AMERICAN COLLEGE OF RHEUMATOLOGY
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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Submitted via Regulations.gov

Re: [FDA-2017-N- 5092] Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirement

Dear Sir or Madam:

The American College of Rheumatology (ACR) represents over 9,500 rheumatologists and health professionals. Rheumatologists provide ongoing care for 50 million Americans with complex chronic and acute conditions that require specialized expertise, including frequent prescription of biologic immunomodulator therapy. We appreciate the opportunity to provide feedback to the Food and Drug Administration's (FDA) on the *Review of Existing Center for Biologics Evaluation and Research Regulatory and Information Collection Requirement.* We appreciate the FDA considering ways to lessen regulatory burden especially when providers and patient care may be adversely affected. That said we believe there are FDA requirements that should be preserved to ensure the safety and efficacy of biologics and biosimilars. Please see our comments below regarding certain regulatory provisions that are strongly supported by the ACR and should be preserved.

Early and appropriate treatment by rheumatologists slows progression of diseases like rheumatoid arthritis, improves patient outcomes, and reduces the need for costly downstream procedures and complicated care made more expensive by advanced disease states. A growing body of evidence shows that by slowing disease progression biologic treatments including biosimilars may reduce costly disease-related complications, including adverse outcomes related to cardiovascular disease, metabolic syndrome, and expensive procedures such as joint replacement.

Biologics and biosimilars serve as lifelines for patients with rheumatic diseases. These innovative treatments are often necessary when other disease-modifying anti-rheumatic drugs (DMARDs) are either ineffective or not tolerated by a patient. Most notably, biologic and biosimilar treatments tend to work rapidly and may achieve control of the disease more quickly – a critical factor when facing a brief window of opportunity for maximum therapeutic effect. To that end the development of biologic and biosimilar guidance from the FDA is vital to ensuring safety, efficacy, and pharmacovigilance.

The ACR strongly supports biosimilar and biologic regulations that are necessary to ensure the safety and efficacy of these therapies, and to provide the necessary level of confidence for their use by patients and providers.

I. We strongly support the FDA's draft requirement that manufacturers use robust switching studies to determine whether alternating between a biosimilar and its reference product three or more times impacts the safety or efficacy of the drug. The use of at least two exposure periods to each drug will simulate what our patients are likely to experience with changing formularies in a multi-payer, multi-state, and ever-changing market. The requirement for multiple switching studies to demonstrate interchangeability is particularly vital in light of the fact that providers will often not know that their patient's medication has been switched.

II. The ACR strongly supports clinical trial development to focus on markers of immunogenicity, such as induction of antidrug antibodies and loss of clinical efficacy, as well as adverse effects due to switching between drugs. This data is critical for providers to be able to assess efficacy and need for changes in therapy. Data collection should continue through robust postmarketing surveillance. The ACR suggests that FDA allow ready access to pharmacovigilance data for investigators to analyze, and that the FDA promotes and disseminates information about the program and the available data.

III. The ACR supports extrapolation of biosimilar treatment indications after a robust and careful identification of a minimum slate of diseases and outcomes to be studied, depending on factors including mechanism of action, target tissue penetration and predicted immunogenicity. We believe extrapolation of indications is crucial for the biosimilar pathway to reduce drug prices.

IV. The ACR supports the FDA requiring meaningful, distinguishing suffixes to help minimize "inadvertent substitution," particularly for biosimilars that have not been determined to be interchangeable. The requirement of distinguishable names for biosimilars will help rheumatologists and other specialists ensure patients continue to receive breakthrough therapies that are both clinically appropriate and effective, without compromising their health or safety. We have long advocated for explicit guidance about distinct names and suffixes for biosimilars in order to prevent inadvertent or inappropriate substitution, to increase prescriber confidence and uptake of use of biosimilars, and to ensure pharmacovigilance.

V. The ACR supports rigorous trials to ensure safety and efficacy of biosimilars and robust review by experts through the approval process.

VI. Finally, we believe that passage of The Biosimilar User Fee Act II (BsUFA II) and the 21st Century Cures Act were critical steps to ensure the FDA has the resources it needs so that biosimilars are approved and available. The ACR supports addition of specific budget authority for FDA to support biosimilars for the purpose of enhancing industry guidance and drug approvals. We believe that supporting the emerging marketplace at this time will enhance cost savings and subsequent access to treatments.

Thus, while working to reduce regulatory burden, we encourage the FDA to maintain these minimal components of review and oversight necessary to preserve safety and ensure efficacy of biologics and biosimilars. The ACR shares the FDA's goal of ensuring that more affordable treatments reach patients as quickly as possible. We applaud the FDA's measured and thoughtful approach to addressing provider confidence concerns while also prioritizing the safety of our patients. We look forward to being a resource for you and working with you to address current and future guidance regarding biologics and biosimilars. Please contact Kayla L. Amodeo, Ph.D., Director of Regulatory Affairs, at kamodeo@rheumatology.org or (202) 210-1797, if you have questions or if we can be of assistance.

Sincerely,

David I. Daikh, MD, PhD
President, American College of Rheumatology