



September 24, 2024

The Honorable Margaret Wood Hassan
324 Hart Senate Office Building
Washington, DC 20510

The Honorable Mike Braun
404 Russell Senate Office Building
Washington, DC 20510

RE: Letter of Support for S. 2780, the Medication Affordability and Patent Integrity Act

To Senator Hassan and Senator Braun:

On behalf of the manufacturers of FDA-approved generic and biosimilar prescription medicines, the Association for Accessible Medicines and its Biosimilars Council (collectively, “AAM”) supports the goal of S. 2780, the Medication Affordability and Patent Integrity Act, which is slated to be considered by the Senate HELP Committee on Thursday, September 26. We appreciate your efforts to improve the information shared by drug sponsors with the Food and Drug Administration (FDA) and the U.S. Patent and Trademark Office (PTO).

AAM is the nation’s leading trade association for manufacturers of generic prescription medicines. AAM’s core mission is to improve the lives of patients by advancing timely access to affordable, FDA-approved generic medicines. The Biosimilars Council, a division of AAM, works to increase patient access to lifesaving, high-value biosimilar medicines.

Because of their low cost and high value to patients and payers, generic and biosimilar medicines today account for 90% of all prescriptions dispensed in the U.S., but only 13% of prescription drug spending. In fact, generic medicines are less than 2% of total U.S. health care spending. The U.S. health care system has saved more than \$3.1 trillion in the last 10 years due to the availability of affordable generic and biosimilar medicines. In 2023, competition from generic and biosimilar medicines resulted in \$435 billion in savings to the health care system, including \$137 billion in savings for the Medicare program.¹ In short, America’s patients and health care providers depend on generic and biosimilar medicines.

Under this legislation, the sponsor of any application, including any drug or biologic application, would need to certify to both the FDA and PTO that information submitted to each agency is consistent with information submitted to the other. This clarification will help address gaming of the patent system by brand manufacturers.

We appreciate the sponsors’ continued efforts with the Chairman and Ranking Member to improve the legislation and we look forward to continuing to work with you to achieve its enactment.

¹ Association for Accessible Medicines. (September 2024) The US Generic and Biosimilar Medicines Savings Report ([Link](#))

Sincerely,

A handwritten signature in black ink, appearing to read "D.R. Gaugh". The signature is fluid and cursive, with the first name "D.R." and the last name "Gaugh" clearly distinguishable.

David R. Gaugh, R.Ph.
Interim President & CEO