



Your Generics and Biosimilars Industry

July 12, 2017

The Honorable Paul Ryan
Speaker
H-232 U.S. Capitol Building
United States House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Democratic Leader
H-204 U.S. Capitol Building
United States House of Representatives
Washington, DC 20515

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Speaker Ryan, Democratic Leader Pelosi, Chairman Walden, and Ranking Member Pallone:

On behalf of the Association for Accessible Medicines (AAM), the leading representative of the generic and biosimilar industry, I write in support of the reauthorization of the Generic Drug User Fee Amendments (GDUFA II) and Biosimilar User Fee Act (BsUFA II) and encourage members to **vote YES on the FDA Reauthorization Act of 2017 (H.R. 2430)**.

Safe, effective and affordable generic medications now account for 89% of all prescriptions dispensed – yet only 26% of total drug costs in the United States.¹ Generic medicines generated \$253 billion in savings for patients and taxpayers in 2016, with more than \$1.6 trillion saved over the last decade due to the availability of low-cost generic medicines. Increased competition and patient access to generic and biosimilar medicines is a critical part of the solution to address rising health care costs.

The FDA Reauthorization Act (FDARA) takes important steps to bring more generic and biosimilar medicines to market over the next five years, increasing competition and patient access to affordable treatments, and helping to address drug costs. GDUFA II builds on the experiences of the last five years through increased transparency and communication, a more efficient review and approval process, and additional resources dedicated to increasing timely review of generic and biosimilar applications. BsUFA II also enhances FDA’s approval process for biosimilars which we expect will improve patient access to these critical medicines.

¹ AAM, “Generic Drug Access & Savings Report,” June 2017, [full report](#).



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Specifically, FDARA provides for 8-month priority review of generic applications for a generic drug that lacks sufficient competition; expedites the review and development of certain generic therapies; provides a 180-day exclusivity to incentivize generic competition to older, off-patent branded drugs; improves communication between FDA and the industry about the status of pending generic drug applications; provides for FDA timelines related to the facility inspection processes; helps identify therapeutic areas with limited competition; and, requires GAO to study the rate of FDA's first cycle approvals with recommendations for improvements to enhance the agency's generic drug approval process. Accordingly, FDARA will increase competition, providing patients with more access to safe, effective, and affordable generic medicines. Access is a value our industry upholds at every opportunity, and affordable medicines are inherently more accessible. Prescription medications do not help patients who cannot afford them. Therefore, we must never take health care access and savings for granted. AAM believes enactment of FDARA will help improve the ability of our members to put needed treatments within the reach of patients.

We appreciate the Sense of the Congress provision recognizing the need to "take administrative actions and enact legislative changes" to lower the cost of prescription drugs for consumers, including policies "to increase competition in the pharmaceutical market, prevent anticompetitive behavior, and promote the timely availability of affordable, high-quality generic drugs and biosimilars." We look forward to working with you and your colleagues to advance additional policies to meet this objective, including addressing anticompetitive conduct that slows access to generic and biosimilar medicines.

Thank you for your consideration of AAM's views and for your efforts to advance the timely reauthorization of GDUFA and BsUFA. We look forward to working with you to advance FDARA and on additional steps Congress can take to expedite access to generic and biosimilar medicines – the only proven, reliable, and tested way to drive down the cost of medicine to help patients, families and our country.

Sincerely,

Chester "Chip" Davis, Jr.
President and Chief Executive Officer

cc: U.S. House of Representatives