Patterson Belknap Webb & Tyler LLP

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Second Circuit Declares Off-Label Promotion Ban Unconstitutional: Implications for False Claims Act Defendants

On December 3, 2012, the United States Court of Appeals for the Second Circuit held that the First Amendment protects pharmaceutical companies who truthfully promote the lawful, off-label use of prescription drugs from criminal prosecution in *United States v. Caronia*, __ F. 3d ___, 2012 WL 5992141 (2d Cir. Dec. 3, 2012). This decision has attracted widespread attention from the government, the FDA, and the pharmaceutical industry, prompting questions as to whether *Caronia* could be the beginning of the end of the FDA's prohibition on off-label promotion.

The constitutional and regulatory implications of *Caronia* are significant and it is unclear how this decision will affect civil liability under the False Claims Act ("FCA"),[1] one of the primary tools used by the government to penalize off-label promotion. This Client Alert analyzes the potential FCA implications of *Caronia*, assessing how this decision may affect defenses available to companies accused of violating the FCA for alleged off-label marketing.

Case Background

Alfred Caronia was a sales representative for Jazz Pharmaceutical (formerly Orphan Medical, Inc.), which manufactures Xyrem, a powerful nervous system depressant. In 2002 and 2005, the FDA approved Xyrem to treat various conditions associated with narcolepsy. Xyrem also demonstrated effectiveness for other indications, which were not approved by the FDA.

As part of an investigation of Orphan for off-label promotion begun in 2005, the government taped two conversations between Caronia and physicians, in which he plainly promoted the use of Xyrem for unapproved indications. The government brought criminal charges against Caronia and a physician in 2007 for marketing a "misbranded" drug in violation of the Food Drug & Cosmetic Act ("FDCA") and for conspiracy to market a misbranded drug, arising out of the defendants' off-label promotion. At trial the government did not contest the truthfulness of the information Caronia shared with the physician. The jury convicted Caronia of conspiracy to introduce a misbranded drug into interstate commerce and Caronia appealed to the Second Circuit, arguing that the government prosecuted him directly for his truthful speech in violation of his First Amendment rights.

A divided panel of the Second Circuit agreed. Judge Chin, writing for the majority, reasoned that the FDCA does not expressly criminalize off-label promotion and references "promotion" only as evidence of a drug's intended use. As the court noted, however, the FDA has concluded that "[a]n approved drug that is marketed for an unapproved use (whether in labeling or not) is misbranded because the labeling of such drug does not include 'adequate instructions for use.'" The court held that, in prosecuting Caronia, the government "treated promotional speech as more than merely evidence of a drug's intended use – it [] construed the FDCA to prohibit promotional speech as misbranding itself." The court highlighted that, because physicians may prescribe drugs off-label, this interpretation deprived physicians and patients from receiving truthful information about lawful uses of prescription medications from those most knowledgeable: pharmaceutical companies and their representatives.

1 31 U.S.C. § 3729 *et seq*.

Relying heavily on *Sorrell v. IMS Health, Inc*., 131 S. Ct. 2653 (2011), in which the Supreme Court held that the First Amendment protected the use of prescription data for targeted pharmaceutical marketing, the Second Circuit held that the government may not criminalize truthful promotion of off-label drug usage by pharmaceutical companies. The court noted that the restriction at issue in *Caronia* was "content-based" and "speaker-based." Targeted speech regarding lawful activity (the prescription of FDA approved drugs for off-label uses) by a particular category of speakers (pharmaceutical manufacturers), is therefore subject to heightened scrutiny under *Sorrell*. The court further held that the FDA's prohibition on off-label marketing was not narrowly tailored to advance the government's interests, as required by *Central Hudson Gas & Electric Corp. v. Public Service Commission of New York*, 447 U.S. 557 (1980). "As off-label drug use itself is not prohibited, it does not follow that prohibiting the truthful promotion of off-label drug use 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." "Numerous, less speech-restrictive alternatives are available" to accomplish this goal.

Judge Livingston dissented, reasoning that, with regard to the First Amendment issue, the FDA has a strong interest in ensuring that pharmaceutical manufacturers seek FDA approval for its products, and the restriction on off-label marketing is narrowly tailored to that interest. "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. Prohibiting such promotion is thus one of the few mechanisms available to encourage participation in the approval process."

The FCA Implications of *Caronia*

Although the government prosecuted Caronia for criminal misbranding under the FDCA, the Second Circuit's decision—and any subsequent review by other appellate courts, the Supreme Court or the FDA—may have implications for FCA defendants. As the *Caronia* court noted, physicians may use their medical judgment to prescribe drugs for any indication regardless of FDA approval, a freedom which the Supreme Court has characterized as an "accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine."[2] Under Medicaid and Medicare regulations, however, a prescription is reimbursable only if used for a "medically accepted indication,"[3] defined as a use approved by the FDA or supported by one of three specified drug compendia.[4] Otherwise, reimbursement by Medicare and Medicaid is technically not permitted and some courts have held that a request for reimbursement for such a prescription constitutes a "false claim" for payment under the FCA.[5]

The Department of Justice and the whistleblowers awarded standing in FCA cases—known as *qui tam* relators—have used this premise many times to allege that off-label promotion either "causes" a false claim for payment by encouraging off-label prescriptions, a subset of which may be submitted to Medicare or Medicaid under 31 U.S.C. § 3729(a)(1)(A), or that off-label promotion constitutes a "false record or statement material to a false or fraudulent claim" under 31 U.S.C. § 3729(a)(1)(B). The FCA imposes steep penalties on a defendant who causes a false or fraudulent payment[6] and the DOJ has used the FCA to recover billions of dollars from defendants who allegedly market drugs off-label, characterizing the FCA as "[o]ne of the most powerful tools" in combating Medicare and Medicaid fraud.[7]

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2 *Buckman Co. v. Plaintiffs' Legal Comm*., 531 U.S. 341, 350 (2001).
3 42 U.S.C. §§ 1395w-102(e)(1)(A), 1396b(i)(10), 1396r-8(k)(2)(3).
4 *Id*. § 1396r-8(k)(6) (Medicaid); *Id*. § 1395w-102(e)(4) (Medicare); *see id*. § 1396r-8(g)(1)(B)(i) (listing compendia).
5 *See, e.g. United States ex rel. Rost v. Pfizer*, 507 F.3d 720 (1st Cir. 2007); *United States ex rel. Polansky v. Pfizer*, 2009 WL 1456582 (E.D.N.Y. May 22, 2009); *United States ex rel. Hess v. Sanofi-Synthelabo, Inc*., 2006 WL 1064127 (E.D. Mo. Apr. 21, 2006).
6 The FCA imposes treble damages and $5,500 - $11,000 per false claim. 31 U.S.C. § 3729(a)(1).
7 *See* Department of Justice Press Release, "Amgen Inc. Pleads Guilty to Federal Charge in Brooklyn, N.Y.; Pays $762 Million to Resolve Criminal Liability and False Claims Act Allegations." Dec. 19, 2012 *available at* http://www.justice.gov/opa/pr/2012/December/12-civ-1523.html (noting that the settlement involving off-label promotion "represents the single largest criminal and civil False Claims Act settlement involving a biotechnology company in U.S. history").

Caronia may provide some useful defenses to FCA defendants. Where the plaintiff's theory of FCA liability rests on truthful, non-misleading off-label promotion defendants may argue that, like Caronia, they are being penalized for truthful speech under the guise that off-label promotion evinces "intent" to violate another law. The government often argues in FCA cases that the ubiquity of Medicare and Medicaid beneficiaries renders any pharmaceutical marketing strategy an implicit solicitation for government payment, and therefore any form of off-label promotion causes false claims. Under *Caronia*, defendants may argue that this theory of FCA liability identifies "speech alone as the proscribed conduct" subjecting it to First Amendment scrutiny. Under *Central Hudson*, *Sorrell*, and now *Caronia*, by prohibiting content-based and speaker-based speech, arguably the FCA must be narrowly tailored to advance the government's interest in preventing Medicare and Medicaid fraud, a strict standard that defendants may argue such a broad reading of FCA liability does not satisfy. Although *Caronia* arose under criminal misbranding provisions and the FCA is a civil statute, the Supreme Court has declared that the treble damages imposed by the FCA "are essentially punitive in nature"[8] and "[t]he very idea of treble damages reveals an intent to punish past, and to deter future, unlawful conduct"[9] analogous to the FDCA's misbranding prohibition.

Conclusion

The FCA repeatedly has been characterized as a fraud statute[10] and fraud is not protected by the First Amendment.[11] Nevertheless, the government has sought to use the FCA to pursue claims based on truthful, non-misleading pharmaceutical promotion. Given the holding in *Caronia*, it is open to question whether a company can be subjected to FCA liability where a physician, in his or her medical judgment, uses such information to treat a patient with an off-label prescription reimbursed by the government. Caronia undoubtedly changed the tenor of this discussion, but until the Supreme Court weighs in on this question or the FDA revises its regulations, off-label promotion may still be effectively prohibited, and the DOJ and qui tam relators may continue to bring FCA suits for alleged off-label promotion. Patterson Belknap will continue to monitor developments in this area.

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8 *Vermont Agency of Natural Resources v. United States ex rel. Stevens,* 529 U.S. 765, 784–85 (2000).
9 *Id*. at 786.
10 *See United States ex rel. Cafasso v. General Dynamics C4 Systems, Inc.*, 637 F.3d 1047, 1054–55 (9th Cir. 2011); *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 379 (4th Cir. 2008); *United States ex rel. Mikes v. Strauss*, 274 F.3d 687, 693 (2d Cir. 2001).
11 *See Virginia Bd. Of Pharmacy v. Virginia Citizens Consumer Council, Inc*., 425 U.S. 748, 771 (1976).

Author credit for this alert goes to Aileen M. McGill, an associate in the firm's Litigation group.

Michael F. Buchanan	**212-336-2350**	**mfbuchanan@pbwt.com**
Joshua A. Goldberg	**212-336-2441**	**jgoldberg@pbwt.com**
Peter C. Harvey	**212-336-2810**	**pcharvey@pbwt.com**
Daniel S. Ruzumna	**212-336-2034**	**druzumna@pbwt.com**
Harry Sandick	**212-336-2723**	**hsandick@pbwt.com**
Saul B. Shapiro	**212-336-2163**	**sbshapiro@pbwt.com**
Peter W. Tomlinson	**212-336-2977**	**pwtomlinson@pbwt.com**