

Cahill Represents Amarin in Settlement of First Amendment Lawsuit with FDA

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After prevailing against the FDA in August 2015, receiving a preliminary declaration that "Amarin may engage in truthful and non-misleading speech promoting the off-label use of Vascepa," and that, "such speech may not form the basis of a prosecution for misbranding," Amarin Pharma, Inc. and several individual doctor plaintiffs have amicably settled the underlying lawsuit with the FDA and other government defendants.

The terms of the settlement make the preliminary ruling final, provide Amarin with an optional procedure for receiving pre-clearance from FDA on certain proposed promotional statements, create a dispute resolution mechanism to avoid future disputes, and provide for continuing jurisdiction from the court over any future disputes arising out of the settlement.

This precedent-setting litigation and settlement ensures that healthcare providers will have greater access to truthful and non-misleading information to aid in making treatment decisions and ensures that such promotion cannot lead to criminal sanctions.

Attorneys

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