# Congress Considers CREATES Act With Support From FDA, FTC

**Key Takeaways:**

- H.R. 2212 and S.R. 974 are twin bipartisan bills, known as the Creating and Restoring Equal Access to Equivalent Samples Act ("CREATES Act"). The bills were introduced in the House and Senate in April 2017.

- If passed the proposed legislation would aid generic pharmaceutical manufacturers by:

> (i) entitling them under certain conditions to an affirmative injunction mandating access to product samples of innovator drugs that are distributed pursuant to an FDA-imposed Risk Evaluation and Mitigation Strategy ("REMS"), so that the generic may conduct equivalence testing; and
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> (ii) widening the FDA's authority to approve alternative REMS programs for generics and/or to require that innovator firms share their REMS with their rival manufacturers.

- The legislation is designed to prevent delays in generic competition that are allegedly caused when a patent-holding drug manufacturer refuses to distribute product to a would-be generic rival for equivalence testing, or when the patent holder refuses to afford the generic access to its REMS program.

- The CREATES Act goes beyond traditional antitrust doctrine in that it would require no showing of anticompetitive harm nor give deference to the general notion in antitrust law that a firm may choose with whom it will deal.

- At a hearing this past July, representatives from both the FTC and the FDA expressed support for the Act, arguing that it would help to ensure faster generic entry and corresponding price reductions on drugs that are subject to REMS program requirements.

- As a practical matter, passage of the Act may lessen the FTC's interest in pursuing such cases under the antitrust laws, since private relief would become more readily available (and easier to obtain) through the Act than via an FTC enforcement action.

**Background**

When the FDA determines that risk prevention measures beyond ordinary labeling requirements are necessary to ensure that the benefits of a particular drug outweigh its corresponding risks to the public, the agency may require the drug's manufacturer to develop a REMS program. For certain pharmaceuticals, REMS programs include "elements to assure safe use" ("ETASU"), which may in turn include restrictions on the distribution of the drug. Innovator drug companies whose products are subject to these REMS protocols sometimes have been accused of abusing REMS distribution restrictions to make it difficult or impossible for generic drug manufacturers to obtain product samples necessary for bioequivalence testing, a requirement for generic manufacturers to gain abbreviated new drug approval from the FDA for their versions of the branded drug. Similarly, brand manufacturers have been accused of refusing to share their REMS program protocols with their generic counterparts as part of a single shared REMS, likewise hindering/delaying generic drug approval.

On July 27 2017, the House Judiciary Committee, Regulatory Reform, Commercial and Antitrust Law Subcommittee held a hearing to discuss potential antitrust abuses within the Food and Drug Administration's generic approval process. The focus of the hearing was on the extent to which innovator pharmaceutical companies allegedly abuse REMS and other processes to delay or prevent generic competition. Hearing witnesses indicated that Congressional action, such as approval of the CREATES Act, would facilitate generic entry.

**The CREATES Act would effectively guarantee generic access to product samples and REMS**

The CREATES Act reflects a Congressional attempt to "deter pharmaceutical companies from utilizing anticompetitive behavior" by providing generic companies a right of action in federal court to obtain branded drug samples, and by affording the FDA wider authority to approve alternative REMS proposals from generic manufacturers or to order that a single shared REMS program be used in certain instances. Under this proposed legislation, which was originally introduced in 2016, a generic drug manufacturer may receive authorization from the FDA to obtain sufficient quantities of a particular product that is covered by a REMS with ETASU. Should the branded company marketing the drug then refuse to provide samples to a requesting generic manufacturer within 31 days of the generic's request (or of the branded company's receipt of a copy of the FDA authorization, whichever is later), the generic company may obtain an affirmative injunction in federal court, in addition to attorneys' fees and potential monetary damages. The CREATES Act also affords the FDA discretion to approve comparable alternative REMS programs for the same small molecule, or to require that a single shared REMS be used when comparable alternatives are not available.

**The CREATES Act would sidestep traditional antitrust analysis**

While the goal of the CREATES Act is to deter "anticompetitive behavior" (a task usually reserved for the federal antitrust laws), it should be noted that it would bypass traditional antitrust doctrine in favor of a limited but absolute right for generic manufacturers to access their branded rivals' products and intellectual property. For nearly 100 years, the Supreme Court has recognized under the antitrust laws the "right of trader or manufacturer … freely to exercise his own independent discretion as to parties with whom he will deal."[1] While this right applies only "in the absence of any purpose to create or maintain a monopoly,"[2] the Court has "been very cautious in recognizing … exceptions, because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm."[3]

Under the CREATES Act, there would be no requirement for an analysis of competitive effects, nor of whether the branded manufacturer could offer a justification for its refusal to deal (although a showing that legitimate business justifications were lacking would be required before the court would award punitive damages, unless the refusal continued after the court had issued an initial injunction). Thus the new legislation would effectively sidestep traditional antitrust doctrine.

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[1] United States v. Colgate & Co., 250 U.S. 300 (1919).

[2] *Id.*

[3] Verizon Communications v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 408 (2004).

It is in part for this reason that both the FTC and FDA testified at the Subcommittee Hearing in support of the proposed legislation.

- The FTC's then-acting Bureau of Competition Director, Markus Meier, testified that although the agency has reviewed over 100 potential instances in which a branded company allegedly relied on REMS to forestall generic entry, it had been unable to find an ideal "test case" under the antitrust laws. Meier further categorized antitrust litigation as a "slow," "expensive", and "uncertain" process. Thus he favored the proposed legislation as a means of shortening and improving the path to market for generic competitors.
- FDA Commissioner Dr. Scott Gottlieb testified at the hearing that although, under the Food and Drug Administration Amendments Act ("FDAAA"), the FDA has the authority to engage with the Department of Justice to prevent branded companies from using REMS programs to forestall ANDA approval, the Agency has not taken any enforcement action against branded pharmaceutical companies for improperly using a REMS program to block generic entry. Commissioner Gottlieb referred to the FDAAA process as "complicated" and "time consuming." Moreover, he indicated that the FDA does not view itself as a competition regulator.

**The CREATES Act does not preclude antitrust enforcement, but it may reduce FTC incentives to pursue antitrust cases**

Although the CREATES Act specifically states that "nothing in this section shall be construed to limit the operation of any provision of the antitrust laws," passage of the Act seemingly would lessen the need for antitrust enforcement in such cases. First, any case that may be ripe for FTC enforcement under the antitrust laws (and many others that may not merit antitrust enforcement) could presumably be more easily prosecuted under the new law by the generic manufacturer. Second, the FTC generally is limited to seeking injunctive relief (which the CREATES Act would provide without requiring traditional antitrust proof). While the agency can, in certain instances, seek disgorgement as an antitrust remedy, it would be likely to do so only in a case in which the branded manufacturer could offer no legitimate business justification for its conduct. But this is also where the CREATES Act would allow for monetary relief "sufficient to deter the license holder from failing to provide other eligible product developers with sufficient quantities." Thus, FTC enforcement of the antitrust laws in this area would seem to offer no particular benefit that could not be more easily achieved by a private litigant under the CREATES Act.

**Conclusion**

The CREATES Act offers what is effectively a regulatory solution, albeit a limited one, to a purported antitrust problem. Frustrated by conduct that they see as delaying generic entry (and its corresponding price competition) proponents of the Act seek to replace traditional antitrust doctrine with a regulatory fix designed to favor lower price generic competitors over their innovator rivals. The Act currently is under consideration in Congress.