



AMERICAN COLLEGE
OF RHEUMATOLOGY
EDUCATION • TREATMENT • RESEARCH

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February 16, 2016

The Honorable Mike Shirkey
Michigan State Senate
Chair, Senate Health Policy Committee
320 Farnum Building
Lansing, MI 48933

Dear Senator Shirkey:

On behalf of the American College of Rheumatology (ACR), I would like to provide comments regarding **House Bill 4812** concerning substitution of interchangeable biological products. A crucial component this issue is the timely notification of changes in patients' therapies. **Notification to prescribers of substitutions is necessary for patient safety and must be part of any legislation that Michigan's legislature considers.** Biologics are more sensitive and complex drugs than their chemical counterparts and should not be compared to generic substitution of chemical drugs. Notification to the prescriber must be required to ensure that no interruption occurs in the patient's treatment plan. It is also important that the changes be accurately documented in the patient's medical record and that prescribers maintain the ability to indicate if prescriptions should be dispensed as written.

Rheumatologists are excited to have the opportunity to utilize biosimilars as an emerging treatment option. **However, predicting how a patient will respond to a biosimilar or interchangeable biologic may be challenging, and therefore patient safety is a critical concern.** Biologics are very sensitive to changes in manufacturing, and even minor changes in structure, purity, or other chemical property may impact immunogenicity and the anti-drug immune response in an individual patient. **The slightest variation from the original biologic or change in manufacturing may produce an immune response or other potentially serious side effect, and may increase healthcare costs via emergency room visits or worse, hospitalizations.**

We are aware that the FDA will approve biosimilars that are safe and effective, but as the FDA has yet to establish guidelines on biosimilars, it is encouraging that the Michigan General Assembly is giving consideration to legislation to ensure patient safety through appropriate provider engagement and notification. **Notification should not be viewed as an onerous task but a necessary component in a treatment plan. Potential cost savings for the healthcare system will not be realized if patients have adverse events that require hospitalization.**

The ACR seeks to advance rheumatology through programs of education, research, advocacy and practice support that foster excellence in the care of people with arthritis and rheumatic and musculoskeletal diseases. In accordance with the mission of the organization, the College often provides support and comments in areas related to its mission of advancing rheumatology.

Sincerely,

Joan M. Von Feldt, MD, MSEd
President, American College of Rheumatology