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Patients for Biologics Safety & Access

Statement of
Larry LaMotte on behalf of
Patients for Biologics Safety and Access (PBSA)
FDA Oncologic Advisory Committee Meeting
July 17, 2017

Patient for Biologics Safety and Access (PBSA) is a coalition of more than 20 patient advocacy organizations representing millions of Americans who suffer from serious, life-threatening diseases that are difficult to diagnose and treat. Our members typically experience a health care system that takes years to identify appropriate providers, produce an accurate diagnosis, and discover the best course of treatment to bring greater stability for more optimal health outcomes. The introduction of biologic products has provided many of our members with an effective therapy for the first time in their lives. We appreciate the opportunity to submit testimony and participate in today's Advisory Committee meeting.

As patient advocates, our goal is to ensure patient safety is paramount as the FDA implements the Biologics Price, Competition, and Innovation Act (BCPIA). We are eager to realize BPCIA's promise of creating a regulatory pathway for new, safe, and effective biosimilars that could add choices and additional treatment options for our patient communities. However, patients with rare and chronic diseases are keenly aware of the possible risks associated with biologics and biosimilars, including immunogenicity, and the lack of long-term safety data for new treatments that are often taken to manage diseases for many years.

We are now at a critical phase of implementation of the BPCIA. The two products being considered today are biosimilars of two widely-used biologic products (Avastin and Herceptin) and could be the sixth and seventh biosimilars to be approved, with many other applications in the pipeline. . In addition, FDA has draft guidance on the crucial issue of interchangeability pending finalization and patient education efforts yet to be undertaken. Moreover, FDA is also finalizing their work with Congress on the reauthorization of the Biosimilar User Fee Act.

We want to take this opportunity to share the patient perspective on key biosimilar policy and patient safety issues.

1) **FDA should promptly issue final guidance on interchangeability that takes into account patient input, and should do so prior to approving any biologic as interchangeable.** For patients, the issuance of final guidance takes on an urgency given the recent steps taken by major insurers and pharmacy benefit managers (PBM) in the absence of such guidance. While none of the four biosimilars approved by the FDA were approved as interchangeable products, payers are moving forward this year with formulary changes and other coverage changes that could force patients who are stable on their treatments to switch to non-interchangeable biosimilars. This effectively circumvents the patient safety protections Congress put in place for interchangeability**. To protect stabilized**

patients from non-medical switching, we call on the FDA to develop guidance on substitution of non-interchangeable biosimilar products that errs on the side of patient safety. Appropriate clinical and scientific parameters will help guide effective payer policies and enhance patient safety.

2) FDA's final guidance on interchangeability should:

- **Appropriately reflect the clearly different and higher standard for interchangeability provided by Congress to protect patient safety, including substantial clinical testing beyond that required for finding a product to be biosimilar**. The FDA clearly recognized this at its July 12, 2016 Advisory Committee meeting. In response to a question from the Advisory Committee chair, FDA leaders indicated that the "single-transition" data provided by the applicant is to ensure that the transition does not lead to "any major devastating immune-mediated adverse events." Additionally, the FDA stated that, "We clearly don't think that this study design would be sufficient to address interchangeability."

- **Require that an application for interchangeable designation demonstrate the product is interchangeable for each condition for which the reference product is approved.**

- **Be designed to recognize and anticipate a future marketplace that may have multiple approved biosimilars and interchangeable products for the same indications**. For example, it should take into account a future where patients may be switched to and from reference products, non-interchangeable and interchangeable biosimilars over decades for the treatment of chronic conditions. The scope of required switching studies should consider this and account for the fact that many patients take biologics for chronic conditions for many years and could be switched back and forth multiple times.

- **Require interchangeable biosimilars to have distinct non-proprietary names with meaningful suffixes.**

3) Since biosimilars go through an abbreviated review process and are regularly approved to treat conditions for which they have not undergone clinical studies, **FDA must require aggressive post-market tracking and reporting to detect safety problems.** The biologic originator of the product before the Advisory Committee today had rare serious adverse events that led to a Black Box warning on its labeling. We believe this kind of rare but potentially fatal event warrants an even more aggressive post-marketing tracking and reporting requirement for newly approved biosimilars with no safety track record in the U.S. FDA must also have adequate staffing and other resources in place to carry out aggressive post-marketing tracking of biosimilars. Recent reports have exposed substantial weaknesses in the agency's current post-marketing tracking system, including the SENTINEL system. This makes accurate and aggressive post-marketing tracking even more essential for patient safety.

4) PBSA has long called on the FDA to give appropriate priority to the patient voice in the course of implementation of the BPCIA. Dr. Jeffrey Shuren, Director of FDA's Center for Devices and Radiologic Health (CDRH) recently announced that CRDH will be launching what he termed a "patient engagement advisory committee" that he said would be "made up of just patient representatives to tackle the issues that matter most to them." This seems like an excellent idea

and one that would make sense to apply to other covered product classes. **Because biosimilars are an important new class of drugs for which FDA is still finalizing its processes for approving and monitoring post-approval, we call on you to advance the creation of a similar "patient engagement advisory committee" for biosimilars.** Doing so would add crucial patient input and should serve to build patient confidence in this new category, both of which are critical for success of biosimilars.

5) PBSA has continually raised with FDA the **need for a substantial effort to educate patients and prescribers about biosimilars.** We once again extend our commitment to you that we are ready and eager to help the agency develop and implementation of an initiative to educate prescribers and patients about biosimilars, the difference between biosimilars and generic drugs, and the difference between non-interchangeable biosimilars and interchangeable products.

Thank you in advance for taking the time to consider our views on these very important patient protection issues. If you have any questions, please contact Larry LaMotte, Vice President, Public Policy at the Immune Deficiency Foundation (IDF) at llamotte@primaryimmune.org or 443-632-2552.

Sincerely,

Lawrence A. LaMotte

On behalf of Patients for Biologics Safety and Access

American Autoimmune Related Diseases Association
Arthritis Foundation
Committee of Ten Thousand
Crohn's & Colitis Foundation of America
Dystonia Medical Research Foundation
GBS/CIDP Foundation International
Hemophilia Federation of America
Hepatitis Foundation International
Immune Deficiency Foundation
International Foundation for Autoimmune Arthritis
Jeffrey Modell Foundation
Lupus and Allied Diseases Association
Lupus Foundation of America
National Alliance on Mental Illness
National Organization for Rare Disorders
Platelet Disorder Support Association
Pulmonary Hypertension Association
RetireSafe
Scleroderma Foundation
Spondylitis Association of America
United Spinal Association
US Hereditary Angioedema Association
US Pain Foundation