

PRESS RELEASE

Bert Rein, in *Bloomberg BNA* Column, Discusses Future of FDA Drug Approval Regime Following *Amarin* Decision

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In a column published today by *Bloomberg BNA's Pharmaceutical Law & Industry Report*, Wiley Rein founding partner Bert W. Rein discusses the August 7 ruling concerning First Amendment protection for a pharmaceutical manufacturer's off-label promotion of an approved drug, and the ruling's impact on the U.S. Food and Drug Administration's (FDA) current drug approval regime and related False Claims Act litigation. In *Amarin v. FDA*—one of the most significant recent rulings of its kind—Judge Paul Engelmayer of the U.S. District Court for the Southern District of New York granted a motion for preliminary injunction in favor of Amarin Pharma, Inc., affirming the merits of the biopharmaceutical company's First Amendment claims.

According to Mr. Rein's article, the court unequivocally concluded that Amarin was constitutionally entitled to "engage in truthful and non-misleading speech promoting the off-label use" of its drug Vascepa and that "such speech may not form the basis of a prosecution for misbranding."

The article points out that the FDA is now faced with a decision to either appeal the decision, with the hope of eventual review from the Supreme Court of the United States, or wait to bring a subsequent challenge to off-label promotion in another circuit court. The *Amarin* court, Mr. Rein noted, observed that the fundamental problem in the FDA's off-label speech approach was that its 1962 premise—speech is a form of regulatable conduct—has been superseded by later changes in First Amendment commercial speech doctrine.

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Click [here](#) to read the article, "*Amarin v. FDA—Can the Current FDA Drug Approval Regime Survive?*"

Mr. Rein has been recognized as a Washington "Visionary" by *The National Law Journal* and a "Leading Food and Drug Lawyer" by the *Legal Times*.