



Academy of
Managed Care
Pharmacy®

July 27, 2017

Hon. Tom Marino
Chair, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Hon. David Cicilline
Ranking Member, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

RE: Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act – H.R. 2212

Dear Chairman Marino and Ranking Member Cicilline:

On behalf of the Academy of Managed Care Pharmacy (AMCP), I wanted to take this opportunity to express our strong support for the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 2212), bipartisan legislation to increase competition and patient access to safe and affordable generic and biosimilar medicines. AMCP is pleased that you will be holding a hearing on this important legislation later this week. We are encouraged that the legislation has bipartisan support and optimistic that with that support the Committee will mark-up the bill and advance it to the House 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). In particular, 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 recently 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 for blocking generic firms from accessing the testing samples they need."¹ This legislation would strengthen the FDA's efforts to lift barriers to generic drug competition.

¹ 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/>

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”² and over 18 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,” 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 holding this important hearing. Patients will benefit from your efforts to bring safe and affordable generic and biosimilar medicines to market at the earliest possible date to increase patient access. Please do not hesitate to contact AMCP’s Director of Legislative Affairs, Reginia Benjamin, at (703) 683-8416 or rbenjamin@amcp.org if we can provide additional information.

Sincerely,

A handwritten signature in black ink, appearing to read "Susan Cantrell". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Susan A. Cantrell, RPh, CAE
Chief Executive Officer

² Kaiser Family Foundation, “Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs,” May 2017.