CLIENT UPDATE

SECOND CIRCUIT CONCLUDES TRUTHFUL OFF-LABEL PROMOTION IS NOT UNLAWFUL: FREE SPEECH, BUT NOT A FREE PASS (YET)

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On December 3, 2012, the United States Court of Appeals for the Second Circuit issued a split decision in a highly anticipated ruling in *United States v. Caronia*, No. 09-5006-CR (2nd Cir. Dec. 3, 2012), a potentially watershed decision relating to pharmaceutical companies' ability to promote off-label uses of FDA-approved products. A majority of the three-judge panel vacated the 2009 conviction of a former sales representative on the ground that his misbranding conviction based on truthful off-label statements violated the First Amendment's free speech guarantee.

Alfred Caronia, a former pharmaceutical sales consultant for Orphan Medical (later acquired by Jazz Pharmaceutical, Inc.) was responsible for promoting Xyrem, a narcolepsy treatment. Caronia and a company speaker were recorded by a physician informant making statements relating to unapproved uses of Xyrem. Caronia was charged under the Federal Food, Drug, and Cosmetic Act ("FDCA") with one count of conspiracy to introduce a misbranded drug into interstate commerce and one count of introducing a misbranded drug into interstate commerce. 21 U.S.C. §§ 331(a) & 333(a)(1). He was convicted by a jury on the conspiracy count but acquitted on the substantive misbranding count, and later sentenced to probation. Caronia subsequently appealed to the Second Circuit Court of Appeals.

MAJORITY DECLINES TO CONSTRUE FDCA AS CRIMINALIZING TRUTHFUL OFF-LABEL PROMOTION

The two-judge majority first determined that Caronia's conviction was based solely on truthful off-label promotional statements, citing to a number of passages from the prosecutors' arguments to the jury and the trial court, as well as the judge's charge to the jury. The majority then concluded that Caronia's conviction had no basis in the law, rejecting the government's longstanding position and holding that the FDCA does not prohibit or criminalize truthful off-label promotion.

The majority explained that the FDCA does not expressly prohibit off-label promotion. Rather, the FDCA prohibits "misbranding," which is defined as the introduction or delivery for introduction into interstate commerce of a drug that fails to bear "adequate directions for use." 21 U.S.C. §§ 331(a) & 352(f). FDA regulations define "adequate directions for use" as "directions under which the lay[person] can use a drug safely and for the purposes for which it is intended." 21 C.F.R. § 201.5. As construed by the majority, although the FDCA arguably allows for off-label promotional statements to serve as evidence of intent to distribute a drug without providing adequate directions for use, the FDCA does not expressly prohibit off-label promotion itself.

Further, any such prohibition would, in the majority's view, raise concerns under the First Amendment. As a result, the majority invoked the principle of constitutional avoidance, pursuant to which courts will avoid ruling on the constitutionality of a statute if an otherwise acceptable construction is possible, and declined to construe the FDCA as criminalizing truthful off-label promotion. Because the majority interpreted Caronia's conviction as based solely on off-label promotional statements, rather than the statements being used as evidence of intended use, his conduct was not prohibited by the FDCA.

CONVICTION BASED SOLELY ON TRUTHFUL OFF-LABEL PROMOTION VIOLATES RIGHT TO FREE SPEECH

Finding that Caronia's prosecution was premised solely on the government's theory that truthful off-label promotion can be banned, the majority proceeded to analyze the constitutionality of the conviction under the Supreme Court's decisions in *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011) and *Central Hudson Gas & Electric Corp. v. Public Service Comm'n of New York*, 447 U.S. 557 (1980), two prior precedents on commercial speech.

The majority first concluded that a prohibition on truthful off-label speech imposes both content- and speaker-based restrictions, requiring heightened scrutiny. Furthermore, such a prohibition does not withstand this level of scrutiny because it does not directly advance the government's stated interests, namely, preserving the efficacy and integrity of the FDA's drug approval process and reducing patient exposure to unsafe and ineffective

drugs. The majority focused on the fact that off-label prescribing and use are perfectly legal, and that the FDA has recognized in other contexts that truthful and non-misleading medical information about off-label uses can serve the public interest (*e.g.*, by permitting dissemination of off-label information through scientific journals and in response to unsolicited requests). Accordingly, prohibiting off-label promotion while simultaneously allowing off-label use interferes with the ability of physicians and patients to receive potentially relevant treatment information, which may be detrimental to public health.

The majority further held that a total ban on truthful off-label promotion is not narrowly drawn to further the government's goals, and that less restrictive means are available, for example, guiding physicians and patients in distinguishing misleading and truthful information; developing warning or disclaimer systems, or safety tiers within the off-label market; imposing ceilings or caps on off-label prescriptions; or prohibiting off-label use altogether. Because the government's means are not "narrowly tailored" to its ends, a complete ban on truthful and non-misleading promotion violates the First Amendment.

DISSENTING OPINION DISAGREES AND RAISES POLICY CONCERNS

The dissenting judge disagreed with the majority's finding that Caronia was convicted based on his speech alone, finding instead that his off-label statements were used as evidence of a conspiracy to introduce a prescription drug into interstate commerce with the intent that it be used in ways that its labeling neither disclosed nor described. The dissent further concluded that Caronia's conviction did not violate his right to free speech, noting that the prohibition on off-label promotion "is a necessary tool for the effective functioning of a regulatory system that the Supreme Court has endorsed as legitimate," and expressing concern that, under the *Caronia* ruling, companies would have "little incentive to seek F.D.A. approval" for new products.

POTENTIAL IMPLICATIONS OF *CARONIA* AND NEXT STEPS

The *Caronia* decision brings a welcome analysis of First Amendment issues to the subject of off-label promotion, which the pharmaceutical industry has long urged. At least in the Second Circuit, it is no longer possible for the government to secure a conviction simply by showing that an individual or company promoted the off-label use of a drug, without more. That said, although the implications of the decision potentially are far-reaching, for the moment its scope is relatively limited and its future somewhat uncertain. Companies should therefore proceed with caution in implementing changes to policies or procedures as a result of the decision.

First, the court's ruling only binds the Second Circuit Court of Appeals and federal district courts in New York, Connecticut, and Vermont. It remains to be seen whether courts in

other federal circuits will find the majority's reasoning persuasive and follow the Second Circuit's lead.

Second, the decision potentially could be reviewed by the full Second Circuit Court of Appeals in an "*en banc*" review, which would not be surprising given re-hearing is more likely when novel questions of constitutional and statutory law are implicated, or by the U.S. Supreme Court. In either case, the decision could be revised or overruled.

Third, the decision must be interpreted in the context of the facts before the court. The majority concluded that the government in Caronia's case had based its theory of criminality solely on truthful off-label statements, rather than on any grounds explicitly set forth in the FDCA. For example, Caronia was not accused of making false or misleading statements, which clearly are prohibited under the FDCA. 21 U.S.C. § 331(a). Although the majority's interpretation that the FDCA does not prohibit truthful off-label speech makes it more difficult for the government to bring an off-label criminal case, in reality the government likely will re-couch its theories of liability to frame the off-label promotion as evidence of the defendant's unlawful intent and/or to find some element of untruthfulness in the statements. For instance, the government may well argue that off-label promotion is misleading absent sufficient clinical support for the off-label use.

Fourth, it is not inconceivable that Congress could take legislative action to limit the impact of the decision by remedying some of the issues identified by the court, so as to meet the "narrowly tailored" tests under *Sorrell* and *Central Hudson*.

Finally, it is also worth noting that if left intact, *Caronia* could have an impact on other federal enforcement actions, including under the False Claims Act, in which relators and the government typically predicate liability on alleged off-label promotion. Similarly, *Caronia* could limit the Department of Health and Human Services Office of the Inspector General's application of the exclusion remedy to pharmaceutical companies in prosecutions alleging off-label promotion.

For the present, although the implications of the *Caronia* ruling are intriguing, and the focus on First Amendment issues is welcome, companies should consider proceeding with caution before implementing significant changes to promotional policies and procedures relating to off-label promotion. Further favorable developments in the law, and the fate of *Caronia* itself, will be highly instructive in crafting future company practices.

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Please do not hesitate to contact us with any questions.

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