



May 11, 2017

The Honorable Tom Marino  
United States House of Representatives  
Washington, DC 20515

The Honorable David Cicilline  
United States House of Representatives  
Washington, DC 20515

Dear Rep. Marino and Rep. Cicilline:

On behalf of the American College of Physicians (ACP), I am writing to convey our appreciation for your leadership in preventing some brand-name drug-companies from using statutorily required Food and Drug Administration (FDA) risk and safety programs to stifle other companies' development of generic and biosimilar versions of brand-name drugs. We applaud your bipartisan effort in drafting the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017, H.R. 2212, and strongly support the bill's intent to improve patient access to prescription drugs and biological products, which we recognize as a growing need as consumer pharmaceutical costs continue to rise.<sup>i</sup>

The ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 148,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Unfortunately, there have been anti-competitive practices by a few manufacturers of brand-name drugs to prevent or delay other companies from developing alternative lower-cost products. These few brand-name manufacturers utilize the FDA's Risk Evaluation and Mitigation Strategies (REMS) process and its accompanying Elements to Assure Safe Use (ETASU) requirements in a manner that prevents development of lower-cost alternatives. In some instances, the REMS process and ETASU requirements have been used to deny availability of drug samples and impede participation in FDA safety protocols. Using the REMS process and ETASU requirements in this way by a few brand-name drug companies keeps lower-cost generics and biosimilars off of the market, thereby decreasing patient access to lower-cost medications.

The ACP strongly supports using multiple approaches—such as cost and price transparency and greater flexibility for public programs to leverage volume purchasing—to stem the increasing cost of prescription drugs. **The College also strongly believes that establishing policies or programs that may increase competition for brand-name and generic drugs and biologics should be implemented.**<sup>ii</sup>

The CREATES Act of 2017 attempts to stop these anti-competitive actions by determining when the denial of adequate samples and when impeding participation in a joint-safety protocol have occurred and creates a pathway for the lower-cost manufacturer to bring a cause of action in federal court for injunctive relief. The federal court may also award damages for future deterrence of similar actions by the brand-name manufacturer. The Act will remove a delaying tactic used by a few name-brand manufacturers and make it easier and faster for other manufacturers to pursue bringing lower-cost alternatives to market and increase patient access.

ACP greatly appreciates your bipartisan leadership in working to improve patient access to prescription drugs and biological products through this legislation. We stand ready to serve as a resource and welcome the opportunity to work with you as you continue to advance this bill through the 115th Congress.

Sincerely,

A handwritten signature in black ink, appearing to read "Jack Ende", with a long, sweeping horizontal flourish extending to the right.

Jack Ende, MD, MACP  
President

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<sup>i</sup> Daniel, Hilary, Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians, *Ann. Intern. Med.* 2016; 165:1

<sup>ii</sup> Daniel, Hilary, Stemming the Escalating Cost of Prescription Drugs: A Position Paper of the American College of Physicians, *Ann. Intern. Med.* 2016; 165:2