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First Amendment Prohibits Criminal Prosecution of Truthful Off-Label Promotion

Second Circuit holds that the government will be required to prove more than simple off-label promotion for misbranding prosecutions under the FDCA.

On December 3, the U.S. Court of Appeals for the Second Circuit ruled in a highly anticipated, divided (2-1) panel decision that truthful, non-misleading speech by pharmaceutical manufacturers and their sales representatives promoting the off-label use of medications approved by the U.S. Food and Drug Administration (FDA) is protected from criminal prosecution by the Free Speech Clause of the First Amendment. The panel's decision in *United States v. Caronia*[1] vacated and remanded the federal conviction of Jazz Pharmaceuticals sales representative Alfred Caronia for conspiracy to introduce a misbranded drug into interstate commerce—a misdemeanor violation of the federal Food, Drug, and Cosmetic Act (FDCA). Finding that the prohibition and criminalization of a pharmaceutical manufacturer's truthful speech promoting off-label use would violate the First Amendment, the majority applied the principle of "constitutional avoidance" in deciding that the FDCA does not prohibit such speech. In doing so, the Second Circuit now requires that the government prove more than simple off-label promotion for misbranding prosecutions under the FDCA.

Background

Under the FDCA's regulatory scheme, which requires that a prescription drug be approved by the FDA for specific uses before a manufacturer may introduce the drug into interstate commerce, physicians may lawfully prescribe, and patients may lawfully use, prescription medicines for uses not approved by the FDA ("off label"). However, the FDCA makes it a criminal offense to introduce "into interstate commerce . . . any . . . drug . . . that is . . . misbranded." Under the FDCA, a drug is "misbranded" if its labeling fails to bear "adequate directions for use," meaning, directions under which a drug can be used safely for the purposes for which it is intended. Although the FDCA does not expressly prohibit off-label marketing, the majority stated that the government had "construed the FDCA to prohibit promotional speech as misbranding itself."[2]

In 2005, Caronia was tape-recorded by a government informant, on two occasions, promoting the off-label use of Xyrem. Xyrem was a medication approved by the FDA for the treatment of a limited number of narcolepsy symptoms; however, the informant's recording captured Caronia marketing the drug for both "unapproved indications and unapproved subpopulations."[3] Caronia was subsequently charged with two misdemeanor violations of the FDCA: conspiracy to introduce a misbranded drug into interstate commerce and introducing a misbranded drug into interstate commerce. In 2008, the U.S. District Court for the Eastern District of New York denied Caronia's motion to dismiss, in which he argued that his conduct was protected by the First Amendment. At trial, the district court instructed the jury that a drug "'manufacturer, its agents, representatives and employees, are not permitted to promote uses for a drug that have not been cleared by the [FDA].'"[4] The jury returned a conviction under the conspiracy charge and Caronia was sentenced to a one-year term of probation and 100

1. *United States v. Caronia*, No. 09-5006-cr, 2012 WL 5992141 (2d Cir. Dec. 3, 2012), *available at* http://www.ca2.uscourts.gov/decisions/isysquery/a9f74f01-4b92-4438-9693-7cf50fb04518/6/doc/09-5006_complete_opn.pdf.

2. *Id.* at *3.

3. *Id.* at *4.

4. *Id.* at *7.

hours of community service.

Second Circuit's Majority Decision

In attempting to uphold the conviction, the government first urged on appeal that the First Amendment was not implicated in the conviction, claiming Caronia's speech promoting the off-label uses of Xyrem was only used as *evidence* of the intended use of the medication, rather than serving as the basis of the conviction itself. But Judge Denny Chin, writing for the majority, rejected this argument outright based on the trial court record, citing passages where the government "repeatedly argued that Caronia engaged in criminal conduct by promoting and marketing the off-label use" of the medication. The court held that the record made "clear that the government prosecuted Caronia *for* his promotion and marketing efforts."[5]

Moving on, the court held that the FDCA does not criminalize the "simple promotion of a drug's off-label use because such a construction would raise First Amendment concerns."[6] Relying heavily on the U.S. Supreme Court's 2011 decision in *Sorrell v. IMS Health, Inc.*,[7] which held unconstitutional on First Amendment grounds a Vermont regulation prohibiting pharmaceutical companies from using prescriber-identifying information for marketing purposes, the majority found that the prohibition of off-label marketing was both content based, because the express purpose was to diminish the effectiveness of off-label drug marketing by manufacturers, and speaker based, because it targeted only drug manufacturers. Accordingly, the Second Circuit found that the limitations of off-label promotional statements would be subject to heightened scrutiny under *Sorrell* as applied to content- and speaker-based speech limitations.

Ultimately, the court held that the FDCA construction urged by the government could not pass such heightened scrutiny. First, it found that, because off-label drug use is lawful, promotion of off-label drug use—provided it is not false and misleading—concerns lawful activity. Second, it found that the government's asserted interests in drug safety and public health are substantial. Third, it found that, because off-label drug use itself is not prohibited, the government's prohibition of off-label promotion did not "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."[8] The majority noted that, in fact, "interfer[ing] with the ability of physicians and patients to receive potentially relevant treatment information . . . could inhibit, to the public's detriment, informed and intelligent treatment decisions."[9] Fourth, the majority found that "the government's construction of the FDCA to impose a complete and criminal ban on off-label promotion by pharmaceutical manufacturers is more extensive than necessary to achieve the government's substantial interests" and proposed a variety of possible alternatives.[10] Thus, the court concluded that the misbranding provisions of the FDCA neither prohibit nor criminalize the truthful off-label promotion of FDA-approved prescription drugs.

Dissent

In dissent, Judge Debra Ann Livingston disagreed that the government prosecuted Caronia for his speech alone and argued that she would confirm his conviction because the First Amendment "has never prohibited the government from using speech as evidence of motive or intent." The majority's decision, she stated, "calls into question the very foundations of our century-old system of drug regulation."[11] Judge Livingston urged that, even if offering Caronia's speech as evidence of intent implicates the First Amendment, application of the FDCA's misbranding provision to Caronia's case survived heightened scrutiny. First, she argued that the prohibition on off-label promotion directly advances a substantial government interest because, if drug manufacturers were allowed to promote FDA-approved drugs for non-approved uses, they would have little incentive to seek FDA approval for those uses because any substance that may be legally sold for some purposes may then be promoted by its

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5. *Id.* at *9.
6. *Id.* at *8.
7. *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653, 180 L. Ed. 2d 544 (2011).
8. *Caronia*, 2012 WL 5992141, at *13.
9. *Id.*
10. *Id.* at *14.
11. *Id.* at *15 (Livingston, J., dissenting).

manufacturer for any purpose—so long as the manufacturer's statements are merely unsubstantiated, rather than demonstrably false or misleading. Second, she argued that the prohibition was also the least restrictive way of advancing the government's interests. Criticizing the majority's proposed less-restrictive alternatives, Judge Livingston posited that permitting manufacturers to engage in off-label promotion undermined the FDCA's entire scheme of drug regulation.

Implications

The government and others who seek to bring legal action against drug manufacturers based on alleged off-label promotion are likely to argue that the Second Circuit's decision is limited in scope. Indeed, the majority acknowledged that speech can properly be used as evidence in a criminal prosecution but did not reach the question of whether the First Amendment would have barred Caronia's conviction had the government's prosecution and the district court's jury instructions limited the evidence of Caronia's off-label marketing to prove the element of intent for the misbranding charge.

The decision is nonetheless significant for several reasons. Most notably, it draws an important distinction between off-label marketing and misbranding and thus requires the government to prove something more than mere off-label promotion—such as proof that the off-label promotion was false or misleading—in order to obtain a criminal misbranding conviction. In fact, in its briefing, the government *conceded* that "[p]romoting an approved drug for off-label uses is not itself a prohibited act under the FDCA."

In addition, the decision is a significant recognition that off-label promotion is protected commercial speech—the regulation, penalization, or punishment of which may be subject to heightened scrutiny. It is also an express acknowledgment by a leading appellate court that (a) the FDCA does not expressly prohibit off-label promotion, (b) off-label drug use and prescribing are lawful, and (c) the government's construed prohibition applies only to manufacturers and their employees and not other actors, such as physicians or academics. While these are generally well-recognized principles, only a few courts to date have acknowledged them in published decisions.

Whether this decision will spark a broader change in FDA policy is yet to be seen, as we suspect the court's decision is far from final. A rehearing en banc, or a petition for certiorari to the U.S. Supreme Court, is a possible next step. In the interim, however, manufacturers have a new basis for arguing that government efforts to pursue pharmaceutical companies for truthful off-label promotion are overreaching and improper.

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