



It's Déjà Vu All Over Again: FDA Sued Again in Off-Label Promotion Case

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To quote the late Yogi Berra, it must feel like déjà vu all over again for the Food and Drug Administration (FDA) (or, if you prefer, Crosby, Stills, Nash & Young's song, "Déjà Vu" ("We have all been here before")). Fresh off its recent loss in the Amarin court decision concerning off-label promotion, the agency again finds itself the defendant in another similar lawsuit concerning whether FDA can silence a company's truthful and non-misleading communications about off-label uses. Our Bulletin on the Amarin decision can be accessed here.¹ This time, it is Pacira Pharmaceuticals, Inc. challenging FDA's authority.² Perhaps not surprisingly, Pacira brought its challenge in the United States District Court for the Southern District of New York, the same forum where FDA lost the Amarin case, hoping for a similar result.

Background

Without describing the entire 70+ page Complaint, here are some background facts.

- Pacira has approval to market its prescription drug, Exparel® (bupivacaine liposome injectable suspension), for single-dose administration into the surgical site to produce post-surgical analgesia.
- In September 2014, FDA issued a Warning Letter to Pacira, contending that the company promoted its product for pain relief in surgeries not listed in the label, i.e., unapproved and off-label uses, and, thus, misbranded the product.
- Pacira cites its First Amendment free speech rights to promote its product in a truthful and non-misleading manner (Amarin made similar arguments). The company maintains the information presented is, indeed, consistent with the approved, on-label indication.
- The company also claims that, under the Due Process Clause of the Fifth Amendment, FDA must establish rules that expressly notify the prohibitions for a particular drug. Pacira asserts that it has a broad, approved indication and, after three years post approval, FDA attempted to limit promotion of the product beyond two specific indications – surgeries for bunions and hemorrhoids. Pacira contends the agency's regulations as applied to the company are vague. In addition, it alleges FDA failed to provide fair notice about what Pacira could lawfully promote and what FDA considered to be prohibited, thus representing a retroactive, ex post facto penalty.
- Pacira alleges that FDA violated the Administrative Procedure Act when it attempted to narrow what the company believes was a broad indication, and where it had supporting clinical data for the claims promoted, without following regulatory rules to modify the drug's label.
- In the Complaint, Pacira claims it sought to meet with FDA to better understand FDA's interpretation, but to no avail. FDA ultimately issued a close-out letter to Pacira, indicating it considered the Warning Letter issue to be resolved.
- Pacira's Complaint seeks declaratory relief and a preliminary and/or permanent injunction to prevent FDA from taking enforcement action that could violate the company's legal rights.

¹ <http://www.agg.com/Another-One-Bites-the-Dust-FDA-Doesnt-Like-the-Fishy-Smell-of-the-Latest-Court-Decision-on-Off-Label-Dissemination-08-19-2015>.

² Pacira Pharmaceuticals Inc. v. U.S., No. 1:15-cv-07055-RA (S.D. NY filed Sep. 8, 2015).

AGG Observations

- FDA has not responded formally to the lawsuit at this time, so it is not clear how it will argue its case, or if it will take a different position from that asserted in the Amarin case.
- As noted, the case has been brought in the same jurisdiction where the Amarin case favored the drug company. Pacira clearly hopes it has a receptive court, but the facts of each case are distinct.
- FDA has not said much, if anything, post-Amarin, except it is public that Amarin and FDA are discussing settlement options. We believe the agency is struggling to find a balance whereby it can maintain its jurisdictional authority to take enforcement action against what it perceives to be unlawful promotion, while possibility conceding some authority when the off-label information is truthful and not misleading.
- As we noted in our last Bulletin, one important issue that remains unresolved is who decides what is truthful and not misleading – the company, FDA, or the court. Without this answer, we will likely continue to see companies challenge FDA, particularly in the Southern District of New York.
- We know, because clients call us daily, that companies, whether pharmaceutical (or biological or medical device), are re-evaluating potential off-label promotional dissemination approaches, in light of recent developments. We remind clients that the courts have not given carte blanche power to manufacturers to promote off-label; we are not (yet) in the Wild West. The information must still be truthful and not misleading, which might require prominent disclosures, disqualifiers or limitations in promotional pieces, among other things. It bears repeating that the Federal Food, Drug, and Cosmetic Act provides that, in determining whether a promotion is misleading, it must be taken into account (among other things) not only representations made or suggested, but also:
 - ...the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling, or advertising thereof or under such conditions of use as are customary or usual.³
- A company's Promotional Review Committee (or PRB, LMR, MLR, or whatever it might be called within a specific company), where we serve as legal representative for many clients, must remain the gatekeeper. Furthermore, non-FDA-related issues, such as False Claims Act prosecution or product liability exposure, must be considered and not discounted or dismissed.

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The Chinese proverb, "May you Live in Interesting Times," comes to mind. We will continue to follow and provide updates on new developments.

³ See 21 U.S.C. § 321(n).

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