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

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Abstract/Executive Summary
Historically, the US Food and Drug Administration (FDA) had sweeping powers to enforce restrictions on the marketing and promotion of medical products for off label purposes. However, several recent cases in the federal court system have weakened this authority by supporting the free speech rights of pharmaceutical companies to market off-label, provided that their statements are truthful and non-misleading. The regulatory landscape surrounding off label marketing is now in flux, and the further evolution – and eventual result – of such free speech rights for pharmaceutical and medical device companies remains unclear from legal, regulatory, and business perspectives. Here, we provide an update to the original white paper detailing the opportunities and risks going forward for pharmaceutical, device, and diagnostic companies considering an expansion of off-label marketing following these recent rulings.

Update

The ruling provided by the United States District Court for the Southern District of New York in Amarin vs. the FDA significantly altered the landscape surrounding restrictions on off-label marking and the enforcement powers of the FDA.[1] Following this August 2015 decision, the next steps for the FDA, pharmaceutical companies, and device manufacturers were unclear, as the ruling could be appealed in 60 days or the issuance of new regulations by the FDA could offer new clarity.

Pacira Pharmaceuticals jumped directly into the post-Amarin fray by filing a lawsuit (in the same Southern District of New York court as Amarin) against the FDA for blocking the broad marketing of Exparel in surgeries beyond bunionectomy and hemorrhoidectomy with a fall of 2014 warning letter.[2] Notably, the Pacira suit received the backing of pharmaceutical trade groups, such as Pharmaceutical Research and Manufacturers of America (PhRMA) and the Medical Information Working Group (a consortium of major drug manufacturers), who filed amicus briefs. The Amarin ruling is also being applied to medical devices, as in the cases of Patrick Fabian and Howard Root, who were indicted for the off-label marketing of medical devices.[3] Fabian and Root are fighting their indictments claiming that their statements in the marketing of devices are covered as free speech under the Amarin ruling.

FDA's strategy for post-Amarin regulation of the off-label promotion of pharmaceuticals and medical devices remains unclear. The FDA declined to appeal Amarin, and more recently settled the Pacira lawsuit.[4] The settlement is very favorable to Pacira, with the nearly unprecedented withdrawal of the previous FDA warning letter and an FDA statement that Exparel can be used in a variety of surgeries not investigated in the pivotal clinical trials. Although the FDA is likely to interpret this settlement narrowly, the FDA's enforcement power has been significantly diminished. Going forward, the settlement may embolden other challenges to the FDA. The settlement may also reflect a long-standing FDA strategy of attempting conflict avoidance in this arena. For example, the FDA adopted more narrow guidelines to resolve the argument in Washington Legal Foundation vs. Friedman and attempted to limit the scope of the Amarin lawsuit by offering defined conditions under which Amarin could distribute information on

off-label uses.[1] It is possible that the FDA is avoiding conflict now to allow for the development of new official guidance that will bring increased clarity to the boundaries off-label promotion. Going forward, in order to avoid lawsuits similar to the Pacira lawsuit, the FDA may also subject labels to increased scrutiny to avoid ambiguities concerning on- or off-label marketing. Finally, it is notable that this recent litigation has centered on the District Court for the Southern District of New York, and the FDA may pursue litigation in a different, more favorable district to force resolution of local inconsistencies by an appellate court with broader reach with the hopes of overturning the Amarin decision.

Overall, with the expiration of the Amarin appeal deadline and the settlement of the Pacira case, the FDA's enforcement power over off-label promotion has been greatly reduced. With little threat of regulatory consequences and without new official guidance, pharmaceutical and device companies are likely to push the envelope of off-label promotion. However, a looming, larger concern for these companies may be increased financial liability and risk associated with off-label promotion.

References

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