

Court sides against FDA in "off-label" drug promotion case

August 7 2015, by Matthew Perrone

The maker of a prescription fish-oil pill won an early victory Friday against the Food and Drug Administration over its right to publicize unapproved uses of its drug.

The preliminary ruling in U.S. District Court could strengthen the pharmaceutical industry's ability to distribute information about drug uses that have not been cleared by the FDA. That issue has been contested for years by the FDA and the companies it regulates.

According to Friday's decision, Amarin has the First Amendment right to give doctors truthful information about non-approved indications of its drug Vascepa, which is used to lower a certain kind of fat.

The FDA has 60 days to appeal the ruling. A spokeswoman for the agency declined to comment on the ruling.

Drugmakers are not allowed to advertise drugs for "off-label" uses, or those that have not been cleared by the FDA as safe and effective. But companies' ability to distribute independent materials about their drugs—such as medical journal articles—has been subject to years of legal debate.

The FDA approved Vascepa in 2012 for patients with abnormally high levels of triglycerides, a type of fat found in the bloodstream. But the agency rejected a second use that would have allowed the company to market the pill to patients with lower triglycerides who also take

statins—drugs used to lower cholesterol. The agency said the company needed to submit more data on whether lowering triglycerides actually translates into fewer heart problems in those patients. And FDA regulators suggested that distributing information about the alternate use would be illegal.

Amarin responded in May with a pre-emptive lawsuit, arguing that FDA efforts to stop the company from sharing "off-label" information would violate the company's free speech protections. Judge Paul Engelmayer agreed in a 71-page opinion.

"Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa," states the opinion, released Friday.

Legal experts noted that the decision only applies to the 2nd U.S. Circuit Court of Appeals, which includes New York, Connecticut and Vermont. A 2012 decision in that circuit set a similar precedent, overturning the conviction of a pharmaceutical salesperson who engaged in off-label promotion.

Some lawyers said Friday that other companies could follow a similar path by filing lawsuits in the second circuit.

"This is the first case where a company has achieved the right, for First Amendment purposes, to engage in off-label promotion," said James Beck, who represents pharmaceutical companies for the Reed Smith law firm.

Other experts were less convinced of the cases' importance. Analyst Ira Loss noted that the FDA neutralized many of Amarin's points in a court filing released in June. The agency essentially said that it did not take issue with many of the company's plans and that it would have permitted them if the company had consulted regulators before filing its lawsuit.

"The FDA said they could do all those things weeks ago," said Loss. "If they want to strut and think they accomplished a great achievement by beating the FDA in court they're free to do it."

Vascepa is a prescription strength form of an [omega-3 fatty acid](#) found in wild fish. Fish oil is thought to lower [heart disease risk](#), though no definitive studies have yet established that benefit.

Amarin Corporation PLC is based in Dublin, Ireland. Its U.S. shares rose 28 cents, or 13.9 percent, to close at \$2.32 on Friday.

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