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FDA and Amarin Reach Settlement on First Amendment and Off-Label Statements

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FDA agrees to allow truthful and non-misleading off-label promotion.

On March 8, the US District Court for the Southern District of *New York* approved settlement terms in connection with ***Amarin Pharma, Inc., et al. v. U.S. Food & Drug Admin., et al.***, the ***FDA***'s ongoing legal dispute concerning Amarin Pharma Inc.'s (Amarin's) promotion of off-label claims for their pure eicosapentaenoic omega-3 fatty acid product Vascepa®.[1]

In the priorUS District Court decision, the court affirmed the importance of the US Court of Appeals for the Second Circuit's *Caronia* case, finding that pharmaceutical and medical device companies have a constitutionally protected right to provide truthful and non-misleading information regarding off-label uses of their products.[2] This previous *Amarin* decision also ruled against the FDA and upheld the rights of a pharmaceutical manufacturer to make truthful and non-misleading statements regarding off-label uses of its FDA-approved drug, including the right to affirmatively make those promotional statements through sales representatives to healthcare providers (HCPs). Further, the court held that truthful and non-misleading promotional statements to HCPs alone may not form the basis of a prosecution for misbranding.

Terms of the Settlement Agreement in *Amarin*

Under the settlement agreement, FDA agrees to be bound by the District Court's decision that Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa® to treat patients with persistently high triglycerides, and under *Caronia*, such speech may not form the basis of a prosecution for misbranding. Further, the FDA agrees that the materials that were provided as a basis for the court decision, including the disclosures and scientific information that Amarin proposes to provide relating to the use of Vascepa® for the treatment of patients with persistently high triglycerides, as modified by the court order, are truthful and non-misleading.

The parties agree that Amarin will bear the responsibility for assuring that future communications to

doctors regarding off-label use of Vascepa® are truthful and not misleading, which is something companies already routinely assess when evaluating their promotional statements. This agreement, however, goes one step further in that it also contains provisions for Amarin, at its discretion, to provide up to two communications regarding the off-label use of Vascepa® per year to FDA for comment and identification of objections, under defined timelines. The process described in the agreement imposes time requirements on FDA for providing feedback to Amarin on its off-label communications, for Amarin to respond, and most importantly allows the parties to submit a motion to the District Court to hear any disputed claims for review and resolution. The feedback mechanisms and court review process exist until 2020. These procedures are in addition to any procedures generally available to Amarin for obtaining FDA comments on promotional materials under existing FDA regulations. It has been reported that FDA has taken the position that this settlement is case specific and is not more broadly applicable.

Key Takeaways

The benefits to Amarin of the settlement agreement are significant and provide a pathway for the company to not only continue to engage in truthful and non-misleading communications about the use of Vascepa® for the treatment of patients with consistently high triglycerides, but also to have the benefit of certainty of the status of future off-label promotions regarding Vascepa®. The opportunity for Amarin to continue to use the same court to hear unresolved disputes likely will temper FDA comments, knowing that the District Court is the “back stop” to check overly aggressive interpretations of whether proposed communications are misleading.

More generally, the agreement by FDA to settle this litigation, along with its earlier public statement that it is reviewing its standing policies concerning First Amendment protection of off-label promotion, suggests continued acknowledgement by FDA that access to truthful and non-misleading information about unapproved uses of drugs will result in better treatment decisions by HCPs for their patients.

Further, FDA’s agreement to accept the District Court’s decision on the scope of First Amendment protection for the distribution of truthful and non-misleading scientific information about unapproved uses may provide manufacturers with greater opportunities to communicate to HCPs. How FDA will respond to future activities regarding unapproved uses, though, is yet to be seen and companies should expect FDA to continue to strictly scrutinize the substance and intent behind any such promotion.

In addition, the *Amarin* decision and this settlement should deter FDA and the US Department of Justice from pursuing misbranding and related actions under the False Claims Act against pharmaceutical companies based upon the mere truthful and non-misleading communication about off-label uses. Whether the acceptance of the agreement by the FDA will cause state attorneys general and class action plaintiffs to reconsider the likely success of pursuing similar claims under other laws is unclear.

[1] Stipulation and Order of Settlement, *Amarin Pharma, Inc., et al. v. U.S. Food & Drug Admin., et al.,* No. 15 Civ. 3588 (S.D.N.Y. Mar. 8, 2016).

[2] *Amarin Pharma, Inc., et al. v. U.S. Food & Drug Admin., et al.,* 119 F. Supp. 3d 196 (S.D.N.Y., 2015).

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