Open Letter to Congress: Harmful Unintended Consequences of the CREATES Act of 2016

November 14, 2016

Members of Congress:

On behalf of the members and activists represented by our various organizations, we write today to express our grave concerns with legislation that is similar to provisions of S. 3056, the CREATES Act of 2016. The specific provisions of concern expose many patients to serious and unnecessary health risks. At the same time, this proposed language is a gift to trial lawyers that will open up the flood gates to costly litigation, undermine intellectual property rights, increase health care costs and delay the development of new treatments.

Senator Patrick Leahy (ACU lifetime rating: 5%), the leader of this effort, has stated that he wants to speed-up the process of bringing generic pharmaceutical drugs to market; an admirable goal, indeed. While we certainly support ensuring drugs remain affordable for all consumers, this current proposal will result in many harmful unintended consequences.

For certain drugs—namely ones with known, serious risks that are used to treat very serious life-threatening illnesses—the FDA has created a safety protocol known as "risk evaluation and mitigation strategies with elements to assure safe use" (REMS with ETASU, for short). Drugs subject to these standards go through a rigorous process to avoid severe or even fatal consequences to patients as well as for anyone who handles or administers them.

The legislation under consideration undermines this safety process, making it far more likely for potent drugs to fall into the hands of those without appropriate training or practice in handling or administering them. In a recent letter to Congress, the Patients Alliance for Drug Safety Protections noted that the bill does not require a generic company's protections during testing of its drug to meet the same standard of safety as the REMS for the approved innovator drug. We agree, and believe there may be more to Senator Leahy's intentions than he has acknowledged.

Existing regulations already allow generics and brand name 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. But some in Congress view all forms of property rights—including intellectual property—more as hindrances rather than as Constitutionally-protected rights. Congress should examine and improve the current REMS system if changes need to be made, but we see no improvement in throwing this process into the hands of trial lawyers, which the current proposals would do through this ill-conceived litigation process.

Under the proposed legislation, brand named pharmaceutical companies would be required to turn over drug samples to generic makers within 31 days after requests are made, or risk costly lawsuits and fines, even when plaintiffs cannot show *any* harm. We believe these proposals to create new private rights of action for the first time ever are contra-indicated to FDA's mission in protecting the public health.

Worse, courts could undermine the intellectual property rights of patent holders simply by finding that the aggressive timelines mandated in the proposal had not been met. These timelines 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 by bringing their generic copies to market. They could even use these penalties to hold innovative companies hostage and create new trial lawyer incentives for massive litigation. Innovative companies put in this upside-down position will have to direct

resources away from their core missions—creating and producing valuable life-saving drugs—to fighting these suits.

Maybe it should not be a surprise that the Manhattan Institute's Center for Legal Policy discovered that Senator Leahy "has received more than twice as much money from lawyers since 2005 as he has from any other industry, and those donations overwhelmingly come from the plaintiffs' bar." http://www.manhattan-institute.org/pdf/TLI-KStreet.pdf.

Ultimately, this legislation is a gift to the trial bar and creates a cottage industry of companies requesting drug samples simply for the opportunity to use litigation as a means for a potential payday.

History tells us that cutting corners when it comes to product safety and engaging in frivolous litigation, especially to get your hands on something you didn't create, 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 this dangerous legislation will have both on innovation and safety.

Sincerely,

Dan Schneider, Executive Director
American Conservative Union

J. Kenneth Blackwell, Distinguished Fellow
American Civil Rights Union

Phil Kerpen, President
American Commitment

Grover Norquist, President
Americans for Tax Reform

Peter Pitts, President
Center for Medicine in the Public Interest

Ed Martin, President
Eagle Forum Education & Legal Defense Fund

Mario Lopez, President
Hispanic Leadership Fund

Seton Motley, President
Less Government

Colin Hanna
Let Freedom Ring

Wayne Winegarden, Ph.D., Sr. Fellow Business & Economics
Pacific Research Institute

*All organizations listed are for identification purposes only.