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Legal Sidebar

The CREATES Act of 2019 and Lowering Drug Prices: Legal Background & Overview

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On February 5, 2019, the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 (CREATES Act) was reintroduced in both the Senate and the House. The bill, first introduced in the 114th Congress (S. 3056) and again in the 115th Congress (S. 974 and H.R. 2212), aims to facilitate the timely entry of lower-cost generic and biosimilar versions of brand-name drugs and biological products (i.e., products such as vaccines and blood components that are derived from living organisms) to promote competition in the market for such products. Specifically, the CREATES Act aims to address the concern that some brand manufacturers have improperly restricted the distribution of their products, including by invoking a distribution safety protocol known as Risk Evaluation and Mitigation Strategies (REMS), to deny generic product developers access to samples of brand products. (For ease of reference, this Sidebar uses "generic product" to refer to both generic drugs and biosimilars). Because generic product developers need samples to conduct certain comparative testing required by the U.S. Food and Drug Administration (FDA), some have attributed the inability to timely obtain samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act would create a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms."

This Sidebar provides an overview of the generic drug and biosimilar application process, noting the view that some brand manufacturers have used restricted distribution to deny generic product developers the brand samples needed for regulatory approval. It next explains how the existing legal framework addresses these practices and how the CREATES Act would modify that legal framework.

Generic Drug and Biosimilar Application Process

To encourage market entry by generic drugs, the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act, P.L. 98-417) created an expedited pathway for generic drug approval. Unlike a brand manufacturer, who must submit an extensive new drug application (NDA) that includes, among other things, clinical trial data, a generic manufacturer may submit an abbreviated NDA (ANDA) that demonstrates that the generic is bioequivalent to a previously approved brand drug. Similarly, the Biologics Price Competition and Innovation Act of 2009 (BPCIA, P.L. 111-148) created an expedited

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pathway for the approval of a biological product that is either biosimilar to or interchangeable with a biological product previously licensed under a Biologics License Application (BLA).

To conduct the necessary comparative testing to prove bioequivalence, biosimilarity, or interchangeability, a generic product developer must have access to samples of the relevant brand product in sufficient quantities. For products subject to normal distribution channels, obtaining brand samples generally does not present a significant hurdle—the generic product developer can purchase the product from licensed wholesalers. However, some brand products are subject to restricted distribution that limits how they can be sold.

Restricted Distribution and Sample Denial

The distribution of a brand product can be restricted in one of two ways. First, a brand manufacturer can voluntarily place its products into restricted distribution in order to have more control over who can purchase their products. Second, some high-risk drugs are subject to more restrictive distribution strategies and safety protocols under statute and FDA regulations.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food and Drug Administration Amendments Act of 2007 (FDAA Act, P.L. 110-85), FDA may require the sponsor of an NDA or BLA to submit a proposed REMS, a risk management plan that uses strategies beyond labeling to ensure that the benefits of the drug or biologics outweigh its risks. Examples of less restrictive REMS requirements include medication guides for patients and communication plans for healthcare providers. More restrictive REMS programs have elements to assure safe use (ETASU), which can include prescriber and dispenser certification requirements, patient monitoring or registration, or controlled distribution that limits how the product can be sold. If a brand product is subject to REMS with ETASU, the brand manufacturer and the generic product developer generally must agree on a single, shared REMS system before the generic product goes on the market. However, FDA can waive the shared REMS requirement and allow the generic product developer to use a different, comparable system.

Since the enactment of the FDAA Act, some generic product developers have complained that they have been unable to access the samples needed for comparative testing because of restricted distribution. According to Scott Gottlieb's July 2017 testimony before the House Subcommittee on Regulatory Reform, Commercial, and Antitrust Law, some brand manufacturers have impeded generic product developers' ability to obtain samples by implementing their own restrictions on distribution (e.g., through contract provisions that deny sales to potential generic product developers). Alternatively, if their products are subject to REMS with ETASU, some brand manufacturers have either (1) invoked the restricted distribution component of a REMS with ETASU to deny sales to generic product developers; or (2) used the existence of REMS with ETASU to substantially prolong negotiations over the sale of samples or the development of a single, shared REMS system.

Existing Law Governing Sample Denials

The existing statutory and regulatory framework offers little legal recourse to generic product developers who have been denied access to or experience long delays in obtaining samples. As an initial matter, there are no statutes or regulations that specifically prohibit a company from imposing voluntary distribution restrictions on its products. For products subject to REMS, the FDAA Act includes a general prohibition that brand manufacturers should not use their REMS to "to block or delay approval of an application ... to a drug that is subject to the abbreviated new drug application." Critically, however, the act sets forth no enforcement mechanism that would effectuate this prohibition—it neither authorizes FDA to create an administrative enforcement process nor creates a private right of action for aggrieved generic product developers. An early version of the FDAA Act (H.R. 2900) included a provision that affirmatively required a brand manufacturer to provide a sufficient quantity of a product subject to REMS to a generic

product developer for bioequivalence testing. The final version of the bill, however, omitted this provision, and, as a result, there is no specific obligation under the law for brand manufacturers to provide samples to generic product developers.

In light of this statutory framework, as well as FDA's longstanding view that "issues related to ensuring that marketplace actions are fair and do not block competition would be best addressed by [the Federal Trade Commission]," FDA has not asserted that it has the authority to compel the sale of samples for comparative testing. Instead, to help generic product developers obtain access to samples, FDA has, on request, reviewed generic product developers' proposed comparative study protocols to assess whether they provide safety protections comparable to those in the applicable REMS, and if so, issued letters to the brand manufacturers stating so. The letters would also state that FDA will not consider it a violation of the REMS for the brand manufacturers to sell samples of the relevant products for comparative testing. These FDA letters, however, do not purport to compel the provision of samples, and their legal effect has been disputed.

Given the lack of recourse under FDA law, generic product developers seeking to compel the sale of samples have instead filed actions alleging antitrust violations. The most typical claim is a monopolization claim under Section 2 of the Sherman Act, alleging that the brand manufacturer has unlawfully maintained a monopoly over the relevant market for the brand product by refusing to sell samples or otherwise unreasonably delaying the sale of samples in order to impede generic entry.

A generic product developer's ability to obtain relief for sample denial under antitrust law is currently uncertain. Under longstanding antitrust precedents, a company—even a monopolist—generally does not have a duty to deal with its competitors. A refusal to deal, however, could be an antitrust violation if it constitutes a willful effort to maintain monopoly power via anticompetitive means, but the case law has not provided a clear standard for this exception to the general rule. Moreover, some courts have held that a refusal to deal is only anticompetitive if the monopolist seeks to terminate a prior course of dealing with the competitor, while other courts have held that termination of a prior course of dealing is merely strong evidence of anticompetitive intent but is not required to establish antitrust violation. This difference in interpretive approach can be dispositive—because a generic product developer often would have no prior course of dealing with the brand manufacturer, the generic product developer would have no antitrust recourse before a court that has adopted or chooses to adopt the former approach. Even before a court that adopts the latter approach, a generic product developer's road to relief can be lengthy and filled with uncertainty. To date, courts appear to have addressed the sample denial issue in a handful of cases. Most of the cases that have been permitted to proceed beyond the motion to dismiss stage were resolved by settlements, meaning that courts have not had the opportunity to offer significant guidance. The two cases that have not settled continue to be litigated today, more than four years after they were first filed. It is unclear when, if at all, those courts will shed light on the relevant refusal to deal standard.

The CREATES Act of 2019

The CREATES Act seeks to address the uncertainties in the existing legal framework by creating a private cause of action that generic product developers can use to initiate expedited litigation to obtain the brand samples they need. Instead of asserting an antitrust claim, the bill would allow a generic product developer to sue to compel the provision of brand samples, if specific statutory elements are met.

For brand products not subject to a REMS with ETASU (including a product that is subject to voluntary restrictive distribution imposed by the brand manufacturer), the generic product developer would need to show that:

1. it had made a request for samples,

2. the brand manufacturer failed to deliver, on commercially reasonable, market-based terms, sufficient quantities of the samples within 31 days of receiving the request, and
3. as of the filing date of the action, it is still unable to obtain sufficient quantities of the needed samples on commercially reasonable, market-based terms.

For products subject to REMS with ETASU, the bill would first create a process by which the generic product developer can request from FDA an authorization to obtain sufficient quantities of the relevant samples. FDA would issue the authorization if it determines that the generic product developer has agreed to comply with or otherwise met the safety conditions or requirements deemed necessary by FDA. The process outlined in the bill appears to largely codify the FDA's existing practice, but would give FDA's authorization legal effect as a component of the statutory claim. In this situation, the generic product developer would need to show elements (1) and (3) above, and that the brand manufacturer failed to deliver, on commercially reasonable, market-based terms, sufficient quantities of samples either within 31 days of receiving the request *or* within 31 days of receiving notice of FDA's authorization, whichever is later.

If a generic product developer prevails by meeting either set of elements, the bill would require the court to issue injunctive relief compelling the brand manufacturer to provide the samples without delay and award attorney's fees and costs. If the court finds that the brand manufacturer delayed providing the samples without a "legitimate business justification," the court could also award monetary damages. These damages are not to exceed the revenue the brand manufacturer earned on the product during the period beginning on the day that is 31 days after the receipt of the request for samples (or, if the product is subject to REMS with ETASU, on the day that is 31 days after the receipt of the FDA notice of authorization, if that date is later), and ending on the date on which the generic product developer receives sufficient quantities of the brand sample.

The bill would also provide FDA more latitude to approve a separate REMS system that the generic product developer could use if it cannot reach an agreement on a shared strategy with the brand manufacturer. Specifically, rather than requiring the use of a shared system as the default, the bill would amend the relevant statutory provisions to permit the use of a shared system or a different but comparable system as available alternative options.

To address the concern that a more relaxed REMS requirement may expose the brand manufacturers to liability, the bill includes a provision that limits the brand manufacturer's liability against claims arising out of a generic product developer's failure to follow adequate safeguards during the development and testing of the generic product.

The CREATES Act appears targeted to address an issue that several stakeholders view as undermining the intended operation of the Hatch-Waxman Act and the BPCIA—the timely development of generic products entering the market. Based on the existing legal framework, there are several potential legal avenues that could be used to address the issue, including additional statutory guidance on the relevant antitrust standards, clarification on FDA's authority to enforce the prohibition against improper sample denials, and the approach ultimately adopted by the CREATES Act—the creation of a private cause of action for generic sample developers to compel the provision of brand samples through judicial proceedings. New legal questions may arise under this approach, as the remedy created under the bill, while not unprecedented, is unusual in this context because there is generally no private right of action under the FFDCA. At the same time, the broader debate over the CREATES Act and competing legal remedies often centers on questions of efficacy that are detailed in other CRS products.

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