

The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2017

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. The CREATES Act was originally introduced by Senators Leahy, Grassley, Klobuchar and Lee in June of 2016.

- **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 the first delay tactic to bring an action in federal court for injunctive relief (i.e. to obtain the sample it needs). The bill also authorizes a judge to award damages to deter future delaying conduct. The revised version of the CREATES Act also 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.

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 estimates that the bill would result in a \$3.3 billion net decrease in the federal deficit. 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.

Support for the CREATES Act

The CREATES Act as introduced is supported by consumer groups, physicians, pharmacists, hospitals, insurers, antitrust experts, and other groups, including:

AARP
The Campaign for Sustainable Rx Pricing
Consumers Union
Public Citizen
American College of Physicians
American Hospital Association
America's Health Insurance Plans
Healthcare Supply Chain Association
CVS Health
Coalition to Reduce Spending
Academy of Managed Care Pharmacy
National Association of Chain Drug Stores
Pharmaceutical Care Management Association
Express Scripts
Blue Cross Blue Shield Association
Premier Healthcare Alliance
Prime Therapeutics
Public Sector Healthcare Roundtable

"We welcome the bipartisan effort to close this loophole through the [CREATES Act of 2017], which as you know comes at an important time. Voters, Republican and Democrat alike, have identified the price of prescription drugs as their number one health care concern, and they are asking for solutions to encourage more innovation and affordability in the prescription drug market. This bill is one step closer to that goal." – **John Rother, The Campaign for Sustainable Rx Pricing**, March 17, 2017

"AARP is pleased to endorse the 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. Left unchecked, these unnecessary delays could cost consumers, government programs, taxpayers and the healthcare system billions of dollars annually." – **AARP**, April 27, 2017

"The Act would promote welfare-enhancing competition. . . without inappropriately undermining the intellectual property rights of individuals who bring forth new innovative medical treatments. The Act also would not impose undue burdens on the manufacturers of brand name drugs and biologics. . . The CREATES Act takes a pragmatic, measured, well-tailored approach to promoting generic drug entry."

– **Alden Abbott, The Heritage Foundation**, June 21, 2016

"The [CREATES Act of 2017] takes direct aim at two tactics brand-name drug makers are using to keep affordable generic choices from getting to market for consumers -- blocking access to drug samples for testing, and blocking access to safe distribution protocols. Brand-name drug makers are manipulating FDA safety requirements to prolong their monopoly profits at the expense of consumers. This bipartisan bill creates a clear path to overcome these anti-consumer roadblocks to generics competition." --**George Slover, senior policy counsel, Consumers Union**, April 24, 2017

Frequently Asked Questions

Q. Will the CREATES Act harm patient safety, because it allows generics to obtain samples of drugs that are subject to a REMS safety protocol?

A. No. Generic manufacturers can only use the CREATES Act to obtain samples of a REMS-covered drug if the FDA pre-approves the generic's proposed safety protocols. Even for drugs that are not subject to a REMS safety protocol (and thus do not need FDA pre-approval before using the CREATES Act), the FDA closely monitors testing by generic product developers. The changes to the bill also grant the FDA more discretion to adopt additional protocols to ensure patient safety before authorizing a generic to receive samples of a REMS-covered drug.

Q. Will the CREATES Act expose brand-name drug manufacturers to frivolous litigation?

A. No. The CREATES Act establishes a limited legal pathway that can be used only by generic manufacturers that face the specific delay tactic addressed by the bill. The primary remedy is limited, injunctive relief to end the delay. Brand-name manufacturers are protected from frivolous litigation by an affirmative defense for which they need only show that the product is available for purchase on market-based terms and that they have not placed restrictions on its sale to eligible manufacturers. Damages are available only if the generic proves that the brand acted without a legitimate business justification, and damages are capped.

Q. Will the CREATES Act limit patient access to drugs that are experiencing a drug shortage?

A. No. Generic manufacturers cannot use the CREATES Act to obtain samples of a drug that is experiencing a temporary shortage, ensuring the product is available for patient use. If the drug shortage lasts more than 6 months, however, the CREATES Act allows generic manufacturers to seek samples, because generic entry is an important tool to address drug shortages that last for an extended period of time.

Q. Does the CREATES Act force brand-name manufacturers to sell their product to generic manufacturers, when generics should have to bargain like everyone else in the open market?

A. No. Generic manufacturers cannot use the CREATES Act to obtain samples if the product is available to the generic manufacturer in the open market. The CREATES Act simply provides a tailored legal avenue for the generic to obtain samples for development and testing when it has been unable to do so in the open market. The generic must still pay for the sample on commercially reasonable terms.

Q. Does the CREATES Act force brand-name manufacturers to enter into shared safety protocols with a generic manufacturer, even if the brand-name manufacturer has a patent on its safety protocol or if the generic manufacturer is demanding unreasonable terms?

A. No. The CREATES Act provides clear authority for the FDA to approve either shared safety protocols or separate protocols. A shared safety protocol will only be adopted if the parties agree or the FDA determines that no separate protocol can be approved under the stringent safety standards.

Q. Does the CREATES Act expose brand-name manufacturers to liability if the generic mishandles samples of the drug?

A. No. The CREATES Act expressly protects brand-name manufacturers from liability arising from a generic manufacturer's failure to follow adequate safeguards during its use of the samples.

Q. Is the CREATES Act necessary when existing law already prevents brand-name companies from using REMS restrictions to block generic competition?

A. Unfortunately yes. Current law does not provide a clear remedy when brand-name companies restrict access to samples or refuse to negotiate shared safety protocols to delay generic entry. Although most brand-name companies do not engage in these delay tactics, the few that do should not be permitted to use regulatory restrictions to prevent generic competition. The CREATES Act creates a

limited, tailored legal pathway to short-circuit these delay tactics and facilitate timely generic entry to the marketplace, promoting competition and saving patients and taxpayers billions of dollars a year.