December 22, 2014

Caleb Briggs, PharmD
Center for Drug Evaluation and Research
United States Food and Drug Administration
10903 New Hampshire Avenue WO31-2417
Silver Spring, MD 20993

Dear Dr. Briggs:

On behalf of the millions of arthritis patients and thousands of rheumatologists and health professionals we represent, the Arthritis Foundation and the American College of Rheumatology welcome the opportunity to provide written comments related to the FDA Oncologic Drugs Advisory Committee January 7th 2015 meeting. Like many cancer drugs, a number of drugs used to treat arthritis and other rheumatic diseases are biologics. Since the January meeting will focus on the Sandoz biosimilar application, we wanted to provide you with our position on biosimilar guidance. Our organizations have urged the FDA to adopt a policy of distinguishable names for all biologic products, and we encourage you to carefully consider patient safety issues as the Advisory Committee continues its work in the coming months.

There are a number of reasons distinguishable names are important:

- **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.** Many physicians believe that drugs with shared nonproprietary names are approved for all the same indications. A 2014 survey of physicians in Europe who prescribe both biologic and biosimilar medications showed that a majority of them believed two products that shared a name were approved for the same indications.[1] Because biologics and biosimilars are 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.

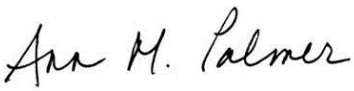
[1] *Generics and Biosimilars Initiative Journal*, vol. 3 issue 2 (2014), available: http://gabi-journal.net/asbm-2013-european-prescribers-survey-report.html.

- **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 American College of Rheumatology and the Arthritis Foundation believe 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 or 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 or her health care provider exactly what is being injected or what was infused. This would be complicated, if not impossible, if the patient or their 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. Again, we thank you for the opportunity to provide written comments to the Advisory Committee. If you have any questions or if we can be of any assistance, please contact Sandie Preiss, AF Vice President of Advocacy and Access, at spreiss@arthritis.org or (202) 887-2910 or Adam Cooper, ACR Senior Director of Government Affairs, at acooper@rheumatology.org or (404) 633-3777.

Sincerely,



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