Client Alert

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New Settlement Highlights FDA's Diminishing Power Over Off-Label Promotion

By Erin Bosman, Julie Park, and Brittany Scheinok

In a surprising turn of events, Pacira Pharmaceuticals, Inc. and the Food and Drug Administration (FDA) announced that they have settled their dispute regarding the off-label promotion of Exparel, one of Pacira's anesthetic drugs. This settlement represents the latest marker of the FDA's diminishing power to regulate off-label promotion.

BACKGROUND

Off-label promotion is the promotion of a drug for indications not approved by the FDA, which the FDA contends is a violation of the Federal Food, Drug, and Cosmetic Act (FDCA). The FDCA prohibits the introduction into interstate commerce of any drug that is misbranded.[1] Under the FDCA, a drug may be misbranded for a number of reasons, including false or misleading labeling or labeling that fails to include adequate directions for use.[2]

Recent case law developments have drawn attention to the issue of off-label promotion. In 2012, the Second Circuit issued a ruling in *United States v. Caronia*, a case involving First Amendment challenges to the regulation of off-label promotion.[3] The court held that the government cannot criminally prosecute pharmaceutical manufacturers and their representatives under the FDCA for truthful, non-misleading speech promoting the off-label uses of FDA-approved drugs.[4]

More recently, the pharmaceutical company Amarin secured a preliminary injunction against the FDA in another case involving off-label promotion and the First Amendment.[5] In *Amarin*, a federal district court confirmed that the FDA may not bring a misbranding action based on truthful promotional speech alone. These decisions have led many to believe that the FDA's ability to regulate off-label promotion may be waning.

PACIRA'S LAWSUIT AGAINST THE FDA AND SUBSEQUENT RESOLUTION

Pacira's anesthetic drug Exparel was approved by the FDA in 2011. During the approval process, Exparel was evaluated in two clinical trials involving surgery for the removal of bunions and surgery for the removal of hemorrhoids. The "Indications and Usage" section of Exparel's label stated that Exparel is a "local anesthetic,

[1] 21 U.S.C. § 331(a).

[2] 21 U.S.C. §§ 352(a), (f).

[3] *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012).

[4] For more information on *United States v. Caronia*, see our previous client alert available at http://media.mofo.com/files/Uploads/Images/121205-US-v-Caronia.pdf.

[5] *Amarin Pharma, Inc. v. FDA*, No. 1:15-cv-03588 (S.D.N.Y. Aug. 7, 2015).

indicated for administration into the surgical site to produce postsurgical analgesia." However, after listing the clinical trials that evaluated Exparel, the "Clinical Studies" section of the label stated that Exparel "has not been demonstrated to be safe and effective in other procedures."

Despite this language, some of Pacira's promotional materials suggested that Exparel could be used in various surgical procedures other than those involving the removal of bunions or hemorrhoids. In September 2014, the FDA issued a warning letter to Pacira, stating that these promotional materials misbranded the drug within the meaning of the FDCA. According to the FDA, Pacira's promotional materials violated the FDCA by stating that Exparel was intended for new uses for which it lacked FDA approval.

In September 2015, Pacira filed a lawsuit against the FDA seeking declaratory and injunctive relief. In its complaint, Pacira claimed that the FDA had violated its First Amendment rights by restricting truthful and non-misleading speech and had violated the Administrative Procedure Act by failing to observe required procedures for modifying a drug's label. Additionally, Pacira's complaint alleged that the FDA's regulations were vague and operated as a retroactive, ex post facto penalty, thus violating due process under the Fifth Amendment.

On December 15, 2015, Pacira announced that it had reached an amicable resolution with the FDA. In the settlement agreement, the FDA reversed its position with respect to Exparel's approved uses. The agreement reached by the parties stated that Exparel has, since 2011, been approved for administration in a variety of surgeries, not limited to those studied in its clinical trials. Thus, the parties dismissed the lawsuit and the FDA agreed that Pacira is not restricted to marketing Exparel only for use in the surgeries tested in the drug's clinical trials.

LIKELY IMPACT OF THE PACIRA AND FDA SETTLEMENT

Following the decisions in *Caronia* and *Amarin*, this settlement agreement may be another sign of the FDA's waning power to regulate off-label promotion, especially in the face of First Amendment challenges. However, several factors may limit the implications of this resolution.

Unsurprisingly, the FDA itself is attempting to limit the implications of the settlement agreement. The FDA noted in a statement that "this resolution is specific to the parties involved in this matter." Furthermore, this settlement may be attributable to the existing broad language in Exparel's label. For example, the label stated that Exparel was "indicated for administration into the surgical site to produce postsurgical analgesia." The FDA may not have agreed to settle with Pacira if Exparel's label did not already include this broad language of indication, which arguably included indications of use beyond those specifically tested in the clinical trials.

The full impact of this resolution is yet to be seen. However, the settlement certainly continues the trend of limiting the FDA's ability to regulate truthful, non-misleading statements regarding off-label uses.

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