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Second Circuit Invalidates Misbranding Conspiracy Conviction on First Amendment Grounds

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In a decision with potentially important implications for the pharmaceutical industry and for government regulation of commercial speech more generally, a divided Second Circuit panel yesterday vacated the conviction of a pharmaceutical sales representative for conspiracy to introduce a misbranded drug into interstate commerce in violation of the Food, Drug and Cosmetics Act (FDCA) on the ground that his conviction rested solely on speech promoting an FDA-approved prescription drug for off-label uses. Because the decision in *United States v. Caronia*, No. 09-5006-cr (2d Cir. Dec. 3, 2012), left open the possibility that speech promoting off-label uses could still be used as evidence of a drug's intended use for purposes not approved by the FDA to support a misbranding charge, the exact breadth of the decision's implications are uncertain. But, at a minimum, it establishes that truthful, non-misleading speech by sales representatives is not enough, standing alone, to support a misdemeanor misbranding prosecution in one important region of the country, and it likely paves the way for further First Amendment challenges not only to federal misbranding investigations, but also to federal regulation of other types of commercial speech.

Background

Under the FDCA, drugs must be approved by the FDA for specific uses before they can be sold in interstate commerce. 21 U.S.C. § 355(a)-(d). To obtain FDA approval, a manufacturer must demonstrate, through clinical trials, the drug's safety and effectiveness for each intended use. But once approved for any use, they may be prescribed by physicians for unapproved, or "off-label," uses as well. See *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) (citing 21 U.S.C. § 396). The FDCA prohibits introducing drugs into interstate commerce that are "misbranded," which means, among other things, lacking directions for the drug's use which would enable a layperson to use the drug safely and for its intended uses. *See* 21 U.S.C. § 331(a); 21 C.F.R. § 201.5. In recent years, the government has gained major settlements from leading pharmaceutical companies in part based on allegations of off-label promotion.

Caronia marketed a drug that was approved by the FDA to treat two conditions in narcolepsy patients. Slip Op. at 12. According to the Second Circuit, the evidence showed that Caronia

promoted the drug's use for unapproved indications and unapproved populations. *Id*. at 14-16. The jury convicted Caronia of conspiring to introduce a misbranded drug into interstate commerce.[1] The district court rejected Caronia's contention that his conviction was inconsistent with the First Amendment.

The Second Circuit's Decision

The Second Circuit threw out Caronia's conviction. Applying the principle of constitutional avoidance, the majority (Judges Chin and Raggi) interpreted the FDCA as not criminalizing a pharmaceutical sales representative's truthful, non-misleading speech promoting an approved drug's off-label use because a contrary reading would raise serious questions about the FDCA's consistency with the First Amendment.

Invoking *Sorrell*, the majority applied heightened scrutiny to the government's reading of the FDCA because it imposed speech restrictions that were both content-based, distinguishing speech about FDA-approved uses of drugs from speech about off-label uses, and speaker-based, targeting one category of speakers, namely, pharmaceutical manufacturers, while allowing others to speak freely. Slip Op. at 36-41. The majority concluded that a criminal prohibition of off-label promotion by pharmaceutical sales representatives could not be justified even under the "less rigorous intermediate" four-part test for commercial speech established in *Central Hudson Gas & Electric Corp. v. Public Service Commission of N.Y.*, 447 U.S. 557 (1980). First, because the FDCA permits doctors to prescribe and patients to use drugs for off-label purposes, the promotion of off-label uses is not in and of itself false or misleading and concerns lawful activity. Slip Op. at 42. Second, the government's asserted interests—preserving the effectiveness and integrity of the FDCA's drug approval process and reducing patient exposure to unsafe and ineffective drugs—are substantial. *Id*. at 42-43. But third, the majority concluded, the government's construction of the FDCA does not directly advance the government's interests because off-label drug use itself is not prohibited and prohibiting pharmaceutical manufacturers from sharing truthful, non-misleading information about lawful off-label uses "paternalistically" interferes with the ability of doctors and patients to receive potentially relevant treatment information—and thereby potentially undermines public health. *Id*. at 43-47. And fourth, the majority determined, the government's means of restricting off-label promotion was more extensive than necessary.[2] *Id*. at 48-51. The majority assumed without deciding, though, that speech promoting off-label uses could be used as evidence of the drug's intended uses and thus as part of the evidence demonstrating that a defendant contributed to misbranding by selling a drug intended for an unapproved use for which there were no adequate directions on the label. *Id*. at 32 & n.10, 51. The majority left unclear where the dividing line lies between such a prosecution theory and the theory presented and rejected in *Caronia.* It concluded "simply that the government cannot prosecute pharmaceutical manufacturers and their representatives under the FDCA for speech promoting the lawful, off-label use of an FDA-approved drug." *Id.* at 51.

Judge Livingston in dissent contended that Caronia's conviction should have been upheld. First, she reasoned, the First Amendment does not prohibit prosecutors from using speech as evidence of intent, and Caronia's speech was used simply as evidence of the drug's intended uses. Slip Op.

Dissent at 6-19.[3] Second, she argued, even if one were to apply commercial speech principles , Caronia's conviction should be upheld. *Id*. at 19, 27. According to the dissent, nearly every commercial speech case involves content- and speaker-based speech restrictions. But such restrictions are justified by the government's interest in protecting consumers from commercial harms, such as unsafe or ineffective drugs. If drug manufacturers may promote FDA-approved drugs for non-approved uses, in Judge Livingston's view, they would have little incentive to seek FDA approval for those uses, and the FDA would not be able to play its role in assessing and assuring the safety and effectiveness of drugs for particular uses. *Id*. at 19-27.[4]

Implications

1. Misbranding Investigations and Prosecutions. The *Caronia* decision knocks out, within the area covered by the Second Circuit, prosecution of misbranding based solely on truthful, non-misleading marketing statements by sales representatives to doctors. It remains to be seen, however, whether the government can continue to prosecute such cases where speech is used solely as evidence of an intended, off-label, use. The decision also does not address felony misbranding, *i.e.*, misbranding with intent to defraud or mislead.

2.Further Review. The decision presents a dilemma for the government concerning further review. The government may seek en banc review before the full Second Circuit or it may seek Supreme Court review by petition for certiorari. But if it seeks Supreme Court review, it would do so without the disagreement among courts of appeals that typically justifies Supreme Court intervention and it would go up with an unfavorable decision below. In another important case raising First Amendment concerns as one basis for rejecting the government's preferred theory for prosecutions, the government recently declined to seek Supreme Court review.

3. The First Amendment and Commercial Speech. The current Supreme Court has by and large taken a broad view of the protections afforded by the First Amendment's Free Speech Clause. *See United States v. Alvarez*, 132 S. Ct. 2537 (2012) (defendant's false claim to have won the Congressional Medal of Honor protected by the First Amendment); *Snyder v. Phelps*, 131 S. Ct. 1207 (2011) (anti-homosexual speech in public place outside a military funeral protected by the First Amendment); *Citizens United v. FEC*, 558 U.S. 310 (2010) (corporate expenditures on speech expressly advocating the election or defeat of a candidate protected political speech under First Amendment). *Sorrell* showed the Court's approach to commercial speech is equally solicitous. Encouraged by *Sorrell* and now *Caronia*, First Amendment challenges to government regulation not only of off-label pharmaceutical promotion but also of other forms of commercial speech, such as certain forms of privacy regulation on the internet, may gain renewed vigor.

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[1] According to the Second Circuit's description, the jury acquitted Caronia on another prong of the conspiracy count—"[i]t was part of the conspiracy" that Caronia, together with others, marketed the drug for unapproved uses while knowing the drug's labeling lacked adequate directions for such uses—and on a separate misbranding count—marketing the drug for unapproved uses while knowing the drug's labeling lacked adequate directions for those uses. Slip Op. at 16-19, 23-24.

[2] The majority identified several alternatives means of enforcement that it deemed less restrictive:

guiding doctors and patients in differentiating between misleading or false promotion and truthful information; developing disclaimer systems or safety tiers in the off-label market to distinguish between drugs; requiring pharmaceutical manufacturers to list all intended indications when they first apply for FDA approval; creating ceilings on off-label prescriptions; reminding doctors of or supplementing the legal liability surrounding off-label treatment decisions; or prohibiting off-label drug uses altogether. Slip Op. at 48-50.

[3] In support of this approach, the dissent pointed to *Whitaker v. Thompson*, 353 F.3d 947 (D.C. Cir. 2004). Slip Op. Dissent at 17-18.

[4] The dissent also contended that prohibiting off-label promotion by drug manufacturers is the least restrictive way of advancing the government's interests, and that the alternatives asserted by the majority would not be similarly effective. Slip Op. Dissent at 24-25.

Authors

Brent J. Gurney

PARTNER

brent.gurney@wilmerhale.com

+1 202 663 6525

Stephen A. Jonas

RETIRED PARTNER

+1 617 526 6000

Howard M. Shapiro

PARTNER

howard.shapiro@wilmerhale.com

+1 202 663 6606