The Honorable Mitch McConnell
The Honorable Charles Schumer
United States Senate
Washington, D.C. 20510

May 7, 2019

Dear Majority Leader McConnell and Minority Leader Schumer,

We, the undersigned consumer groups, write to express our support for S. 340, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. This bill will stop abusive delaying tactics that brand-name prescription drug makers are using to prolong their monopoly profits by delaying the development and market entry of more affordable generic and biosimilar alternatives.

At recent hearings held by the House Committee on Oversight and Reform, the Senate Finance Committee, and the House Committee on Ways and Means, experts testified that these delaying tactics are a serious problem and have gotten worse in recent years. The CREATES Act deals with two such tactics – blocking generic and biosimilar drug companies from obtaining samples they need for testing, and blocking them from participating in FDA-required safety protocols.

The first delaying tactic is when brand-name drug companies prevent potential biosimilar and generic competitors from purchasing samples of the branded product. These samples are needed for testing the more affordable alternatives to ensure that they are equivalent to the brand-name drugs, which is required for FDA approval. The CREATES Act allows biosimilar or generic drug manufacturers to bring actions in federal court for injunctive relief so they can obtain the samples they need. It also allows courts to award damages against the brand-name drug companies if they behave in an especially egregious manner; this would serve as a deterrent against this anticompetitive behavior.

The second delaying tactic is when brand-name drug companies have medicines that require a distribution safety protocol (more commonly referred to as a Risk Evaluation Mitigation

Strategy, or REMS) and use this requirement as an excuse to block competition. Many of these companies refuse to allow generic or biosimilar competitors to participate in this safety protocol. The CREATES Act gives the FDA increased discretion to approve alternate safety protocols instead of always requiring that brand-name companies and generic/biosimilar companies develop shared safety protocols. The FDA would have to approve the alternative safety protocols, and they would have to meet the same standards already in place.

Americans overwhelmingly support congressional action to lower the costs of prescription drugs – according to one poll, 83% of Americans support passage of the CREATES Act.[1] The Congressional Budget Office found that this proposal would save the federal government $3.9 billion over ten years, principally by lowering Medicare and Medicaid spending on prescription drugs.[2] Savings of a similar magnitude could be expected for the rest of the health care marketplace.

In May 2018, the FDA publicly identified brand-name drug companies that appeared to be refusing to provide the samples needed for testing.[3] The list showed 164 inquiries that the FDA had received from generic and biosimilar drug makers complaining that they had been refused samples, covering over 50 drugs. Brand-name companies on the list included Celgene, Actelion, GlaxoSmithKline, Pfizer, Valeant Pharmaceuticals International. BioMarin Pharmaceutical, Gilead Sciences, and Novartis Pharmaceuticals.

Last week, the House Judiciary Committee approved the CREATES Act on a strong bipartisan voice vote.

We are encouraged that the CREATES Act currently has thirty-two Senate cosponsors, with strong bipartisan support. The bill has the support of many different organizations, including health care providers, health insurers, employers, unions, antitrust experts, elected officials, ordinary citizens, and consumer groups.

Increasing drug prices have rendered prescription drugs unaffordable for many Americans, and too many people are being forced to choose between medicines and other basic necessities. The CREATES Act will help alleviate that problem. We urge its swift approval.

Sincerely,

Consumer Action
Consumer Federation of America
Consumer Reports
Families USA
NETWORK Lobby for Catholic Social Justice
U.S. PIRG

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[1] https://www.patientsforaffordabledrugsnow.org/creates-act-poll.
[2] CBO Analysis of H.R. 965, CREATES Act of 2019, April 25, 2019. Available at https://www.cbo.gov/publication/55181.
[3] Sheila Kaplan. *F.D.A. Names and Shames Drug Makers to Encourage Generic Competition.* New York Times, May 17, 2018. Available at https://www.nytimes.com/2018/05/17/health/drug-prices-generics-fda.html.