Patients for Biologics Safety & Access

January 30, 2018

The Honorable Greg Walden
Chairman
The Honorable Frank Pallone J
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

Dear Chairman Walden and Ranking Member Pallone.:

As representatives of millions of Americans and their families whose lives are affected by biologics and biosimilars, we write to urge you to convene an oversight hearing by the Energy and Commerce Committee to assure that patient safety and access are being fully protected as the U.S. Food and Drug Administration (FDA) continues implementation of the Biologics Price Competition and Innovation Act (BPCIA) and more biosimilars enter the market.

As you know, the BPCIA created a regulatory pathway for biosimilars, adding choice and additional treatment options for the communities we represent. While our diverse health populations are eager for new and affordable treatments, people with rare and chronic diseases recognize the need to ensure new biologics and biosimilars meet rigorous safety standards.

To date, the FDA has approved a total of nine biosimilars. Five biosimilars were approved in 2017 alone, and many more applications are expected. While the FDA has issued several final guidance documents regarding biosimilars, the agency has yet to issue final guidance surrounding the key patient safety issues of interchangeability and labeling.

PBSA has long encouraged the FDA to take additional steps to protect people from harmful insurance practices such as non-medical switching involving non-interchangeable biosimilars. This practice by insurers and pharmacy benefit managers (PBMs) can force medically stable patients to switch to a biosimilar medication that has not been approved by the FDA as interchangeable. Such actions can undermine the higher standard Congress established for products to be approved as interchangeable and pose safety risks for people with chronic conditions who rely on treatments to manage their health.

Additional steps must be taken to ensure that, as more treatments become available, people are protected from unintended negative health outcomes resulting from non-medical switching and insurers and PBMs are adhering to new laws that protect Americans living with complex chronic and rare conditions and their families from these unfair practices.

As new products are approved and come to market, it is critical that post-marketing surveillance activities, overseen by the FDA, be evaluated to assure aggressive tracking of adverse events for all biologics, newly approved biosimilars, and future interchangeable products, so that safety concerns are promptly and accurately identified and addressed. There is no such FDA capability to track adverse events, and to our knowledge, no plan to develop such a plan to do so in the near future. This is unacceptable.

And as more biosimilars come to market, the need for a substantial and sustained effort to educate consumers and prescribers about this new class of drugs becomes more urgent. We are pleased that the FDA has begun a prescriber education initiative and PBSA is providing feedback on that effort. We look forward to working with the FDA on a similar initiative in 2018, focused on those individuals from various disease states who rely on such innovative pharmacologic products. We know the Committee shares our view that having the patient voice front and center in the development and execution of education efforts is key to the future confidence in and efficacy of biosimilars.

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PBSA believes a Committee hearing on all of these topics would help to ensure the effective and efficient implementation of BPCIA while furthering the Committee's goal of promoting enhanced access to and affordability of safe and effective treatments. We urge you to schedule a BPCIA oversight hearing before your Committee early in 2018 and ensure the voices of people with rare and chronic diseases are represented at such hearings.

Thank you for your attention to our request. PBSA looks forward to working with you as you continue to work on this crucial patient access and safety issue. If you have any questions about our request, please contact Larry LaMotte, Vice President, Public Policy, Immune Deficiency Foundation (IDF) at llamotte@primaryimmune.org or 443-632-2552.

Sincerely,

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
National Psoriasis Foundation
Platelet Disorder Support Association
Pulmonary Hypertension Association
RetireSafe
Scleroderma Foundation
Spondylitis Association of America
United Spinal Association
US Hereditary Angioedema Association
U.S. Pain Foundation