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Coalition of State Rheumatology Organizations

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The Honorable Chuck Schumer
U.S. Senate
322 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Johnson
U.S. House of Representatives
568 Cannon House Office Building
Washington, DC 20515

The Honorable Mitch McConnell
U.S. Senate
317 Russell Senate Office Building
Washington, DC 20510

The Honorable Hakeen Jeffries
U.S. House of Representatives
2433 Rayburn House Office Building
Washington, DC 20515

Re: *Biosimilar Red Tape Elimination Act* (S.2305)

The Coalition of State Rheumatology Organizations (CSRO) would like to share concerns regarding *Biosimilar Red Tape Elimination Act* (S.2305), which aims to increase access to cost effective biosimilars but will have serious unintended consequences. CSRO serves the practicing rheumatologist and is comprised of over 40 state rheumatology societies nationwide with a mission of advocating for excellence in the field of rheumatology and ensuring access to the highest quality of care for the management of rheumatologic and musculoskeletal disease.

Rheumatologic disease is systemic and incurable, but innovations in medicine over the last several decades have enabled rheumatologists to better manage these conditions. With access to the right treatment early in the disease, patients can generally delay or even avoid damage to their bones and joints, as well as reduce reliance on pain medications and other ancillary services, thus improving their quality of life.

The *Biosimilar Red Tape Elimination Act* (S.2305) attempts to improve patient access to more cost effective biosimilars by eliminating the FDA's interchangeability determination process and corresponding switching studies. Instead, the bill establishes the presumption that an approved biosimilar is also interchangeable with the reference biologic without the need for additional studies.

CSRO appreciates and acknowledges the FDA's evolving confidence in the safety and efficacy of biosimilars. We support the FDA's flexibility in demonstrating interchangeability, particularly by permitting the use of comparative analytical and clinical data without requiring additional switching studies, which should improve patient access to lower-cost alternative therapies. However, the broad scope of this bill has far-reaching implications.

When the FDA deems a biosimilar as interchangeable, it allows pharmacists to substitute them for the reference product at the pharmacy without consulting the prescribing doctor. This is similar to pharmacy substitution of generic drugs for brand-name drugs. Except at this point in time the "interchangeable" biosimilars can only be substituted for the reference product not other biosimilars.

It is important that the FDA continues to have unique standards for this designation at this time and not allow all biosimilars to be deemed interchangeable without additional evaluation. That would exacerbate existing challenges posed by payer practices in the form of non-medical switching, step-therapy, prior authorization, and other utilization management tactics. Unique standards for granting interchangeability status, though sometimes ignored by payers, provide a necessary safeguard that helps guide clinical decision-making and protects patients from the potentially harmful effects of inappropriate drug switching.

Further, when patients are switched to a new therapy (different name, different packaging) without prior notice to their physicians, it increases the risk of the nocebo effect—a phenomenon where patients experience negative side effects simply because they believe the medication has been changed and no one told them about it. This can lead to decreased efficacy and increased side effects, further complicating treatment. The FDA recognizes the importance of the physician's role in ensuring appropriate patient care, and a similar emphasis on physician involvement is necessary when it comes to the substitution of complex biologic therapies.

While we support the bill sponsor's efforts to enhance the biosimilar market, it is essential that the FDA retains oversight and maintains rigorous standards for biosimilar interchangeability. Congress must allow the FDA to ensure that the interchangeability designation continues to signify a high level of confidence in a biosimilar's ability to be switched numerous times with the reference product without compromising safety or efficacy.

We appreciate your consideration, and we are happy to further detail our comments to the Committee upon request.

Respectfully,

Gary Feldman, MD, FACR
President
Board of Directors

Madelaine A. Feldman, MD, FACR
VP, Advocacy & Government Affairs
Board of Directors

CC: U.S. Senate Committee on Health, Education, Labor & Pensions
U.S. House Committee on Energy & Commerce
Members of the GOP Doctors Caucus