

Litigators of the Week: Floyd Abrams and Joel Kurtzberg of Cahill Gordon

By Scott Flaherty

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It's not exactly unusual for Floyd Abrams, the dean of the First Amendment bar, to find himself litigating a case whose significance reaches past a particular client.

And as Abrams and his partner Joel Kurtzberg showed in a challenge they brought in May against the U.S. Food and Drug Administration, it's not unusual for the cases to end with a win.

On Aug. 7, the two Cahill Gordon & Reindel partners persuaded a federal judge in Manhattan to block the FDA from bringing potential off-label marketing claims against their client, the Irish drugmaker Amarin Pharma Inc. In a highly anticipated ruling for the pharmaceutical industry, U.S. District Judge Paul Engelmayer agreed with the lawyers that the Constitution generally protects drugmakers' right to make truthful statements about their products.

The decision paves the way for Amarin to promote its fish oil cholesterol drug, Vascepa, for certain off-label uses that haven't received explicit FDA approval. The FDA generally prohibits companies from promoting drugs for unapproved uses, but Engelmayer's ruling means that Amarin's off-label promotions will be insulated from misbranding claims as long as the company disseminates "truthful and nonmisleading" information.

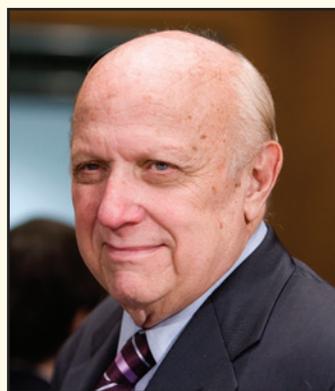
"The reason we went to court," Abrams said Thursday, "was to both obtain a ruling that would allow our client to proceed to engage in the speech that we believe it was entitled to, but also to make it clear, on a broader level, that the FDA was simply overstepping."

Vascepa's FDA approval only extends to treating "very high" triglyceride levels. But doctors also frequently prescribe the drug to patients who suffer from "persistently high" triglycerides, based on a clinical study that demonstrated Vascepa's effectiveness for that condition.

While the FDA hasn't questioned the results of that study, it hasn't formally approved the drug for "persistently high" triglyceride patients, making that an off-label use. Hoping to promote its drug to a wider group of patients, Amarin hired Cahill for advice on whether the FDA's regulations might violate the First Amendment.

"It became clear that the company and the individual doctors felt passionately about this issue," Kurtzberg said.

The company chose an experienced team. Abrams' First Amendment bona fides are known to anyone who follows the law,



and his role as counsel to amicus filer Sen. Mitch McConnell in *Citizens United v. Federal Election Commission* only cemented his reputation. (It no doubt earned him some new critics as well.) Kurtzberg, for his part, made news earlier this year for representing New York Times journalist James Risen as the U.S. Justice Department sought to identify Risen's confidential sources.

In Amarin's case, Abrams and Kurtzberg both presented arguments at a July 7 preliminary injunction hearing. The lawyers said that the FDA was poised to prosecute if Amarin or its employees promoted Vascepa to treat persistently high triglycerides. That sort of FDA enforcement action, they argued, would effectively punish Amarin for sharing study results that even the FDA didn't dispute.

Arguing for the government, assistant U.S. attorney Ellen London maintained at the hearing that a ruling in the company's favor "has the potential to eviscerate FDA's drug approval regime and the many public benefits that this system has achieved."

Engelmayer nevertheless sided with Abrams and Kurtzberg, holding that the FDA's argument couldn't survive a 2012 decision by the U.S. Court of Appeals for the Second Circuit. In *U.S. v. Caronia*, the Second Circuit overturned the criminal conviction of a drug sales representative who had promoted a drug for off-label uses, but whose promotion efforts relied on true statements.

"If the speech at issue is found truthful and nonmisleading, under *Caronia*, it may not serve as the basis for a misbranding action," the judge wrote in his decision last week.

Abrams, not surprisingly, said the judge got it right.

"Depriving the public of truthful information—let alone depriving doctors and other medical professionals of truthful information about the drugs—strikes at the heart of what the First Amendment is intended to protect," he said.