



the campaign for
SUSTAINABLE Rx PRICING
Transparency. Competition. Value.

July 19, 2017

The Honorable Tom Marino
Chairman
Subcommittee on Regulatory, Reform,
Commercial and Anti-Trust Law
House Judiciary Committee
U.S. House of Representative
Washington, DC 20510

The Honorable David Cicilline
Ranking Member
Subcommittee on Regulatory, Reform,
Commercial and Anti-Trust Law
House Judiciary Committee
U.S. House of Representatives
Washington, DC 20510

Dear Chairman Marino and Ranking Member Cicilline:

The Campaign for Sustainable Rx Pricing (CSRxP) is a broad-based coalition of leaders, comprising physicians, nurses, hospitals, consumers, health plans, PBMs, pharmacists, and businesses, that promotes bipartisan, market-based solutions to lower drug prices in America.

We write today to voice the strong support of our coalition and its members for the Creating and Restoring Equal Access to Equivalent Samples (“CREATES”) Act. This bipartisan legislation would help to end a longstanding pattern of anticompetitive behavior by branded pharmaceutical companies that distorts markets by thwarting generic competition and results in higher prescription drug prices for consumers, job creators, and taxpayers.

CSRxP is committed to increasing transparency, competition, and value in the prescription drug market. We applaud your commitment to combating anticompetitive behavior that blocks access to affordable generic drugs. Currently, drug companies can use a loophole in U.S. laws to deny samples of their branded drugs to generic manufacturers in order to keep generic companies from pursuing the necessary research to comply with FDA regulations and bring alternate products to market. This practice restricts competition in the market and often leaves patients with fewer choices for their medications. As a result, patients may be at the mercy of a single drug company for the medication they need to stay healthy, and that company is free to set the price for the medication indiscriminately. Such practices put a financial strain on patients and drive up health care expenses for everyone

We represent a wide swath of healthcare stakeholders and patient safety is our foremost concern. As such, we fully support the goals of the Federal Drug Administration’s Risk Evaluation and Mitigation Strategies program as a tool for patient safety. These REMS are important components of the overall patient safety regime that work to ensure that the benefits of a given medication subject to FDA-mandated REMS outweigh the potential deleterious effects.

Because of the important contribution that REMS make to patient safety, it is all-the-more disappointing that certain branded pharmaceutical companies have cynically abused this program to deny potential generic and biosimilar competitors the requisite samples needed to conduct equivalency testing, gain FDA approval, and compete in the marketplace.

Generic competition is demonstrably beneficial for consumers, job creators, and taxpayers. A [recent study](#) (funded by none other than the Pharmaceutical Research and Manufacturers of America (PhRMA)), found that “oral generics cost 80% less than the brands they replace within five years.” Because generic or biosimilar entry into the market precipitates significant price reductions, the anticompetitive abuses that the CREATES Act addresses result in enormous unnecessary costs that burden the entire healthcare system. A 2014 [study](#) by Matrix Global Advisors found that abuse of the REMS program to stifle generic and biosimilar competition costs the healthcare system \$5.4 billion annually, including \$1.8 billion in extraneous government spending.

The CREATES Act is a targeted, procompetitive, and market-based solution to this problem that has plagued the healthcare system for far too long. We thank the bipartisan, bicameral sponsors for their work to promote competition and lower drug prices for consumers, job creators, and taxpayers alike, and hope that the Judiciary Committee will consider this legislation this year.

Sincerely,

A handwritten signature in black ink that reads "John Rother". The signature is written in a cursive style with a large, looping initial "J".

John Rother,
Executive Director
Campaign for Sustainable Rx Pricing (CSRxP)