November 10, 2026

The Honorable Mike Johnson
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

The Honorable Hakeem Jeffries
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable John Thune
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Chuck Schumer
Minority Leader
United States Senate
Washington, DC 20510

RE: Biosimilar Red Tape Elimination Act (H.R. 5526/S. 1954) and Expedited Access to Biosimilars Act (H.R. 9661/S. 1414) — Request for Floor Consideration

Dear Speaker Johnson, Minority Leader Jeffries, Majority Leader Thune, and Minority Leader Schumer:

We write to urge immediate floor consideration of two bipartisan bills -- the Expedited Access to Biosimilars Act (H.R. 9661/S. 1414) and the Biosimilar Red Tape Elimination Act (H.R. 5526/S. 1954). These measures have advanced through the committees of jurisdiction with strong bipartisan support and are ready for final passage. Together, they would lower prescription drug costs by removing outdated barriers to biosimilar competition.

Specifically, H.R. 9661/S. 1414 clarifies that comparative efficacy and other additional clinical studies are not automatically required when existing analytical and pharmacokinetic evidence is sufficient. The legislation preserves the Food and Drug Administration's (FDA) authority to require studies when scientifically warranted and requires early notice to manufacturers when additional studies are needed. This would reduce unnecessary costs and delays without weakening safety standards, while preserving innovators' intellectual property rights.

Likewise, H.R. 5526/S. 1954 would facilitate greater access to biosimilars as affordable drug therapy options for millions of patients by eliminating a regulatory obstacle regarding interchangeability. Every biosimilar already must show no clinically meaningful differences in safety, purity, or potency. The separate "interchangeable" designation adds cost and confusion, suppresses pharmacist substitution, and has no counterpart in other major regulatory systems. Recent actions by the FDA support both reforms. The agency has concluded that switching studies generally are not needed, recommended that comparative efficacy studies be the exception rather than the rule, and streamlined pharmacokinetic testing.[1] But guidance is not law, and the statutory interchangeability distinction can be removed only by Congress. The FDA has done what it can; Congress should finish the job.

[1] U.S. Food and Drug Administration. (2025, October). *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies: Guidance for Industry* (Draft guidance). U.S. Department of Health and Human Services.

These bills would make the FDA's science-based approach durable, strengthen competition, and deliver lower prices without mandates or price controls. Biosimilars typically cost 15 to 35 percent less than their reference products and have already generated more than $56 billion in savings.[2] Congress can expand those savings by eliminating unnecessary studies and the artificial two-tier approval system that restricts pharmacist substitution.

We respectfully urge you to bring both bills to the floor of the House and Senate and send them to the President's desk this year to help drive more competition in prescription drugs, resulting in better access by employers and patients to more affordable drug therapies.

Respectfully,

Alliance of Community Health Plans
American Behcet's Disease Association
Beta Cell Action
The Biosimilars Forum
Caregiver Action Network
The Coalition to Protect and Promote Association Health Plans
Corporate Health Care Coalition
Doctors for America
Economic Alliance for Michigan
The ERISA Industry Committee
Families USA
Foundation for Sarcoidosis Research
Gateway Business Health Coalition
Get the Medications Right Institute
Houston Business Coalition on Health
Lehigh Valley Business Coalition on Healthcare
Michigan Health Purchasers Coalition
National Alliance of Healthcare Purchaser Coalitions
National Consumers League
NETWORK Lobby for Catholic Social Justice
Patients Rising
RetireSafe
Rhode Island Business Grop on Health
Salud y Farmacos
Self-Insurance Institute of America
State of West Virginia Rheumatology Society
Texas Business Group on Health
U.S. PIRG
Washington Health Alliance

[2] Association for Accessible Medicines. Sept.3, 2025. 2025 U.S. Generic & Biosimilar Medicines Savings Report.