February 6, 2018

Dear Member:

On behalf of the members and activists represented by our various organizations, we write to express our strong opposition to the CREATES Act (S. 974 and H.R. 2212). The legislation includes some admirable goals, but it would expose many patients to serious and unnecessary health risks. In addition, it is primarily designed to benefit trial lawyers and non-innovators, undermining intellectual property rights, delaying the development of new treatments, and increasing the cost of healthcare.

The bill's sponsors assert that their intention is to prevent branded pharmaceutical companies from improperly delaying competition from generic competitors. We agree that robust competition is a fundamental principle of free enterprise. However, the intellectual property rights of innovators, the safety of patients, and the integrity of Food, Drug and Cosmetic Act are also at issue here. Any legislation in this area must not put the business goals of non-innovators and professional litigators ahead of property rights, safety and fairness.

For a small number of drugs and drug categories (presently 45), the FDA mandates "risk evaluation and mitigation strategies (REMS) with "elements to assure safe use" (ETASU). These are drugs with known, serious risks that are used to treat very serious life-threatening illnesses. In each case, the FDA has determined that the serious risks associated with the drugs are outweighed by their benefits, but only if strict and often very expensive safety protocols are followed. Drugs subject to REMS with ETASU go through a rigorous process to avoid severe or even fatal consequences to patients and professionals who may handle or administer them.

The CREATES Act undermines this important safety process, making it much more likely that dangerous drugs may fall into the hands of individuals who lack appropriate training or practice in handling or administering them. In a letter to Congress, the Patients Alliance for Drug Safety Protections noted that the bill does not require a generic manufacturer's protections during testing to proposed competing products to meet the same standard of safety as the REMS for innovator products.

We note that the vast majority of existing REMS with ETASU drugs already have generic competitors, have generics presently in the FDA approval pipeline, or have been passed over by generic manufacturers for various reasons despite the availability of samples for comparison testing. Existing regulations already allow generic and brand name to companies to work out the terms for sharing samples of REMS drugs so that generic companies are able to test their products before patents expire. However, some in Congress view all forms of property rights--including intellectual property--more as a hindrances

than as Constitutionally-protected rights. We disagree. If the rights of innovators are not protected, there will be less innovation--which will mean fewer medical therapies and less overall prosperity.

Congress should examine and improve the current REMS system if changes need to be made, but we see no improvement in introducing--for the first time--a private right of action into the Food Drug and Cosmetics Act. We believe this will take gravely important decision-making processes from researchers and the FDA and put them into the hands of trial lawyers and judges. The CREATES Act's massive penalties--equal to all revenue from a product--will create incentives to put safety and fairness behind business considerations, undermining the FDA's mission of protecting the public health.

Under the bill's provisions, courts could undermine the intellection property rights of patent holders simply by finding that the aggressive timeline mandates in the proposal has not been met. This timeline would create an irresistible incentive for many generic companies to avoid engaging in constructive negotiations, since the potential penalties are many times greater than what they could earn simply by bringing their own product to market. We do not believe this is accidental. This ability to hold innovator companies "hostage" will force innovators to direct resources away from their core missions--creating and producing valuable life-saving drugs--to fighting these suits.

Ultimately, this legislation is a gift to the trial bar and will create a cottage industry of companies requesting drug samples simply for the opportunity to use litigation as a means for a potential payday. Cutting corners when it comes to product safety and engaging in frivolous litigation, especially to get one's hands on someone else's invention, rarely yields good results. As Congress continues to work to improve the health and wellness of our citizens, we ask that you seriously consider the very negative impact the CREATES Act will have on both innovation and safety.

Sincerely,

Daniel Schneider, Executive Director
The American Conservative Union

Phil Kerpen, President
American Commitment

Grover Norquist, President
Americans for Tax Reform

Seton Motley, President
Less Government

Sally Pipes, President and CEO
Pacific Research Institute

Ed Martin, President
Phyllis Schlafly Eagles

David Williams, President
Taxpayers Protection Alliance