UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* MATTHEW CESTRA *et al.*, Plaintiffs, vs. CEPHALON, INC., *et al.*, Defendants.	10 Civ. 6457 (SHS)

STATEMENT OF INTEREST OF THE UNITED STATES OF AMERICA

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Pursuant to 28 U.S.C. § 517 and the Court's Order of October 8, 2013 [Docket No. 77], the United States of America (the "Government"), by its attorney, Preet Bharara, United States Attorney for the Southern District of New York, respectfully submits this statement of interest in connection with the pending motion of Cephalon Inc. ("Cephalon") that seeks to dismiss the second amended complaint ("SAC") filed by Relator Mathew Cestra ("Relator").[1] Although the United States has not intervened in this case and is not a formal party, it remains the real party in interest in this action. *See United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 930 (2009).

The False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA" or "False Claims Act") is the United States' primary tool to redress fraud on the Government. Thus, the United States has a keen interest in the interpretation and application of the False Claims Act. Accordingly, the United States submits this Statement of Interest to advise the Court of its position that the Second Circuit's recent decision in *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), does not preclude a cause of action under the False Claims Act based on a manufacturer's off-label marketing of a prescription drug causing the submission of false claims to federal health care programs. The Government takes no position on the outcome of the other issues in Cephalon's motion to dismiss, but notes that if the Court accepts Cephalon's main argument that the SAC does not meet the particularity requirements of Federal Rule of Civil Procedure 9(b), it need not reach Cephalon's argument regarding the application of the First Amendment to the False Claims Act.

[1] In this Statement of Interest, Cephalon's motion to dismiss the SAC [Docket No. 52] is cited as "Mot.," Relator's opposition to the motion [Docket No. 67] is cited as "Opp.," and Cephalon's reply brief [Docket No. 74] is cited as "Reply."

Contrary to Cephalon's contention, the *Caronia* case, which involved a criminal prosecution under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 331 *et seq.* ("FDCA"), is inapposite to this False Claims Act matter. As discussed below, the FCA does not prohibit off-label promotion of prescription drugs; rather, the FCA prohibits conduct that causes the submission of false claims to the Government for payment. The First Amendment is, thus, not implicated in the context of an FCA claim, such as this one, where a defendant causes others to submit false claims for payment to the Government for non-reimbursable prescription drugs. Moreover, false and misleading speech, to the extent it is alleged in the SAC, is not protected under the First Amendment. *See Caronia*, 703 F.3d at 165 n.10 ("Of course, off-label promotion that is false or misleading is not entitled to First Amendment protection.").

A. The *Caronia* Decision Addresses Criminalization of Truthful, Off-Label Marketing

In *Caronia*, the defendant, an employee of a pharmaceutical company, was convicted of conspiring to distribute a misbranded drug in interstate commerce, in violation of the FDCA, 18 U.S.C. § 371 and 21 U.S.C. § 331(a). *See id.* at 152. Caronia had been responsible for organizing speaker programs to promote use of the drug in question, which had been approved by the FDA for treating certain conditions associated with narcolepsy in adults up to age 65. *See id.* at 157. At some of these programs, Caronia was recorded telling physicians that the drug could also be used to treat off-label uses such as daytime sleepiness, insomnia, fibromyalgia, restless leg syndrome, and Parkinson's disease, and was effective in patients as young as 8-10 years old and over 65 years old. *See id.* "The government did not argue at trial, nor d[id] it argue on appeal, that the promotion in question was false or misleading." *Id.* at 166 n.10.

On appeal, the Second Circuit vacated Caronia's conviction. *See id.* The Court recognized the longstanding rule that off-label promotion is not itself prohibited under the

FDCA. *See id.* at 153-55. The Government agreed, and argued that Caronia had not in fact been prosecuted for off-label marketing in and of itself, but that his off-label marketing was properly used as *evidence* of the unlawful intended use of the drug, *i.e.*, the promotional activity demonstrated an objective intent that the product be used for an unapproved indication. *See id.* at 160-61. The Second Circuit assumed without deciding that off-label marketing can be used to show evidence of intent. *See id.* at 161. But the Court of Appeals disagreed that the Government at trial used marketing evidence only to show intent; rather, it found that the Government prosecuted Caronia *for* his promotion and marketing efforts, which was not a crime. *See id.* at 162. The Court then held that it would be unconstitutional to impose criminal liability for truthful, off-label promotion of a drug. *See id.* at 162-69; *cf. United States v. Harkonen*, No. C 08-000164 (MHP), 2009 WL 1578712, at *4-8 (N.D. Cal. June 4, 2009) (First Amendment not implicated by a prosecution of false and misleading speech), *aff'd*, 510 F. App'x 633, 635-37 (9th Cir. 2013), *cert. petition filed*, 82 U.S.L.W. 3090 (Aug. 5, 2013).[2]

B. Relator's FCA Claims Do Not Implicate the First Amendment

Relator's claims against Cephalon arise under two subsections of the FCA, 31 U.S.C. §§ 3729(a)(1)(A) and (a)(1)(B). *See* SAC ¶¶ 427-33. Relator alleges that Cephalon provided false and misleading information about non-reimbursable off-label uses of its cancer drug

[2] Cephalon's citation to *Long v. Rhone-Poulenc Rorer, Pharmaceuticals, Inc.*, No. 98 Civ. 7307, 1999 WL 680867 (N.D. Ohio Feb. 23, 1999), is misplaced. *See* Mot. at 15. The *Long* case involved a retaliation claim under Ohio law brought by a plaintiff who claimed he was fired for complaining about off-label marketing at the company, *see Long*, 1999 WL 680867, at *1, and had nothing to do with the FCA or the submission of false claims to the Government. The court dismissed the whistleblower claim because the plaintiff did not know that off-label marketing was a crime, which was required knowledge under the state statute. *See id.* at *1-2. For the same reason, the court dismissed the plaintiff's common law public policy tort theory. *See id.* at *2. Contrary to Cephalon's claim, the court did not "reject[] whistleblower claim in part on ground that restrictions on off-label marketing of drugs violate First Amendment," *see* Mot. at 15, but only noted, without any analysis, "First Amendment problems," *Long*, 1999 WL 680867, at *3.

Treanda to physicians in order to induce them to write prescriptions for such indications (and otherwise took actions to encourage such prescriptions) that were submitted to federal health care programs such as Medicaid and Medicare. *See id.* ¶¶ 92-172, 200-18. As relevant here, Section 3729(a)(1)(A) "imposes civil liability on any person who 'knowingly . . . causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval.' To state a claim under this section, [a relator] must allege that (1) there was a false or fraudulent claim (2) [the defendant] knew it was false or fraudulent, (3) [the defendant] . . . caused it to be presented, to the United States, and (4) it did so to seek payment from the federal treasury." *United States ex rel. Pervez v. Beth Israel Med. Ctr.*, 736 F. Supp. 2d 804, 811 (S.D.N.Y. 2010) (quoting 31 U.S.C. § 3729(a)(1)(A)) (footnotes omitted). "Section 3729(a)(1)(B) imposes liability . . . where a person 'knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.' Under this provision, [a relator] must allege that: (1) [the defendant] made, or caused [the payee] to make, a false or fraudulent record or statement (2) [the defendant] knew it to be false or fraudulent, and (3) it was material to a claim." *Id.* (quoting 31 U.S.C. § 3729(a)(1)(B)) (footnote omitted). "As is apparent, some of the elements are common to both causes of action. In each case, there must have been a 'claim.' Either the claim itself, under subsection (a)(1)(A), or a record or statement material to a claim, under subsection (a)(1)(B), must have been false or fraudulent. And the defendant must have known that the claim or statement was false or fraudulent." *Id.*

For FCA cases predicated on off-label drug marketing, the central question is whether the defendant's marketing caused the submission of false claims, *i.e.*, claims for off-label uses that are not covered or reimbursable by federal health care programs. *See, e.g.*, *See United States ex*

rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 51-53 (D. Mass. 2001) ("The alleged FCA violation arises — not from unlawful off-label marketing activity itself — but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct."); *United States ex rel. Simpson v. Bayer Corp.*, No. 05 Civ. 3895(JLL), 2013 WL 4710587, at *10-11 & n.16 (D.N.J. Aug. 30, 2013) (same); *Strom ex rel. United States v. Scios, Inc.*, 676 F. Supp. 2d 884, 886 (N.D. Cal. 2009) ("Because the [Medicare] statute permits reimbursement only for 'reasonable and necessary' treatments, [an off-label prescription] in a context where it is not 'reasonable' or 'necessary' would be statutorily ineligible for reimbursement. This satisfies the FCA's requirement of a 'false' statement."); *United States ex rel. Rost v. Pfizer, Inc.*, 253 F.R.D. 11, 13-14 (D. Mass. 2008).

As both the Relator and Cephalon note, federal health care programs generally cover drugs for medically accepted indications. For cancer drugs like Treanda, medically accepted indications include those listed on the FDA-approved label and may also include certain off-label indications supported by a citation in an approved drug compendium if certain other conditions are met. *See* 42 U.S.C. § 1396r-8(k)(6) (Medicaid); *id.* § 1395x(t)(2)(B) (Medicare); *see also* Mot. at 17-19 (collecting sources); Opp. at 17-18 (same). However, when a manufacturer engages in the marketing of drugs for indications that are not FDA approved for that drug or not otherwise supported by a compendium listing, its conduct may cause false non-covered claims to be submitted to federal health care programs, and liability under the FCA may lie. *See, e.g.*, *Bayer*, 2013 WL 4710587, at *11; *Scios*, 676 F. Supp. 2d at 891-92; *Pfizer*, 253 F.R.D. at 16-17.[3] Accordingly, the False Claims Act does not on its face create liability for off-label

[3] Though they agree on the governing legal principles, the parties disagree about whether Treanda's off-label use for first-line treatment of indolent non-Hodgkin's lymphoma is

promotion of a drug. Instead, the FCA prohibits conduct that knowingly causes the submission of false claims, such as claims for treatments that are not "reasonable and necessary." *See Scios*, 676 F. Supp. 2d at 891-92.

As such, the case before this Court does not implicate the First Amendment concerns raised in *Caronia*. The FCA does not prohibit speech; rather, it is a remedy for actions that cause the submission of a false claim for payment to the Government. *See* 31 U.S.C. § 3729(a)(1)(A). Indeed, as a statutory matter, it is irrelevant whether a party causes the submission of a false claim by words, by conduct, or by a combination of both. *See id.* § 3729(a)(1)(A), (B) (penalizing anyone who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.").

Moreover, and contrary to Cephalon's contention, the fact that a person can knowingly cause the submission of false claims through speech does not suddenly transform this prohibited activity (false claim) into protected speech. "'[I]t has never been deemed an abridgment of freedom of speech . . . to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed.'" *Jews for Jesus, Inc. v. Jewish Community Relations Council of N.Y., Inc.*, 968 F.2d 286, 295-96 (2d Cir. 1992) (quoting *Giboney v. Empire Storage & Ice Co.*, 336 U.S. 490, 502 (1949)) ("[S]imply because speech or other expressive conduct can in some circumstances be the vehicle for violating a statute directed at regulating conduct does not render that statute unconstitutional."). Just as the Government may prohibit price-fixing conspiracies under the antitrust laws even when speech is instrumental to the conspiracy, so may the Government

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reimbursable by Medicare and Medicaid under the relevant compendia rules. *See* Mot. at 17-20; Opp. at 17-20; Reply at 8-9. The Government takes no position on this factual question.

prohibit companies from knowingly causing the submission of false claims even when speech is the means by which they cause the false claims to be submitted. [4]

Finally, *Caronia* did not concern false or misleading off-label marketing. To the extent that the SAC alleges that Cephalon engaged in false and misleading promotion of the drugs, the Court should reject Cephalon's assertion that its alleged conduct is somehow protected by the First Amendment. *See* Opp. at 15-16 (citing SAC ¶¶ 92-172, 200-18). *See Caronia*, 703 F.3d at 163 ("to warrant First Amendment protection, the speech in question must not be misleading and must concern lawful activity").

In short, the driving concern behind the *Caronia* decision, *i.e.*, whether criminal liability exits for off-label truthful speech in and of itself, is simply not before the Court in the context of this motion to dismiss. While the Government does not take a position on the outcome of the other issues in Cephalon's motion to dismiss the SAC, the Government respectfully submits that Cephalon's argument regarding the application of the First Amendment to the False Claims Act should be rejected.

[4] Thus, the cases Cephalon cites for the proposition that speech cannot be used as the basis for civil liability, *see* Mot. at 14 n.15, are inapposite. None of the cases cited involve the FDCA or the FCA, or the submission of false claims to the Government. For example, *National Association for the Advancement of Colored People v. Claiborne Hardware Co.*, 458 U.S. 886 (1982), involved, *inter alia*, whether non-violent boycott activity could result in liability for losses as a result of the constitutionally protected boycott. In the other cases cited by Cephalon, the courts dismissed suits against private citizens where the claims against these citizens arose from their petitioning of local government officials for actions that the plaintiffs disfavored. *See Aknin v. Phillips*, 404 F. Supp. 1150 (S.D.N.Y. 1975) (dismissing conspiracy suit by nightclub owner against a citizen who petitioned the local government to shut the nightclub down), *aff'd by oral opinion*, 538 F.2d 307 (2d Cir. 1976); *Weiss v. Willow Tree Civic Ass'n*, 467 F. Supp. 803, 817 (S.D.N.Y. 1979) (dismissing federal civil-rights claims against civic association that opposed a zoning request made by a religious group).

CONCLUSION

In the event the Court reaches the First Amendment argument, the Government respectfully submits that for the foregoing reasons, the Court should not dismiss the Second Amended Complaint on the ground that the First Amendment prohibits the False Claims Act claim at issue.

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Respectfully submitted,

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