

American
Autoimmune Related
Diseases Association
(AARDA)

Arthritis Foundation
(AF)

Committee of Ten
Thousand (COTT)

Crohn's and Colitis
Foundation of
America (CCFA)

Dystonia Medical
Research Foundation
(DMRF)

GDS/CIDP Foundation
International

Hemophilia
Federation of America
(HFA)

Hepatitis Foundation
International (HFI)

Immune Deficiency
Foundation (IDF)

International
Foundation for
Autoimmune Arthritis

Jeffrey Modell
Foundation

Lupus and Allied
Diseases Association
(LADA)

Lupus Foundation of
America

National Alliance on
Mental Illness (NAMI)

National Organization
for Rare Disorders
(NORD)

National Psoriasis
Foundation (NPF)

Platelet Disorder
Support Association
(PDSA)

Pulmonary
Hypertension
Association (PHA)

RetireSafe

Scleroderma
Foundation

Spondylitis
Association of
America

United Spinal
Association

US Hereditary
Angioedema
Association (US
HAEA)

US Pain



June 24, 2016

Janet Woodcock, MD
Director, Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock and other FDA leaders,

Patients for Biologics Safety & Access (PBSA) is a coalition of 24 patient advocacy organizations dedicated to protecting patient access to safe and effective biologics. Together, our organizations represent millions of Americans who suffer from serious, life-threatening diseases that are difficult to diagnose and treat. We are writing to thank you for taking the time to meet with us on May 19, 2016, to discuss issues related to implementation of the Biologics Price Competition and Innovation Act (BPCIA). The meeting was both positive and productive. We also want to thank you for the May 20, 2016 response received from Commissioner Califf and you in response to our April 19, 2016 letter. We very much appreciate your attention to our concerns and suggestions and look forward to continuing our dialogue in the weeks and months to come.

We wanted to follow up on a number of points raised in our meeting and in your letter.

First, we are pleased with your stated willingness to consider our suggestions for changes to the draft guidance on labeling. Two ideas that came up during the meeting that are constructive approaches to provide patients more information while not making the labeling too dense. The idea of providing a link in the labeling to pertinent clinical testing data and adverse event information specific to the biosimilar was also discussed. Using an abbreviation or symbol to indicate when an indication was approved based on extrapolation of data rather than clinical testing was also raised. We urge you to adopt both in your final guidance.

Second, the dialogue centered on switching of biosimilars is important. While we recognize FDA can't fully control what payers will do to incentivize switching patients to biosimilars, there are steps the Agency can take to protect patients who are stable on their biologic therapy. First, we strongly agree with Dr. Woodcock's suggestion during our meeting that FDA could publish an official statement, switching a stable patient to a non-interchangeable biosimilar holds risks and only physicians (in consultation with patients) should make or drive such a decision. This would provide a significant pro-patient safety step and we strongly encourage FDA to promptly implement this measure. Given the patient experience with biologics, in which an array of payer and Pharmacy Benefit Manager (PBM) tactics have meant that these patients who were either stable and/or controlling their disease have had to undergo multiple therapy switches. We urge you on their behalf to require evidence to assure the safety of multiple switches rather than the theoretical but not realistic idea of a "one-time" switch or transition.

Third, in our meeting Dr. Woodcock expressed a willingness to consider our recommendation to require future biosimilar advisory committees to vote separately on indications. This would be an important step toward increasing patient and prescriber confidence in biosimilars and we urge you to implement it starting with the next biosimilar advisory committee meetings on July 12 and 13, 2016.

Fourth, the Coalition is pleased that you shared our belief that costs, while important, should not be factored into FDA approvals or advisory committee discussions. We urge you to take steps to instruct committee members prior to their meetings, starting with the July and 12th and 13th meetings, to state this at the start of the public meetings and to have a mechanism for reminding committee members of this factor, should it enter into committee discussions. We know that you agree that we should never have a situation where advisory committee members are voting on approval of new products based on cost, not solely based on safety and efficacy.

Thank you for your openness to assuring patients have at least five (5) business days to review advisory committee materials prior to future biosimilar advisory committee meetings. This will be particularly important with the two upcoming meetings, as we will have likely double the amount of material to review. As we discussed, this will make it possible to better prepare thoughtful comments and questions to enhance patient input and confidence in the process.

During the meeting FDA expressed a desire for “trust” and patient input. PBSA stressed the need for stronger pharmacovigilance system that is user friendly for patients. While budget constraints are understood, we want to continue to collaborate with you on this issue, as the current system is not adequate and does not engender patient trust and confidence.

Lastly, we look forward to working with you to better educate patients about biosimilars. We hope that PBSA will be of assistance and serve as a resource to help develop and test educational materials. We are also committed to helping FDA disseminate this information to our members.

Thank you again for your time, consideration and efforts. We look forward to continuing this constructive dialogue to assure patient safety and access.

Sincerely,

Lawrence A. LaMotte
On behalf of Patients for Biologics Safety and Access

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