Alliance of Specialty Medicine

25TH ANNIVERSARY

Sound Policy. Quality Care.

August 28, 2025

The Honorable Bill Cassidy, MD
Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC, 20510

The Honorable Bernie Sanders
Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC, 20510

RE: The Biosimilar Red Tape Elimination Act (S.1954)

Dear Sens. Cassidy and Sanders:

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 regarding the *Biosimilar Red Tape Elimination Act (S.1954)*, which was reintroduced and referred to the Senate Committee on Health, Education, Labor, and Pensions.

This legislation addresses the designation of interchangeable biosimilar products. Unlike generic drugs, which are small molecules, reference products and their biosimilars are derived from living organisms, making the structure of these drugs more complex and introducing more variability in the manufacturing of these products. Not all biosimilars are designated by the U.S. Food & Drug Administration (FDA) as interchangeable products, which must meet additional requirements before they can be granted this designation by the FDA. The Alliance is 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.

All fifty states currently have laws specific to the interchangeability of biological products, which the Alliance has closely engaged in the development of state policies related to biosimilar prescribing and substitution. We appreciate that S. 1954 would not supersede existing state laws that require provider

consent[1] before a pharmacist can automatically substitute an interchangeable biosimilar for the reference biologic or allow the prescriber to prevent automatic substitution with an interchangeable biosimilar on the patient's prescription.

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.

Under the *Biologics Price Competition and Innovation Act*, the 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.1954) 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 (PBM) 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 plan covers prescription drugs. Step-therapy protocols may require patients to try and fail a health plan preferred medication before being covered by the physician-prescribed medication. Many health plans 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 health plan 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.

[1] State laws in Alabama, Indiana, South Carolina, Washington and Puerto Rico require the pharmacist to obtain explicit prescriber authorization before dispensing an interchangeable biosimilar.

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.1954) before advancing this legislation.

Thank you for your attention to this important issue.

Sincerely,

American Academy of Facial Plastic and Reconstructive Surgery
American Association of Neurological Surgeons
American Gastroenterological Association
American Society of Cataract & Refractive Surgery
American Society of Plastic Surgeons
American Society of Retina Specialists
American Urological Association
Coalition of State Rheumatology Organizations
Congress of Neurological Surgeons

CC: U.S. Senate Committee on Health, Education, Labor & Pensions
U.S. House Committee on Energy & Commerce