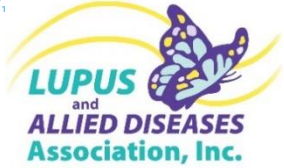

September 2019

The undersigned patient and provider organizations have come together in support of common principles around increasing uptake of biosimilar biological products. We recognize that the biosimilars market is nascent in the United States, and that patients and providers play a vital role in increasing trust, confidence, and uptake of these products. We are united in our belief that biosimilars hold promise in driving competition and providing additional access options for patients in the biological products market, which could ultimately increase access to appropriate therapies for patients with serious and chronic conditions, and could facilitate increased patient adherence to prescribed medications.

Principle 1: Patient trust in the safety and efficacy of biosimilars, and physician confidence in prescribing them, are crucial factors for driving broader uptake.

- FDA is a vital resource that patients, physicians, and others turn to for trusted information. The agency will continue to be an essential source for providing education and communication about biosimilar products to patients, physicians, and other health care stakeholders.
- We are committed to fostering peer-to-peer opportunities for patients to learn from one another about all biological products and sharing their experiences with policymakers.
- Patient and provider organization websites are a vital resource for patients and providers to get trusted information about biological products, including biosimilars.

Principle 2: The language health care stakeholders use to talk about biosimilars matters.

- Many stakeholders use different terms to describe biosimilars, which can lead to confusion and bias.
- Using language from the FDA can help avoid unintentional bias and accurately convey concepts that are often nuanced and complex.
- When discussing potential adverse impacts, distinctions should be made regarding transitions between reference biologics versus transitions between a reference biologic and a biosimilar. Stakeholders should come together on a common set of terms to describe these differences.

Principle 3: Public policies play a critical role in fostering increased access and competition in the biological products market.

- Improved access includes the assurance of affordable out-of-pocket costs for patients.
- Formulary restrictions continue to be a barrier, even for infused drugs; the current rebate structure remains an obstacle.
- Patients and physicians should have the ability to choose which FDA-approved biological product is the medically appropriate course of treatment based on each patient's unique circumstances.

We call on all health care stakeholders, including policymakers, brand manufacturers, biosimilars manufacturers, payers, pharmacy benefit managers, and employers to join us in our efforts to increase education about and access to biosimilar biological products. A thriving biologics market that allows and facilitates appropriate access to all biological products, including biosimilars, is critical to fulfilling the promise of lower costs for patients. The time is now.

Alliance for Patient Access
American Academy of Dermatology Association
American Autoimmune Related Diseases Association
American Cancer Society–Cancer Action Network
American College of Rheumatology
American Gastroenterological Association
American Society of Clinical Oncology
Arthritis Foundation
Crohn's and Colitis Foundation
Leukemia and Lymphoma Society
Lupus and Allied Diseases Association
Lupus Foundation of America
National Organization for Rare Disorders
National Organization of Rheumatology Managers
National Patient Advocate Foundation
National Psoriasis Foundation
Scleroderma Foundation