September 17, 2014

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Biosimilars Naming Concerns and Meeting Request

Dear Commissioner Hamburg:

As organizations representing millions of Americans who suffer from serious, life-threatening, and difficult to diagnose diseases, we, the undersigned patient advocate groups, write to request a meeting with you to discuss important considerations from patients' perspective on the implementation of the Biologics Price Competition and Innovation Act (BPCIA). Specifically, we would like to discuss our concerns about the naming of biosimilar biologic products, and the importance of a clear FDA policy requiring distinguishable names for all biologics, including biosimilars.

Our reasons for urging distinguishable nonproprietary names for biological medicines center on our collective goal to ensure that patient safety and positive clinical outcomes remain top priorities in BPCIA implementation. Our concerns also are consistent with those expressed in a recent letter to you from eleven specialty societies and nearly two dozen individual physicians in the areas of rheumatology, neurology, and other specialties where biologics are frequently prescribed. These physicians, who included nineteen members of the National Physicians Biologics Working Group, likewise urged that biologic products "must have distinguishable nonproprietary names" for several reasons, including the need to ensure that physicians and pharmacists know the exact product being prescribed; the need for physicians and patients to understand the distinctions between products' characteristics and approved indications; and the importance of tracking adverse events and clinical outcomes on a product-specific basis. Put simply, physicians and patients alike recognize that it is imperative from a safety and effectiveness perspective to ensure that each biologic product has a distinct and distinguishable name. We are deeply concerned that shared names would undermine transparency and jeopardize patient safety.

We understand that other stakeholder groups have met with FDA to communicate their position, including stakeholders supporting shared nonproprietary names for biosimilars and their reference products. We would like an opportunity to discuss our perspective with FDA, as well, on behalf of our members who rely on biologic products and who know all too well that different treatments—even if "similar"—can cause varied reactions for different patients, particularly those with complex diseases. What works for one patient with a complex condition often will not work for another patient with the same disease.[1] We believe that our collective perspective as patient advocates is important for FDA to consider, consistent with our shared goal to advance patient-centered care that both promotes innovation and protects the public health.[2]

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[1] *See, e.g.*, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), "Handout on Health: Systemic Lupus Erythematosus," http://www.niams.nih.gov/HEALTH_INFO/LUPUS/DEFAULT.ASP#Lupus_6 (May 2013) (noting that "lupus is different in different people and is characterized by autoimmunity in various systems of the body," and that "[m]any symptoms can come and go overtime," such that a treatment plan must be based on the patient's specific symptoms and characteristics, and "tailored to the individual's needs"); NIAMS, "Handout on Health: Rheumatoid Arthritis," http://www.niams.nih.gov/health_info/Rheumatic_Disease/default.asp#ra_10 (April 2013) (describing various treatments for rheumatoid arthritis and how they may vary from person to person); Am. College of Rheumatology, "Sjögren's Syndrome," http://www.rheumatology.org/Practice/Clinical/Patients/Diseases_And_Conditions/Sj%C3%B6gren_s_Syndrome/ (noting that "[s]ymptoms vary in type and intensity" and describing several types of treatments that may work in "some" patients but not others, depending on the patient's specific characteristics and symptoms).

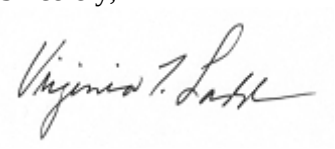
[2] *See, e.g.*, Remarks of FDA Commissioner Margaret A. Hamburg, M.D. (July 26, 2010), *available at* http://www.fda.gov/NewsEvents/Speeches/ucm220447.htm ("At the FDA, for example, we view every issue through the lens of public health, because, as many of you know, the fundamental mission of our agency is to promote and protect the public

"Similar" products, by definition, are not *identical*, and any dissimilarity can result in significant differences for patients in terms of efficacy and safety. Given the complex, chronic, and often life-threatening nature of autoimmune disorders, cancers, primary immune deficiencies, and a number of other rare diseases, such as hemophilia, and additional conditions that rely on biologics for treatment, as well as how they interact with other conditions that a patient might have or other medications that a patient may need, a transparent naming system is essential. Patients and prescribers must be able to understand readily which product it is being prescribed and to track cleanly patients' reactions and responses to that particular therapy. Shared nonproprietary names would result in "pooled" data that clouds clinical outcomes assessments and can be dangerous to patients.

We share the FDA's goals to ensure the safety, effectiveness, and accessibility of medicines approved for use by U.S. patients. The BPCIA holds promise for our members in terms of encouraging the development of additional therapies for a number of diseases that, currently, have very limited treatment options. We believe that a policy requiring distinguishable names strikes an appropriate and important balance in helping facilitate a pathway for additional biologic treatment options while preserving patient safety and transparent tracking of how medicines are being used and the resulting outcomes for patients.

On behalf of the undersigned organizations, we thank you for your consideration and your work on this important issue. We look forward to an opportunity to meet with you and your colleagues to discuss our perspective and recommendations in greater detail. For questions and follow up relating to this letter, please contact Patricia Barber with the American Autoimmune Related Diseases Association (AARDA), at PBarber@aarda.org or 586-776-3900.

Sincerely,



Virginia T. Ladd
President/Executive Director, AARDA

On behalf of

American Autoimmune Related Diseases Association

American Behcet's Disease Association

Arthritis Foundation

Coalition for Pulmonary Fibrosis

Crohn's & Colitis Foundation

Dysautonomia International

Immune Deficiency Foundation

International Foundation for Autoimmune Arthritis

Myasthenia Gravis Foundation of Illinois

National Psoriasis Foundation

Platelet Disorder Support Association

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health. And we are dedicated to fulfilling both parts of that mission … promotion through discovery and innovation and protection through the delivery of safe and effective products for consumers. Our ultimate goal is … an approach that meets the unique challenges of the 21st century while prioritizing health and well-being above all else.")

Relapsing Polychondritis Awareness and Support Foundation

Sjogren's Syndrome Foundation

The Myositis Association

U.S. Pain Foundation

cc:
Dr. Karen Midthun, Director, Center for Biologics Evaluation and Research
Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research
Ms. Sally Howard, Deputy Commissioner for Policy, Planning and Legislation
Ms. Lisa Barclay, Chief of Staff
Ms. Jeanne Ireland, Senior Advisor to the Commissioner