



## Sound Policy. Quality Care.

November 6, 2024

The Honorable Chuck Schumer  
Majority Leader  
United States Senate  
322 Hart Senate Office Building  
Washington, DC 20510

The Honorable Mike Johnson  
Speaker  
United States House of Representatives  
568 Cannon House Office Building  
Washington, DC 20515

The Honorable Mitch McConnell  
Minority Leader  
United States Senate  
317 Russell Senate Office Building  
Washington, DC 20510

The Honorable Hakeem Jeffries  
Minority Leader  
United States House of Representatives  
2433 Rayburn House Office Building  
Washington, DC 20515

### **RE: The Biosimilar Red Tape Elimination Act (S.2305)**

Dear Majority Leader Schumer, Speaker Johnson, Minority Leader McConnell, and Minority Leader Jeffries:

The Alliance of Specialty Medicine (Alliance) is a coalition of national medical specialty societies representing more than 100,000 physicians and surgeons. We are dedicated to the development of sound health care policy that fosters patient access to the highest quality specialty care. The undersigned member organizations of the Alliance of Specialty Medicine write to express our concerns related to the *Biosimilar Red Tape Elimination Act (S.2305)* regarding the designation of interchangeable biosimilar products. Specifically, we are concerned with the presumption that an approved biosimilar product may be deemed interchangeable with the reference biologic product without requiring additional switching studies by the biopharmaceutical manufacturer.

The Alliance has closely engaged in the development of state policies related to biosimilar prescribing and substitution, which are currently in effect in 35 states. We are acutely monitoring the safety considerations that should be considered as more biosimilar versions of existing biologic medicines become treatment options for our patients. Many physician specialties, including retina, gastroenterology, eye surgery, rheumatology and plastic surgery, work directly with biologic products, which are complex molecules. Depending on the patient's unique biology, disease progression, and other clinical factors, one biologic or biosimilar therapy may be clinically indicated, recommended and prescribed over another.

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American Academy of Facial Plastic and Reconstructive Surgery • American Academy of Otolaryngology-Head and Neck Surgery  
American Association of Neurological Surgeons • American College of Mohs Surgery • American College of Osteopathic Surgeons  
American Gastroenterological Association • American Society for Dermatologic Surgery Association  
American Society of Cataract & Refractive Surgery • American Society of Echocardiography • American Society of Plastic Surgeons  
American Society of Retina Specialists • American Urological Association • Coalition of State Rheumatology Organizations  
Congress of Neurological Surgeons • National Association of Spine Specialists • Society of Interventional Radiology

Under the *Biologics Price Competition and Innovation Act*, the U.S. Food & Drug Administration (FDA) established specific requirements that allow biosimilars to be considered interchangeable. Interchangeable biosimilars generally undergo additional switching studies that prove there is no change in safety or efficacy of the biosimilar and the reference biologic product. During these switching studies, the patient must alternate between the reference biologic and the biosimilar product multiple times over a designated period. These studies are critical in ensuring the safety, efficacy and quality of interchangeable biosimilar products with their reference drugs.

We are concerned that the *Biosimilar Red Tape Elimination Act (S.2305)* would no longer require these switching studies, which have been an integral part of physician confidence and understanding of interchangeable biosimilar products. It's important to note that the same biologic product may be used for several different disease states, and switching studies help build confidence that the biosimilar will respond interchangeably with the biologic for each disease state. Without these switching studies, physicians cannot be certain how patients will respond to the biosimilar medication.

Furthermore, we are cautiously concerned that health insurance plans and their pharmacy benefit managers may use this Act as a vehicle to exacerbate existing step therapy protocols. A medication step-therapy protocol establishes a specific sequence in which a group health plan or a health insurance issuer covers prescription drugs. Step-therapy protocols may require patients to try and fail an insurer preferred medication before being covered by the physician-prescribed medication. Many insurers have instituted this practice to help control the costs of expensive medications, like biologics. Once a biosimilar is deemed interchangeable, health plans may indiscriminately switch patients back and forth between medications depending on whichever drug has formulary preference and delivers the most lucrative rebate.

While this practice may initially reduce insurer costs, it can have devastating health consequences for patients and ultimately lead to more expensive health care costs in the long run. Patients who are denied first coverage of medications recommended by their physicians can end up with poor health outcomes due to adverse health events, which can lead to costly hospitalizations. In the era of personalized medicine, patients with chronic diseases, such as inflammatory bowel disease, rheumatoid arthritis, cancer, psoriasis or age-related macular degeneration may respond differently to various medications used to treat these diseases. We caution Congress to be mindful of these PBM manipulations at the expense of patient access.

Advances in medical treatment have transformed the way we fight certain diseases. Biologics, and biosimilars, will continue to be an important treatment option for patients. However, we urge you to consider the underlying impact of the *Biosimilar Red Tape Elimination Act (S.2305)* before advancing this legislation.

Thank you for your attention to this important issue.

Sincerely,

The Alliance of Specialty Medicine

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