

December 21, 2015

The Honorable Susan Collins  
413 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Claire McCaskill  
703 Hart Senate Office Building  
Washington, DC 20510

Dear Chairman Collins and Ranking Member McCaskill –

During the Committee’s December 9<sup>th</sup> hearing titled, “Sudden Price Spikes in Off-Patent Drugs: Perspectives from the Front Lines,” numerous comments were made regarding the abusive practices of some brand manufacturers that prevent generic competition. We agree that the increasing use of restricted access programs to block generic entry into the market seriously impedes patients’ ability to access safe, effective and affordable life-saving medications.

As you know, the intent of the Food & Drug Administration’s (FDA’s) Risk Evaluation and Mitigation Strategies (REMS) program is to ensure that the benefits of a drug or biological product outweigh its safety risk. These FDA-mandated programs provide additional information to patients and providers, and in certain cases restrict the distribution of the product so that only certain approved entities can dispense the drug. When Congress passed legislation in 2007 authorizing REMS, it recognized that companies could use these programs to delay generic competition and therefore explicitly prohibited such conduct in the statute. However, due to a loophole, certain companies have been using tactics that initially grew out of REMS Elements to Assure Safe Use (ETASU) requirements to delay generic competition for REMS and non-REMS products alike.

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. 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 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.

In fact, one senior level brand pharmaceutical executive has even explicitly admitted to this practice. When he was asked about potentially approving a sale to a generic manufacturer he 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 generics], no matter what. But I’m certainly not going to make it easier for them.<sup>1</sup>*

In the House, Representatives Steve Stivers and Peter Welch have introduced The Fair Access for Safe and Timely (FAST) Generics Act (H.R. 2841) a commonsense measure to address these types of abuses while prioritizing patient safety and public health. The bill would establish clear processes that would facilitate the provision of product samples to generic manufacturers and prevent companies from denying the implementation of shared REMS programs. The bill also defines certain anticompetitive practices with respect to restricted access programs, thus closing the existing loophole around current REMS prohibitions. We believe this proposal is worth serious consideration from your committee.

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<sup>1</sup> “How Martin Shkreli prevents generic versions of his pricey pill.” *Pharmalot*. October 2015. <http://pharmalot.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/>

Thirty years ago, Congress enacted the Hatch-Waxman Act, one of the most successful pieces of health care legislation to become law. It opened up the pharmaceutical marketplace to competition by creating a balance between patient access to safe and affordable, life-saving medicines and incentives for the development of new, innovative drug products. 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 delay generic competition and undermine the intent of Hatch-Waxman at the expense of America's patients. The FAST Generics Act is just one more way to curb practices that artificially increase prescription drug prices in this country. We applaud you and your committee for your efforts on this issue, and hope to continue to be able to work together.

Sincerely,

Academy of Managed Care Pharmacy (AMCP)  
Express Scripts  
Generic Pharmaceutical Association (GPhA)  
Healthcare Supply Chain Association (HSCA)  
National Association of Chain Drug Stores (NACDS)  
National Coalition on Health Care (NCHC)  
Ohio Public Employees Retirement System (OPERS)  
Premier healthcare alliance  
Prime Therapeutics  
Public Sector HealthCare Roundtable  
UAW Retiree Medical Benefits Trust

CC:

Members of the Senate Special Committee on Aging