ConsumersUnion®
POLICY & ACTION FROM CONSUMER REPORTS

May 10, 2017

The Honorable Tom Marino, Chairman
The Honorable David Cicilline, Ranking Member
Committee on the Judiciary
U.S. House of Representatives
Washington, D.C. 20515

Dear Chairman Marino and Ranking Member Cicilline:

Consumers Union, the policy arm of Consumer Reports, appreciates your continuing leadership in promoting competition, and specifically in promoting the availability of affordable generic alternatives to prescription drugs, as evidenced in your introduction of H.R. 2212, the Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act.

We have long supported efforts to bring down the high cost of prescription drugs – in our advocacy work, as well as in our publications, such as our August 2016 article, "Is There a Cure for High Drug Prices?"[1] That article reported on the results of a nationally representative telephone poll, conducted by our Best Buy Drugs program last spring, of more than 2,000 consumers who take prescription medications. Disturbingly, we found recent price hikes on a range of medications, from longtime generics used to treat common conditions such as diabetes, high blood pressure, and high cholesterol, to new treatments for diseases such as hepatitis C.

We strongly support your bipartisan legislation. Consumers benefit significantly when more affordable generic alternatives are available for the prescription medications they need. We have long supported government efforts, including the Hatch-Waxman Act, to expedite the ability of generic alternatives to

[1] http://www.consumerreports.org/drugs/cure-for-high-drug-prices/.

make it to market, after appropriate testing to ensure their safety and efficacy as the generic equivalents for FDA-approved drugs. And we have long been concerned by anti-competitive tactics on the part of brand-name drug makers that keep generics from making it to market as a choice for cost-conscious consumers.

Your bill addresses two of these anti-competitive tactics, both of which take unfair advantage of FDA requirements designed to ensure that drugs are safe and effective. One tactic is to refuse to sell samples of the drug to a generic company for FDA-required testing to show that the generic product is bioequivalent to the brand-name product. The other tactic is to block participation by the generic company in FDA-required distribution safety protocols, known as a Risk Evaluation Mitigation Strategy, or REMS. In both instances, a legitimate FDA safety requirement is exploited by the brand-name drug maker to block competition, and thereby artificially prolong its monopoly profits at the expense of consumers.

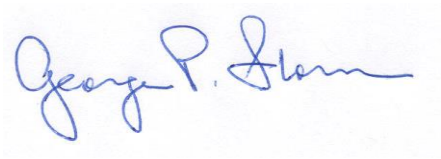
These tactics were reportedly behind the astronomical post-acquisition price hike by Turing Pharmaceuticals of Daraprim, from $13.50 per tablet to $750. Daraprim is the best treatment for toxoplasmosis, a deadly infection that people with compromised immune systems are particularly susceptible. Fortunately for patients – that is, until recently – for decades this drug has been off-patent, and widely available on ordinary distribution channels to wholesalers and retail pharmacies. But two months before the acquisition, reportedly as a condition of the deal, Daraprim was restricted to a closed pharmacy system, and obtaining samples then became exceedingly difficult.

There are signs that these anti-competitive, anti-generic, anti-consumer tactics are spreading, and it is important to stop them quickly. We don't want to go through another round of what happened with another such tactic – "pay for delay" deals to entice generics to put off entry. It took more than a decade of sustained effort on the part of the Federal Trade Commission and private parties to establish an effective antitrust enforcement beachhead against that tactic. And even after the Supreme Court definitively ruled, in its 2013 *Actavis* decision, that the antitrust laws *do* apply to "pay for delay," the brand-name drug makers have shifted more indirect and subtle forms of pay-off, claiming that the Supreme Court's decision only applies to pay-offs in cold, hard cash.

And now, faced with these new tactics, we believe the stakes for consumers are high enough, and the wrong is clear enough, without having to go through another prolonged and expensive fight in the courts. We support your straightforward proposal to give generic companies a clear path to keep these tactics from succeeding – by giving generics a clear legal right to obtain the samples they need, and by allowing generics to establish their own safe distribution protocols when those are required.

We look forward to working with you to enact your legislation into law. Thank you for your leadership in acting to protect competition in the prescription drugs marketplace, and its benefits to consumers.

Sincerely,



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