White Collar Criminal Defense, Regulatory Compliance and Special Investigations Update

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Ninth Circuit Affirms Prosecution for Off-label Marketing

Over the past two years, courts began to recognize that at least some off-label marketing is protected lawful commercial speech under the First Amendment. Specifically, the Second Circuit in New York in a case called *United States v. Caronia* held that truthful off-label marketing is a form of protected First Amendment commercial speech that cannot be prosecuted under 21 U.S.C. §333 of the Food, Drug and Cosmetic Act ("FDCA"). The Ninth Circuit issued an opinion last week that reaffirmed the ability of federal authorities to prosecute false statements concerning off-label promotion. In truth, despite the decision in *Caronia*, prosecution for off-label marketing remains a high priority for the FDA and the U.S. Department of Justice, and companies are well-advised to thoroughly vet such materials before they are communicated to the public.

The judges in *Caronia* relied heavily upon the Supreme Court case of *Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653 (June 23, 2011), which held that a Vermont statute prohibiting pharmaceutical companies from engaging in truthful marketing activities offended the First Amendment. While some commentators opined that *Caronia* was the death knell of prosecutions for off-label use, such a conclusion is misplaced. The Second Circuit did not strike down any portion of the FDCA in *Caronia*, nor did it limit the government's authority to prosecute individuals or entities under the FDCA for off-label marketing that is allegedly false or misleading.

In *United States v. Harkonen*, a former CEO of a pharmaceutical company was convicted of wire fraud for issuing a fraudulent press release touting the performance of one of the company's drugs in clinical trials. In more detail, Harkonen was convicted for his role in publicizing misleading information (in a press release) about using the drug Actimmune for the treatment of lung disease, an "off-label" use of the medicine that was not approved by the FDA. The executive challenged the conviction as an unconstitutional infringement of his First Amendment rights, claiming that the press release was possibly misleading, but not fraudulent. The Ninth Circuit summarily rejected this argument in an unpublished opinion. The Ninth Circuit held that the term "to defraud" has its commonplace definition and includes "any sort of dishonest method or scheme" and any "trick, deceit, chicane or overreaching." Therefore, according to the Ninth Circuit, "statements are fraudulent if 'misleading or deceptive' and need not be 'literally false.'"

This holding seems to follow *Caronia* and insulates a company and its employee from prosecution under the FDCA if the off-label marketing statements are true. However, that is not the end of the game. The opinion also makes it clear that in the context of the wire fraud statute, that is not the case. As noted above, the term "to defraud" is broadly construed and could open a company or employee to a federal prosecution if an overzealous prosecutor seeks to hold that a literally true statement is, nonetheless, deceptive or overreaching. Vulnerability to this type of prosecution only reinforces the need for companies to draft their promotional materials with great care, and to train and monitor the sales staff in an attempt to ensure that the dialogue with the medical care professionals or the consumers is not in any way misleading or overreaching. A full copy of the *Harkonen* opinion can be found here.

For more information, please contact the White Collar Criminal Defense, Regulatory Compliance and Special Investigations Practice Group at Lane Powell: whitecollar@lanepowell.com

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