



June 12, 2026

The Honorable Bill Cassidy  
Chairman  
Senate Committee on Health,  
Education, Labor and Pensions  
455 Dirksen Senate Office Building  
Washington, D.C. 20510

The Honorable Bernie Sanders  
Ranking Member  
Senate Committee on Health,  
Education, Labor and Pensions  
332 Dirksen Senate Office Building  
Washington, D.C. 20510

**Re: Opposition to Inclusion of the Biosimilar Red Tape Elimination Act (S. 1954) in Senate Health Legislation**

Dear Chairman Cassidy, Ranking Member Sanders, and Members of the Committee:

On behalf of the Alliance for Safe Biologic Medicines (ASBM), we respectfully urge you to exclude the Biosimilar Red Tape Elimination Act (BRTEA, S. 1954) from any Senate health package considered by the Committee on Health, Education, Labor and Pensions.

ASBM supports patient access to safe and affordable biologic medicines. We support biosimilar competition as an important tool to expand treatment options and reduce costs. BRTEA, however, would not meaningfully advance those goals. Instead, it would remove a scientific determination currently entrusted to the Food and Drug Administration (FDA), undermine the balanced framework governing biosimilar substitution in all fifty states, reduce physician and patient confidence in biosimilars as a class, and dramatically expand the power of insurers and pharmacy benefit managers (PBMs) to non-medically switch patients among biologic medicines.

Most importantly, the legislation is premised on a misunderstanding of both existing law and the scientific distinction between biosimilars and generic drugs.

**BRTEA Is Unnecessary; FDA Already Has Discretion in Approving Interchangeables**

As you are aware, “interchangeable” biosimilars are those which under state laws can be substituted at the pharmacy level by third parties such as insurers or pharmacy benefit managers (PBMs) without physician involvement; the sponsors of these biosimilars have demonstrated to the FDA, through data, that substitution will not negatively impact safety or treatment efficacy.

Proponents of BRTEA frequently argue that current FDA requirements for interchangeability are duplicative, burdensome, or dependent upon mandatory switching studies. This is inaccurate. FDA has never required switching studies by default to approve a biosimilar as interchangeable. Rather, the agency evaluates each product individually and determines what evidence is necessary to satisfy the statutory standard that a biosimilar may be substituted without compromising safety or effectiveness.

FDA already possesses the authority that BRTEA proponents claim it lacks. The agency may rely on analytical similarity, comparative pharmacokinetic and pharmacodynamic data, immunogenicity

evidence, and the totality of evidence when determining whether a biosimilar qualifies as interchangeable. FDA has repeatedly exercised this flexibility. Of the first 27 interchangeable biosimilars approved, 12 were approved without switching studies. The existing framework is working: it permits scientific flexibility while preserving FDA's authority to determine, product by product, whether the evidence supports safe substitution.

BRTEA is therefore unnecessary. It does not eliminate a requirement that currently exists in law or provide FDA with authority it lacks. Instead, it removes FDA's scientific discretion and replaces it with a blanket statutory declaration that every biosimilar automatically receives interchangeable status.

### **Biosimilars Are Safe and Effective—But Not Generics**

The most consequential flaw in BRTEA is that it inappropriately applies a generic-drug substitution framework to products that major regulators around the world have consistently recognized are not generics.

FDA's own educational materials state plainly that "biosimilars are not generics—and important differences exist between them." The European Medicines Agency likewise explains that "a biosimilar is not regarded as a generic of a biological medicine" because the complexity and natural variability of biologic medicines do not permit exact replication. Regulators including Brazil's ANVISA, Health Canada, Australia's Therapeutic Goods Administration, Japan's PMDA, and the World Health Organization have made similar statements recognizing this basic scientific distinction.

Congress recognized that distinction when it enacted the Biologics Price Competition and Innovation Act. Rather than treating biologics as small-molecule drugs, Congress created a distinct approval pathway and a distinct standard for interchangeability. States then spent years modernizing pharmacy practice laws to permit third-party substitution of biosimilars. Those reforms were supported by physicians, pharmacists, and patient organizations because they included a critical safeguard: **automatic substitution by someone other than the physician would be permitted only when FDA separately determined that switching would not affect safety or efficacy.**

BRTEA would remove this safeguard and upend the agreement upon which all fifty state biosimilar substitution laws were built.

### **Physicians Oppose BRTEA's "Genericization" Approach; Support Maintaining Current FDA Approval System**

BRTEA's "genericization" approach is strongly opposed by physicians and would likely undermine confidence in biosimilars. The success of biosimilars in the United States has been built on confidence in FDA's rigorous, science-based review process. Physicians increasingly prescribe biosimilars because they trust the integrity of that framework.

Treatment plans are not one-size-fits-all. Many patients spend years finding a biologic therapy that works for them, and physicians are understandably reluctant to switch a stable patient unnecessarily. BRTEA would allow PBMs and insurers to force non-medical switches even when FDA has not

determined that switching would have no impact on safety or efficacy. This de facto nationwide forced-substitution scheme could jeopardize treatment stability for millions of Americans.

Recent survey<sup>1</sup> data demonstrate that physicians overwhelmingly support maintaining FDA's current approach in which an interchangeable biosimilar must undergo individual evaluations to determine the impacts of switching on patient safety and efficacy:

- 87% of physicians prefer switching patients to a biosimilar only if it has been **rigorously evaluated for its impact on safety and efficacy when switched from an originator biologic**.
- 88% support the FDA requiring interchangeable biosimilars to undergo individual evaluations to determine the impacts of switching on patient safety and efficacy.
- **Only 11% of respondents are in favor of deeming all biosimilars interchangeable without these evaluations, as BRTEA would do.**

These findings show that physician confidence comes not from reducing FDA review, but from knowing that FDA scientists continue to evaluate each product according to established scientific standards. Congress should be cautious about altering a framework that has successfully fostered both physician confidence and biosimilar utilization.

### **BRTEA Does Not Align the U.S. with Europe, It Creates an Unprecedented, Generic-Style Forced-Substitution System**

BRTEA is often justified as a way to align U.S. policy with Europe. That claim is misleading. While European regulators permit physician-directed use of biosimilars when prescribing, pharmacy-level substitution by third parties remains rare in Europe and is frequently prohibited in many advanced European countries. Thus, BRTEA would not harmonize U.S. policy with Europe; it would move the United States toward a broader automatic-substitution model than exists across much of Europe.

By automatically deeming all biosimilars interchangeable, Congress would impose a generic-style, third-party automatic substitution model nationwide. Products that Congress, FDA, physicians, pharmacists, and patient advocates have long recognized are not generics would suddenly be treated as if they were. The practical effect would be immediate: insurers, PBMs, and other third parties would gain authority to non-medically switch patients among biologics based on profitability, formulary preferences, rebate arrangements, or other financial considerations, regardless of whether FDA had separately evaluated the evidence supporting safe substitution.

As you know from your longstanding oversight of the prescription drug marketplace, PBMs and insurers already exercise substantial control over patient access through formularies, rebate arrangements, utilization management, and other mechanisms. Congress has spent years examining how these practices can distort treatment decisions and place financial considerations ahead of individualized patient care.

---

<sup>1</sup> <https://safebiologics.org/asbm-physician-survey-on-interchangeable-biosimilars-finds-support-for-maintaining-current-standards/>

## **Savings From Forced Switching Accrue to PBMs, Not Patients**

Senator Cassidy, you have rightly and repeatedly expressed concern that discounts, rebates, and other savings negotiated within the drug supply chain do not consistently translate into lower out-of-pocket costs or improved access for patients. If PBMs have not consistently passed existing savings through to patients, Congress should be skeptical of claims that granting PBMs broader authority to force-switch patients will automatically benefit patients. BRTEA expands PBM power but contains no mechanism requiring that any resulting savings be shared with patients.

BRTEA would hand PBMs and insurers a significant new tool to control treatment decisions based on economic considerations. It would expand the power of the very market actors whose influence over prescribing and patient access has become the subject of growing bipartisan concern. This is counter to your efforts to improve accountability and transparency in the marketplace.

## **BRTEA Does Little to Address the Actual Barriers to Biosimilar Uptake**

The U.S. biosimilar market is already demonstrating robust competition. Humira provides a clear example: more than ten biosimilars have entered the market, several have received interchangeable status, and competition has driven prices dramatically downward. Yet market access continues to be determined primarily by formulary placement, rebate arrangements, and PBM contracting practices—not by FDA’s interchangeability standards.

Lowering or eliminating FDA’s evidence-based interchangeability determination will not change those incentives. PBMs will continue to favor the products that best fit their economic arrangements. **The principal effect of BRTEA would be to expand third-party switching authority while doing little to address the market dynamics that actually govern biosimilar access and putting patient health at risk in favor of PBM profits.**

## **Conclusion**

As a physician and longtime advocate for evidence-based health policy, you have consistently emphasized the importance of allowing scientific expertise—not politics or commercial interests—to guide healthcare decision-making. The current biosimilar framework reflects that principle. It gives FDA flexibility to evaluate evidence case by case, allows interchangeable biosimilars to be approved without switching studies when justified by the science, preserves physician confidence, and maintains safeguards against inappropriate third-party substitution.

BRTEA would not strengthen that framework. It would remove FDA discretion, genericize products that regulators universally acknowledge are not generics, undermine the foundation of state substitution laws, and dramatically expand the authority of insurers and PBMs to non-medically switch patients among biologic therapies.

For these reasons, we respectfully urge you to oppose inclusion of the Biosimilar Red Tape Elimination Act in any Senate health package and to preserve FDA’s evidence-based authority to evaluate interchangeability.

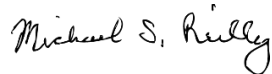
Thank you for your consideration.

Sincerely,

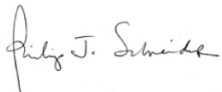
Sincerely,



Ralph McKibbin, MD FACP FACG AGAF  
Chairman



Michael Reilly, Esq.  
Executive Director, Alliance for Safe Biologic Medicines



Philip J Schneider MS FASHP FFIP  
Advisory Board Chair  
Alliance for Safe Biologic Medicines

**ASBM Steering Committee Members:**

Alliance for Patient Access  
American Academy of Dermatology  
Autoimmune Association  
Association of Clinical Research Organizations  
Colon Cancer Alliance  
Global Colon Cancer Association  
Global Healthy Living Foundation  
Health HIV  
International Cancer Advocacy Network  
Kidney Cancer Association  
Lupus and Allied Diseases Association, Inc.  
National Hispanic Medical Association  
National Psoriasis Foundation  
ZeroCancer

cc: Senate Committee on Health, Education, Labor and Pensions (HELP) Members