

February 5, 2019

The Honorable Chuck Grassley
United States Senate
Washington, DC 20510

The Honorable Patrick Leahy
United States Senate
Washington, DC 20510

The Honorable Amy Klobuchar
United States Senate
Washington, DC 20510

The Honorable Mike Lee
United States Senate
Washington, DC 20510

Dear Senators Grassley, Leahy, Klobuchar and Lee:

We, the undersigned, commend you for your leadership, commitment to reducing out-of-control prescription drug prices, and efforts to stop anti-competitive abuses that keep drug prices high for patients. We were encouraged by the Senate Judiciary Committee's bipartisan approval of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S. 974) last Congress. On the reintroduction of this legislation in the 116th session of Congress, we again pledge our support for the CREATES Act and look forward to continuing to work with you to get this bill across the finish line this year.

The CREATES Act is a bipartisan, market-based solution to increase competition and thus lower prescription drug prices for patients and consumers. This reform helps speed the introduction of generic and biosimilar medicines by facilitating the purchase of brand name drug samples on market-based terms from pharmaceutical companies who otherwise would use anticompetitive tactics to block access. The CREATES Act will help ensure that brand-name pharmaceutical companies cannot take advantage of regulatory rules to forestall the competition that is essential for access and innovation. With its enactment, the CREATES Act will save patients and taxpayers \$3.9 billion over ten years, according to the Congressional Budget Office, by allowing lower-priced generic drugs to enter the market earlier.

We also recognize and appreciate the commitment from Health and Human Services (HHS) Secretary Alex Azar and Food and Drug Administration Commissioner (FDA) Scott Gottlieb, M.D. on this important issue. Both have elevated awareness of brand manufacturer "gaming" of FDA regulatory rules to deny would-be generic competitors the ability to purchase samples of brand-name drugs necessary to conduct the FDA-required testing and bring more affordable medicines to market. Secretary Azar recently noted: "We know that certain brand-name manufacturers are abusing the system by blocking access to samples and hiding behind FDA's rules when they do it...They're using laws intended to promote the public health to pad their profits instead." Moreover, last year, the FDA released new guidance and published a database identifying more than 160 instances where access to samples was at issue.

Unfortunately, the use of these anti-competitive tactics has increased over the years and the cost to patients, health care providers, and taxpayers now amounts to billions of dollars annually. The CREATES Act would deliver those savings to patients by establishing a clear process for FDA to ensure the appropriate safety measures are in place, as well as a limited legal pathway that can be used only in instances when a brand company has continued unjustifiably to deny the purchase of samples. In testimony before Congress, the Federal Trade Commission offered its support of the CREATES Act as it “protects the competitive process by eliminating incentives and opportunities for branded manufacturers to engage in manipulation of the REMS process to delay generic entry.”

Thank you again for reintroducing the CREATES Act and for your leadership in advancing meaningful solutions to lower the prices of prescription drugs. We look forward to working with you to advance this bipartisan solution into law this year.

Sincerely,

AARP
Academy of Managed Care Pharmacy
AFL-CIO
Alliance of Community Health Plans
Alliance for Retired Americans
American Academy of Dermatology Association
American Academy of Family Physicians
American College of Physicians
American Consumer Institute
American Gastroenterological Association
America’s Health Insurance Plans
American Hospital Association
Anthem
ASHP
Association for Accessible Medicines
Black Women’s Health Imperative
Blue Cross Blue Shield Association
Blue Cross Blue Shield of Arizona
Blue Cross Blue Shield of Michigan
Blue Shield of California
Campaign for Sustainable Rx Pricing
Center for Freedom and Prosperity
Coalition for Affordable Prescription Drugs
Coalition to Reduce Spending
Consumer Action
Consumer Reports
CVS Health
Doctors for America
Families USA
Federation of American Hospitals
FreedomWorks

Friends of Cancer Research
Frontiers of Freedom
Healthcare Supply Chain Association
Greater New York Hospital Association
Innovation Defense Fund
Institute for Liberty
Kaiser Permanente
Knowledge Ecology International
National Association of Hispanic Nurses
National Coalition on Health Care
National Multiple Sclerosis Society
Patients for Affordable Drugs
Pharmaceutical Care Management Association
Premier healthcare alliance
Prime Therapeutics
Public Citizen
Public Sector HealthCare Roundtable
Vizient