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Client Alert

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FDA Issues New Policy To Prevent Innovator Biologics Companies From Withholding Samples to Delay Biosimilar Competition

On December 11, 2018, Dr. Scott Gottlieb, the Commissioner of the Food and Drug Administration ("FDA") issued a statement announcing the agency's new actions to advance its biosimilars policy framework. Tucked into one of the four guidance documents issued with the statement, is a new policy intended to spur competition in the biologics industry as part of the Trump Administration's war on drug pricing. Specifically, this new policy is intended to prevent innovator biologics companies from withholding samples of reference products from biosimilars companies for the purpose of delaying competition.

By way of background, innovator biologics companies have been accused of using concern about non-compliance with risk evaluation mitigation strategies ("REMS") as a false pretense for withholding samples from biosimilar companies -- when the real reason for withholding the samples is to delay competition by preventing the companies from doing the testing necessary to support biosimilar applications. The new policy addresses this by providing biosimilar companies with a mechanism to ask FDA to issue a letter to the reference product manufacturer alleviating REMS concerns. The letter from FDA to the reference product manufacturer would state that providing samples to the biosimilars company would not violate the REMS for the reference product because the biosimilars company has procedures in place comparable to the necessary REMS. Although this policy is new in the biosimilars space, a similar policy has been in place for drugs since 2014.

This new policy is the latest of several issued by FDA this year intended to spur competition in the pharmaceutical industry, by addressing perceived anticompetitive behaviors, which Dr. Gottlieb has dubbed "shenanigans."

In May of this year, FDA posted a Reference Listed Drug (RLD) Access Inquiry List. That list memorializes unvetted *allegations* made by generic drug manufacturers to FDA that innovator drug companies withheld samples, in an effort to delay competition by preventing them from conducting the bioequivalence testing necessary to submit abbreviated new drug applications ("ANDA"). This list has been referred to as a "shaming list," and there is concern that it may provide fodder for Congressional investigations, enforcement actions by the Federal Trade Commission ("FTC"), and/or plaintiffs lawsuits.

Just one month later, in June, FDA issued two draft guidances in an effort to ensure that innovator drug and biologics companies were not slow-walking shared system REMS negotiations to delay generic entry. By way of background, before a generic drug with certain types of REMS, known as Elements to Assure Safe Use ("ETASU"), can be approved, the Food, Drug, and Cosmetic Act requires the generic drug manufacturer and the manufacturer of the reference product to have "shared system REMS," i.e., infrastructure, in place to implement the ETASU. Shared system REMS may include, for example, web portals for use by patients and healthcare professionals, electronic recordkeeping databases, and healthcare professional training courses. Innovator drug and biologics companies have been accused of slow-walking these negotiations to delay competition. To address potential gaming, one draft guidance issued by FDA in June establishes "best practices" for shared system REMS negotiations, including a recommendation that the parties submit a plan to FDA by the midpoint of the ANDA review cycle (which is typically a 10 month review cycle). The other guidance issued in June clarifies how the generic companies involved in the negotiations can submit waiver requests when the burden (e.g., delayed generic entry) of participating in the shared system REMS outweighs the benefits (e.g., efficiencies for companies, health care professionals, and patients associated with using shared infrastructure).

Then, in October of this year, FDA issued revised draft guidance regarding the process for reviewing 505(q) citizen petitions. 505(q) citizen petitions have the potential to delay the approval of pending generic drug or biosimilar marketing applications. To prevent abuse, Congress gave FDA authority to summarily deny a 505(q) petition if the agency determines that the "primary purpose" of the petition is to delay competition. To better protect the 505(q) citizen petition process from abuse, the revised draft guidance sets forth factors that FDA will consider to determine whether the "primary purpose" of a petition is to delay generic entry. The revised draft guidance also states that if FDA determines that a petition was submitted with the "primary purpose" of delaying generic entry, FDA will memorialize that determination in its citizen petition response and refer the matter to the FTC.

On December 11, when Dr. Gottlieb issued the latest policy -- the policy targeted at preventing innovator biologics companies from using false pretenses to withhold samples -- he stated that the agency would be paying "equal attention" to anticompetitive practices in the biologics space as it is paying to similar practices in the drugs space. That statement was not new; it was similar to statements that Dr. Gottlieb made when he announced the Biosimilars Action Plan in July of this year. But, it is a reminder that more FDA actions are to come. We would not be surprised, for example, if FDA posts a "shaming list" in the biologics space similar to the RLD Access Inquiry List, among other things. Given FDA's continued focus on these issues, pharmaceutical companies should be on alert for associated FTC enforcement actions, Congressional investigations, and plaintiffs lawsuits.

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