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Client Alert

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Second Circuit Rules Off-Label Promotion Is Protected Speech

On December 3, 2012, the United States Court of Appeals for the Second Circuit reversed the conviction of a pharmaceutical sales representative, who had been found guilty of promoting off-label uses for a drug product, holding that the conviction violated his First Amendment free speech rights.[1] The 2-1 decision by a three-judge panel of the Second Circuit could potentially affect future government prosecutions in the off-label promotional arena, but it is too early to conclude whether this ruling will have broad applicability and, thus, ultimately slow down off-labeling enforcement by the Department of Justice or the Food and Drug Administration (FDA).[2] It is not yet known whether the government will request an *en banc* rehearing before the entire Second Circuit or appeal the case to the United States Supreme Court.

Background

The case, *U.S. v. Caronia,* involved the conviction of Alfred Caronia, a sales representative for a pharmaceutical company, who was found guilty of conspiracy to introduce a misbranded drug into interstate commerce by promoting an off-label use of an approved drug product. Caronia claimed that he was convicted solely for his speech — for promoting an FDA-approved drug for off-label use — in violation of his right of free speech under the First Amendment.

The Second Circuit agreed, vacated the judgment, and remanded the case to the district court.

Highlights of the Court Decision

The majority opinion is based on the determination that the Federal Food, Drug, and Cosmetic Act (FDCA) does not expressly prohibit the "promotion" or "marketing" of drugs for off-label uses. The court pointed out that off-label drug usage by physicians and patients is not unlawful, and FDA's drug approval process anticipates potential off-label uses. The court acknowledged that FDA regulations do recognize the promotional statements of a pharmaceutical company or its representatives can serve as proof of a drug's intended use and, therefore, off-label promotional statements could presumably constitute evidence of an intended use of a drug which FDA

1 U.S. v. Caronia, 2012 U.S. App. LEXIS 24831 (2d Cir. 2012).
2 While the case focused on the activities of a pharmaceutical sale representative, the case could have applicability to other FDA-regulated industries where off-label promotion occurs.

has not approved, in violation of the FDCA. However, the court took issue with FDA's authority to prohibit speech about off-label uses – standing alone – as "misbranding" under the FDCA. Indeed, the court framed the principal question on appeal as follows: whether the government's prosecution of Caronia under the FDCA only for promoting an FDA-approved drug for off-label use was constitutionally permissible.

The following are the key points of the majority opinion:

- The court rejected the government's contention that it did not prosecute Caronia solely for promoting the off-label uses. The government argued that the First Amendment was not relevant to the conviction, contending instead that Caronia was not prosecuted solely for his speech, but instead for his role in misbranding the drug in question. In short, FDA argued Caronia's off-label promotion served merely as "evidence of intent," or evidence that the off-label uses were intended uses for which the drug failed to provide any directions. The Second Circuit concluded that, even assuming the government can support a misbranding violation by offering evidence of a defendant's off-label promotion to prove a drug's intended use, that is not what happened in this case.
- Instead, the majority pointed out that the litigation strategies and arguments advanced by the government in the trial court, and the district court's instructions to the jury, clearly demonstrated the government's position that Caronia's speech by itself was the proscribed conduct. Because the FDCA does not expressly prohibit off-label speech, the court declined "… to construe the FDCA's misbranding provisions to criminalize the simple promotion of a drug's off-label use by pharmaceutical manufacturers and their representatives because such a construction — and a conviction obtained by the government's application of the FDCA — would run afoul of the First Amendment."
- In concluding that the prosecution violated Caronia's free speech rights, the Second Circuit applied the United States Supreme Court's 2011 decision in *Sorrell v. IMS Health*,[3] which involved a Vermont statute that imposed restrictions on use of prescriber-identifying information for marketing purposes, to evaluate whether the government's theory of prosecution violated the First Amendment. The court noted that, in *Sorrell*, the Supreme Court held that "[s]peech in aid of pharmaceutical marketing ... is a form of expression protected by the ... First Amendment," and because the Vermont statute disfavored speech with a particular content (marketing) when expressed by certain disfavored speakers (pharmaceutical manufacturers), it unconstitutionally restricted speech. Drawing on the *Sorrell* Court's holding, the Second Circuit reasoned that a similar analysis was required in this case. Accordingly, the Second Circuit reasoned that the government's interpretation of the FDCA's misbranding provisions to prohibit off-label promotion was content-based because it distinguishes between "favored speech" (i.e., speech about the uses FDA has approved for a drug) and "disfavored speech" (i.e., off-label promotion) on the basis of the ideas or views expressed. Moreover, the court determined that the restriction imposed on Caronia was "speaker-based," because it targets one kind of speaker (pharmaceutical manufacturers and sales representatives), while allowing others (e.g., physicians and academic researchers) to speak about off-label uses without restriction.

3 131 S.Ct. 2653 (2011).

- The court held that, because off-label drug use itself is not prohibited under the FDCA, it does not follow that prohibiting the truthful promotion of off-label drug usage by a particular class of speakers would directly further the government's goals of preserving the efficacy and integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective drugs.
- The majority opinion also observed that:
  - prohibiting off-label promotion by a drug manufacturer will interfere with the ability of physicians and patients to receive important treatment information – "such barriers to information about off-label use could inhibit, to the public's detriment, informed and intelligent treatment decisions";
  - the First Amendment directs courts to be "especially skeptical of regulations that seek to keep people in the dark for what the government perceives to be their own good";
  - "the government's construction" of the statute "essentially legalizes the outcome – off-label use – but prohibits the free flow of information that would inform that outcome"; and
  - the government had less speech-restrictive options and non-criminal penalties available to accomplish its objectives, such as caps on off-label prescriptions, enactment of laws affecting the legal liability surrounding off-label promotion and treatment decisions, or prohibitions on off-label use altogether where the off-label drug use is of exceptional concern for public safety.

The dissenting opinion disagreed with the majority's heightened scrutiny review, as it contended that such an analysis has not been used in other cases involving the use of speech as evidence of intent. The dissenting opinion also said that the court decision "calls into question the very foundations of our century-old system of drug regulation," and argued that if pharmaceutical companies "were allowed to promote FDA-approved drugs for nonapproved uses, they would have little incentive to seek FDA approval for those uses."

AGG Comments

Although the decision can rightfully be viewed as a major victory for pharmaceutical companies, there are several factors that will affect whether the *Caronia* decision will lead to broad ramifications for the pharmaceutical industry.

- The Second Circuit's decision is limited to FDA-approved drugs for which off-label use is not prohibited, and the decision is not a blanket condemnation of FDA's ability to regulate the marketing of prescription drugs. Rather, the court concluded simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA solely for speech promoting the lawful, off-label use of an FDA-approved drug.
- The majority focused on truthful statements made by the company representative. The decision would undoubtedly have been different if the speech or conduct of a pharmaceutical company or sales representative were false or misleading. Under existing precedent, courts will not protect false or misleading product communications. Accordingly, we recommend companies remain vigilant in their review of promotional materials and activities.

- The case was decided by the Second Circuit, which means that the ruling only applies to those courts in this federal circuit (New York, Connecticut, and Vermont). Other courts outside the Second Circuit are not bound by the decision, and it remains to be seen whether the majority's reasoning will influence other courts facing similar off-label cases in the future. Furthermore, the government could decide to bring an enforcement action in another court, outside of the Second Circuit, and seek a different outcome.
- Different facts may lead to a different decision in a future case, either in the Second Circuit or elsewhere. The majority opinion articulated its rationale for its decision, focusing on specific facts and the government's prosecution of Caronia's speech. With this court's playbook of analysis, the government could bring another case, with different facts and more of an emphasis on evidence of intent to commit a misbranding offense, and not on off-label speech alone, and potentially achieve a different result, thereby reinforcing its enforcement authority.
- The decision was not unanimous (2-1 decision), and the strong dissenting opinion demonstrates that the legal issues surrounding off-label promotion remain subject to debate. The final word on the government's ability to prosecute off-label speech by pharmaceutical companies and sales representatives will likely have to come from the Supreme Court.
- We continue to advise caution. The case, while a victory for the pharmaceutical industry, is very fact-specific and, as noted, includes a rigorous dissent. The government will likely assess its next steps (after licking its wounds), but it seems unlikely the government, whether FDA, the Department of Justice, or both, will simply stop its enforcement in this area. We do not believe the final chapter has been written on the subject, and we will continue to monitor and update on any new developments.