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## EAGLE FORUM EDUCATION & LEGAL DEFENSE FUND

January 11, 2018

The Honorable Mitch McConnell  
Majority Leader  
U.S. Senate  
S-230 The Capitol  
Washington, D.C. 20510

The Honorable Paul Ryan  
Speaker of the House  
U.S. House of Representatives  
H-232 The Capitol  
Washington, D.C. 20515

Dear Mr. Majority Leader and Mr. Speaker:

Eagle Forum Education & Legal Defense Fund writes to share some serious concerns regarding the CREATES Act (H.R. 2212), which we understand to be under consideration for inclusion as a “pay-for” in the FY 2018 omnibus appropriation bill, whose deadline is January 19. As you know, Eagle Forum ELDF has a long track record of engaging in patent policy issues, which the CREATES Act directly and significantly would affect.<sup>1</sup>

There are responsible means of promoting competition from safe, effective generic medicines, such as the Hatch-Waxman Act procedures and the Food and Drug Administration’s recent steps implementing the 21st Century Cures Act provisions to streamline regulatory hurdles. However, the CREATES Act takes an approach that could instead create new risks to patient safety, while forcing innovators to disclose intellectual and proprietary property under the gun of a litigation scheme tilted against them.

The CREATES Act would divert from a key element of our patent system that has led to America’s pace of medical progress. In order to promote invention that advances our nation’s economic progress, including medical advancement, the Founders provided inventors exclusivity over the commercial exploitation of an invention for an appreciable period of time. The United States has wisely retained — and benefitted from — patent exclusivity and comparable regulatory forms of exclusivity, including for medical innovation, whose long, expensive path from discovery to marketed product may exceed the patent term. Exclusivity of patents, trade secrets, and other intellectual property and competitively sensitive information extends to regulatorily required patient safety measures known as REMS (risk evaluation and mitigation strategy); however, the proposed legislation would reduce IP protections for REMS.

CREATES would vastly weaken protection of brand companies’ intellectual property interests in the product and processes of the REMS (e.g., distribution, storage, other controls) by enabling generic drug makers to use litigation procedures designed to force accession, regardless of the potential patient safety risks or the costs from forced sharing of patents and other IP. This proposed, unprecedented private right to sue does not require generic firms first to make good-faith efforts to obtain reference drug samples through regular market channels. Instead, unreasonably short deadlines, lack of consideration of mitigating circumstances, and other means of depriving due process and justice almost guarantee a “sue-

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<sup>1</sup> Erika Lietzan, “A Second Look at the CREATES Act: What’s Not Being Said,” *Federalist Society Review*, Vol. 17, Issue 3, October 2016

first, ask-questions-later” disposition among both generic competitors and their lawyers.<sup>2</sup>

Thus, CREATES would raise the likelihood of exposing patients to unmitigated health and safety risks or products that fall short of the innovator drug’s safety and effectiveness.

Therefore, we believe it unwise to enact such far-reaching, untested proposals, especially as a budgetary offset without regard to the serious policy concerns at issue. We strongly urge that you forego using such policy proposals as the CREATES Act in the budgetary and appropriations context, leaving them to appropriate vetting through regular order. Thank you for considering the input of Eagle Forum Education & Legal Defense Fund.

Faithfully,

A handwritten signature in blue ink, appearing to read 'Ed Martin', with a long horizontal flourish extending to the right.

Ed Martin  
President

cc: Sen. Charles Grassley  
Sen. Orrin Hatch  
Sen. Lamar Alexander  
Rep. Robert Goodlatte

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<sup>2</sup> Jim Edwards, “Congress May Benefit Trial Lawyers, Endanger Patients, Rob Innovators and Undermine Patent Rights,” Phyllis Schlafly Eagles blog, September 15, 2017 (<http://www.phyllisschlafly.com/congress-may-benefit-trial-lawyers-endanger-pati-1119>)