February 1, 2019

The Honorable Kurt Schrader
U.S. House of Representatives
2431 Rayburn House Office Building
Washington, D.C. 20515

To Congressman Schrader:

On behalf of the Association for Accessible Medicines (AAM), we write to raise serious concerns about the Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act (H.R. 938). The BLOCKING Act, if enacted, would have the unintended impact of reducing competition in the prescription drug market and thus lead to patients continuing to pay the high-cost of brand-name drugs for longer. While there are many steps Congress could take to increase competition and enhance patient access to more affordable FDA-approved generics and biosimilars, this proposed legislation would have the opposite effect. In fact, it undermines the only incentive provided to generic manufacturers to challenge the patent thickets created by brand-name drug companies. For these reasons AAM opposes H.R. 938 and urges your colleagues not to support this misguided legislation.

For more than 30 years, the Hatch-Waxman Act has provided an incentive for generic manufacturers to enter the market by awarding a 180-day period of exclusivity for being the first to successfully challenge a patent protecting an expensive brand-name drug monopoly. This foundational incentive has helped to deliver nearly $1.8 trillion in savings to patients and the health care system – including $265 billion in 2017 – over the last decade.[1] In recent years, however, generic and biosimilar manufacturers have found it increasingly difficult to bring more affordable medicines to market due to rampant patent abuse. Of the roughly 100 best-selling brand-name drugs, more than 70 percent obtained a patent to extend their monopoly beyond the initial 20 years.[2]

Challenging weak or questionable patents is an expensive endeavor without any guarantee of success. When one considers the patent thickets established around the top-selling brand-name drugs, it is fair to question whether patients will in a timely manner be able to benefit from competition from more affordable, FDA-approved

[1] AAM, Generic Drug Access & Savings Report 2018, available online (accessed Jan. 2019).
[2] Feldman, Robin, May Your Drug Price Be Evergreen, December 2018, available online (accessed Jan. 2019).

generics and biosimilars. In 2017 alone, the top-12 grossing brand-name drugs were granted 71 patents on average for each drug.[3] This level of patent protection delays competition by up to 38 years – well past Congressional intent.[4]

Rather than address this increasing trend of patent abuse by brand-name companies, however, the BLOCKING Act instead undermines the only incentive generic manufacturers have to challenge these patent thickets. Weakening the 180-day period of exclusivity for first generics ensures more weak and questionable patents stay in place, delaying the entry of generic medicines into the market. As a result, patients will continue to pay the high price of brand-name drugs without competition from more affordable FDA-approved generic medicine.

Moreover, no evidence has been provided to date to justify changes to the 180-day exclusivity for first generics. Concerns about the potential for "parking" of applications were adequately addressed by Congress as part of the Medicare Modernization Act of 2003. FDA's current statutory and regulatory authority allow the agency to conclude that 180-day exclusivity will not be awarded to a first applicant that does not diligently pursue approval. Specifically, current law states: "If FDA concludes that a first applicant is not actively pursuing approval of its ANDA, FDA may immediately approve an ANDA(s) of a subsequent applicant(s) if the ANDA(s) is otherwise eligible for approval."[5]

For these reasons, AAM and our members oppose the BLOCKING Act. We strongly encourage Congressional efforts be focused on what's driving prescription drug prices to be out of reach for too many patients, such as abuse of the patent system, and to advance solutions, like those proposed in the Prescription for Savings, that lead to meaningful savings at the pharmacy counter.

Sincerely,

Chester "Chip" Davis, Jr.
President and CEO

[3] I-MAK, Overpatented, Overpriced, August 2018, available online (accessed Jan. 2019).
[4] Ibid.
[5] 21 C.F.R. § 314.107(c)(3).