STOP the "Genericization" of Biosimilars

Under pressure from insurers, PBMs, and manufacturer trade groups, FDA is moving to strip away the evidence required to ensure that patients will remain stable after switching to a biosimilar—and opening the door to mass, profit-driven switching of stable patients.

BIOSIMILARS: SAFE, EFFECTIVE — BUT NOT GENERICS

Biosimilars are lower-cost versions of biologic medicines used to treat conditions such as rheumatoid arthritis, psoriasis, and cancer. **Unlike generic copies of traditional chemical drugs (typically pills), biosimilars are not identical to the medicines they reference.** For this reason, an insurance company or pharmacy benefit manager (PBM) may not automatically substitute a biosimilar without prior physician approval, which is commonly accepted with generics.

Treatment plans are not one-size-fits-all. Patients often try many safe and effective medicines before finding one that works best for them. For this reason, physicians are reluctant to switch a stable patient unnecessarily.

Under state law, only biosimilars that provide additional data to FDA—proving a patient can switch back and forth with no change in safety or efficacy—may be substituted at the pharmacy level. These are called **interchangeable biosimilars**.

State medical societies and patient groups agreed to permit biosimilar substitution in their states only with these limits. Weakening or eliminating these patient protections would betray the commitments policymakers made to physicians and patients.

THE WORLD'S REGULATORS AGREE: BIOSIMILARS ≠ GENERICS

- **FDA:** "Biosimilars are not generics—and important differences exist between them."
- **WHO:** "The generic approach is not suitable for the licensing of biosimilars."
- **EMA:** "a biosimilar is not regarded as a generic of a biological medicine."
- **Health Canada:** "unlike generic drugs, biosimilars can never be identical to their reference biologic drug."
- **TGA:** "a biosimilar is not a generic biological medicine."
- **PMDA:** "the approach used for generic chemical drugs is not applicable because the active ingredient of a biosimilar- cannot be completely identical to that of the reference product"
- **ANVISA:** "a biosimilar is not an exact replica of the reference-and, hence, cannot be considered as generic."

GENERICIZING BIOSIMILARS?

In a keynote address at a September 19, 2025 FDA workshop, George Tidmarsh, Director of the FDA's Center for Drug Evaluation and Research (CDER), announced: **"We are ready for the 'genericization' of biosimilars."** As the *Pink Sheet* reported[1]: "In my mind, [the] analytical revolution brings biosimilars very, very close to generic drugs. And in the generic drug world, of course, we just characterize the molecule."

Tidmarsh calls the current biosimilar testing framework "quite burdensome." But the comparison to generics contradicts decades of FDA and EMA statements affirming that biologics, including biosimilars, are not small-molecule drugs and cannot be "fully characterized".

LOWER STANDARDS = HIGHER INSURER/PBM PROFITS

While physicians choose medicines based on clinical data and patient history, insurers and **PBMs choose based on economic factors—typically selecting the product that offers the largest profit after manufacturer rebates and other discounts.**

If FDA lowers approval standards for interchangeable biosimilars—or simply declares all biosimilars interchangeable—**it would give insurers and PBMs even greater power to switch stable patients to the most profitable product, now unconstrained by current clinical safety and efficacy guardrails.**

But it would not address financial incentives that determine PBM formulary design.

WHY ANALYTICS ALONE AREN'T SUFFICIENT

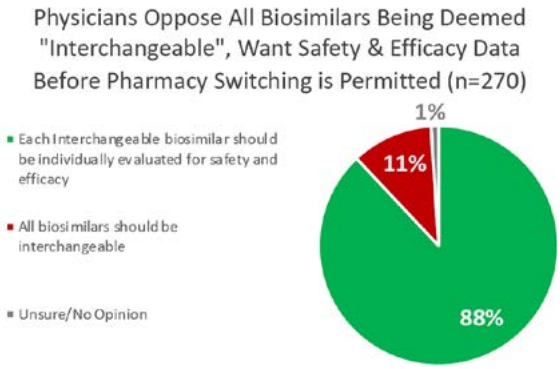
At its workshop, FDA acknowledged that analytics can't capture many real-world variables that affect safe biosimilar substitution. Device design, delivery methods, and use-environment differences lie "outside the reach of analytics alone." Even with state-of-the-art characterization, laboratory data cannot account for patient-specific factors such as comorbidities, concomitant therapies, prior treatment failures, or individual immunogenicity risks—all of which determine real-world safety and effectiveness. This is why the interchangeability statute **requires demonstrating the same clinical result "in any given patient."**

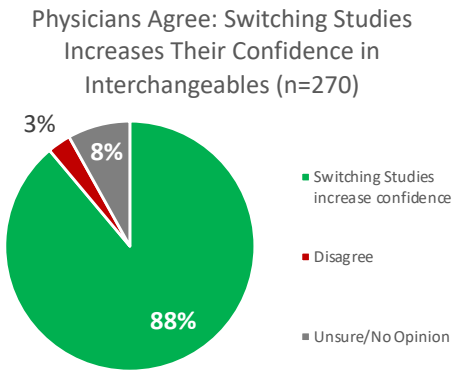
Moving from an "analytics + targeted clinical confirmation" model to an "analytics-only" approach may speed approvals but risks reducing prescriber confidence and jeopardizing treatment stability when device, human-factor, or environmental variables differ.

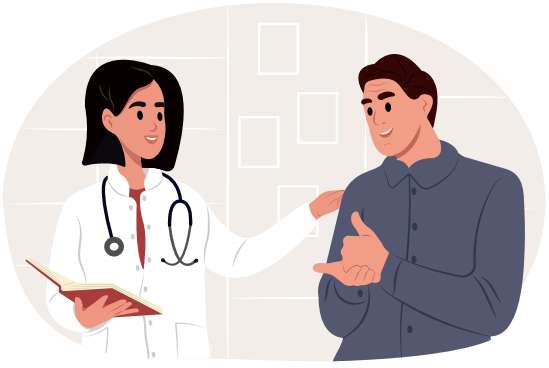
PHYSICIANS STRONGLY OPPOSE "GENERICIZING" BIOSIMILARS

- **A recent survey[2] of 270 U.S. physicians revealed that only 11% support treating all biosimilars as generics.**
- **88% want to retain the current case-by-case interchangeability standard** requiring additional data to support safe third-party switching.
- **58% of U.S. physicians strongly oppose[3] biosimilar substitution by anyone other than the prescriber** for non-medical reasons such as cost or profitability.
- Most physicians say they are **more comfortable** prescribing an interchangeable (57%) and with one being substituted (59%) precisely **because the manufacturer provided the additional switching data** that FDA is now being pressured to eliminate.
- Like their U.S. counterparts, **European physicians (73%) strongly oppose[4] pharmacy substitution of biosimilars.** Unsurprisingly, automatic substitution is rare—and often banned—in advanced European countries.

Weakening FDA standards to permit mass pharmacy substitution of all biosimilars rejects scientific fact, international norms, and physician consensus. **It would jeopardize treatment stability for millions of U.S. patients and erode hard-earned physician and patient trust in these medications.**







DATA DRIVES PHYSICIAN & PATIENT CONFIDENCE IN BIOSIMILARS

Biosimilars are not generics. **FDA should maintain the current, evidence-based interchangeability framework that gives physicians and patients confidence in biosimilar substitution.** FDA should reject any "all-interchangeable" approach that would create a generic-style automatic substitution model.

FDA's standards don't block patient access—PBM formularies do. Policymakers should instead address PBM formulary and rebate practices, the true access barrier.

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