

June 7, 2018

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Dianne Feinstein
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Feinstein:

We, the undersigned, commend you for your leadership and commitment to reducing out-of-control prescription drug prices and stopping anti-competitive abuses that keep drug prices high. We are encouraged that the Senate Judiciary Committee has noticed a markup of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S. 974). We thank you for your efforts to move this important piece of legislation through the Committee.

We appreciate the commitment from Health and Human Services (HHS) Secretary Alex Azar and Food and Drug Administration Commissioner (FDA) Scott Gottlieb on this important issue. Both have noted their concerns with “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 a generic competitor to market. As Secretary Azar said last month, “[w]e 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.”

And these are not isolated incidents; they are pervasive and systematic attempts to thwart generic and biosimilar competition. Congress attempted through Hatch-Waxman to strike a balance between providing incentive for innovation through limited market exclusivity, and ensuring affordability through generic competition once that limited market exclusivity expires. These abuses inappropriately delay generic competition, impeding access and affordability. They are also extraordinarily costly to patients, providers, private payers and taxpayers.

FDA recently posted a list of brand drugs where access to samples by generic and biosimilar manufacturers has been an issue. Patient access to low-cost alternatives for over 50 medicines was delayed as a result of these anti-competitive tactics. One recent analysis from Kaiser Health News estimates that Medicare & Medicaid spent \$12 billion on these 50 drugs in 2016, while these manufacturers raised their drug prices by double-digits since 2012.

The CREATES Act is a bipartisan, market-based reform that will speed the introduction of generic and biosimilar competition for brand-name drugs. It is a highly-targeted remedy that will end the anticompetitive abuses utilized by some brand-name manufacturers, help restore the balance between innovation and affordability that Congress intended, and achieve the goal of

more affordable prescription drugs. The Congressional Budget Office has estimated that enacting the CREATES Act would save \$3.8 billion over ten years.

We sincerely thank you and your colleagues who have supported the CREATES Act, and we encourage all members of the Committee to vote in favor of the bill.

Sincerely,

AARP
AFL-CIO
Alliance for Retired Americans
Alliance of Community Health Plans
America's Health Insurance Plans
America's Physician Groups
American College of Physicians
American Consumer Institute
American Hospital Association
American Gastroenterological Association
American Society of Health System Pharmacists
Anthem
Ascension
Association for Accessible Medicines
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
Cancer Prevention and Treatment Fund
Chronic Illness Advocacy & Awareness Group
Coalition to Reduce Federal Spending
Colorado Consumer Health Initiative
Consumers Union
CVS Health
Doctors for America
Express Scripts
Families USA
Federation of American Hospitals
FreedomWorks
Greater New York Hospital Association
Healthcare Supply Chain Association
Kaiser Permanente
Knowledge Ecology International
National Coalition on Health Care
National Committee to Preserve Social Security and Medicare
National Physicians Alliance
Patients for Affordable Drugs

People of Faith for Access to Medicines
Pharmaceutical Care Management Association
Premier healthcare alliance
Prime Therapeutics
Public Citizen
Social Security Works
Universal Health Care Foundation of Connecticut
Vizient

Cc: Senator Patrick Leahy