April 27, 2017

The Honorable Chuck Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable Tom Marino
Judiciary Committee
United States House of Representatives
Washington, D.C. 20515

The Honorable Patrick Leahy
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable David Cicilline
Judiciary Committee
United States House of Representatives
Washington, D.C. 20515

Dear Senators Grassley and Leahy, and Representatives Marino and Cicilline:

As stakeholders firmly committed to fostering patient access to affordable medicines and pharmaceutical competition, we would like to thank you for introducing the bicameral and bipartisan Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act. The bill would provide a clear solution to abusive, anticompetitive business practices that increase costs to the American health care system by impeding patient access to generic and biosimilar medicines.

Since it was created in 2007, the Food & Drug Administration's (FDA's) Risk Evaluation and Mitigation Strategies (REMS) program has been an important tool for patient safety by ensuring that the benefits of a drug or biological product outweigh its safety risk. FDA-mandated REMS programs can, and do, serve a compelling public good by providing additional information to patients and providers. Yet some have been exploiting a loophole in the law and abusing the REMS Elements to Assure Safe Use (ETASU) requirements to prevent competition for products with and without required REMS programs.

Specifically, certain companies are employing restricted distribution networks to deny manufacturers of generics and biosimilars access to product samples they need to obtain FDA approval and market entry. Many of these restricted distribution setups are implemented completely independently from FDA mandates, and exist solely to exert control of who purchases the product. These abuses are growing and the resulting delay in generic and biosimilars competition is costing patients, the federal government, and the health care system billions of dollars annually. A July 2014 analysis by Matrix Global Advisors[1] found that abusing these restricted access programs to prevent generic competition costs the health care system $5.4 billion annually, including $1.8 billion to the federal government. Equally alarming, as companies expand this practice to biosimilars, it could result in approximately $140 million in lost savings for every $1 billion in biologics sales.

Abusers of this practice have not denied the existence of the financial incentive for this obstruction. When asked about potentially approving a sale to a generic manufacturer one executive responded:

> *Most likely I would block that purchase. We spent a lot of money for this drug. We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to make*

[1] *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry*

generics], no matter what. But I'm certainly not going to make it easier for them.[2]

Without access to these samples, generic and biosimilars approvals are blocked and patients are left without access to more affordable medicines. The CREATES Act would give generic and biosimilar manufacturers a clear and efficient pathway to combat these bad actors. The bill targets two forms of anticompetitive behavior used by certain brand manufacturers to stifle generic and biosimilar entry: refusal to provide adequate samples to gain approval, and denying generic and biosimilar access into to an FDA approved single-shared REMS program. Additionally, courts would be empowered to award damages that would provide sufficient incentives to encourage good-faith dealing by brand manufacturers from the outset. The CREATES Act would ensure patient safety by requiring that only appropriate manufacturers receive these samples through an affirmative authorization from FDA that satisfies any relevant safety concerns.

Over 30 years ago, the Hatch-Waxman Act opened up the pharmaceutical marketplace to competition by creating a balance between patient access and brand innovation. Competition from generic drugs has saved the health care system $1.46 trillion over the past decade and $227 billion in 2015 alone. Companies that exploit restricted access programs – whether under the pretext of an FDA-mandate or on their own accord - delay generic competition and undermine the intent of Hatch-Waxman at the expense of America's patients. The CREATES Act is a common sense solution that will prevent such abuses, and further patient access to safe, effective, and affordable medications. We thank you again for your incredible efforts in introducing this bill.

Sincerely,

AARP
Academy of Managed Care Pharmacy
America's Health Insurance Plans (AHIP)
American College of Physicians
American Society of Health System Pharmacists
Association for Accessible Medicines and The Biosimilars Council
BlueCross BlueShield Association
Campaign for Sustainable Rx Pricing
Coalition to Reduce Spending
CVS Health
Express Scripts
Frontiers of Freedom
Healthcare Supply Chain Association
Pharmaceutical Care Management Association (PCMA)
Premier healthcare alliance
Prime Therapeutics
Public Citizen
Public Sector HealthCare Roundtable

CC:
Hon. Mike Lee, Hon. Amy Klobuchar, Hon. Tom Cotton, Hon. Sheldon Whitehouse, Hon. John McCain, Hon. Richard Blumenthal, Hon. Susan Collins, Hon. Claire McCaskill, Hon. Dick Durbin, Hon. Diane Feinstein

[2] "How Martin Shkreli prevents generic versions of his pricey pill." *Pharmalot*. October 2015.