AARP
Real Possibilities

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June 20, 2016

The Honorable Charles Grassley
Chairman
Senate Committee on the Judiciary
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Patrick Leahy
Ranking Member
Senate Committee on the Judiciary
152 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Mike Lee
Chairman
Subcommittee on Antitrust, Competition Policy and Consumer Rights
224 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Amy Klobuchar
Ranking Member
Subcommittee on Antitrust, Competition Policy and Consumer Rights
152 Dirksen Senate Office Building
Washington, DC 20510

Dear Senators Grassley, Leahy, Lee and Klobuchar:

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.

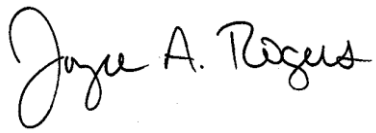
The high cost of prescription drugs can reduce patient access to life-saving medications. Further, the growing number of brand name and specialty drugs with remarkably high prices has led many to question whether the costs associated with these products are sustainable. The timely availability of generic and biosimilar drugs 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.

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 KJ Hertz at (202) 434-3732 on our Government Affairs staff.

Sincerely,



Joyce A. Rogers
Senior Vice President
Government Affairs

CC: Members of the Senate Judiciary Committee