Congress is about to let insurance companies switch your medicine — without your doctor's OK, and without the science to back it up.

The Biosimilar Red Tape Elimination Act (BRTEA, S. 1954) would declare that every biosimilar, upon approval, is automatically "interchangeable" — meaning insurers and pharmacy benefit managers (PBMs) could substitute it for your prescribed medicine at the pharmacy counter, without your physician's involvement. No more case-by-case FDA determination of whether that switching would reduce safety or efficacy.

> "While for some biologics we know [switching] is safe, for others we might not. That's why the FDA's role in determining when more testing is needed is critically important."
>
> *- Aaron Kesselheim, MD JD MPH*
> *Professor of Medicine,*
> *Harvard Medical School*
> *Congressional testimony*
> *April 8, 2025*

WHAT BRTEA IGNORES: BASIC SCIENCE

Biosimilars are not generics. Every major regulator in the world agrees:

- **FDA:** "Biosimilars are not generics — and important differences exist between them."
- **European Medicines Agency:** "A biosimilar is not regarded as a generic of a biological medicine."
- **Health Canada**, Australia's **TGA**, Japan's **PMDA**, Brazil's **ANVISA**, and the **World Health Organization** all say the same.

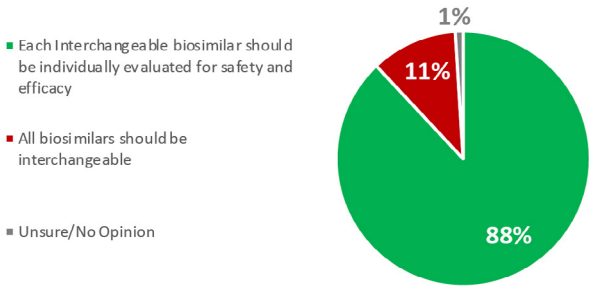
Today, FDA evaluates each biosimilar individually — some qualify for interchangeable status, some don't yet have the evidence to support it.

BRTEA collapses that distinction: biosimilars FDA has found safe to switch and biosimilars FDA has not confirmed are safe to switch would be treated identically — all deemed "interchangeable" on approval day.

U.S. PHYSICIANS OVERWHELMINGLY OPPOSE BRTEA

Doctors know treatment isn't one-size-fits-all. Many patients spend years finding the specific biologic that stabilizes their arthritis, Crohn's, psoriasis, or cancer. A forced switch driven by insurer or pharmacy profitability instead of a patient's chart can undo that hard-won stability.

- **A recent survey[1] of 270 U.S. physicians revealed that only 11% support treating all biosimilars as generics.**
- **88% want to FDA to continue requiring product-by-product evaluation of switching safety** to support safe third-party switching.
- **58% of U.S. physicians strongly oppose[2] biosimilar substitution by anyone other than the prescriber** for non-medical reasons such as cost or profitability.



BRTEA WOULD GIVE BIOSIMILARS A LOWER INTERCHANGE STANDARD THAN GENERICS

Even simple, chemically-identical generic drugs don't get automatic pharmacy-substitution rights.

State substitution laws are built around FDA's **therapeutic equivalence** rating: a pharmacist can't swap a generic for the brand product without the prescriber's sign-off unless FDA has made that determination. Between 1982 and 2025, FDA reviewed 18 individual generic drug products — including common medicines like rivaroxaban, carbamazepine, and tacrolimus —that lacked the evidence to deem them safe for automatic switching (FDA's "BX" designation).

These generics remain approved, safe, and effective. They simply can't be substituted at the pharmacy without a doctor's authorization — because FDA said the proof wasn't there.

Under BRTEA, biosimilars could never receive that same "not yet proven" status. Every biosimilar, on approval, would be automatically deemed interchangeable and substitutable — no FDA review of switching safety, no way to withhold the designation even when the evidence doesn't support it.

IT'S NOT "ALIGNING WITH EUROPE"

Supporters of BRTEA misleadingly say it aligns U.S. policy with that of the European Union. This is due to the term "interchangeable" meaning something entirely different in Europe. There, it refers to the ability of *physicians to choose a biosimilar when prescribing*- not shifting those decisions to health plans or pharmacists, as BRTEA would mandate.

Like their U.S. counterparts, **European physicians (73%) strongly** oppose[3] **pharmacy substitution of biosimilars.**

In Europe, pharmacy-level substitution without a doctor's involvement is rare, — and banned outright in many countries.

BRTEA would make the U.S. a global outlier, handing insurers and pharmacies substitution power that no advanced regulatory system currently permits.

BRTEA doesn't cut "red tape" — it cuts FDA out of a safety decision that belongs with scientists, not politicians.

It also cuts physicians and patients out of treatment decisions and hands them solely to insurance companies and PBMs.

Tell Congress: Listen to physicians, the regulatory community, and basic science. Biosimilars aren't generics- don't pretend they are.

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