

The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019

Ending the Abusive Tactics that Delay Patient Access to More Affordable Medicine

The Creating and Restoring Equal Access To Equivalent Samples (“CREATES”) Act targets abusive delay tactics that are being used to block the development of more affordable, FDA-approved generic and biosimilar medicines. The CREATES Act is a market-based solution with wide, bipartisan support. **Cosponsors include 29 Senators: Leahy (chief sponsor), Grassley, Klobuchar, Lee, Feinstein, Baldwin, Blumenthal, Booker, Brown, Collins, Cotton, Cruz, Daines, Durbin, Ernst, Fischer, Hassan, Kennedy, King, Menendez, Murkowski, Paul, Rounds, Smith, Stabenow, Tester, Whitehouse, and Young.**

The CREATES Act would crack down on anti-competitive practices by:

- **Allowing the Purchase of Samples.** The first delay tactic addressed by the CREATES Act occurs when brand-name drug companies prevent potential biosimilar and generic competitors from obtaining samples of the branded product, which are necessary to develop more affordable alternatives and prove that the medicine is equivalent to the brand-name product, a prerequisite for FDA approval.
- **Ensuring FDA Safety Standards Apply.** The second delay tactic addressed by the CREATES Act occurs when brand-name drug companies 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 biosimilar and generic competitors to participate in the safety protocol with the explicit intent to delay competition.

For instances when access to samples is blocked, the CREATES Act permits a biosimilar or generic manufacturer to bring an action in federal court for injunctive relief (i.e. to obtain the sample it needs) and limited damages may be awarded as a deterrent in certain particularly egregious cases. The CREATES Act also allows the FDA more discretion to approve alternative safety protocols, rather than require the two parties to develop shared safety protocols. Any safety protocol must be approved by the FDA and must meet the same rigorous statutory standards already in place.

The CREATES Act is intended to provide an efficient, tailored path for biosimilar and generic drug manufacturers to obtain the samples necessary as part of the standard FDA-process to bring the lower-cost medicines to market and lower prescription drug costs for patients. **The Congressional Budget Office estimates that the CREATES Act would lower federal spending on prescription drugs by \$3.9 billion** and research shows that the savings to patients with employer-based health insurance and the health care system overall would be far greater.

Public polling shows overwhelming, bipartisan support for Congressional action to lower the cost of prescription drugs. Nearly three-quarters of the public views prescription drug costs as unreasonable, and one in four patients indicate not filling a prescription due to its cost. Additionally, 83 percent of the public - Americans from across the political spectrum - support passage of the CREATES Act. The CREATES Act is a common-sense, market-based, cost-saving measure that increases patient access to more affordable medicine.

FDA’s “Name and Shame” List

In May 2018, FDA for the first time publicly identified brand-name drug companies that abuse FDA’s safety programs or erect their own restricted distribution systems to delay competition from generic and biosimilar manufacturers. The FDA’s list shows 164 inquiries covering more than 50 prescription drugs where access to samples was at issue. In recent years, according to FDA testimony to Congress, the number of inquiries has increased.

It's time to shed light on these practices and call out the manufacturers who may be abusing the rules that built our free market for drugs. They're using laws intended to promote the public health to pad their profits instead." --- HHS Secretary Alex M. Azar II

"I consider these tactics unfair and exploitative practices, and they're in direct conflict with our broader public health goals." --- FDA Commissioner Scott Gottlieb, M.D.

The Federal Trade Commission also raised its concern about these alarming strategies designed to thwart competition.

"The Commission supports the goals of the CREATES Act to protect the competitive process by eliminating incentives and opportunities for branded manufacturers to engage in manipulation of the REMS process to delay generic entry." --- Marcus Meier, Acting Director, FTC

Support for the CREATES Act

The CREATES Act is supported by more than 90 organizations representing consumer groups, physicians, pharmacists, hospitals, insurers, antitrust experts, and more, including:

AARP
Campaign for Sustainable Rx Pricing
Consumer Reports
Public Citizen
American College of Physicians
American Hospital Association
America's Health Insurance Plans
Patients for Affordable Drugs
FreedomWorks
Families USA
I-MAK
National Association of Hispanic Nurses
National Multiple Sclerosis Society
Social Security Works
Friends of Cancer Research
Coalition for Affordable Prescription Drugs
Coalition to Reduce Spending
Blue Cross Blue Shield Association

"The CREATES Act will put an end to anticompetitive practices used by some drug manufacturers to thwart generic competition and artificially keep drug prices high. It is a market-based solution that will help speed generics and biosimilar competition to the marketplace and provide real relief for patients who cannot afford the drugs on which they depend. The problem is the price, and more competition is the proven solution." – **The Campaign for Sustainable Rx Pricing**, June 14, 2018

"AARP is pleased to endorse the CREATES Act, which will help eliminate barriers to developing safe and effective generic and biosimilar alternatives. More competition in the prescription drug market means lower prices for patients, and we urge Congress to pass this important bipartisan legislation immediately." – **AARP**, January 30, 2019

"[CREATES] would hone in like a laser on the problem of unjustified delaying tactics that thwart competition. Because it is narrow and carefully targeted, it would avoid the problem of abusive, economically harmful excessive litigation that drives up business costs without justification ... The CREATES Act, now before Congress is a 'win-win' for free market drug market competition and for American consumers. This bipartisan legislation merits passage." – **Alden Abbott, The Heritage Foundation**, December 20, 2017

“Both of these tactics, refusal to share samples and failure to fairly negotiate shared REMS programs, establish de facto monopolies for original drug producers, but they’re easily fixed by the CREATES Act ... Congress should end illegal monopolies and help Americans afford their medications by passing the CREATES Act, all without increasing the size of government.” – **Andrew Magloughlin, FreedomWorks**, July 24, 2017

Frequently Asked Questions

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

A. No. Under the CREATES Act, generic manufacturers can only purchase 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 CREATES Act also grants 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 a 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. 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 many brand-name drug 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.

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