

July 24, 2018

The Honorable Lamar Alexander
U.S. Senate

RE: S. 974 -- Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act

Dear Senator Alexander:

On behalf of the Academy of Managed Care Pharmacy (AMCP), I am writing to express our strong support for the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S. 974), bipartisan legislation designed to increase patient access to safe and affordable generic and biosimilar medicines and marketplace competition. AMCP was pleased that the bill continued to garner bipartisan support when it was voted out of the Judiciary Committee. We are seeking your support for the bill now that the bill is on the Senate Legislative Calendar.

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, some brand name pharmaceutical companies block generic and biosimilar drug manufacturers from purchasing samples, which are used to conduct the bioequivalence testing necessary to file an application for approval with the Food and Drug Administration (FDA). In particular, one method that certain 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, FDA Commissioner Scott Gottlieb 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. 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".² This problem is causing unnecessary delays in patients' access to safe and affordable generic and biosimilar medications.

Those who oppose this bill have argued that it will endanger patient safety because it would allow generic manufacturers to obtain samples of drugs that are subject to a REMS safety protocol. Generic manufacturers can only use the CREATES Act to obtain samples of a REMS-covered drug if the FDA pre-approves the generic manufacturer's proposed safety protocols. This bill also grants the FDA more

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/>

² 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>

discretion to adopt additional protocols to ensure patient safety before authorizing a generic manufacturer to receive samples of a REMS-covered drug³. Further, 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 a brand company permits 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”⁴ and with 68 health care stakeholders representing diverse interests including AMCP, AARP, (physicians, patients, hospitals, health plans, employers and unions), calling for congressional action to provide “generic and biosimilar manufacturers a clear and efficient pathway to combat these bad actors,” the time to pass this legislation is now.

To guard against practices that prevent generic drug developers from obtaining samples necessary to bring new accessible generic and biosimilar drugs to patients, Congressional action is imperative. The CREATES Act would provide a safe, efficient and targeted pathway to end these abusive, anti-competitive tactics. Lastly the Congressional Budget Office estimates that the bill would result in a \$3.8billion net decrease in the federal deficit.³

AMCP advocates for policies that encourage innovation and competition among new, cutting-edge medicines, biosimilars and other established therapies – so providers have options to better serve patient health and prevent unnecessary costs. CREATES will benefit patients by bringing safe and affordable generic and biosimilar medicines approved by the FDA to market at the earliest possible date. Please support those efforts with your vote in favor of S. 974. If we can provide you with additional information, please do not hesitate to contact AMCP’s Director of Legislative Affairs, Regina Benjamin, at (703) 683-8416 or rbenjamin@amcp.org. Thank you for your consideration.

Sincerely,



Susan A. Cantrell, RPh, CAE
Chief Executive Officer

³ Senator Patrick Leahy, “Leahy-Grassley CREATES Act to Lower Prescription Drug Prices Clears Judiciary Committee,” press release, June 14, 2018. <https://www.leahy.senate.gov/press/061418createsmarkuprelease>

⁴ Kaiser Family Foundation, “Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs,” May 2017. <https://www.kff.org/health-costs/press-release/poll-majorities-of-democrats-republicans-and-independents-support-actions-to-lower-drug-costs-including-allowing-americans-to-buy-drugs-from-canada/>