

August 14, 2014

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

Dear Commissioner Hamburg:

As organizations representing specialist physicians and individual physicians who prescribe biologics with regularity and often to patients in fragile health, we would like to provide the Food and Drug Administration with our shared perspective on the implementation of the Biologics Price Competition and Innovation Act (BPCIA).

Unlike many physicians who may never prescribe a biologic, our physician members work in specialty areas where biologics are frequently prescribed because the health and lives of our patients depend on them. Very often, we are using these complex treatments to care for the most severely ill patients, who require a myriad of therapies to regulate their illnesses and ameliorate their symptoms. These innovative medicines can be lifesaving, but they are also complex; even the same brand of medicine made by the same manufacturer, let alone similar medicines made by different manufacturers, may cause different reactions among patients with the same medical diagnoses and similar physical characteristics. As such, we feel it is imperative to provide the FDA with our perspective, which we offer with the health and safety of those we treat in mind and which is especially timely as the agency begins to evaluate the first application submitted in the U.S. for licensing of biosimilars.

We are specifically concerned about the naming of biosimilars. The question of whether a follow-on product will share a nonproprietary name with its reference product is critical. We believe the products must have distinguishable nonproprietary names for the reasons outlined below.

First, as the name implies and in light of current technology, a biosimilar will only be similar, but not identical to the reference product for the foreseeable future. Distinct nonproprietary names will help to alert physicians that each product, while safe and effective, may differ slightly. Rather than deter physicians from prescribing these products, we believe that allowing physicians to know the exact product that they are prescribing will increase confidence, thus encouraging more robust utilization of biosimilars than may develop without this transparency.

Second, a recent survey¹ of physicians who prescribe biologics and biosimilars in Europe indicated that 61% of the respondents believed that if two products shared an International Nonproprietary Name (INN), they were approved for all of the same

¹ *Generics and Biosimilars Initiative Journal*, vol. 3 issue 2 (2014), available: <http://gabi-journal.net/asbm-2013-european-prescribers-survey-report.html>.

indications. This is not necessarily the case and a misunderstanding can be potentially dangerous. While education can help, we cannot expect that all prescribing physicians will have a clear understanding of these regulatory distinctions. A more direct way of avoiding prescriber confusion is to ensure that the products have distinct nonproprietary names.

Third, distinguishable names will help prevent inappropriate pooling of adverse events by clearly identifying which product a patient was prescribed. Although National Drug Code (NDC) numbers can identify the manufacturer of a given medication or biosimilar, this information is not readily available to the treating physician. It is critical with medicinal molecules of this size and complexity, and with such potential for immunogenicity, that prescribers and the FDA have the ability to quickly and clearly trace the cause of any adverse reaction and—where a product-specific problem is identified—to alert other prescribers, pharmacists and patients using that product.

Fourth, in light of the perception among many physicians that a shared nonproprietary name implies approval for all of the same indications, the FDA's decision on interchangeability between indications may largely be rendered moot once biosimilars enter the U.S. marketplace, if the biosimilar shares a nonproprietary name with the reference product.

It is for these reasons that we believe the naming issue is so critical and why we have joined forces to write our views on this specific implementation question. We hope that you will find our views useful.

Should you have any questions, please contact Dr. Dennis Cryer (denniscryer@cryerhealth.com), Dr. Gregory Schimizzi (gfschimizzi@gmail.com), Dr. David Charles (info@allianceforpatientaccess.org), or any of the undersigned organizations.

Thank you for your consideration.

Sincerely,

Organizational Signers:

Alliance for Patient Access

American Academy of Asthma Allergy and Immunology

American Academy of Clinical Endocrinologists

American Academy of Dermatology

American Academy of Neurology

American College of Rheumatology

American Urological Association

Association of Black Cardiologists

Clinical Immunology Society

Coalition of State Rheumatology Organizations

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

Individual Physician Signers:

Dennis Cryer, MD – *Genetics and Metabolism, Washington, DC*
Gregory Schimizzi, MD – *Rheumatology, Wilmington, NC*
David Charles, MD – *Neurology, Nashville, TN*
Bert Petersen, MD – *Breast Cancer Surgery, New York City, NY*

National Physicians Biologics Working Group Members:

Tanya Bilchik, MD – *Neurology, Hartford, CT*
Howard Blumstein, MD – *Rheumatology, Mount Sinai, NY*
Robert Cowan, MD – *Neurology, Stanford, CA*
Robin Dore, MD – *Rheumatology, Tustin, CA*
Matthew Gold, MD – *Neurology, Winchester, MA*
John Goldman, MD – *Rheumatology, Atlanta, GA*
Mitch Goldstein, MD – *Perinatal & Neonatal Medicine, Loma Linda, CA*
Stephen Grill, MD – *Neurology, Elkridge, MD*
Howard Hoffberg, MD – *Physical Medicine and Rehabilitation, Owings Mills, MD*
Joseph Huffstutter, MD – *Rheumatology, Hixson, TN*
Roger Kobayashi, MD – *Allergy and Immunology, Omaha, NE*
Georgia Montouris, MD – *Neurology, Boston, MA*
Bhalchandra Parulkar, MD – *Urology, Worcester, MA*
Warren Rizzo, MD – *Rheumatology, Scottsdale, AZ*
Bruce Rubin, MD – *Neurology, Miami, FL*
Jack Schim, MD – *Neurology, Oceanside, CA*
Robert Shapiro, MD, PhD – *Neurology, Burlington, VT*
Joshua Stolorow, MD – *Rheumatology, San Antonio, TX*
Robert Yapundich, MD – *Neurology, Hickory, NC*

cc:

The Honorable Lamar Alexander
Sylvia M. Burwell, Secretary, HHS
Rima Cohen, Counselor to the Secretary for Health Policy, HHS
Francis S. Collins, MD, PhD, Director, NIH
Bill Corr, Deputy Secretary, HHS
Leslie Dach, Senior Counselor to the Secretary, HHS
Paul T. Dioguardi, Director, IEA
Shaun Donovan, Director, OMB
Jim Esquea, Assistant Secretary for Legislation, HHS
Thomas Frieden, Director, CDC
Richard G. Frank, Assistant Secretary for Planning and Evaluation, HHS
The Honorable Tom Harkin
Marc Garufi, Chief, Public Health Branch, OMB
Wanda K. Jones, Dr.P.H., Acting Assistant Secretary for Health, HHS
Jimmy Kolker, Assistant Secretary of Global Affairs, HHS
Richard Kronick, PhD, Director, AHRQ
Rear Admiral Boris D. Lushniak, MD, MPH, Acting Surgeon General, HHS

The Honorable Frank Pallone, Jr.
Andrea Palm, Chief of Staff, HHS
The Honorable Joe Pitts
Dori Salcido, Acting Assistant Secretary for Public Affairs, HHS
William B. Schultz, General Counsel, HHS
Jeremy Sharp, Deputy Assistant Secretary, Discretionary Health Programs, HHS
Howard Shelanski, Administrator, OIRA
Marilyn B. Tavenner, Administrator, CMS
The Honorable Fred Upton
May K. Wakefield, PhD, RN, Administrator, HRSA
The Honorable Henry Waxman