February 6, 2018

The Honorable Mitch McConnell Majority Leader United States Senate Washington, DC 20510 The Honorable Paul Ryan Speaker U.S. House of Representatives Washington, DC 20510

The Honorable Charles Schumer Democratic Leader United States Senate Washington, DC 20510 The Honorable Nancy Pelosi Democratic Leader U.S. House of Representatives Washington, DC 20510

Dear Majority Leader McConnell, Leader Schumer, Speaker Ryan, and Leader Pelosi:

The undersigned organizations write to voice our strong support for the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S. 974/H.R. 2212) and encourage Congress to pass this important, bipartisan legislation as soon as possible.

President Trump remarked in his State of the Union address that the "injustice of high drug prices [is] one of our top priorities." It is also a top priority for voters across the country, and Congress has a golden opportunity to make a real impact on prescription drug prices by passing the CREATES Act.

Each of our organizations is committed to ensuring that Americans have access to the life-enhancing and life-saving medications that they need at an affordable price. It is undisputed that the key driver of affordability in prescription drugs is competition from generics once the market exclusivity has expired on a brand-name medication. Unfortunately, manufacturers of brand name drugs often go to great lengths to stave off competition from generics in order to keep prices high.

In particular, certain companies abuse the Food and Drug Administration's (FDA) regulatory rules that allows them to use a tool designed to protect patient safety as a pretext to deny generic manufacturers the ability to purchase the samples they need to bring more affordable FDA-approved drugs to market. These actions contradict Congressional intent. Through this anti-competitive abuse, brand companies extend their monopoly pricing power, costing patients and the healthcare system an additional \$5.4 billion annually.

The CREATES Act is a narrowly targeted, bipartisan, pro-competition, and market-based solution to these abuses that cost patients, job-creators, and taxpayers billions of dollars each year. The CREATES Act is a step towards restoring the balance that Congress attempted to strike in Hatch-Waxman, between providing incentive for innovation through exclusivity while providing for affordability through generic competition.

We thank the bipartisan, bicameral sponsors of this important legislation for the work that they have done to, in the words of FDA Commissioner Scott Gottlieb, "end the shenanigans" by certain brand companies, and we strongly encourage Congress to pass the CREATES Act without delay.

Sincerely,

## **AARP**

Academy of Managed Care Pharmacy

Alliance of Community Health Plans

America's Health Insurance Plans

American College of Physicians

American Consumer Institute

American Hospital Association

American Society of Health-System Pharmacists

Anthem

Ascension

Association for Accessible Medicines

Autistic Self Advocacy Network

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

Coalition to Reduce Federal Spending

Colorado Consumer Health Initiative

**CVS Health** 

Consumers Union

**Doctors for America** 

**Express Scripts** 

Families USA

Federation of American Hospitals

FreedomWorks

Greater New York Hospital Association

Healthcare Supply Chain Association

I-MAK (Initiative for Medicines, Access & Knowledge)

Kaiser Permanente

Knowledge Ecology International

National Coalition on Health Care

National Committee to Preserve Social Security and Medicare

Patients For Affordable Drugs

Pharmaceutical Care Management Association

People's Action Institute

People of Faith for Access to Medicines

Premier Healthcare Alliance

Prime Therapeutics
Public Citizen
Social Security Works
Union for Affordable Cancer Treatment
Universal Health Care Foundation of Connecticut
Vizient