

The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016

Preventing Abusive Tactics that Delay the Creation of Affordable Generic Drugs

The Creating and Restoring Equal Access to Equivalent Samples (“CREATES”) Act targets abusive delay tactics that are being used to block entry of affordable generic drugs.

- **Sample-sharing.** The first delay tactic addressed by the CREATES Act occurs when brand-name drug companies prevent potential generic competitors from obtaining samples of the branded product, so the generic company cannot perform the testing necessary to show that its product is equivalent to the brand-name product, a prerequisite for FDA approval.
- **Participation in a shared safety protocol.** The second delay tactic addressed by the CREATES Act occurs when brand-name manufacturers whose products require a distribution safety protocol (known as a Risk Evaluation Mitigation Strategy with Elements to Assure Safe Use, or “REMS with ETASU”) refuse to allow generic competitors to participate in that safety protocol, again undermining the generic’s ability to gain FDA approval.

The CREATES Act allows a generic drug manufacturer facing one of these delay tactics to bring an action in federal court for injunctive relief (i.e. to obtain the sample it needs, or to enter court-supervised negotiations for a shared safety protocol). The bill also authorizes a judge to award damages to deter future delaying conduct.

The CREATES Act is intended to provide an efficient, tailored path for generic drug manufacturers to obtain relief so they can continue working to bring their lower-cost product to market. The Congressional Budget Office has estimated that similar legislation would save the government over \$2 billion in direct savings over 10 years. The savings to consumers and private insurance companies would likely be far greater.

Nearly three-quarters of the public view prescription drug costs as unreasonable, and one in four patients say they have not filled a prescription because of cost. The CREATES Act is a commonsense, cost-saving measure to promote the creation of safe and affordable generic drugs.

The Turing Case & Other Examples of Strategic Delays

The CREATES Act’s importance is illustrated by the recent controversial actions of Turing Pharmaceuticals, which in 2015 increased the price of its anti-parasitic drug Daraprim from \$13.50 to \$750 per pill overnight – an increase of 5000%. A former Turing employee has testified that an “integral part” of Turing’s plan to increase the price of Daraprim was restricting Daraprim’s distribution so that generics could not obtain samples to manufacture a lower-price alternative.

Antitrust authorities, the FDA, and generic companies report that other companies are using similar strategies to delay generic entry. The Chairwoman of the FTC has testified that the FTC is “very concerned” about potential abuses of drug distribution systems to impede generic competition. The FDA’s Director of the Center for Drug Evaluation and Research has testified that as of January 2016, the FDA had received over 100 inquiries from generic product developers who were unable to access samples of an innovator drug to compare and test their generic product.

The Senate Judiciary Committee’s Subcommittee on Antitrust, Competition Policy and Consumer Rights has scheduled a hearing on the CREATES Act for June 21, 2016.

Support for the CREATES Act

The CREATES Act is supported by consumer groups, generic drug manufacturers, antitrust experts, physicians, pharmacists, hospitals, insurers and other groups that advocate for lower-cost drugs, including:

The Generic Pharmaceutical Association (GPHA)
AARP
Consumers Union
Families USA
National Coalition on Healthcare
Center on Medicare Advocacy
Public Citizen
American College of Physicians
American Hospital Association
Healthcare Supply Chain Association
National Association of Chain Drug Stores
Pharmaceutical Care Management Association
Express Scripts
Blue Cross Blue Shield Association
Premier Healthcare Alliance
AFL-CIO
American Federation of Teachers
Public Sector Healthcare Roundtable
UAW Retiree Medical Benefits Trust

“The [CREATES Act of 2016] will remove a delaying tactic used by a few name-brand manufacturers and make it easier and faster for other manufacturers to pursue bringing lower-cost alternatives to market and increase patient access.” – **American College of Physicians**, June 13, 2016

“We support this valuable legislation because it clears unnecessary barriers to timely market access for generic medications. . . America’s working families have a direct stake in ensuring that access to lower-cost generic drugs is not delayed. Skyrocketing increases in drug costs are a key driver of overall health care cost growth and, in turn, a major factor behind the unrelenting increase in the out-of-pocket and premium costs borne by workers with health insurance. We look forward to working with you to enact this important legislation.” – **AFL-CIO**, June 13, 2016