
Cahill Prevails for Amarin and Physicians in Precedent-Setting First Amendment Case

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A Cahill litigation team prevailed on behalf of Amarin Corporation plc ("Amarin") and a group of physician plaintiffs in *Amarin Pharma Inc. et al. v. Food and Drug Administration et al*, a closely watched First Amendment lawsuit filed in the United States District Court for the Southern District of New York.

The precedent-setting case challenged the constitutionality of the FDA's restrictions on off-label promotion by Amarin of its lead product, Vascepa® (icosapent ethyl) capsules. Amarin filed the case preemptively to shield itself from FDA prosecution for promoting to healthcare professionals a body of truthful and non-misleading information related to Vascepa that goes beyond current FDA-approved labeling for the drug. Presenting medical professionals with truthful information, the Company argued, was constitutionally protected speech, and further argued that FDA restrictions limiting such speech would prevent most physicians from making fully-informed treatment decisions to high-risk cardiovascular disease patients.

On August 7, 2015, U.S. District Court Judge for the Southern District of New York, Paul A. Engelmayer, granted Amarin's application for preliminary relief, declaring that "Amarin may engage in truthful and non-misleading speech promoting off-label use of Vascepa," and that, "such speech may not form the basis of a prosecution for misbranding." The court further held that "the combination of statements and disclosures that Amarin proposes to make to doctors relating to the use of Vascepa to treat persons with persistently high triglycerides, as such communications have been modified herein, is truthful and non-misleading."

The decision opens more direct paths to communicate truthful and non-misleading information about Vascepa clinical trial results and the state of science relevant to the potential of Vascepa to reduce the risk of cardiovascular disease. With such information readily available, healthcare professionals will be better able to assess for themselves how best to choose among available treatment options for their patients.

Attorneys

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