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# THE COALITION OF STATE RHEUMATOLOGY ORGANIZATIONS

## Statement for the Record

## HOUSE ENERGY AND COMMERCE COMMITTEE SUBCOMMITTEE ON HEALTH HEARING:

## "Examining Implementation of the Biologics Price Competition and Innovation Act"

**February 4, 2016**

The Coalition of State Rheumatology Organizations, or CSRO, is a group of state and regional professional rheumatology societies formed to advocate for excellence in rheumatologic disease care and to ensure access to the highest quality care for the management of rheumatologic and musculoskeletal diseases. Our coalition serves the practicing rheumatologist in charge of patient care for these illnesses, including the use biologic agents. Rheumatologists have extensive experience in the treatment of rheumatoid arthritis, psoriatic arthritis, and other autoimmune inflammatory diseases with biologic agents and look forward to having lower cost biosimilar agents approved by the Food and Drug Administration (FDA). We are concerned about patient safety in regards to pathways to approval, naming, post-approval pharmacovigilance, and non-medical substitutions. We urge the Committee to consider the following policy points when evaluating FDA's implementation of the Biologics Price Competition and Innovation Act (BPCIA):

**Automatic indication extrapolation upon approval would be a grievous error in the approval process.**

Biosimilars can never be totally identical with the innovator compound for a number of molecular reasons. They can have different effects in different diseases if they are not precisely identical and they may interact with the patient's immune system creating immunologically mediated adverse effects (AEs). A biosimilar currently nearing approval by FDA is Remsima, a product that seeks to copy REMICADE (infliximab), a treatment for that is approved for eight indications, including rheumatoid arthritis. The reference product manufacturer generated clinical data to obtain approval of each of those indications. Requiring some data from the biosimilar applicant for each indication would be a wise course for such a large and complicated monoclonal antibody used in populations of patients who are not at all identical. It is CSRO's position that indication extrapolation be avoided and each agent be tested for efficacy, safety, and adverse effects in each indication in the application.

**Biosimilars must be readily identifiable by a distinct and distinguishable non-proprietary name. This policy must be extended to any biosimilar that is determined to be interchangeable.**

This will assist physicians and patients in determining precisely which agent is involved in any adverse reaction and will help prevent misattributing the reactions of any biosimilars to the parent (innovator) compound. CSRO has urged the FDA to require distinct nonproprietary names for several reasons. First, distinct names will help to alert physicians that each product, while safe and effective, may differ slightly. We believe that allowing physicians to know the exact product being dispensed to a patient when a biologic agent is prescribed will increase physician confidence and thus encourage more robust utilization of biosimilars than without this transparency.

Second, a recent survey of physicians who prescribe biologics and biosimilars in Europe found that 61% of respondents believed that, if two products share the same International Non-Proprietary Name (INN), the products are approved for use in all of the same indications as the innovator product.[1] This may not necessarily be true.

Third, distinguishable names will help prevent inappropriate pooling of adverse events by clearly identifying which product was dispensed to a particular patient. Although National Drug Code (NDC) numbers can identify the manufacturer of a given medication or biosimilar, this information is not readily available to the treating physician and will likely be completely unknown to the patient. It is critical with medicinal molecules of this size and complexity, and with such potential for immunogenicity, that prescribers and the FDA have the ability to quickly and clearly trace the cause of any adverse reaction. Where a product-specific problem is identified, other prescribers, pharmacists, and patients using that product can be more easily notified.

And finally, in light of the perception among many physicians that a shared nonproprietary name implies approval for all of the same indications as the innovator product, the FDA's decision on indication extrapolation may largely be rendered moot if the biosimilar shares an INN with its reference product.

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

In light of these concerns, we were pleased when FDA issued proposed guidance requiring biosimilars to bear a unique suffix to the INN.[2] We have urged FDA to finalize that guidance and to extend that policy to interchangeable biosimilars as well. We believe that the policy concerns underlying our call for distinguishable names outlined above are not diminished in the case of interchangeable biosimilars.

**Pharmacovigilance will be more complicated with biosimilars and will require a new and updated tracking system.**

Pharmacovigilance issues will be more complicated with biosimilars – especially with biosimilar monoclonal antibodies and fusion proteins – than with small molecule generics. Small molecule generics with simpler structures can be expected to have no significant difference in efficacy when identical doses are administered if absorption, bioavailability, and excretion are also identical. After approval of biosimilars for monoclonal antibodies, fusion proteins and smaller protein agents and in light of these products' possible immunogenicity and efficacy differences, the FDA must develop and replace outdated methods used for small molecule pharmacovigilance in order to more accurately monitor differences in adverse effects.

**Non-medical switching must be strongly discouraged.**

It is imperative that automatic substitutions be discouraged for biosimilars without an FDA interchangeability designation. Insurance company policy will favor the product that is the least expensive and the most rebate-positive (i.e. profitable) agent, maybeeven if it is inferior or less effective in the disease state being treated.

If a product is substituted, physician and patient notification must take place at the time of dispensing. There must be an opportunity for physicians to discuss the substitution with the patients before they actually start the medication. While FDA has no jurisdiction over payment policies that drive substitution, the Centers for Medicare and Medicaid Services (CMS) clearly does. In addition, we do believe that the FDA, in its mission to protect the public health, has a responsibility to clearly elucidate the potential problems with non-medical switching and strongly discourage third parties from interfering with doctor and

[2] "Nonproprietary Naming of Biological Products: Guidance for Industry" (August 2015). Available: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm459987.pdf.

patient decision making. The individual patient's health and well-being should continue to be at the heart of any FDA decision and recommendation.

With regard to CMS, that agency recently finalized a payment policy whereby all biosimilars for a given reference product share a J-code. This is a poor policy as it will create confusion for prescribers and reduce the incentive for manufacturers to invest in the development of biosimilars. CMS has unofficially indicated that it would assign a two-digit product specific Healthcare Common Procedure Coding System (HCPCS) code, but it is our understanding that this is an unprecedented policy, and thus we are concerned that this may not be a realistic and workable approach.

In addition, separate J-codes are needed in order to be in agreement with distinct non-proprietary naming systems. The World Health Organization recently finalized its non-proprietary naming proposal for all biological products, which will require a unique suffix. FDA has proposed a similar policy, which is currently awaiting finalization. CMS must follow in the footsteps of the scientists, professionals, WHO and (by preliminary indications) the FDA, who are knowledgeable in this area. We urge CMS to provide each biosimilar with its own, distinct J-code.

**CONCLUSION**

It is important that the voices of physicians prescribing these agents and the patients treated with these agents be considered in the formulation of policy and implementation of new biosimilar approval pathways. In closing, we restate our policy positions in the hope that these will be helpful as the Energy and Commerce Committee conducts oversight on implementation of the BPCIA:

- A biosimilar must seek approval for each indication that the reference product is approved for;
- All biosimilars must carry distinct nonproprietary names, including interchangeable biosimilars;
- The Agency must update and improve its existing pharmacovigilance systems to effectively track these complex agents once they are in the marketplace;
- Given FDA's mission of protecting the public health, the agency must strongly discourage non-medical switching between products; and
- CMS must assign each biosimilar a unique J-code.

On behalf of the Coalition of State Rheumatology Organizations, I thank the Committee for the opportunity to present these policy points. Should you have

questions or require additional information, please do not hesitate to reach out to Dr. Gregory Schimizzi, gfschimizzi@gmail.com.