

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<sup>1</sup> 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

---

<sup>1</sup>Ian Lloyd and Alexandra Shimmings. *Pharma R&D Annual Review 2018*. (Pharma Intelligence, May 16, 2018) Accessed Apr. 23, 2019 <https://pharmaintelligence.informa.com/resources/product-content/sitecore/shell//~/media/informa-shop-window/pharma/files/pdfs/pharma-rd-annual-review-webinar-2018-slides.pdf>.

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 Practitioner  
Bill Frear, Patient  
Bonnie Jamison  
Brandy L. Davis  
C.G. Sherman, Retired  
Carlene Harrison, Patient

Carol Arbaczewski, Patient  
Catherine Mrakovcich  
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  
Deserae 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 Enochs  
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