Off-Label Promotion and Product Liability: Are Industry's Recent Court Wins in One Space a Win in the Other?

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The pharmaceutical industry has recently felt empowered and emboldened by recent litigation that would seemingly allow companies to distribute, proactively, information about unapproved uses, i.e., off-label, so long as the information is truthful and not misleading. However, companies must, nevertheless, consider potential product liability ramifications. There is no indication that, because firms may now be allowed certain latitude in one area, they are immune from product liability exposure.

We have prepared Bulletins on the Amarin[1] and Pacira[2] court cases, so we will not discuss them here.

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.

In light of recent developments, many companies are re-evaluating potential off-label promotional dissemination approaches. We know; clients are asking.

The courts have not given carte blanche power to manufacturers to promote off-label. 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.

A company's Promotional Review Committee, Legal/Medical/Regulatory review Committee, or similar group must remain the gatekeeper. Furthermore, non-FDA-related issues, such as product liability exposure, must be considered and not discounted or dismissed. A jury might not be as forgiving if little Johnny or Grandma is injured as a result of a product's off-label use, which could be traced back to a manufacturer's promotional efforts.

While it might be possible to create product information, even if off-label, that will pass legal scrutiny, it is important to remember that the "truthful and not misleading" standard seems to be the norm, however that might be interpreted. So, a company should recognize that this broad standard might be beneficial in an FDA sense (allowing more freedom to distribute) but, potentially, problematic if named as a defendant in a product liability lawsuit (where a judge and jury might impose a strict and

1 http://www.agg.com/another-one-bites-the-dust-fda-doesnt-like-the-fishy-smell-of-the-latest-court-decision-on-off-label-dissemation-08-19-2015/

2 http://www.agg.com/Can-We-Still-Be-Friends--FDA-and-Pacira-to-Settle-Lawsuit-Relating-to-Off-Label-Promotion-10-28-2015/

narrow interpretation favoring an injured party). Distribution of an off-label piece, without internal review, is not advisable, notwithstanding the potential FDA opportunities, when one factors in possible product liability exposure.

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