

MEDIA MENTION

Bert Rein Discusses Appeals Court Ruling's Impact on Off-Label Drug Marketing

The Coalition for Healthcare Communication
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Wiley Rein founding partner Bert W. Rein discussed the future of off-label drug marketing during a January 23 webinar—hosted by the Drug Information Association (DIA)—on a federal appeals court ruling that could force the U.S. Food and Drug Administration (FDA) to change some of its restrictions.

In December 2012, the U.S. Court of Appeals for the Second Circuit in New York vacated, on First Amendment grounds, the 2008 conviction of a sales representative who had marketed a drug for uses other than those approved by the FDA, in *United States v. Caronia*. The government cannot prosecute drug company representatives for speech promoting the legal, off-label use of a drug that the FDA has approved for other purposes, the court said.

When asked about the likelihood of an appeal, Mr. Rein said the FDA would probably want to leave the ruling alone and not challenge it before the U.S. Supreme Court, according to a Coalition for Healthcare Communication (CHC) article on the webinar. The DIA webinar was moderated by CHC Executive Director John Kamp.

During a discussion of how to allow truthful claims about unapproved uses and control false claims—while still retaining the value of an FDA approval—Mr. Rein suggested that the FDA might consider third-party validators of credibility. He noted that many group validators, such as Wikipedia, exist online, and would allow the FDA to recognize collections of data on drugs that are in widespread use, according to the article.

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With the *Caronia* decision, there was a clear disconnect between the appeals-court majority and the FDA's view of the facts and law, Mr. Rein said. While the FDA argued that pharmaceutical companies should only be allowed to discuss approved uses of drugs, the court sided with the defendant's position that the agency is not entitled to criminalize truthful communication between a drug manufacturer and a prescriber, he said. But Mr. Rein noted that the court's one dissenting member expressed concerns about the FDA's ability to approve and regulate drugs under that reasoning.

"The FDA thinks it can stop [off-label communication], but this issue is not easily resolved under the Food, Drug & Cosmetic Act," Mr. Rein said. "FDA wants to think of these as two separate drugs—one that is approved and one that is not—but that is not the case. This case focuses on a problem raised in the Supreme Court decision in *IMS v. Sorrell* regarding the selective regulation of speech" against a company speaker. The *Caronia* majority found selective regulation to be unsupported under the First Amendment, according to the CHC article.

Mr. Rein has been recognized by *Legal Times* as Washington's "Leading Food and Drug Lawyer."