May 13, 2019

The Honorable Nancy Pelosi
Speaker of the House
The Capitol H-232
Washington, DC 20515

The Honorable Kevin McCarthy
House Republican Leader
The Capitol H-204
Washington, DC 20515

Dear Speaker Pelosi and Leader McCarthy:

On behalf of the Association for Accessible Medicines (AAM), we write today to encourage the U.S. House of Representatives to fix the Bringing Low-Cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act (H.R. 938) and the Protecting Consumer Access to Generic Drugs Act (H.R. 1499) before proceeding to a vote. In contrast to the intended goals of lowering the cost of prescription drugs, these proposals would reduce generic and biosimilar competition in the prescription drug market and patients would continue to pay the high cost of brand-name drugs for longer. Without changes, AAM opposes the BLOCKING Act and the Protecting Consumer Access to Generic Drugs Act.

Two critical elements are currently available to achieving successful generic entry: 1.) the 180-day exclusivity period provided to the first filer generic manufacturer that is able to successfully challenge a patent and reach the market; and 2.) the right of two private parties to reach a settlement providing for competition earlier than the expiration of the last patent. The BLOCKING Act and the Protecting Consumer Access to Generic Drugs Act, however, are overly broad in their applicability and would lead to a number of unintended consequences that undermine the ability of generic and biosimilar manufacturers to deliver more affordable medicine to patients. The BLOCKING Act would, for example, lead generic manufacturers to lose the 180-day exclusivity incentive through no fault of their own and due to issues pending with the FDA, while the Protecting Consumer Access to Generic Drugs Act would lead to fewer overall pro-competitive agreements that accelerate patient access to generics and biosimilars.

Moreover, previous legislative and judicial action has already solved for the problems that the BLOCKING Act and the Protecting Consumer Access to Generic Drugs Act seek to address. In 2003, Congress provided the FDA with the authority to conclude that 180-day exclusivity for first generics will not be awarded if approval is not diligently pursued. In 2013, the Supreme Court ruled in *FTC v. Actavis* that settlement agreements with "large, unjustified payments" should be subject to anticompetitive review and challenge. As a result, the number of potential "pay-for-delay" settlements have declined from a height of 40 pre-*Actavis* to only one in FY16, according to the Federal Trade Commission.

To address our concerns about the unintended consequences, AAM has over the last few months offered several alternatives and recommended improvements to both the BLOCKING Act and the Protecting Consumer Access to Generic Drugs Act.[1] We would be glad to discuss these further with you and the sponsors. AAM appreciates that the intended goal with these policies is to reduce some of the barriers to competition that delay patient access to more affordable medicine; unfortunately, however, the opposite is true.

If the two proposals are passed without significant modifications to address the unintended consequences, the deck would further be stacked against generic and biosimilar manufacturers who, due to abuse of the patent system and other anti-competitive tactics, are finding it increasingly difficult to bring new medicines to patients. Enactment of these policies will increase the litigation costs and risks for generic and biosimilar manufacturers, resulting in fewer patent challenges against brand-name drugs, and lead to patients paying the high price of brand-name drugs due to extended monopolies.

Sincerely,

Chester "Chip" Davis, Jr.
President and CEO

[1] Testimony to the House Energy and Commerce Subcommittee on Health, March 13, 2019, available online; Letter to sponsors of the BLOCKING Act, February 1, 2019; Letter to the House Judiciary Committee on patent settlements, April 30, 2019; Legal analysis on the BLOCKING Act, January 18, 2019; Legislative language and recommended improvements provided on March 25 and May 7, 2019 on the BLOCKING Act, and on November 30, 2018 and March 19, 2019 on patent settlements.