March 12, 2019

The Honorable Frank Pallone, Jr.
Chairman
House Committee on Energy & Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Committee on Energy & Commerce
2322 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member Walden:

On behalf of the millions of patients and consumers we collectively represent, we write today in support of the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (H.R. 965/ S. 340). The CREATES Act takes important steps to stop the now well-established abuse of one of the Food and Drug Administration's (FDA) primary safety programs that prevents lower-cost generics from being developed. Public health is undermined when pharmaceutical companies circumvent the FDA's rules with the sole purpose of delaying competition. We urge the Committee to advance this critical patient-focused legislation to enhance competition and maintain the FDA's role in ensuring the highest level of patient safety.

Over ten years ago, Congress provided the FDA with a new tool to further assure the safe use of prescription drugs. The Food and Drug Administration Amendments Act of 2007 allowed for Risk Evaluation and Mitigation Strategy (REMS) programs to be put in place to ensure the safe handling and distribution of certain drugs. In response to concerns that the new requirements would provide a new avenue for anti-competitive behavior, Congress specified that this new tool should not be gamed in a way to delay patient access to more affordable generic medicine.

Abuse of the FDA's safety programs, unfortunately, occurred in spite of congressional intent and has only increased over time. The FDA now reports more than 170 complaints across 55 different medicines have been received by the agency as of February 2019.

Pam Holt is a retired teacher from Indiana who suffers from multiple myeloma. To keep her cancer at bay, she takes the drug Revlimid with a list price of over $250,000 per year. Even on Medicare Part D the drug was unaffordable, and after just one year it sent Pam $10,000 into debt. She made the heartbreaking decision to refinance her house to afford the drug.

Revlimid is just one example of abuse of our current system. Its manufacturer, Celgene, has refused to provide product samples to generic competitors looking to create a lower-cost alternative. The CREATES Act will address these abuses and encourage generic drug competition. It achieves this while protecting patient safety.

The CREATES Act codifies the FDA's current practice of ensuring generic drug manufacturers are able to safely handle branded doses and that all materials contain comparable safety protections. All bioequivalence testing is subject to review by an institutional review board and must comply with patient informed consent provisions. These elements importantly provide another layer of protection for patients.

Moreover, the FDA must assure the same level of patient safety is provided when determining whether to waive the shared safety protocols. Notably, the CREATES Act maintains the requirement in current law that a different system will provide comparable protections for patients. As FDA leadership has noted, a single shared system will continue to be the agency's goal and only waived when the public health impact of delayed generic entry outweighs the benefits of a shared system.

Our organizations strongly believe in the FDA's ability to ensure patient safety when it comes to the process of obtaining samples and providing limited waivers to the shared safety protocols. The CREATES Act enhances and maintains the FDA's patient safety role, while ending the abuse of its safety programs. We encourage all members of the committee to support the CREATES Act as introduced.

Thank you for considering our views.

Sincerely,

AARP
Friends of Cancer Research
National Multiple Sclerosis Society
Patients for Affordable Drugs