ARTHRITIS FOUNDATION®
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NATIONAL OFFICE
1330 West Peachtree St., NW, Ste 100
Atlanta, GA 30309
Tel (404) 872-7100
fax (404) 872-0457

August 22, 2014

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

Dear Commissioner Hamburg:

As the largest non-profit health organization addressing the needs of the more than 50 million adults and 300,000 children living with arthritis in the United States, **the Arthritis Foundation urges the FDA to adopt a policy of distinguishable names for all biologic products, including biosimilars.** Biologics have revolutionized the treatment of rheumatoid arthritis and other inflammatory forms of arthritis, preventing joint damage and preserving function and mobility for many people. However, not everyone has access to biologics due to high costs and/or limited availability. The Arthritis Foundation welcomes the potential for increased access to biologic therapy when biosimilars enter the market.

Since the FDA has accepted the first application for a biosimilar, and other companies are planning to follow suit, the issue of naming biosimilars must be addressed promptly. As the FDA finalizes its guidance on licensing biosimilars, the Arthritis Foundation urges the agency to hold patient safety as the highest priority. We believe that requiring distinguishable names for all biologic products would ensure that patient safety is given the highest priority.

There are a number of reasons distinguishable names are important to patients:

- **Biosimilars are not bioequivalent.** Biosimilars are not exact replicas of the innovator biologic. There will be subtle product variations in cell lines and manufacturing processes that can have significant and serious consequences. Further, biologic medications often work differently for different people. The inherent challenge of treating these complex diseases and predicting the response of a particular patient would increase exponentially if the identities of the therapies were not clear. Likewise, risk for the patient increases as delay in finding an effective therapy means potential ongoing joint destruction.
- **Shared names can cause confusion among physicians.** A 2014 survey of physicians in Europe[1] suggests that many physicians believe that drugs with shared nonproprietary names are approved for all the same indications. The study further suggests that 61% of physicians who prescribe both biologic and biosimilar medications believe two products that share a name are approved for the same indications. Because biologics and biosimilars are

[1] *Generics and Biosimilars Initiative Journal*, vol. 3 issue 2 (2014), available: http://gabi-journal.net/asbm-2013-european-prescribers-survey-report.html.

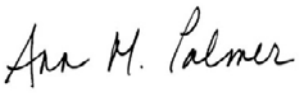
inherently different, this misunderstanding can have a severe impact on patients. The easiest way to avoid this type of misunderstanding is to require distinguishable names for all biologic products.

- **Distinguishable names allow for transparency in notification and substitution.** Since biosimilars are not exact replicas of biologics, distinguishable names will help make it as clear as possible for the pharmacist, patient, and physician to know exactly which product the patient is receiving. The Arthritis Foundation believes the patient and prescribing physician should be notified within 24 hours by the pharmacist when a substitution has taken place, and the pharmacist and the prescribing physician should keep records of any substitutions made for a minimum of 5 years. Such records may be invaluable in case the patient's condition changes over time, or an adverse reaction or disease evolution occurs.

- **Distinguishable names will strengthen adverse event tracking and post-marketing surveillance.** It is important that adverse events are tracked separately for biologics and biosimilars. The licensed health care practitioner needs to know exactly which product his/her patient is receiving in order to monitor efficacy, adjust dosages and accurately report adverse events if they occur. Long-term, post marketing, registry-based data collection is necessary to monitor for less common - but nonetheless important - adverse events. In the case of an adverse event, the patient needs to be able to communicate to his/her health care provider exactly what is being injected or what was infused. This would be complicated, if not impossible, if the patient or his/her physician is unaware of the specific product the patient received.

The complexity of the care of arthritis patients and the complexity of biologic medications make a policy of distinguishable names for biologics and biosimilars critical for maintaining the highest level of patient safety. We believe the FDA shares our commitment to making patient safety a priority and we would welcome an opportunity to continue to dialogue on this topic. Please contact Sandie Preiss, Arthritis Foundation Vice President of Advocacy and Access, at 202-887-2910 or spreiss@arthritis.org with questions or for more information.

Sincerely,



Ann M. Palmer
President and CEO
Arthritis Foundation