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April 29, 2019

The Honorable Jerrold Nadler
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, DC 20515

The Honorable Doug Collins
U.S. House of Representatives
2142 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Nadler and Ranking Member Collins,

Public Citizen is a national consumer advocacy organization with more than 500,000 members and supporters. We work to advance the public interest across many different issues, including ensuring prescription drugs are made safe, effective and affordable.

We write to you today to express our support for the *Preserve Access to Affordable Generics and Biosimilars Act* (H.R. 2375) and the *Creating and Restoring Equal Access to Equivalent Samples Act of 2019* (*CREATES Act*) (H.R. 965). Generic competition is critical to lowering prescription drug prices. One analysis in the New England Journal of Medicine found that robust generic competition can achieve price reductions of 80 percent or more below the pre-competition price. In Europe, market entry of biosimilars have provided reduced prices not only for biosimilars and their respective reference products, but also the associated product classes. Generic medicines have saved the health care system more than $1 trillion in the past decade.

But prescription drug manufacturers engage in a variety of tactics to thwart and delay generic and biosimilar competition, extending monopoly periods that facilitate exorbitant and unaffordable prices.

One such tactic is the abuse of Risk Evaluation and Mitigation Strategy (REMS) programs. In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which included new requirements to provide additional safeguards for use of certain high-risk prescription drugs through Risk Evaluation and Mitigation Strategy (REMS) programs. While REMS programs can help ensure safety with certain drugs, brand name companies at times abuse REMS programs to prevent potential competitors from attaining FDA approval for generic and biosimilar products that, once approved, would compete with the originator's drug.

These abuses from brand-name drug companies take three forms: 1) invoking the existence of a REMS program as a rationale for denying a generic company access to a sample they require to pursue an abbreviated new drug application (ANDA), 2) attaining method patents on a REMS program itself to prevent generic firms from making use of the same REMS program as required under the FDAAA, and 3) refusing to negotiate a shared REMS with a generic firm to prevent launch of a competing generic product that is otherwise ready for FDA approval.

While the CREATES Act could be strengthened to address anticompetitive patenting of REMS, the measures of the bill provide strong remedies to the other two forms of REMS abuse. By curbing REMS

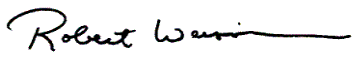
abuses, the CREATES Act is estimated to save taxpayers more than three billion dollars over the next decade.

Brand-name and generic or biosimilar manufacturers also delay the introduction of more affordable medicines by entering into anti-competitive agreements. These "pay-for-delay" deals benefit manufacturers, who share monopoly profits, but directly harm consumers, who face high prices. The Federal Trade Commission has estimated that the deals cost consumers billions of dollars every year.

The *Preserve Access to Affordable Generics and Biosimilars Act* would prohibit brand-name companies from compensating generic drug and biosimilar manufacturers to limit, delay, or otherwise prevent generic and biosimilar entry. The Act would create a presumption that such agreements were anti-competitive, unless the parties demonstrated by clear and convincing evidence that the 1) compensation was for other goods or services, or 2) that the procompetitive benefits of the agreement outweighed its anticompetitive effects.

Ultimately, these bills are just a start. Much more must be done to bring meaningful relief to patients whose health and financial wellbeing is currently being damaged by exorbitant medicine prices. But while the *CREATES Act* and the *Preserve Access to Affordable Generics and Biosimilars Act* are modest in scope, they are nonetheless valuable remedies that could make medicine more affordable for some patients, and we commend the House Judiciary Committee for taking up these measures. We encourage the Committee to advance these these bills, and for Congress to pass them into law without delay.

Sincerely,



Robert Weissman, President
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