Free speech* for pharmaceutical and device companies (*as long as it is truthful and non-misleading) - *Update#2*

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Abstract/Executive Summary

Although the United States Food and Drug Administration (FDA) restricts the promotion of medical products for off-label uses, its enforcement power has been substantially weakened by a string of court decisions and settlements, many of which have occurred within the past year. The regulatory landscape for off-label promotion is uncertain, but here, we provide a further update in our series on the evolution of the FDA's enforcement powers for off-label marketing.

Update 2 (March 2016):

Since the ruling of the United States District Court for the Southern District of New York in *United States v. Caronia* in 2012[1], the landscape surrounding restrictions on off-label marketing and the enforcement powers of the United States Food and Drug Administration (FDA) has been rapidly evolving. Although *Caronia* addressed the free speech right of an individual sales representative, the same district court recently ruled that pharmaceutical companies also possess a similar right to free speech for off-label promotion, provided this speech is truthful and non-misleading (*Amarin Pharma v. US FDA*; 2015).[2] Following these key court decisions, pharmaceutical and medical device companies have pushed to extend their free speech rights in both civil and criminal litigation.

Pacira Pharmaceuticals, with the backing of pharmaceutical trade groups, sued the FDA regarding their marketing of Exparel, leading to a favorable settlement in which the FDA withdrew a warning letter and accepted more expansive marketing of Exparel.[3,4] Although the FDA's settlement in the Pacira case suggests that the FDA's enforcement powers for off-label marketing are waning, the FDA itself is unlikely to feel constrained. Instead, the settlement may be viewed as a way to limit damage to a small number of cases and jurisdictions, allowing the FDA time to issue updated guidance or to pursue more favorable rulings in a different district court.

However, since the Pacira settlement on December 14, 2015, the FDA has continued to cede ground. On March 8th, Amarin Pharmaceuticals and the FDA reached a settlement regarding the off-label marketing of Vascepa that formally ends the litigation of *Amarin v. US FDA*.[5,6] In this settlement, the FDA agreed to the District Court's opinion that Amarin can use truthful and non-misleading speech to promote off-label use of Vascepa. Additionally, the FDA will provide fast track review of proposed Amarin communications to confirm that they adhere to the truthful and non-misleading standard, and disputes from this review process will be arbitrated by the District Court. The Amarin settlement may encourage new litigation against the FDA for restriction of off-label marketing, but it still does not provide one coherent and comprehensive FDA policy for the future. In theory, it maintains the FDA's enforcement authority over false or misleading speech, reserves the FDA's enforcement authority on conduct (as opposed to speech), and allows the FDA to interpret the *Caronia* and *Amarin* decisions as local decisions of the District Court that do not apply to the broader United States.

While the FDA may view the Pacira and Amarin settlements as very restricted, the free speech argument for off-label marketing has clearly gained traction. For example, Patrick Fabian and Howard Root were recently indicted and tried in the United States District Court for the Western District of Texas

for the off-label marketing of the Vari-Lase laser ablation system for treatment of varicose veins.[7,8] The defense moved to dismiss the case under the *Amarin* ruling, but the court ruled that the case would proceed because the government would be using evidence of conduct, not speech, suggesting one way that the impact of the *Amarin* ruling may be restricted. However, the court did instruct the jury that truthful and non-misleading off-label promotion is protected free speech, a key indication that the *Amarin* ruling has become the new standard. Fabian and Root were acquitted on all counts, providing further evidence of the erosion of the FDA's enforcement powers.

With the FDA having ceded a substantial amount of its enforcement power over off-label marketing, many questions still remain about off-label marketing with truthful and non-misleading statements. Two primary concerns for pharmaceutical and medical device companies are the reimbursement of products used off-label and potential liabilities introduced by off-label marketing. It is likely that payers will view off-label indications negatively, and they are unlikely to fund these treatments fully - if at all - reducing their use for the off-label purposes. Pharmaceutical and medical device companies may also open themselves to additional lawsuits if they are promoting the use of products for indications that are not FDA-approved, and it is unclear how courts and juries will interpret the post-*Amarin* landscape. Regardless, it seems likely that more companies will pursue strategies that include off-label marketing using truthful, non-misleading materials.

References

1. *United States v Caronia*. 703 F3rd 149 2nd Cir (2012).
2. Amarin Pharma, Inc. et al v United States Food & Drug Administration et al. No. 1:2015cv03588 - Document 73 (S.D.N.Y. 2015).
3. Doctor RM. Pacira Locked In Legal Battle With Feds Over Exparel Marketing. Tech Times website. http://www.techtimes.com/articles/83136/20150910/pacira-locked-in-legal-battle-with-feds-over-exparel-marketing.htm. September 10, 2015. Accessed September 24, 2015.
4. Lovells H. FDA Settles Pacira's First Amendment Lawsuit. Lexology website. http://www.lexology.com/library/detail.aspx?g=443bb691-f3a5-4d91-9f26-e1f399ab2de2. December 17, 2015, Accessed December 18, 2015.
5. Thomas K. FDA Deal Allows Amarin to Promote Drug for Off-Label Use. New York Times website. http://www.nytimes.com/2016/03/09/business/fda-deal-allows-amarin-to-promote-drug-for-off-label-use.html. March 8, 2015, Accessed March 9, 2015.
6. [Proposed] Stipulation and Order of Settlement. Amarin Pharma, Inc. et al v United States Food & Drug Administration et al. No. 1:2015cv03588 Accessed March 10, 2016. http://files.shareholder.com/downloads/AMRN/1665977958x0x879932/A9BE5FCE-A228-429F-8394-DE4D76DAFACF/AMRN.pdf
7. Carlson J. Med-tech executives look to turn tables on federal prosecutors. Star Tribune website. http://www.startribune.com/med-tech-executives-look-to-turn-tables-on-federal-prosecutors/328270541/. September 19, 2015, Accessed December 18, 2015.
8. Riach KC. Jury Acquits Medical Device CEO Charged with FDA Crimes. Lexology website. http://www.lexology.com/library/detail.aspx?g=83d3594f-b97e-4fc0-84a0-cbb06e44f093. March 7, 2016, Accessed March 10, 2016.