

Bert Rein Discusses U.S. Appeals Court Reversal of Off-Label Drug Marketing Conviction

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Wiley Rein founding partner Bert W. Rein was interviewed by *Bloomberg BNA's Pharmaceutical Law & Industry Report* for a December 3 story on a federal appeals court ruling that could force the Food and Drug Administration to loosen its restrictions on the marketing of prescription drugs for uses other than those approved by the agency.

The Second Circuit U.S. Court of Appeals in New York vacated, on First Amendment grounds, the 2008 conviction of a sales representative who had marketed a drug for unapproved uses, 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.

Experts told *Bloomberg BNA* the December 3 decision could force the FDA to modify its long-standing restrictions on what drug makers can tell doctors about their products. FDA rules allow doctors to prescribe medicines for off-label uses, but companies are not allowed to market the drugs for those purposes.

"The key takeaway is that you cannot say that a manufacturer or a manufacturer's representative merely talking about an off-label use violates the law – that's insufficient," Mr. Rein told *Bloomberg BNA*. He noted that the appeals court, in its majority opinion, struggled to define the nature of the government's compelling interest in regulating speech.

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“On the one hand, the manufacturer can't provide information and promote unapproved uses, but, once a drug is available, a physician can prescribe it for off-label use ... there's a disconnect,” said Mr. Rein, who predicted that the FDA will appeal the Second Circuit ruling.

“This case will be of great concern to the government,” Mr. Rein said. “We haven't seen the end of it.”