



601 E Street, NW | Washington, DC 20049
202-434-2277 | 1-888-OUR-AARP | 1-888-687-2277 | TTY: 1-877-434-7598
www.aarp.org | twitter: @aarp | facebook.com/aarp | youtube.com/aarp

February 5, 2019

The Honorable David Cicilline
U.S. House of Representatives
2233 Rayburn House Office Building
Washington, DC 20515

The Honorable Jim Sensenbrenner
U.S. House of Representatives
2449 Rayburn House Office Building
Washington, DC 20515

The Honorable Peter Welch
U.S. House of Representatives
2187 Rayburn House Office Building
Washington, DC 20515

The Honorable David B. McKinley
U.S. House of Representatives
2239 Rayburn House Office Building
Washington, DC 20515

Dear Representatives Cicilline, Sensenbrenner, Welch and McKinley:

AARP is pleased to endorse the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act that would deter brand name pharmaceutical companies from participating in certain practices that can delay or block the availability of less expensive generic and biosimilar drugs. We appreciate your bipartisan leadership in introducing this legislation to help make lower cost prescription drugs more available to seniors.

Rising prescription drug costs have been devastating to many Americans, especially those aged 50 and over who depend on prescription drugs to keep them healthy. The growing number of brand name and specialty drugs with remarkably high prices -- \$100,000 or more -- has led many to question whether the costs associated with these products are defensible or sustainable. The timely availability of generic and biosimilar drugs -- by increasing competition and helping to lower prices -- will play an important role in addressing these concerns.

The Food and Drug Administration (FDA)-required Risk Evaluation and Mitigation Strategies (REMS) were originally designed to ensure that the benefits of a drug or biologic outweigh its risks. Unfortunately, brand name drug manufacturers are increasingly using REMS programs to effectively block generic drug and biosimilar product development. Left unchecked, these unnecessary delays could cost consumers, government programs, taxpayers, and the health care system billions of dollars annually.

The CREATES Act appropriately targets two forms of anticompetitive behavior that brand name drug manufacturers can use to stifle generic and biosimilar drug entry: refusal to provide access to product samples that are needed to gain FDA approval, and preventing generic and biosimilar manufacturers from joining a distribution protocol applicable to both brand and generic versions of a medicine, or “shared REMS.” Additionally, courts would be empowered to award damages that would provide sufficient incentives to encourage good-faith dealing by brand manufacturers from the outset.

Importantly, the CREATES Act does not undermine or alter any of FDA’s existing safety protocols pertaining to drug approval or distribution. In fact, this legislation requires the FDA to review and approve a generic manufacturer’s application for a covered product subject to a REMS to ensure the manufacturer will adhere to the appropriate safety protections. Moreover, FDA is empowered to impose additional safety protocols on the generic manufacturer if they determine such measures are needed.

We look forward to working with you and your colleagues on both sides of the aisle in support of advancing the CREATES Act. If you have any further questions, please feel free to contact me, or have your staff contact Amy Kelbick at (202) 434-2648 on our Government Affairs staff.

Sincerely,

A handwritten signature in black ink that reads "Joyce A. Rogers". The signature is written in a cursive, flowing style.

Joyce A. Rogers
Senior Vice President
Government Affairs