

Amarin's Off-Label Victory Opens Door To More Injury Claims

By **Sindhu Sundar**

Law360, New York (August 10, 2015, 9:26 PM ET) -- Amarin Pharma Inc.'s landmark win in its New York federal suit against the U.S. Food and Drug Administration upholds drugmakers' right to truthfully promote their products' unapproved uses, but attorneys say this expanded marketing can inadvertently supply more fodder — without the FDA's imprimatur — for failure-to-warn lawsuits.

Amarin won a preliminary injunction Friday against the agency's increasingly controversial ban on drugmakers' ability to promote their drugs for unapproved, or off-label, uses. The Ireland-based drugmaker sought to promote its fish oil-based omega-3 drug Vascepa for patients with lower levels of triglycerides, fatty molecules linked to heart problems, than the group for which the drug is approved.

The agency had argued that such statements by drugmakers, even if truthful, signal a company's intent to promote their products for off-label uses and can put them in the agency's crosshairs. But U.S. District Judge Paul Engelmayer found such statements are protected by the First Amendment if they are truthful and not misleading.

Nonetheless, the implications of the decision particularly for product liability suits are unclear, and attorneys say non-FDA-approved promotions by drugmakers can easily increase the universe of company statements that injured plaintiffs can seize on.

"In theory, this ruling frees companies to promote their drugs more broadly for uses not approved by the FDA, so long as what they say is truthful and not misleading," Jennifer Bragg of Skadden Arps Slate Meagher & Flom LLP said.

"But any arguments that companies might have previously had that their statements were consistent with FDA's approval will not be available, to the extent that cases pertain to alleged injuries from off-label uses of their products," she said.

Judge Engelmayer's decision hinges on the Second Circuit's decision in *U.S. v. Caronia*, in which the appeals court in December 2012 overturned a pharmaceutical sales representative's conviction for off-label promotion involving truthful speech.

Attorneys say Judge Engelmayer's ruling goes a step further than the *Caronia* decision in some significant ways — the *Caronia* decision held that off-label promotion can serve as evidence of a company's intended use for the drug, whereas Judge Engelmayer ruled that any such intention is immaterial because the First Amendment shields companies as long as their statements are truthful.

In some ways, this can help defendants in injury suits, which often dredge up FDA warning letters or U.S. Department of Justice enforcement actions. If off-label marketing doesn't automatically elicit such attention from regulators and prosecutors, that can leave plaintiffs with fewer official actions or statements to lean on.

But the question of what constitutes "truthful" information could itself lead to litigation, even by the FDA, and also could pave the way for disputes over who can decide what information is truthful, according to Susan Burnett of Bowman and Brooke LLP.

"A drug company would still have to tread extremely carefully in making any kind of off-label statements about their drug," Burnett said.

Putting out extra promotional materials that add new information beyond a drug's approved warning label, or which perhaps even undermine the label in some way, could also weaken companies' position in injury suits.

"Let's say you have a product with a boxed warning, and you believe you're protected from failure-to-warn claims; if you at the same time are promoting data that suggests there's no increased risk of that particular outcome indicated in the boxed warning, then you could be accused of engaging in promotional activity that undermines the label," Loren Brown of DLA Piper LLP said.

Some attorneys also believe drugmakers' new power to put out truthful information beyond a product's label could come back to haunt them in unusual ways. Generic-drug makers have been generally able to fend off injury suits arising from their products by arguing that such claims are preempted because the Hatch-Waxman Amendments require generic drug composition and labeling to adhere to that of their branded counterparts.

Some attorneys say plaintiffs might now argue that generic-drug makers have a First Amendment right to put out truthful information about a drug's potential risks, even without FDA approval, and that their failure to do so amounts to negligence.

"I think this decision has huge implications for the preemption doctrine," Lou Bograd of the Center for Constitutional Litigation PC said.

"If it's the case that drug companies have the First Amendment right to make truthful statements about off-label uses, and the FDA cannot prohibit them, then it follows that they would have the First Amendment right to truthfully communicate the risks of their products even if that information isn't on the label of the brand-name products," he said.

But defense attorneys are less certain about such implications, reasoning that generics makers seldom engage in that type of promotion anyway.

"Generic-drug makers' business model is based on price and volume, not on advertising that their drug is better than others," Bragg said. "They don't have usually have that same direct-to-physician interaction [that branded-drug makers have]. So my immediate sense is that I don't think this decision would affect generic injury suits much."

Amarin is represented by Floyd Abrams, Joel Kurtzberg and Michael B. Weiss of Cahill Gordon & Reindel LLP.

The FDA is represented by Preet Bharara, Ellen London, Benjamin C. Mizer, Jonathan F. Olin, Scott R. McIntosh, Michael S. Blume, Andrew E. Clark and Kerala T. Cowart of the U.S. Department of Justice and William B. Schultz, Elizabeth H. Dickinson, Annamarie Kempic, Karen Schifter and Julie Dohm of the U.S. Department of Health and Human Services.

The case is Amarin Pharma Inc. et al. v. Food and Drug Administration et al., case number 1:15-cv-03588, in the U.S. District Court for the Southern District of New York.

--Additional reporting by Jeff Overley. Editing by Chris Yates and Christine Chun.

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