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

Patients for Biologics Safety & Access

March 21, 2017

Dr. Troyen A. Brennan, M.D.
Executive Vice President and Chief Medical Officer
CVS Health Corporation
One CVS Drive
Woonsocket, Rhode Island 02895

Dear Dr. Brennan;

On behalf of the Patients for Biologics Safety and Access (PBSA) Coalition, thank you for meeting with us on January 12 to discuss issues around biosimilars. The discussion was incredibly useful and our coalition hopes to continue the dialogue as more biosimilars enter the marketplace. While the coalition believes biosimilars hold great promise in lowering drug costs and have the potential to be a good option for many patients, we remain concerned about the non-medical switching of stable patients. Specifically, the coalition is very concerned about policies that could require patients who are currently stable on a biologic to switch medications for economic, rather than medical, reasons.

As you know, many patients take biologics essential to managing their chronic conditions for many years to become stable. Any change in their treatment, whether due to non-compliance or switching medications, can increase the risk of adverse events and lead to worsened outcomes. For this reason, the coalition urges all payers not to force stable patients to switch from an originator biologic to a non-interchangeable biosimilar via formulary designs.

Congress explicitly established a more rigorous standard of interchangeability for switching to a biosimilar product from a reference biologic product. Congress made it a point of law that **only** a provider can switch a biologic to a biosimilar unless the biosimilar is deemed by the FDA to be interchangeable. It is the coalition's view that formulary changes, which force stable patients to switch to a biosimilar product that has not been found to meet the interchangeable standard, is legally suspect and undermines this important consumer protection put in law by Congress. Preservation of the physician-patient relationship is of the upmost importance, and decisions about switching medications should rest between the patient and his/her physician.

As CVS crafts policies and formulary decisions around biosimilars, we ask that you continue the dialogue and include patient representation in your decision-making. Further, education of biosimilars – both what they are and how they might affect patients – is vitally important. We hope you will allow PBSA to work with you on patient and physician education about biosimilars, and how best to communicate with patients on formulary policies, exceptions and appeals policies.

In closing, we would like to set up regular calls or other forms of communications as we continue into the new frontier of biosimilars. Our coalition looks forward to hearing from you, and to meeting with you again in the future. In the meantime, please visit http://www.biosimsafety.org/ for more information on our members, activities, and position statements. Please contact Larry LaMotte at llamotte@primaryimmune.org or 443-632-2552 to coordinate communications.

Sincerely,

Lawrence A. LaMotte

On behalf of Patients for Biologics Safety and Access

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