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## WLF Asks New York Federal Court to Strike Down FDA Effort to Ban Manufacturer's Truthful Speech

*(Amarin Pharma, Inc. v. FDA)*

**“FDA ought to focus its attention on preventing manufacturers from making false claims about their products. Its efforts to ban truthful speech violate the First Amendment and harm public health.”—Richard Samp, WLF Chief Counsel**

WASHINGTON, DC—Washington Legal Foundation (WLF) today asked the U.S. District Court for the Southern District of New York to enjoin the Food and Drug Administration's efforts to prevent a drug manufacturer from providing doctors with truthful information about one of its FDA-approved drugs. In a brief filed in *Amarin Pharma, Inc. v. FDA*, WLF argues that the First Amendment prohibits the government from restricting truthful speech, subject only to very rare exceptions.

Plaintiff Amarin Pharma, Inc. manufactures Vascepa, a drug approved by FDA to reduce triglyceride levels in patients with “very high” triglycerides. Doctors also regularly prescribe Vascepa on an off-label basis for patients whose triglyceride levels are only “persistently high,” in light of significant medical evidence that consumption of omega-3 fatty acids (a major ingredient in Vascepa) is associated with reductions in the risk of coronary heart disease. Nonetheless, FDA has threatened to prosecute Amarin (for marketing an unapproved new drug) if Amarin tells doctors about that medical evidence.

WLF's brief notes that Amarin is willing to attach to its statement to doctors whatever qualifying “disclaimers” that FDA may deem important to ensure that doctors are not misled. WLF argues that under those circumstances, FDA's absolute prohibition on any statements about the reduced risk of coronary heart disease violates the First Amendment. WLF points out that the First Amendment requires that the government “narrowly tailor” any commercial speech restrictions designed to reduce the possibility that listeners will be misled, and that courts have held explicitly that “when government chooses a policy of suppression over disclosure—at least where there is no showing that disclosure would not suffice to cure misleadingness—government disregards a far less restrictive means of achieving government's objectives.”

After filing its brief, WLF issued the following statement by Chief Counsel Richard Samp: “FDA ought to focus its attention on preventing manufacturers from making false claims about their products. Its efforts to ban truthful speech violate the First Amendment and harm public health. FDA is denying doctors access to the best available information about FDA-approved drugs and thereby interfering with state-of-the-art medical care.”

*WLF is a national public interest law firm and policy center that regularly litigates in support of free speech rights, including where violations of commercial free speech rights harm patients.*