



**Alliance for
Patient Access**

***, 2026

The Honorable Jason Smith
Chairman
House Committee on Ways & Means
1011 Longworth House Office Building
Washington, D.C. 20515

The Honorable Richard Neal
Ranking Member
House Committee on Ways & Means
372 Cannon House Office Building
Washington, D.C. 20515

The Honorable Brett Guthrie
Chairman
House Committee on Energy & Commerce
2161 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Frank Pallone, Jr.
Ranking Member
House Committee on Energy & Commerce
2107 Rayburn House Office Building
Washington, D.C. 20515

RE: Support for H.R. 10628 – The Biosimilars Access and Affordability Act

Dear Chairman Smith, Ranking Member Neal, Chairman Guthrie and Ranking Member Pallone:

On behalf of the Alliance for Patient Access and the undersigned patient advocacy and clinician-based organizations, we urge your support for the Biosimilars Access and Affordability Act. This legislation is critical to ensure that patients continue to have access to affordable medications, while also supporting a robust biosimilar marketplace.

Since the passage of the Biologics Price Competition and Innovation Act, the biosimilar marketplace in the United States has seen nearly 100 biosimilar products obtain FDA approval. Biosimilars offer new affordable treatment options for patients and, importantly, have saved the health care system over \$56 billion since the first biosimilar became available.¹ In 2024 alone, biosimilars saved \$20.2 billion — nearly double the 2023 figure — demonstrating that as the marketplace matures, savings for both patients and the system follow.²

That said, the current structure of the Medicare Drug Price Negotiation Program “biosimilar delay” provision may serve as a deterrent for future biosimilar development. That provision is intended to allow for an up to two-year delay in negotiations for reference products if a biosimilar option is in development. However, the provision’s current requirements to secure a two-year delay are overly burdensome and unnecessarily stringent, setting a bar few biosimilar programs can realistically clear. Additionally, the “bona fide marketing” standard currently used by CMS is unclear and creates unneeded ambiguity for manufacturers. Together, these requirements make it harder for competition to deliver a lower-cost alternative.

¹ <https://accessiblemeds.org/resources/reports/2025-savings-report/>

² <https://www.pharmacypracticenews.com/Operations-and-Management/Article/12-25/Generic-Biosimilars-Healthcare-Savings/78969>

The targeted changes proposed in this legislation will standardize an opaque process and ultimately benefit patients by ensuring biosimilar development remains viable. The automatic granting of a two-year biosimilar delay will allow biosimilar manufacturers to better plan for market entry and reasonably predict their ability to provide a competitive, lower-cost option. In addition, utilizing the existing *Federal Food, Drug, and Cosmetic Act* standard of entry into interstate commerce to define a truly “marketed” biosimilar agent is a more concrete, understandable way of measuring legitimate competition. Lastly, removal of a government-negotiated price upon entry of a biosimilar will allow for organic competition to bring overall costs down, as we have seen happen with previous biosimilar options.

The Biosimilars Access and Affordability Act ensures that the promise and potential of savings from the Medicare Drug Price Negotiation Program are able to be legitimately realized, without compromising the development of biosimilar options. The mere presence of a biosimilar has led to decreases of nearly 46 percent in the average sales price of certain biologic products after five years. While a negotiated price may generate greater near-term savings, allowing a biosimilar to organically create incentives for lower prices leads to greater long-term savings for the Medicare program.³

We appreciate your and the Committees’ commitment to lowering drug prices and to ensuring that the health care system, and ultimately patients, realize the promise of lower costs from biosimilar options. The undersigned organizations are eager to support H.R. 10628 and to serve as a resource as the bill moves through the legislative process by sharing patient and clinician perspectives, providing technical input on the biosimilar delay provision, and helping to build support among your colleagues. Please consider us a partner in advancing the Biosimilars Access and Affordability Act, and do not hesitate to contact us if we can be of assistance. Thank you for your attention to this important matter.

Sincerely,

AiArthritis
Alliance for Aging Research
Alliance for Vision Research
Arthritis Foundation
Association of Black Cardiologists
Autoimmune Association
Biomarker Collaborative
Bone Health and Osteoporosis Foundation
California Chronic Care Coalition
Chronic Care Policy Alliance
Coalition of State Rheumatology Organizations
Color of Gastrointestinal Illnesses (COGI)
Community Access National Network
Derma Care Access Network
Endocrine Nurses Society
Eosinophilic & Rare Disease Cooperative
Exon 20 Group

Future Leaders in Sight
Global Healthy Living Foundation
Headache and Migraine Policy Forum
Infusion Providers Alliance
International Cancer Advocacy Network
International Pemphigus and Pemphigoid Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Colorado
Macular Degeneration Association
MET Crusaders
National Grange
NRG1 Energizers
PDL1 Amplified
Prevent Blindness
Rare Access Action Project
TED Community Organization
TOUCH, The Black Breast Cancer Alliance

³ <https://academic.oup.com/healthaffairsscholar/article/3/11/qxaf222/8328279>