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 survey[1] 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:

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Bert Petersen, MD – *Breast Cancer Surgery, New York City, NY*

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cc:
The Honorable Lamar Alexander
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