Pharma and Medical Device Industry Victory in Off-Label Marketing Decision

09.22.2015 | UPDATES

The U.S. District Court for the Southern District of New York recently held that the FDA may not constitutionally bring a misbranding action based on truthful and non-misleading off-label promotion of an FDA-approved drug, thereby helping to clarify lingering uncertainty over the scope of First Amendment protection afforded statements by drug representatives, at least in states located in the Second Circuit.

While that decision, *Amarin Pharma, Inc. v. FDA*, issued on August 7, 2015, may have significant repercussions for some misbranding actions, its scope is limited to instances in which the off-label promotion consists solely of truthful and non-misleading statements. And it remains to be seen whether its reasoning will be adopted outside the Second Circuit or will have a significant impact on False Claims Act (FCA) cases alleging off-label promotion.

**Caronia Put to the Test**

In 2012, the U.S. Court of Appeals for the Second Circuit ruled, in *United States v. Caronia*, that, to avoid running afoul of the First Amendment’s protection of commercial speech, the misbranding provisions of the Food Drug and Cosmetic Act (FDCA) must be interpreted as not prohibiting and criminalizing truthful off-label promotion of FDA-approved drugs where such use is itself lawful. Although many commentators understood *Caronia* to severely limit the FDA’s ability to bring misbranding actions based on truthful off-label promotion, the FDA disagreed, taking the position that the *Caronia* decision was narrow in scope and maintaining that it did not substantially limit the FDCA’s reach in actions based on off-label promotion.

*Amarin* puts the FDA’s interpretation of *Caronia* to the test. The dispute in that case stemmed from the FDA’s threats to bring misbranding charges against Amarin if it made certain truthful statements to doctors about the off-label use of its drug Vascepa. In light of those threats, Amarin filed suit, asking the court to declare that the statements were protected by the First Amendment under *Caronia*.

In response, the FDA argued that *Caronia* was a “fact-bound decision that turned on the particular jury instructions and government jury addresses” given at trial and that it consequently did not limit the FDA’s ability to bring a misbranding action against a pharmaceutical manufacturer or its representative where the conduct at issue consists solely of truthful and non-misleading speech promotion of an off-label use of an approved drug. But the *Amarin* court rejected the “FDA’s attempt to marginalize the holding in [Caronia] as fact bound,” instead calling the *Caronia* decision “categorical” and stating that a “fair reading” of it “refutes the FDA’s view that the Second Circuit’s ruling was limited to the facts of Caronia’s particular case.”

**Limits of Decision for Pharmaceutical and Medical Device Companies**

While *Amarin* is unquestionably a victory for the pharmaceutical and medical device industries, it does not give carte blanche permission to engage in unrestrained off-label promotion without fear of FDA action.

First, the decision does not insulate off-label promotion that may be construed to be untruthful or misleading. And the *Amarin* court’s extensive scrutiny of the proposed communications to ascertain whether they were indeed truthful and non-misleading suggests that the outcome of such an inquiry is not always clear or predictable. Indeed, although the court rejected the FDA’s attempt to script what Amarin’s representatives could say, it cautioned that pre-clearance would be prudent:

> Although the FDA cannot require a manufacturer to choreograph its truthful promotional speech to conform to the agency’s specifications, there is practical wisdom to much of the FDA’s guidance, including that a manufacturer vet and script in advance its statements about a drug’s off-label use. A manufacturer that leaves its sales force at liberty to converse unscripted with doctors about off-label use of an approved drug invites a misbranding action if false or misleading (e.g., one-sided or incomplete) representations result. *Caronia* leaves the FDA free to act against such lapses.

Second, despite its forceful rejection of the FDA’s arguments, *Amarin* is a single district court opinion interpreting a single appellate court decision. It remains to be seen how courts in other circuits, that are not bound by *Caronia*, will apply the First Amendment in misbranding actions.

It is also unclear what impact—if any—*Caronia* and *Amarin* will have on the many FCA actions in which a whistleblower alleges that off-label promotion caused the submission of false claims. Indeed, although Amarin asked the court for preliminary relief in connection with potential FCA claims in addition to the threatened misbranding action, the court declined to address the FCA issue on grounds that the controversy was not ripe because there was no pending or threatened action under the FCA. The *Amarin* holding may ultimately have no impact on FCA cases, because the associated claims’ falsity may turn on whether the use is
covered by the payor, not on whether the FDA has approved the use. In other words, a violation of the FDCA is arguably neither necessary nor sufficient to establish a violation of the FCA. And Amarin’s holding is limited, at least facially, to the issue of whether truthful non-misleading speech violates the FDCA. In light of the government’s prolific pursuit of FCA cases relating to off-label marketing, Amarin nevertheless raises serious implications for future government action in this area.

© 2015 Perkins Coie LLP

CONTACTS

David B. Robbins
Partner
Seattle
D +1.206.359.6745

Barak Cohen
Partner
Washington, D.C.
D +1.202.654.6337

Matthew P. Gordon
Partner
Seattle
D +1.206.359.3552

RELATED SERVICES

PRACTICES
• White Collar & Investigations

INDUSTRIES
• Healthcare
• Biotechnology & Pharmaceutical