Immune Deficiency Foundation, American Autoimmune Related Disorders Association (AARDA) and Global Healthy Living Foundation (GHLF) Urge FDA to Require Unique Names for Biosimilar Products

Groups Cite Distinguishable Naming as Critical Component of Transparency in Healthcare

August 8, 2014 - The Immune Deficiency Foundation (IDF), American Autoimmune Related Disorders Association (AARDA), and Global Healthy Living Foundation (GHLF), leading patient organizations representing millions of Americans who suffer from serious, life-threatening, and difficult to diagnose diseases, today announced that they have sent a letter to the U.S. Food and Drug Administration (FDA) urging the Agency to require that all biosimilar medications have unique and distinguishable names in order to protect the safety of patients.

“As patient advocates, we want to ensure that patient safety is a priority as FDA implements the Biologics Price Competition and Innovation Act (BPCIA). This message is especially timely given the recent news that FDA has accepted the first application for approval of a biosimilar… [W]e urge that all biologics, including biosimilars, carry distinguishable non-proprietary names,” said the patient groups in the letter. “By providing clarity of information dating back to the point of prescription, distinguishable names facilitate the process of determining the cause of an adverse event by creating a more expeditious route back to the origin of the problem. Some problems that may be particular to specific biological product may even be entirely untraceable without distinguishable names or other distinct identifiers. Distinguishable naming is a critical component of transparency in healthcare.”

Biologics are complex medicines that are made from living cells. “Biosimilars” are biologics that are similar, but not identical to, a previously approved biologic. Unlike generic versions of small-molecule drugs, there can never be identical versions of biologic drugs.

“As leading patient advocacy organizations, we welcome the advent of biosimilars as a potential opportunity for patients to access effective and affordable care; but not at the expense of patient safety,” continued the groups in the letter.

The full text of the letter to FDA is below.

About The Immune Deficiency Foundation
The Immune Deficiency Foundation, founded in 1980, is the national non-profit patient organization dedicated to improving the diagnosis, treatment and quality of life of persons with primary immunodeficiency diseases through advocacy, education and research. People diagnosed with PI often find it difficult to receive specialized health care, proper diagnosis and treatment. They experience difficulties financing health care, finding educational materials and locating others to share their experiences. IDF helps individuals overcome these difficulties and live healthy and productive lives.
August 1, 2014

The Honorable Margaret Hamburg
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20093

Dear Commissioner Hamburg:

The Immune Deficiency Foundation (IDF), Global Healthy Living Foundation (GHLF), and the American Autoimmune Related Disorders Association (AARDA), all urge you to require distinguishable names for all biologic products. Together, our organizations represent millions of Americans who suffer from serious, life-threatening, and difficult to diagnose diseases. Our members typically experience a healthcare system that takes years to identify the appropriate providers, receive an accurate diagnosis, and identify the best treatment course that will bring greater stability to their daily lives.

As patient advocates, we want to ensure that patient safety is a priority as FDA implements the Biologics Price Competition and Innovation Act (BPCIA). This message is especially timely given the recent news that FDA has accepted the first application for approval of a biosimilar. Many organizations that represent patient populations similar to ours have indicated the critical importance of the patient perspective on the issues your Agency is considering around the implementation of BPCIA.

Biologics are complex molecules that are grown in living cells. Because they are patterned after proteins the body itself produces, biologics can treat many serious diseases in ways conventional medicines cannot. Biologic medicines have dramatically transformed the lives of many of our members and their families. As biosimilars become available in the United States we want to ensure they are safe, accessible, and affordable.

Before approving the first biosimilars in the U.S., the FDA will first need to establish a naming policy for all biologic products, including biosimilars. Given the vast differences between chemical compounds and biologics, we urge that all biologics, including biosimilars, carry distinguishable non-proprietary names. By providing clarity of information dating back to the point of prescription, distinguishable names facilitate the process of determining the cause of an adverse event by creating a more expeditious route back to the origin of the problem. Some problems that may be particular to specific biological product may even be entirely untraceable without distinguishable names or other distinct identifiers. Distinguishable naming is a critical component of transparency in healthcare.

As leading patient advocacy organizations, we welcome the advent of biosimilars as a potential opportunity for patients to access effective and affordable care; but not at the expense of patient safety.

The decision of the Agency on whether to require distinguishable names for biosimilar products approved in the United States is a critical and timely issue that will significantly impact patients. The
undersigned organizations support a policy that requires distinguishable names for all biological medications to ensure accurate tracking of medication utilization and adverse events, and to enable a transparent system.

We thank you for your attention to this important issue. For questions regarding these comments, please contact Larry LaMotte, Vice President, Public Policy, Immune Deficiency Foundation, at llamotte@primaryimmune.org or 443-632-2552.

Respectfully,

Marcia Boyle Seth Ginsberg Virginia Ladd
President & Founder, IDF President, GHLF President & Founder, AARDA

cc:
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