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Second Circuit Rules That Certain Speech Regarding the Off-Label Use of Drugs Is Protected Under the U.S. Constitution

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In a long-awaited decision, on December 3, 2012, a divided panel (2–1) of the U.S. Court of Appeals for the Second Circuit vacated the conviction of Alfred Caronia, a former pharmaceutical sales representative for Jazz Pharmaceuticals whom a federal district court jury found guilty of conspiring to introduce a "misbranded" drug into interstate commerce in violation of the federal Food, Drug and Cosmetic Act ("FDCA").[1] *A copy of the full opinion is available* here.[2] In this case, the majority held that the First Amendment bars the criminal prosecution of pharmaceutical manufacturers or their employees for truthful, non-misleading speech promoting the lawful, off-label use of an FDA-approved drug.

This Client Alert reviews the holding of the case and assesses the potential impact that this case may have for the industry.

Off-Label Use of Drugs as Defined Under the FDCA

Off-Label Use as Misbranding

The U.S. Food and Drug Administration ("FDA") has long held the position that, although off-label promotion by pharmaceutical manufacturers and/or their agents is not expressly prohibited by the FDCA or its attendant regulations, such commercial activities are impliedly prohibited as "misbranding." This position has been accepted by federal and state enforcement authorities. The FDCA prohibits the introduction of a "misbranded" drug into interstate commerce and provides that "misbranding" occurs, *inter alia*, when a product's label is false or misleading[3]—that is, when a drug is placed

[1] Federal Food, Drug and Cosmetic Act (FDCA), 21 U.S.C. §§ 331(a) and 333(a)(1) (2011).
[2] *United States v. Caronia*, No. 09-5006-cr (2d Cir. Dec. 3, 2012).
[3] §§ 331(a) and 352(a).

in interstate commerce without adequate directions for use and adequate warnings.[4] It is the FDA's view that, by definition, a drug fails to bear adequate directions for an off-label use. Therefore, promotion beyond the scope of the product label may be construed as "misbranding" in violation of the FDCA.

United States v. Caronia

The Basis of the Prosecution

The government obtained, through discovery, tape-recorded conversations between Mr. Caronia and health care providers during which Mr. Caronia was alleged to be promoting Xyrem for uses outside the scope of the product's approved FDA labeling. At trial, the government argued that those conversations were "act[s] of misbranding."[5] The jury found Mr. Caronia guilty of conspiracy to introduce a misbranded drug into interstate commerce in violation of the FDCA.[6] On appeal to the Second Circuit, the government argued that these conversations "play[] an evidentiary role in determining whether a drug is misbranded."[7] Specifically, the government argued that "Caronia's promotion of Xyrem for off-label uses served merely as 'evidence of intent' or evidence that the 'off-label uses were intended ones[] for which Xyrem's labeling failed to provide any direction.'"[8]

In reaching its conclusion, the majority of the Second Circuit panel disagreed with the government's contention that Mr. Caronia's speech was introduced merely as evidence of his intent to misbrand Xyrem. The majority concluded that the government did not introduce these conversations as evidence of Mr. Caronia's off-label promotion to prove Xyrem's "intended use and, thus, [its] mislabeling for that intended use."[9] Rather, the majority concluded that the government sought to convict Mr. Caronia for the speech, itself.

The *Caronia* Majority's Analysis

The majority then evaluated whether Mr. Caronia's speech was protected by the First Amendment. In its evaluation, the majority relied on *Sorrell v. IMS Health, Inc.*, a U.S. Supreme Court case.[10] In particular, the majority focused on the *Sorrell* Court's determination that the FDA prohibitions regarding promotional activity by a pharmaceutical manufacturer constitute both speaker- and content-based restrictions on speech, thus, subjecting the FDA's prohibitions to heightened judicial scrutiny.

Once the *Caronia* majority found both speaker- and content-based speech restrictions, the court would have been bound to analyze the government's regulation (i.e., the

[4] § 352(f).
[5] *Caronia,* No. 09-5006-cr, slip op. at 21 (citing Trial Tr. 848).
[6] *Caronia,* No. 09-5006-cr, slip op. at 24.
[7] *Id.* at 27 (citing Gov't Br. 51).
[8] *Caronia,* No. 09-5006-cr, slip op. at 27 (citing Gov't Br. 52).
[9] *Caronia,* No. 09-5006-cr, slip op. at 27-28. The court was clear that it did not decide whether such use would be permissible.
[10] 131 S.Ct. 2653 (2011).

FDCA) as a First Amendment issue, except that the majority, in this case, exercised the doctrine of "constitutional avoidance" and construed "the FDCA as not criminalizing the simple promotion of a drug's off-label use."[11] Instead, the majority concluded that Mr. Caronia was improperly prosecuted, under criminal laws, for his off-label speech, which the court determined to be protected by the First Amendment.[12]

The *Caronia* Majority's Holding

The majority held that the FDCA's misbranding provisions cannot be interpreted as a blanket ban on off-label promotion by pharmaceutical manufacturers. However, the court was clear that its holding did not prevent the FDA from regulating the marketing or promotion of prescription drugs and limited its decision to the truthful off-label promotion of prescription drugs for which an off-label use is not prohibited.[13] The court also stated that more narrowly tailored regulation of speech by the FDA as it concerns off-label use might be permissible.[14]

Conclusions and Potential Key Takeaways from the Holding

- Given the divided panel of the Second Circuit in *Caronia*, there could be a petition for a rehearing of the appeal *en banc*.

- Courts outside of the Second Circuit are not bound by this decision. Similar cases are pending in other jurisdictions, which could decide the issue differently. It is critical that the industry and key stakeholders continue to watch developments as the case law evolves. It is possible that the U.S. Supreme Court also may be asked to review this issue at some later time.

- It was clear to the majority in *Caronia* that the government's basis for the misbranding violation centered on the sales representative's speech and nothing more. Courts, in general, as well as the courts addressing the specific issue in *Caronia* and *Sorrell*, are hesitant to criminalize speech without an articulable public good (such as harm or safety) to be gained from doing so. That is, a desire merely to stop speech is not a sufficient interest (without another countervailing public need) in order to permit the government to regulate or prohibit speech.

- This opinion does not preclude the FDA from using off-label promotion as evidence of a drug's intended off-label use for which the approved label does not contain adequate direction.

- Unfortunately, *Caronia* does not provide a bright-line test to determine which aspects of promotion are purely speech and thus protected by the First Amendment and which aspects of promotion are not protected by the First

[11] *Caronia*, No. 09-5006-cr, slip op. at 26.
[12] *Id.* at 20.
[13] *Id.* at 51.
[14] *Id.* at 48-49.

Amendment when the speech can be used as the basis of finding intent to commit or to conspire to misbrand.

- While some might suggest the *Caronia* decision allows pharmaceutical manufacturers to more broadly promote their products for off-label uses, the holding is narrow in that truthful off-label promotion is not prohibited or criminalized under the FDCA. Further, it is premature to suggest that the FDA will not be permitted to regulate promotional speech.

- Pharmaceutical and medical device manufacturers should consider educating their sales and marketing personnel about the *Caronia* decision in order to prevent misconceptions regarding the scope of the holding and to reiterate the company policies regarding compliant promotion.

- *Caronia* may have a significant impact on FDA criminal prosecutions, particularly when it comes to convincing the Justice Department not to proceed with a particular matter, depending on the facts and circumstances of the case. The decision also will be raised as a defense to civil fraud cases, particularly *qui tam* actions, brought under the federal civil False Claims Act.

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