Your Generics & Biosimilars Industry

BIOSIMILARS COUNCIL™
A DIVISION OF AAM

November 5, 2026

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

The Honorable John Thune
Senate Majority Leader
U.S. Senate
Washington, DC 20510

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

The Honorable Chuck Schumer
Senate Democratic Leader
U.S. Senate
Washington, DC 20510

Dear Speaker Johnson, Leader Thune, Leader Jefrries, and Leader Schumer:

On behalf of the manufacturers who supply generic and biosimilar medicines for America's patients, I would like to thank you for the work that the 119th Congress has invested to maintain and expand patient access to high-quality medicines.

Access to biosimilar and generic medicines has never been more critical. These lower-priced medicines drive vital competition and lower patient out-of-pocket costs. They are central to ensuring patients receive the medicines they need.

As the 119th Congress completes its work, we ask members to consider bipartisan solutions that will reduce spending on and increase patient access to prescription medicines. The Association for Accessible Medicines (AAM) and its Biosimilars Council encourage Congress to ensure the long-term sustainability of generic and biosimilar medicines and safeguard patient access to these lower-cost solutions through the following proposals:

- **Encourage Patient Adoption of Biosimilars by removing the arbitrary distinction between "interchangeable biologics" and "biosimilars."** Consistent with the FDA's recommendation, Congress should deem all biosimilars to be interchangeable unless determined otherwise by the FDA and remove the distinction between biosimilar and interchangeable biologics. The *Biosimilars Red Tape Elimination Act* (H.R 5526 / S. 1954), which was advanced on a bipartisan basis by both the House Energy and Commerce and Senate HELP Committees, would generate meaningful savings for taxpayers and patients while removing an avenue for brand misinformation.

- **Codify FDA's Science-Based Approach to Biosimilars.** To expand patient access to lower-cost medicines, Congress should codify FDA's science-based biosimilar development pathway that reduces unnecessary development costs and risks. The *Expedited Access to*

Biosimilars Act (H.R. 9661 / S. 1414), which was advanced on a bipartisan basis by both the House Energy and Commerce and Senate HELP Committees, would encourage continued investment in biosimilars by limiting comparative efficacy studies in favor of more effective analytical, functional, and pharmacokinetic methodologies for approvals.

- **Stop Patent Abuse & Support Earlier Entry of Biosimilars and Generics.** Anti-competitive patent thickets merely prolong a brand-name drug's monopoly and disrupt the balance between access and innovation created as part of Hatch-Waxman and the BPCIA. Congress should pass the *Eliminating Thickets to Increase Competition (ETHIC) Act* (H.R. 3269 / S. 2276) to prevent brand-name pharmaceutical companies from asserting multiple duplicative patents in slow-moving and costly patent litigation that delays the generic manufacturers bringing lower-cost medicines to market, which could provide billions in federal savings.

- **Protect Skinny Labeling.** Generic labels usually duplicate the brand's label, but where one use is patented, generics can simply drop the patented indication from their labeling. The resulting "skinny label" does not infringe the patented method, but these labels have been under threat from court decisions, before being reaffirmed by SCOTUS in Amarin v. Hikma. Congress should codify a safe harbor and remove any uncertainty by passing the *Skinny Labels, Big Savings Act* (H.R. 6485 / S. 43) to increase access to generic medicines and saving American patients and the healthcare system billions of dollars.

- **Ensure FDA-PTO Coordination.** Currently, incomplete or inconsistent information shared with FDA and the U.S. Patent and Trademark Office can undermine transparency, contribute to uncertainty, and delay generic and biosimilar competition. Congress should pass the *Medication Affordability and Patent Integrity Act* (S. 2658) to require drug and biologic sponsors to certify that information submitted to FDA and USPTO is complete and consistent, while strengthening accountability for failures to disclose information material to patentability. This would create a more predictable and reliable patent system and bring the savings offered by generic and biosimilar drugs to patients sooner.

Ensuring continued patient access through a sustainable generics and biosimilars industry is vital to preserving savings and the value provided to the U.S. health care system. We encourage you to take advantage of this opportunity before the end of this Congress.

Sincerely,



John Murphy III
President & CEO