

Amarin Pharma Preemptively Sues FDA over First Amendment Rights

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On Thursday, May 7, Amarin Pharma took the unprecedented step of proactively suing the **U.S. Food and Drug Administration (FDA)** over the agency's alleged infringement of the company's First Amendment Rights. The case arises from Amarin's desire to market its product, Vascepa, for uses broader than what the FDA has previously approved. While other companies have raised their First Amendment rights as a defense to enforcement actions brought by the FDA and the **Department of Justice (DOJ)**, none so far has taken the step of filing a lawsuit to proactively defend their rights. Vascepa, which consists of a combination of three fatty acids derived from fish, was FDA approved in 2012 for patients with extremely high triglycerides. Amarin wishes to inform physicians of its own internal research which supports the use of Vascepa in patients with persistently high levels of triglycerides. They would also like to be able to make claims, supported but not confirmed by science, similar to those of fish oil supplement makers that the drug may help reduce the risk of coronary artery disease.

The company's position is that providing truthful factual information to physicians about unapproved uses for a drug should be protected free speech under the First Amendment. Specifically, the company has taken the position that educating physicians will expand available treatments for patients, and be beneficial to the overall health of those patients. The case could have far reaching implications for the FDA and the DOJ's ability to seek penalties and other sanctions for off-label promotion of drugs. Both agencies are still actively enforcing the prohibition of off-label promotion through a combination of administrative, civil and, in some cases, criminal enforcement. Needless to say, the life sciences industry will be watching closely as the case unfolds.

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