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## In Major WLF Victory, NY Federal Court Strikes Down FDA Ban on Truthful Speech by Manufacturer

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

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**—Richard Samp, WLF Chief Counsel**

WASHINGTON, DC—The U.S. District Court for the Southern District of New York today preliminarily enjoined the Food and Drug Administration from preventing a drug manufacturer’s efforts to provide doctors with truthful information about an FDA-approved drug. The decision is a major milestone in Washington Legal Foundation’s two-decades-long crusade to require FDA to abide by the First Amendment. The district court agreed with WLF’s argument, set forth in an *amicus* brief filed in June in *Amarin Pharma, Inc. v. FDA*, that the First Amendment prohibits the government from restricting truthful speech, subject only to very rare exceptions.

Plaintiff Amarin Pharma, Inc. is the manufacturer of 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 “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, as it would like to do.

The district court upheld Amarin’s First Amendment right to make each of the statements it seeks to make, with only slight modifications. Significantly, it held that FDA is categorically prohibited from bringing enforcement actions against a drug manufacturer “based on truthful promotional speech alone,” even when the company intends that speech to promote drug sales for off-label uses. The court held that FDA is reading *United States v. Caronia*, a 2012 appeals court decision, too narrowly. *Caronia*, a case in which WLF orchestrated the successful First Amendment arguments, reversed a drug salesman’s conviction for promoting off-label drug uses.

After the decision, WLF issued the following statement by Chief Counsel Richard Samp: “When FDA denies doctors access to the best available information about FDA-approved drugs, it interferes with state-of-the-art medical care. FDA should focus on preventing manufacturers from making false claims about their products. The court correctly held that FDA’s misguided efforts to ban truthful speech violate the First Amendment and harm public health.”

*WLF is a public-interest law firm and policy center that litigates in support of the constitutional rights of businesses to say—and doctors and patients to hear—truthful commercial speech.*