ConsumersUnion®
POLICY & ACTION FROM CONSUMER REPORTS

February 7, 2018

The Honorable Paul Ryan, Speaker
The Honorable Nancy Pelosi, Minority Leader
The Honorable Greg Walden, Chairman, Committee on Energy and Commerce
The Honorable Frank Pallone, Ranking Member, Committee on Energy and Commerce
The Honorable Bob Goodlatte, Chairman, Committee on the Judiciary
The Honorable Jerrold Nadler, Ranking Member, Committee on the Judiciary
United States House of Representatives
Washington, DC 20515

Dear Mr. Speaker, Madam Leader, Chairmen, and Ranking Members:

Consumers Union, the policy division of Consumer Reports, urges your favorable consideration, as part of the pending budget agreement, of legislation that would improve the availability of affordable generic alternatives for prescription drugs. This bipartisan legislation, the Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act, is now pending in the House as H.R. 2212. It would remove two anticompetitive roadblocks imposed by brand name drug manufacturers – one blocks access to samples that generics need for testing, and the other blocks participation by generics in FDA-required protocols for safe distribution and use.

We have long supported constructive efforts to bring down the high prices consumers pay for 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, 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.

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 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.

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

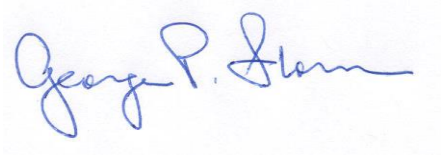
We have supported the CREATES Act since its introduction in June 2016.[2] It addresses two clearly anti-competitive tactics, both of which take unfair advantage of FDA requirements designed to ensure that medications given to American consumers are safe and effective. One tactic is to refuse to sell samples 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 protocols for safe distribution and use, known as a Risk Evaluation Mitigation Strategy, or REMS. In both instances, a legitimate FDA safety requirement is being exploited by the brand-name drug maker to block competition, and to thereby artificially prolong its monopoly profits at the expense of consumers.

These tactics were reportedly behind Turing's astronomical post-acquisition price hike of Daraprim in 2015, for example – from $13.50 per tablet to $750. Daraprim is the best treatment for toxoplasmosis, a deadly infection to which people with compromised immune systems are particularly susceptible. For decades, this drug has been off-patent, and until recently it was 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 became exceedingly difficult.

The CREATES Act gives generic drug companies a clear path to keep these competition-blocking 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.

The Congressional Budget Office has estimated that enacting the CREATES Act would save the Treasury between $3.6 and $3.8 billion over 10 years. The savings to taxpayers – and consumers – is clear. We urge you to take this opportunity to enact the CREATES Act into law – to bring greater competition into the prescription drugs marketplace, and its benefits to consumer pocketbooks.

Sincerely,



George P. Slover
Senior Policy Counsel
Consumers Union

cc: Members, Committee on Energy and Commerce
Members, Committee on the Judiciary

[2] https://www.judiciary.senate.gov/imo/media/doc/06-21-16%20Slover%20Testimony.pdf.