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June 16, 2026

VIA Electronic Mail

The Honorable Bill Cassidy, M.D.
Chairman
U.S. Senate Committee on Health, Education, Labor & Pensions
455 Dirksen Senate Office Building
Washington, DC 20510

Attn: Ms. Kathryn Handler and the Committee's well-respected staff

RE: The Biosimilar Red Tape Elimination Act (S. 1954) — Request to Preserve State Biosimilar Substitution Frameworks Ahead of the June 17 Markup

Dear Chairman Cassidy, Ms. Handler, and the Committee's well-respected staff:

The Community Access National Network (CANN) respectfully writes in advance of the Committee's scheduled markup of the Biosimilar Red Tape Elimination Act (S. 1954) on June 17, 2026.

ABOUT CANN: The Community Access National Network (CANN) is a 501(c)(3) national nonprofit organization (formerly incorporated under the "Ryan White CARE Act Title II Community AIDS National Network") focusing on public policy issues relating to HIV/AIDS and viral hepatitis. CANN's mission is to define, promote, and improve access to healthcare services and support for people living with HIV/AIDS and/or viral hepatitis through advocacy, education, and networking. CANN's coalition-based work is done on behalf of the patient advocacy groups, pharmaceutical partners, and government agencies.

We write because the bill, as drafted, creates a structural risk to a body of state law that legislatures across the country have enacted to protect patients, and because a narrow, technical fix would resolve that risk and allow CANN to support the legislation.

As currently written, we must oppose S. 1954. With a rule-of-construction provision preserving existing state frameworks, we would be more likely to support it. Priorities in legislative construction must recognize pre-existing dynamics, while preserving patient access to the products deemed best suited for a patient's individual circumstances, as determined by the patient and their provider.

What the bill does to the federal anchor for state law

S. 1954 does not merely streamline interchangeability. It amends Section 351(k) of the Public Health Service Act to strike the substantive interchangeability standard in paragraph (4) (the showing that a product produces the same clinical result in any given patient and presents no greater risk on switching or alternating) and replaces it with automatic deeming: every product licensed under the 351(k) pathway is "deemed to be interchangeable" with its reference product as of the transition date 60 days after enactment, or upon licensure thereafter.

The word "interchangeable" survives in the U.S. Code; the FDA finding behind it does not. This matters because every state and the District of Columbia has enacted a pharmacy substitution law triggered by, and referencing, the federal "interchangeable" designation. Those frameworks were written by legislatures that understood "interchangeable" to mean a product the FDA had affirmatively evaluated and found substitutable. S. 1954 would leave those statutes pointing at a federal term whose meaning has changed beneath them, attaching automatically to every biosimilar rather than to products that cleared an FDA interchangeability finding.

This is not a hypothetical concern about a single statute. As a 2023 review documented, most states permit pharmacist substitution of an interchangeable biosimilar without prescriber authorization, but layer on protections calibrated to the federal designation: many condition substitution on the biosimilar costing less than the reference product; nearly all require notice to the prescriber, the patient, or both; and recordkeeping, communication timeframes, and opt-out provisions vary considerably by state. The result is legal uncertainty across all 51 jurisdictions, and the bill does not resolve it.

Where automatic deeming threatens access and competition: the PBM problem

Interchangeability status, by itself, does nothing for a patient if the lower-cost product is not on the formulary. The mechanism that determines whether biosimilar competition reaches patients is formulary design, controlled by pharmacy benefit managers (PBMs) whose financial incentives often run against the lowest-net-cost option. A 2025 study found that state substitution-laws were a significant determinant of whether patients actually received the first interchangeable insulin biosimilar; evidence that the designation alone does not drive access. Following that product's launch, none of the three largest PBMs placed the low-list-price version in a preferred formulary position. Because large PBMs are commonly compensated through rebates and fees calculated on list price, they are incentivized to prefer higher-list-price products with larger rebates over lower-net-cost competitors. Interchangeability designation did not overcome that incentive; formulary control did.

If S. 1954 floods the market by deeming *all* biosimilars interchangeable, it will strip states of the legal clarity they need to police these exact anti-competitive PBM steering practices at the pharmacy counter.

State frameworks, at their best, protect both patients and genuine competition, by conditioning formulary access on a real cost benefit to the patient and orienting the system toward net acquisition cost rather than list price, rebates, or other metrics PBMs can manipulate. Federal legislation should reinforce that orientation, not displace it. **The protections worth preserving are these: that lower-cost biosimilars actually reach**

formularies; that formulary priority track net acquisition cost rather than wholesale acquisition cost (WAC) or rebate-driven incentives; and that automatic substitution cannot become a tool for PBMs to steer patients toward higher-cost, affiliate-owned products.

We respectfully ask the Committee to address the following before or during markup:

1. **How does the bill protect the federal "interchangeable" definition that biosimilar substitution laws in every state and the District of Columbia rely upon?** If the substantive standard in 351(k)(4) is replaced with automatic deeming, what is the intended effect on state statutes that reference the federal designation, and how will pharmacists and prescribers know which products (and which state-law obligations) apply?

2. **Has the Committee considered the legislation's impact on existing state biosimilar substitution frameworks,** and whether additional language is needed to preserve them?

Our request

We urge the Committee to add a rule-of-construction provision making explicit that nothing in the Act displaces, preempts, or alters the authority of states to regulate the substitution of biological products, including state requirements governing patient consent, prescriber notification, recordkeeping, cost conditions, and formulary protections. The concept is narrow: preserve the state frameworks that already exist, regardless of how the federal interchangeability standard evolves by statute or by guidance, while protecting the patient and competition safeguards that states have spent a decade building.

We appreciate the Committee's work on this legislation and welcome the opportunity to provide additional information or technical input.

Respectfully submitted,

Travis J. Roppolo
Managing Director
Community Access National Network (CANN)

On behalf of
Jen Laws
President & CEO
Community Access National Network