



June 13, 2016

The Honorable Chuck Grassley  
Chairman  
Committee on the Judiciary  
United States Senate  
Washington, DC 20510

The Honorable Patrick Leahy  
Ranking Member  
Committee on the Judiciary  
United States Senate  
Washington, DC 20510

The Honorable Mike Lee  
Committee on the Judiciary  
United States Senate  
Washington, DC 20510

The Honorable Amy Klobuchar  
Committee on the Judiciary  
United States Senate  
Washington, DC 20510

Dear Chairman Grassley, Ranking Member Leahy, Sen. Lee, and Sen. Klobuchar:

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 2016 and support the intent of the June 2, 2016, draft of the bill in trying 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>1</sup>

The ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 143,000 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 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 2016 attempts to stop these anti-competitive actions by determining when the denial of adequate samples and when 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 114th Congress.

Sincerely,



Nitin S. Damale, MD, MS, FACP  
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