COVINGTON

CREATES Act Becomes Law

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Pharmaceuticals/Biotech

On December 20, 2019, the President signed the Further Consolidated Appropriations Act, 2020. Effective on that day, Section 610 of Division N of this Act contains provisions previously introduced in various bills as "the Creating and Restoring Equal Access to Equivalent Samples Act" or "CREATES Act." Section 610 establishes a private right of action in which a company that seeks to develop a generic or biosimilar product (referred to as the "eligible product developer") may sue the innovator for an injunction and monetary award for not selling samples of the approved product for developmental testing on a timely and "commercially reasonable" basis. The provision also amends the single, shared REMS provisions of the Federal Food, Drug, and Cosmetic Act ("FDCA").

Section 610 marks a substantial change from prior law, and the provision includes tight timelines for sale of samples to avoid potential exposure to civil liability. Innovators should consider developing standard operating procedures and training programs to ensure their organizations are prepared to address samples requests. Establishing clear processes upfront will be essential to avoiding unnecessary delays and, by extension, minimizing the risk of litigation under this new law. Companies should also be aware that section 610 explicitly carves out any impact of the legislation on existing antitrust law. As a result, in addition to litigation initiated under the new private right of action, antitrust litigation related to a refusal to provide samples also remains a possibility.

Civil Action

Section 610 establishes a private right of action for an "eligible product developer" to sue a "license holder" in federal court if the license holder does not provide "sufficient quantities" of the requested "covered product" on "commercially reasonable, market-based terms." The eligible product developer may seek injunctive relief, attorney's fees, and a monetary award.

Applicability

"License holder" and "covered product" are broadly defined. The former includes the holders of new drug applications, abbreviated new drug applications, and both full and biosimilar biologics license applications. "Covered product" similarly includes a product approved or licensed in any of these applications, as well as a drug-biologic combination and "when reasonably necessary to support approval," any product, including any device, that is marketed or intended for use with the drug or biologic. This term generally excludes drugs in shortage, however.

New Cause of Action

A cause of action under Section 610 has four elements. The eligible product developer (referred to here as the "developer") must prove by a preponderance of the evidence:

- The requested "covered product" is not subject to a risk evaluation and mitigation strategy with elements to assure safe use ("REMS with ETASU") or, if a REMS with ETASU applies to the covered product, the developer has obtained a "covered product authorization" from FDA and provided a copy to the license holder.
- As of the date of filing suit, the developer has not obtained "sufficient quantities" of the requested covered product on "commercially reasonable, market-based terms."
  - "Commercially reasonable, market-based terms" means (a) "a nondiscriminatory price" for the covered product that does not exceed the most recent wholesale acquisition cost for the drug; (b) a schedule for delivery that accords with section 610; and (c) "no additional conditions are imposed on the sale of the covered product."
  - "Sufficient quantities" means an amount of covered product that the developer determines allows it to conduct testing to support an abbreviated application and "fulfill any regulatory requirements relating to approval of such an application."
- The developer requested to purchase samples from the license holder in a written document that: (a) was sent to a named corporate officer of the license holder; (b) was made by certified or registered mail with return receipt requested; (c) specified the developer's individual point of contact and a means for contacting that individual electronically and in writing; and (d) specified a shipping address for the samples.
- The license holder has not delivered to the developer sufficient quantities of the covered product on commercially reasonable, market-based terms within **31 days** of receiving the request (or if later, in the case of a REMS with ETASU product, within 31 days of the license holder's receipt of a copy of the covered product authorization

FDA Authorization Process

An eligible product developer seeking samples of a covered product subject to REMS with ETASU may request a "covered product authorization" from FDA. FDA must act on the request within 120 days under section 610. To obtain authorization for purposes of human clinical trials, a developer must (a) submit specific materials to FDA (protocols, informed consent documents, and informational materials for testing) that include patient safety protections comparable to those provided by the REMS for the covered product or otherwise satisfy the agency that such protections will be provided; and (b) meet any other requirements established by the agency. If the proposed testing does not involve human clinical trials, then the developer must agree to comply with any conditions that FDA deems necessary in order to receive an authorization.

A covered product authorization issued by FDA must state that the license holder will not violate the REMS for the covered product if it provides samples under the terms of the authorization. Section 610 also amends section 505-1 of the FDCA to state that providing samples of a covered product to a developer will not violate any REMS applicable to the covered product.

The authorization process established under section 610 largely codifies FDA draft guidance.[1] One FDA draft guidance, which is applicable to generic drugs for which the reference listed drug ("RLD") has a REMS with ETASU, outlines a process in which the agency reviews protocols, informed consent documents, and informational materials for the proposed bioequivalence study to determine if they provide safety protections comparable to the REMS with ETASU. FDA then may issue a "safety determination letter" indicating that the agency will not consider the RLD sponsor's provision of samples to the developer to violate the REMS. FDA has a performance goal to issue 90% of safety determination letters within 60 days.[2] FDA has stated in draft guidance that the agency would follow a similar process of issuing safety determination letters for samples used in biosimilarity testing.[3]

Section 610(g) states that nothing in section 610, the amendments it makes, or section 505-1 of the FDCA shall be construed to prohibit a license holder from providing a developer samples in the absence of an FDA authorization or to negate the applicability of the REMS with ETASU for the covered product.

Affirmative Defenses

Section 610 sets forth three affirmative defenses for a license holder:

- When the developer requested samples from the license holder, the license holder and its agents, wholesalers, and distributors were not engaged in manufacture or commercial marketing of the covered product and did not have access to inventory of the product to supply to the developer on commercially reasonable, market-based terms.
- The license holder sells the covered product through agents, distributors, or wholesalers; has placed no restrictions, "explicit or implicit," on these entities to sell covered products to eligible product developers; and the covered product can be purchased from these entities in sufficient quantities on commercially reasonable, market-based terms.
- The license holder offered to sell samples to the developer on commercially reasonable, market-based terms within a specified time, but the developer failed to timely accept the offer. For a covered product that is not subject to a REMS with ETASU, the license holder must have made such an offer within 14 days of receiving the request, and the developer must have failed to accept it within 7 days of receipt. For a covered product that is subject to a REMS with ETASU, the license holder must have made an offer within 20 days of receiving the request, and the developer must have failed to accept it within 10 days of receipt.

Remedies

If the developer prevails, the court must order the license holder to provide sufficient quantities of covered product on commercially reasonable, market-based terms "without delay" and award "reasonable" attorneys' fees and costs to the developer. The court also must award a monetary

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[1] *See* FDA, Draft Guidance for Industry: How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD (Dec. 2014); FDA, Draft Guidance for Industry; New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2) (Dec. 2018), at 10-11.

[2] *See* FDA, Draft Guidance for Industry: How to Obtain a Letter from FDA Stating that Bioequivalence Stud

[3] Protocols Contain Safety Protections Comparable to Applicable REMS for RLD (Dec. 2014); FDA, Draft Guidance for Industry; New and Revised Draft

amount if it finds that the license holder delayed providing samples to the developer "without a legitimate business justification" or failed to comply with a court order to provide samples. The monetary amount awarded to the developer must be "sufficient to deter the license holder from failing to provide eligible product developers with sufficient quantities of a covered product on commercially reasonable, market-based terms," not to exceed the revenue earned for the covered product during the period beginning at the end of the 31-day period described above and ending on the date when the developer receives sufficient quantities of the covered product. The court may issue an order to provide samples before conducting further proceedings to determine whether the developer is entitled to fees, costs, and a monetary amount or the amount of such rewards.

Limitation of Liability

Section 610 shields a license holder from liability for a developer's failure to follow adequate safeguards to assure safe use of the covered product during development or testing activities described in section 610 (including the developer's transportation, handling, use, or disposal of the covered product).

Amendments to Law on Single, Shared REMS

Section 610 also amends the prior presumptive requirement under the FDCA that an RLD and any generic drug be subject to a single, shared system of REMS with ETASU absent an FDA waiver. FDA previously published two draft guidance documents on shared REMS and waivers.[4]

Now, under the FDCA as amended by section 610, an applicant submitting an abbreviated new drug application ("ANDA") generally may use either a single, shared REMS with the RLD holder or a "different, comparable aspect" of the ETASU. FDA may require a single, shared REMS if it determines that "no different, comparable aspect of the [ETASU] could satisfy the [ETASU] requirements," however. The statute defines "different, comparable aspect" to mean that the REMS "uses different methods or operational means.. but achieves the same level of safety." Under amended section 505-1, FDA may require modification of an innovator's REMS to accommodate "different, comparable aspects" of the ETASU for the generic drug.

Next Steps

License holders should consider adopting procedures and taking other steps to ensure responses to requests for samples within the short timelines established by section 610. Potential next steps include the following:

- Proactively identify on a company website contact information for a named corporate officer for receipt of sample requests via registered mail. Although not required, this step could help expedite processing of at least some requests.
- Establish internal procedures for identifying a request; channeling request to appropriate team; and reviewing and responding to request in a timely manner.

[4] As on Biosimilar Development and the BPCI
Act (Revision 2) (Dec. 2018), at 10-11.
FDA, Draft Guidance for Industry: Waivers of the Single, Shared System REMS Requirement (May 2018).

- Create template agreement that includes “commercially reasonable, market-based terms” to enable quick responses to samples requests.
- Conduct trainings on new statutory obligations (and penalties) under section 610 and ensure that named corporate officers are aware that they may receive these requests and the company will need to act quickly if so.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our Pharma and Biotech practice:

Ashley Bass	+1 202 662 5109	abass@cov.com
Krista Carver	+1 202 662 5197	kcarver@cov.com
James Dean	+1 202 662 5651	jdean@cov.com
Andrew Lazerow	+1 202 662 5081	alazerow@cov.com
Mingham Ji	+1 202 662 5621	mji@cov.com