May 21, 2015

The Honorable Stephen Ostroff
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Ostroff:

On behalf of organizations that represent physicians who routinely prescribe biologic medicines, we urge the U.S. Food and Drug Administration (FDA) to ensure that biosimilar product labeling contains all needed data for physicians to make appropriate prescribing decisions for their patients.

As FDA is aware, the label is a critical tool for physicians to both make prescribing decisions and manage potential adverse events, including side effects and drug-to-drug interactions. As such, it is of the utmost importance that any drug label be complete and accurate.

We agree with FDA statements provided in its 2012 Draft Guidance "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product" which stated, *"Labeling of a proposed product should include all the information necessary for a health professional to make prescribing decisions, including a clear statement advising that:*

- *This product is approved as biosimilar to a reference product for stated indication(s) and route of administration(s).*
- *This product (has or has not) been determined to be interchangeable with the reference product."*

We are concerned the label of the first approved biosimilar, Zarxio™ (filgrastim-sndz), does not make either statement. Given the level of education that still needs to take place surrounding biosimilars, some physicians may mistakenly view that an identical label implies that a biosimilar is interchangeable with the reference product and has approval for all of the same indications - which we know may not be the case for many biosimilars.

Further, given that a biosimilar – unlike a generic small molecule – has its own clinical data, there will likely be specific information from this data package that will help physicians, including the provision of information on immunogenicity, which can vary from the reference biologic. As such, we urge FDA to give full consideration to what elements of the biosimilar data package would be helpful to physicians.

The Biologics Price Control and Innovation Act of 2009 (BPCIA) and the resulting law creating a regulatory approval pathway for biosimilars, rightly recognize that biosimilars are not generic medicines. Therefore, we urge FDA not to employ a generics-like approach to labeling for biosimilars as it appears to have done with Zarxio.

Greater transparency and inclusion of data will protect patients while increasing physician confidence in the use of biosimilars and encourage greater and informed utilization. We thank FDA for its careful and thoughtful process in determining the policies for biosimilars that will serve patients' best interests, and request the Agency to finalize its policy in favor of transparent, fully informative labels for biosimilars.

Respectfully,

Alliance for Patient Access

American Association of Clinical Endocrinologists

American College of Rheumatology

Biologics Prescribers Collaborative

Clinical Immunology Society

Coalition of State Rheumatology Organizations

Endocrine Society

North American Society for Pediatric Gastroenterology, Hepatology and Nutrition

CC:
Dr. Jonca Bull, Director, Office of Minority Health
Ms. Sylvia Mathews Burwell, Secretary, Health and Human Services
Mr. Shaun Donovan, Director, Office of Management and Budget
Dr. John Jenkins, Director, Office of New Drugs, Center for Drug Evaluation and Research
Dr. Karen Midthun, Director, Center for Biologics Evaluation and Research
Dr. Anne Pariser, Associate Director for Rare Diseases, Center for Drug Evaluation and Research
Dr. Gayatri Rao, Director, Office of Orphan Products Development
Dr. Howard Shelankski, Director, Office of Administration and Regulatory Affairs
Dr. Janet Woodcock, Director, Center for Drug Evaluation and Research