

June 14, 2016

The Honorable Chuck Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Patrick Leahy
Ranking Member
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Mike Lee
Committee on the Judiciary
United States Senate
Washington, DC 20510

The Honorable Amy Klobuchar
Committee on the Judiciary
United States Senate
Washington, DC 20510

Dear Chairman Grassley, Ranking Member Leahy, Senator Lee, and Senator Klobuchar,

As stakeholders firmly committed to fostering pharmaceutical competition and patient access to affordable medicines, we would like to thank you for introducing The 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 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, 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 Advisors¹ 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.

Brand companies have recognized the value of using these tactics. When asked about potentially approving a sale to a generic manufacturer one executive responded:

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

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

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.

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 \$1.68 trillion over the past decade and \$254 billion in 2014 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,

Academy of Managed Care Pharmacy
The American Consumer Institute
Blue Cross Blue Shield Association (BCBSA)
Consumers Union
Express Scripts
Generic Pharmaceutical Association (GPhA) and The Biosimilars Council
Healthcare Supply Chain Association (HSCA)
National Association of Chain Drug Stores (NACDS)
National Coalition on Health Care (NCHC)
Pharmaceutical Care Management Association (PCMA)
Premier healthcare alliance
Prime Therapeutics
Public Citizen
Public Sector HealthCare Roundtable
UAW Retiree Medical Benefits Trust

CC:
Members of the Senate Judiciary Committee

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