



May 9, 2022

The Honorable Frank Pallone  
Chair, Energy & Commerce Committee  
2125 Rayburn House Office Building  
Washington, DC 20515

The Honorable Cathy McMorris Rodgers  
Ranking Member, Energy & Commerce Committee  
2322 Rayburn House Office Building  
Washington, DC 20515

The Honorable Anna Eshoo  
Chair, Health Subcommittee  
272 Cannon House Office Building  
Washington, DC 20515

The Honorable Brett Guthrie  
Ranking Member, Health Subcommittee  
2434 Rayburn House Office Building  
Washington, DC 20515

Dear Chairman Pallone, Ranking Member McMorris Rodgers, Chairwoman Eshoo, and Ranking Member Guthrie:

Thank you for your leadership on *The Food and Drug Amendments of 2022 Act* (H.R. 7667). On behalf of the Association for Accessible Members and its Biosimilars Council, I am pleased to offer our strong support for and endorsement of this bipartisan reauthorization of the Generic Drug User Fee Amendments (GDUFA) and the Biosimilar User Fee Act (BsUFA). *The Food and Drug Amendments of 2022 Act* will increase competition from generic and biosimilar medicines and enhance patient access to lower cost prescription drugs. **For these reasons, we encourage all members of the House Energy & Commerce Committee to vote in favor of *The Food and Drug Amendments of 2022 Act* as introduced.**

Patient access to generic and biosimilar medicines has never been more critical. Over the last 10 years, GDUFA and BsUFA significantly increased the resources available to FDA for review of generic and biosimilars applications. The benefits of Congressional enactment of the FDA user fee programs are undeniable: record levels of generic drugs were approved in 2017-2019, and 35 biosimilar medicines have been licensed to date. The end result is lower prescription drug costs for America's patients. Since the establishment of FDA's generic and biosimilars programs in 2012, patients and the U.S. health care system have saved more than \$2 trillion – including \$469 billion from new generics and more than \$12 billion from biosimilars.

*The Food and Drug Amendments of 2022 Act* will build on this track record of success. Reauthorization of the user fee programs ensures FDA is provided with sufficient resources over the next five years (FY23-27) for the timely review of generic and biosimilar applications. It also includes critical improvements to help facilitate the development of generic medicines, notably clarifying FDA's authority to provide applicants with important information regarding qualitative and quantitative sameness (Q1Q2) of their generic formulations and addressing late-stage labeling changes by brand-name drug manufacturers that could delay generic competition. America's patients will benefit through significant savings at the pharmacy counter because of these policies.

We appreciate your work on behalf of patient access to generic and biosimilar medicines and look forward to working with you to advance this bipartisan legislation into law.

Sincerely,

Dan Leonard  
President & CEO