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TWENTY-TWO LEADING PATIENT ADVOCACY ORGANIZATIONS LAUNCH COALITION TO ENSURE THE VOICES OF PATIENTS ARE HEARD ON FDA DEBATE ON BIOSIMILARS

Patients for Biologics Safety & Access (PBSA) to Advocate for Strong Patient Safeguards for New Class of ‘Biosimilar’ Drugs; Coalition Urges FDA Oversight and Transparency

October 30, 2014 – Twenty-two leading patient advocacy organizations today announced the launch of Patients for Biologics Safety & Access (PBSA), a coalition dedicated to protecting patient access to safe and effective biologic medicines. PBSA members, who represent millions of patients living with serious, life-threatening and difficult-to-treat conditions, plan to ensure that there are adequate patient safety protections in place as FDA creates the regulatory pathway for so-called biosimilar medications. PBSA is the only coalition of patient advocacy organizations speaking solely from the patient perspective.

Biologics are medicines made from living organisms and are far more complex than traditional chemical drugs. Even slight variations in the manufacturing of biologics can result in serious, life-threatening adverse events in patients, millions of whom are already benefiting from these breakthrough medicines. As part of the Affordable Care Act (ACA), Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) establishing authority for FDA to review and approve a new class of drugs known as biosimilars. Biosimilars are highly similar, but not identical to biologic medicines. Because of the uniqueness and complexity of biologics, biosimilars are not and cannot be generic copies of biologic medicines.

“Patients need continued access to safe biologic medicines, and as the FDA creates a regulatory pathway to market for biosimilars, we want to make sure the voices and interests of patients are front-and center,” said Marcia Boyle, President and Founder of the Immune Deficiency Foundation (IDF), a PBSA member. “Biosimilars hold promise for patients with chronic and life-threatening diseases, but that promise should not compromise the safety of patients.”

Members founded Patients for Biologics Safety & Access around the following guiding principles:

- Patients must have access to safe and effective biologic and biosimilar medicines;
- Prescribers and patients should have all the information necessary to make a fully informed choice about whether to use an innovative biologic or biosimilars;
- Steps must be taken to assure appropriate tracking of adverse events for all biologics, including biosimilars, so that safety problems are promptly and accurately identified;
Biosimilars should have unique nonproprietary names to eliminate confusion, allow prescribers to accurately track the therapeutic agent in a patient’s medical record and quickly trace a product to an adverse event.

Biosimilar pathways should support innovation and ensure incentives remain to bring new therapies to market for patients.

“Now is a critical moment for patient safety and biologic medicines. Although FDA has accepted the first applications for approval of biosimilars, the Agency has not yet issued guidance on crucial patient safety issues. I look forward to engaging with the FDA to ensure that there are clear review and approval standards in place to protect patients,” said Sandie Preiss, Vice President of Advocacy and Access at the Arthritis Foundation.

Founding members of Patients for Biologics Safety & Access include:

- Alpha -1 Foundation
- 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
- Jeffrey Modell Foundation
- Lupus Foundation of America
- National Alliance on Mental Illness
- National Hemophilia Foundation
- National Organization for Rare Disorders
- National Psoriasis Foundation
- Platelet Disorder Support Association
- Pulmonary Hypertension Association
- Scleroderma Foundation
- Spondylitis Association of America
- United Spinal Association
- US Hereditary Angioedema Association

For more information about PBSA, please visit www.BiosimSafety.org

About Patients for Biologics Safety & Access
Patients for Biologics Safety & Access is a national coalition representing more than 20 patient advocacy organizations. The goal of the organization is to make sure the voices and interests of patients are heard as the FDA seeks to approve a new category of drugs known as biosimilars. For more information, visit www.BiosimSafety.org or @BiosimSafety

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