

September 19, 2017

The Honorable Mitch McConnell  
Majority Leader  
U.S. Senate  
Washington, D.C. 20510

The Honorable Charles E. Schumer  
Democratic Leader  
U.S. Senate  
Washington, D.C. 20510

Dear Majority Leader McConnell and Democratic Leader Schumer:

As the Senate returns to work this Fall, the undersigned organizations encourage the Senate to consider the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. Our organizations represent a broad-based and diverse cross-section of stakeholders – including providers and payers, physicians and consumers, corporations and unions – all of whom have come together in strong support of the CREATES Act.

For too long, brand-name pharmaceutical manufacturers have exploited patient safety tools in order to stifle generic competition and attendant lower prescription drug prices. The Food and Drug Administration (FDA) Commissioner Scott Gottlieb recently testified on this topic at a hearing in front of the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law:

*For example, we know that sometimes statutory and regulatory requirements, established to ensure the safety and quality of drugs approved by FDA, may also be leveraged – or “gamed” – in an effort to delay generic drug approvals beyond the timeframe the law has intended. This can serve to thwart expected competition.*

This “gaming” by brand-name pharmaceutical companies denies generic manufacturers access to the samples that they require in order to conduct necessary equivalence testing to ensure the quality, efficacy, and safety of a generic drug. As a result of this pattern of anticompetitive practices, brand-name manufacturers are able to stifle generic competition, inflating prescription drug prices by artificially extending their monopoly pricing power far beyond the exclusivity period intended by Congress.

This anticompetitive conduct harms not only the patients who depend on these drugs, but results in an enormous and unnecessary burden on the healthcare system as a whole. A 2014 [study](#) by Matrix Global Advisors found that this type of anticompetitive conduct costs the healthcare system \$5.4 billion annually, including \$1.8 billion in government spending and nearly \$1 billion in out-of-pocket costs for patients.

The CREATES Act is a targeted, market-based, bipartisan solution to this longstanding problem that affects both access to and affordability of prescription medications. We thank the bipartisan, bicameral Congressional sponsors of this legislation, as well as the Food and Drug Administration and the Federal Trade Commission which recently testified favorably about this bill.

We strongly encourage Congress to act on this important bill this fall, and we stand ready to work with Members towards our common goal of promoting competition and lowering drug prices for all Americans.

Sincerely,

AARP  
AFL-CIO  
American College of Physicians  
Anthem  
Alliance of Community Health Plans  
American Hospital Association  
American Society of Health System Pharmacists  
America's Health Insurance Plans  
Ascension  
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 Medicare Advocacy  
Coalition for Affordable Prescription Drugs  
Coalition to Reduce Spending  
CVS Health  
Doctors for America  
Families USA  
Federation of American Hospitals  
Freedom Works  
Greater New York Hospital Association  
Healthcare Supply Chain Association  
Kaiser Permanente  
Knowledge Ecology International  
National Center for Health Research  
National Committee to Preserve Social Security and Medicare  
National Physicians Alliance  
Patients for Affordable Drugs  
Pharmaceutical Care Management Association  
Prime Therapeutics  
Public Citizen  
Social Security Works  
Treatment Action Group  
Vizient  
Walmart

Cc: Chairman Charles E. Grassley  
Cc: Ranking Member Diane Feinstein

Cc: Senator Amy Klobuchar  
Cc: Senator Patrick Leahy  
Cc: Senator Mike Lee