology Organizations
Colorectal Cancer Alliance
Digestive Disease National Coalition (54 patient groups)
Ecosystems Wireless
Florida Society of Rheumatology
Global Colon Cancer Association
Global Liver Institute
Global Pneumonia Prevention Coalition
Harvard Medical School
Hispanic Federation
Hispanic Health Network
ICAN, International Cancer Advocacy Network
International Foundation for Autoimmune & Autoinflammatory Arthritis
Kentuckiana Rheumatology Alliance
Latino Commission on Aids
Looms for Lupus, Inc.
Lupus Alliance of Upstate New York
Lupus and Allied Diseases Association, Inc. (LADA)
Lupus Chat
Lupus Foundation of Colorado
Lupus Foundation New England
Lupus Society of Illinois
Maryland Society for Rheumatic Diseases
Massachusetts, Maine, & New Hampshire Rheumatology Association
Metro Atlanta Rheumatology Society
Michigan Lupus Foundation
Midwest Rheumatology Association
Milwaukee Rheumatology Center
More Than Lupus
National Infusion Center Association (NICA)
National Kidney Foundation
NC Rheumatology Associates
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
1 in 9, The Long Island Breast Cancer Action Coalition
Purple Playas Foundation
RetireSafe
Rheumatology Alliance of Louisiana
South Carolina Rheumatism Society
Spondylitis Association of America
Tennessee Rheumatology Society
Wisconsin Rheumatology Association

**Individual Patients and Healthcare Providers (124)**
Alisha Kines
Alyeene Thomas
Amy Barron
Andrea Christenson, Psoriatic Arthritis Patient
Annette Jones, Disabled
Arrian Angles
Ashley Brown
Audrey Evans
Becky Marsh, Patient
Beth C. French, MS, RN, Nurse Practioner
Bill Frear, Patient
Bonnie Jamison
Brandy L. Davis
C.G. Sherman, Retired
Carlene Harrison, Patient
Carol Arbaczewski, Patient
Catherine Mrakovicich
Cathy Guerrant, Advocate for people with Arthritis
Cathy Pettinichi
Chantelle Marcial
Charles Cloud, Patient
CHM, RN
Christele Felix, Patient
Christine Von Raesfeld, Patient Advocate
Christopher Cloud
D. DeMichele
Daniel Fuentes
Daniel H. Rosler, MD
David Arntsen, Patient & LADA Board Member
Deb Constien, Patient
Deeanne Quist, Patient
Deidre Baptista, Patient
Deserea Constantineau, Arthritis Patient
Diane Wiederholt
Dovie Skidmore
Elaine Schultz, social worker
Elizabeth Liogghio
Elizabeth Santa Cruz, Caregiver
Emily Filmore, Patient
Estela Mata, Patient
Gina Chace
Greta Kemmer, Pharmacist
Heidi Hedges
Helen Cassin, Patient
Hollaine Hopkins, Patient
Hope Dellon
J. Dias
Jackie Taylor, Patient
James E. Mitchell, Jr., Patient
Jane Porter, Patient & LADA Board Member
Janet Christenson, Mother of Psoriatic Arthritis Patient
Jayne Depa
Jennifer M. Cordova, Patient
Joanne Martin
John Lee Bass, Trauma Nurse Practitioner
Joyce Roberts RN
Juana Mata, Patient & LADA Board Member
Judith Neckar, Retired
Julie Gould, Nurse
K. Escoe, BSN, RN
Kandy Herrick
Karen Heskett
Kathleen A. Arntsen, Patient
Kelly Conway, Patient
Kirsten Maeda, Lupus Advocate & LFNC Board member
Kristin Joy Russo, Patient
Kristina Figueroa, Director
Kristy Montero, Support Group Facilitator
LaTanya Blackwell
Lee Ann Kelso
Leonard Campbell
Lila De Penning
Lindsay Palmer, Live Yes! Connect Facilitator
Lisa Allison
Lisa Chandler
Lisa Heinz
 Lisabeth Iglesias, Patient & LADA Board Member
Louella Novak
Luis R. Lopez
Mackenzie Richardson, Patient
Martina Copeland, Federal Correctional Worker
Mary Glovee, Patient
Monica L. Johnson, Independent Patient Advocate
Nicole Ruddy, Patient
Pamela Lynn Taylor, Patient
Patricia Mitchell, Patient
Penina Scullion
Peter Morley, Patient Advocate
Philip Teague, Caregiver & Patient
Raymond Patnaude, Psoriatic Arthritis Patient
Rebecca Fleming, Patient
Rebecca Geraghty, Caregiver & Patient Advocate
Rhonda Painter
Richard Christenson, Father of Psoriatic Arthritis Patient
Roberta Kracht, LCSW Lupus Patient/ Licensed Clinical Social Worker
S. Putek, RN
Samantha Darwak, Caregiver
Sandi Frear, Patient & LADA Board Member
Sarah Cloud
Scott Sims, Software Engineer
Sharon Kay
Shelley Acker
Sofya Kazarian
Spandan Chakrabarti, Patient Advocate
Stephanie Block, MRI Technologist
Stephanie Darwak, Autoimmune advocate/patient
Stephen Barr
Susan Sewell
Tahnee Crain
Teresa Varner, RN
Terry Schooler, Patient
Therese Humphrey, RN/Patient Advocate
Tien Sydnor-Campbell
Tiffany Enoch
Tiffany M. Peterson, Patient
Tiffany Westrich, Patient
Timothy Ramos, Caregiver
Tina Horsky, Pharmacist
Tisa Campbell
Tom Taylor, Patient
Trudi Hoogenboom
Tue Campbell
Veronica Blanchard, RN
Virginia Ladd, Patient