

February 18, 2019

The Honorable Chuck Grassley  
United States Senate  
Washington, DC 20510

The Honorable Patrick Leahy  
United States Senate  
Washington, DC 20510

The Honorable Amy Klobuchar  
United States Senate  
Washington, DC 20510

The Honorable Mike Lee  
United States Senate  
Washington, DC 20510

**RE: Creating and Restoring Equal Access to Equivalent Samples (CREATES)**

Dear Senators Grassley, Leahy, Klobuchar, and Lee:

On behalf of the Academy of Managed Care Pharmacy (AMCP), I wanted to take this opportunity to express our strong support for S. 340, the “Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act,” bipartisan legislation to increase competition and patient access to safe and affordable generic and biosimilar medicines. AMCP is pleased that you reintroduced the legislation in the 116<sup>th</sup> Congress on February 5, 2019. We are encouraged that the legislation will again garner bipartisan support and optimistic that with that support the bill will be reported out of the Judiciary Committee to the Senate floor for consideration.

AMCP is the nation’s leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy’s 8,000 pharmacists, physicians, nurses and other practitioners, manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

As you know, brand name pharmaceutical companies often block generic and biosimilar drug manufacturers from purchasing samples, which are used to conduct the bioequivalence testing necessary in order to file an application for approval with the Food and Drug Administration (FDA). One method that such companies have utilized to stop generic and biosimilar competition is to assert that the Risk Evaluation and Mitigation Strategy (REMS) program allows them to deny samples. In fact, Dr. Scott Gottlieb, FDA Commissioner wrote “We see problems accessing testing samples when branded products are subject to limited distribution . . . in some cases, branded sponsors may use these limited distribution arrangements, whether or not they are REMS – related, as a basis or blocking generic firms from accessing the testing samples they need.”<sup>1</sup> This legislation

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<sup>1</sup> FDA Voice, FDA Working to Lift Barriers to Generic Competition by Scott Gottlieb, M.D. June 21, 2017. <https://blogs.fda.gov/fdavoices/index.php/2017/06/fda-working-to-lift-barriers-to-generic-drug-competition/>

would strengthen the FDA's efforts to lift barriers to generic drug competition. Secretary Azar recently stated that "we know that certain brand-name manufacturers are abusing the system by blocking access to samples and hiding behind FDA's rules when they do it".<sup>2</sup>

This problem is growing and patient access to safe and affordable generic and biosimilar medication is being unnecessarily delayed. The opposition to this legislation has argued that this legislation will endanger patient safety. It should be noted that generic drug developers are already required to adhere to safe handling and other procedures that protect patient safety, and this applies every time brand companies permit the sale of samples for generic drug development. This legislation would simply close an existing loophole.

With nearly nine out of ten Americans (87%) in favor of "making it easier for generic drugs to come to market in order to increase competition and reduce costs"<sup>3</sup> and 50 health care stakeholders representing diverse interests including AARP (physicians, patients, health plans) calling for congressional action to provide "generic and biosimilar manufacturers a clear and efficient pathway to combat these bad actors,"<sup>4</sup> support for this legislation continues to increase.

To ensure that the practices of a handful of brand companies that prevent generic drug developers from obtaining samples necessary to bring new accessible generic and biosimilar drugs to patients and payors, Congressional action is imperative. The CREATES Act would provide a safe, efficient and targeted pathway to end these abusive, anti-competitive tactics.

Thank you for sponsoring this important legislation. Patients will benefit from your efforts to bring safe and affordable generic and biosimilar medicines to market as soon as possible to increase patient access. Please do not hesitate to contact AMCP's Director of Government Affairs, Chris Topoleski at 703-684-2620 or [ctopoleski@amcp.org](mailto:ctopoleski@amcp.org) if we can provide additional information.

Sincerely,



Susan A. Cantrell, RPh, CAE  
Chief Executive Officer

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<sup>2</sup> Prepared Remarks on Drug Pricing Blueprint by Alex M. Azar II, May 14, 2018.

<https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>

<sup>3</sup> Kaiser Family Foundation, "Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs," May 2017.

<sup>4</sup> <https://www.csrpx.org/wp-content/uploads/2019/02/FINAL-CREATES-Act-2.5.19.pdf>