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WSC POLICY BRIEF

The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act

H.R. 2212/S. 974 - Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act

- **House Sponsor:** Tom Marino (R-PA-10)
- **Senate Sponsor:** Patrick Leahy (D-VT)

Brief Summary

The CREATES Act is intended to prevent pharmaceutical companies from blocking companies from producing generic drugs by refusing to sell drugs to the new companies or taking advantage of safety regulation to block new drugs.

Background

The Drug Price Competition and Patent Term Restoration Act of 1984 – commonly referred to as the Hatch-Waxman Act – created the generic drug market in order to balance incentives for innovation with a system that ensures safe, therapeutically equivalent generic drugs are available at lower prices when patents and exclusivities expire. Before a generic drug can be approved by the Food and Drug Administration (FDA) it must demonstrate that it is bioequivalent to the brand-name drug it intends to compete against on the market.

The Food and Drug Administration Amendments Act of 2007 authorized the FDA, when there are safety concerns like increased toxicity or risk factors, to require manufacturers to adhere to a mandatory distribution safety protocol (known as a Risk Evaluation Mitigation Strategy with Elements to Assure Safe Use, or "REMS with ETASU").

Some brand-name drug manufacturers have misused the bioequivalence requirement and REMS programs to block or otherwise delay generic drug manufacturers from bringing a generic drug to market.

Major Provisions of the CREATES Act

Sample-Sharing: The CREATES Act allows a generic drug manufacturer to bring an action in federal court when brand-name drug companies prevent potential generic competitors from obtaining samples of the branded product in order to perform the necessary testing to show that the generic is equivalent. The bill would expedite legal review and change the burden from proving a violation of antitrust law to one in which the generic manufacturer would need

to only prove that sufficient quantity of samples was being withheld by the brand-name manufacturer. The bill authorizes a judge to provide injunctive relief (i.e., to require the brand-name manufacturer to provide the needed samples) and award damages to deter future delaying conduct.

Participation in a Shared Safety Protocol: According to FDA officials, brand-name manufacturers often intentionally delay establishing a single, shared REMS program, which blocks the generic drug from the market. The CREATES Act allows the FDA more discretion to approve alternative safety protocols, rather than require parties to develop shared safety protocols. Any safety protocol approved by the FDA must meet the rigorous statutory standards already in place.

Budgetary Impact

The Congressional Budget Office (CBO) has not officially scored the CREATES Act, but has estimated that similar legislation (H.R. 2051, the Fair Access for Safe and Timely Generics Act) would save the federal government $3.3 billion over 10 years. Advocates say that underestimates the savings. A 2014 study sponsored by generic drug manufacturers identified $5.4 billion annually in lost savings on 40 drugs alone, although the study did not disclose the 40 drugs.

Legislative Activity

The CREATES Act was originally introduced by Sens. Patrick Leahy (D-VT), Chuck Grassley (R-IA), Amy Klobuchar (D-MN), and Mike Lee (R-UT) in June of 2016. The bill was left in the Senate Judiciary Committee.

As of March 18, 2018, the 115th Congress version of the CREATES Act has 20 cosponsors in the Senate (10 Republicans; 9 Democrats; 1 Independent). The House version has 15 cosponsors (7 Republicans; 8 Democrats). While the bill has broad bipartisan support in both chambers, the bill has yet to be brought to either floor for a vote.

Leahy and Marino, the current bill's sponsors in the Senate and House, respectably, pushed to have the CREATES Act included in the Bipartisan Budget Act of 2018 (H.R. 1892) and, when that failed, in the Consolidated Appropriations Act of 2018 (H.R. 1625). Although House leaders initially told Marino that the bill would likely be added to the omnibus, it was ultimately left out of the final version.

Supporters of the bill say that GOP legislators, under heavy lobbying pressure from major drug industry trade groups, have blocked floor votes on the bill and refused to include it as a part of a larger legislative package.

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