NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CENTRAL REGIONAL EMPLOYEES BENEFIT FUND, et al.,	:	CIVIL ACTION NO. 09-3418 (MLC)
Plaintiffs,	:	**MEMORANDUM OPINION**
v.	:	
CEPHALON, INC., et al.,	:	
Defendants.	:	

COOPER, District Judge

Plaintiffs, Central Regional Employees Benefit Fund, North Jersey Municipal Employee Benefits Fund, Southern New Jersey Regional Employee Benefits Fund, Bergen Municipal Employee Benefits Fund, Municipal Reinsurance Health Insurance Fund, and the County of Union (collectively, "plaintiffs"), commenced this putative class action against defendants, Cephalon, Inc. ("Cephalon"), and Cima Labs, Inc. (collectively, "defendants"), alleging violations of the New Jersey Consumer Fraud Act ("NJCFA"), N.J.S.A. § 56:8-1 et seq. (Count I), "fraudulent concealment" (Count II), and "illegal fraud" (Count III). (Dkt. entry no. 1, Compl.) Cephalon removed the action pursuant to 28 U.S.C. §§ 1446 and 1453, on the basis that the Court has subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. § 1332(d). (Dkt. entry no. 1, Rmv. Not.)[1]

[1] It appears that defendant Cima Labs, Inc. ("Cima") has not been served. (Rmv. Not. at 1 n.1.)

Cephalon now moves to dismiss the claims asserted against it for failure to state a claim upon which relief can be granted, pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6). (Dkt. entry no. 5, Mot. Dismiss.) For the reasons stated herein, the Court will grant Cephalon's motion.

BACKGROUND

The plaintiffs are local governmental health and welfare benefit funds, and one county, that directly or indirectly pay for prescription drugs for their employees and other covered beneficiaries, i.e., "third-party payors." (Compl. at 3-5, ¶¶ 1-11.) Cephalon is a manufacturer and distributor of prescription drug products, including Provigil, a stimulant approved by the Food and Drug Administration ("FDA") for the treatment of narcolepsy, shift work disorder, and excessive daytime sleepiness; Gabitril, approved for the treatment of partial seizure disorders; and Actiq and Fentora, which are approved for the management of cancer pain in opiod-tolerant patients with malignancy. (Id. at 6-8, ¶¶ 1, 14-28.)

The plaintiffs allege that Cephalon promotes these drugs for uses other than those approved by the FDA, and that as part of its "off label" marketing efforts, "Cephalon made false representations regarding the use and application of Provigil, Gabitril, Actiq and Fentora." (Id. at 7, ¶ 13.)[2] The plaintiffs

[2] "The term 'off-label' refers to the use of a prescription drug for any purposes–any indication, dosage form, dosage regimen, or

allege that they "were caused to pay for the off label use and/or prescribing of Provigil, Gabitril, Actiq and Fentora," thereby unjustly enriching Cephalon and causing losses "believed to be in the tens of millions of dollars" to the plaintiffs. (Id. at 11, ¶ 50.) The plaintiffs designate their putative class as including "all governmental entities in the United States of America who have been caused to expend monies for Provigil, Gabitril and Actiq as a result of the off label promotion by the defendants." (Id. at 12, ¶ 1.)

Cephalon now moves to dismiss the NJCFA and common law fraud claims. Cephalon contends, inter alia, that the plaintiffs failed to plead specific acts of fraud to support the legal conclusions contained in the Complaint. (Dkt. entry no. 5, Cephalon Br. at 2.) The plaintiffs oppose Cephalon's motion. (Dkt. entry no. 6, Pl. Br.)

DISCUSSION

I. 12(b)(6) Motion to Dismiss Standard

The Court may dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed.R.Civ.P. 12(b)(6). On a Rule 12(b)(6) motion to dismiss, a court generally must accept as true all of the factual allegations in the complaint, and must draw all reasonable inferences in favor of the

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population–not specifically approved by the FDA." In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, No. 06-5774, 2009 WL 2043604, at *2 (D.N.J. July 10, 2009). (See also Compl. at 7, ¶ 11.)

plaintiff. Cal. Pub. Employees' Ret. Sys. v. Chubb Corp., 394 F.3d 126, 134 (3d Cir. 2004); Doe v. Delie, 257 F.3d 309, 313 (3d Cir. 2001). A court, however, need not credit bald assertions or legal conclusions alleged in the complaint. Kanter v. Barella, 489 F.3d 170, 177 (3d Cir. 2007); Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009) ("Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice."). The plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555-56 (2007) (citation omitted).

The plaintiffs' common law fraud claims are subject to the heightened pleading standards of Rule 9(b), which requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed.R.Civ.P. 9(b). "The purpose of Rule 9(b) is to provide notice of the precise misconduct with which the defendants are charged and to prevent false or unsubstantiated charges." Rolo v. City Inv. Co. Liquidating Trust, 155 F.3d 644, 658 (3d Cir. 1998) (internal quotation and citation omitted). "To satisfy this standard, the plaintiff must plead or allege the date, time, and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." Frederico v. Home Depot, 507 F.3d 188, 200 (3d Cir.

2007). The allegations also must include "who made a misrepresentation to whom and the general content of the misrepresentation." Lum v. Bank of Am., 361 F.3d 217, 224 (3d Cir. 2004).

II. Plaintiffs' New Jersey Consumer Fraud Act Claim

Defendants move to dismiss the plaintiffs' claim brought pursuant to the NJCFA. That statute provides in relevant part:

> The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice.

N.J.S.A. § 56:8-2. The term "person" as used in the NJCFA includes, inter alia, natural persons, partnerships, corporations, companies, trusts, business entities and associations. N.J.S.A. § 56:8-1(d).

To state a NJCFA claim, a plaintiff must allege the following elements: "(1) unlawful conduct by defendant; (2) an ascertainable loss by plaintiff[s]; and (3) a causal relationship between the unlawful conduct and the ascertainable loss." Bosland v. Warnock Dodge, Inc., 964 A.2d 741, 749 (N.J. 2009).

Cephalon argues that the plaintiffs, as third-party payors of prescription medication benefits, are not "consumers" under

the NJCFA. (Cephalon Br. at 20-22.) The nature of the transaction, not the identity of the purchaser, determines whether the NJCFA is applicable. J & R Ice Cream Corp. v. Cal. Smoothie Lic. Corp., 31 F.3d 1259, 1273 (3d Cir. 1994). For a NJCFA plaintiff "to be a consumer respecting the transaction in question, [a] business entity must be one who uses [economic] goods, and so diminishes or destroys their utilities." City Check Cashing, Inc. v. Nat'l State Bank, 582 A.2d 809, 811 (N.J. App. Div. 1990) (quotation omitted) (second alteration in original).

The court in In re Schering-Plough Corp. Intron/Temodar Consumer Class Action considered the question of whether the third-party payor plaintiffs in that case were "consumers" entitled to sue under the NJCFA, and concluded that third-party payors "essentially serve as middlemen or insurers, paying all or part of the cost of a beneficiary's drugs in return for a stream of payments from the beneficiary." 2009 WL 2043604, at *31-*32. Because third-party payors do not use or consume prescription medications themselves, they are not "consumers" within the meaning of the NJCFA, and that statute is therefore inapplicable to the circumstances alleged in the Complaint. Id. at *32; see Bracco Diagnostics, Inc. v. Bergen Brunswig Drug Co., 226 F.Supp.2d 557, 560-62 (D.N.J. 2002). The Court will dismiss the plaintiffs' NJCFA claim with prejudice, finding that amendment of

the Complaint as to Count I would be futile. See Shane v. Fauver, 213 F.3d 113, 117 (3d Cir. 2000).[3]

III. Plaintiffs' Common Law Fraud Claims

Cephalon contends that the plaintiffs' claims of "fraudulent concealment" and "illegal fraud" fail as a matter of law. (Cephalon Br. at 7.) The Court agrees.

A claim for common law fraud includes five elements: (1) a material misrepresentation of a currently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages. Gennari v. Weichert Co. Realtors, 691 A.2d 350, 367 (N.J. 1997); see DeRobbio v. Harvest Communities of Sioux City, Inc., No. 01-1120, 2002 WL 31947203, at *5-*6 (D.N.J. Oct. 30, 2002) (applying Gennari standard to both fraud and fraudulent concealment claims).

The plaintiffs' common law fraud claims fail to meet the pleading requirements of Twombly, Iqbal, and Rule 9(b). Count II of the Complaint, fraudulent concealment, refers to a "transaction and/or providing of the prescription drugs Provigil, Gabitril, Actiq and Fentora." (Compl. at 17, ¶ 2.) The Court is at a loss to discern to what "transaction[s]" the plaintiffs refer, as the Complaint fails to identify or explain the who,

[3] The Court will, sua sponte, dismiss that claim insofar as it is asserted against Cima as well.

what, where, why, and how of any "transaction." (See also id. at 16, ¶ 8 ("The aforementioned misrepresentations were material to the transaction(s) at issue.").) Mere allegations that Cephalon provided prescription drugs, without saying to whom or under what circumstances, wholly fail to state a claim for fraud. Frederico, 507 F.3d at 200; Lum, 361 F.3d at 224. Count II also states that "the defendant's intentional concealment and/or failure to disclose and/or misrepresentations regarding the off label uses constitute fraud." (Compl. at 17, ¶ 3.) This is a naked legal conclusion that will not satisfy the plaintiffs' pleading burden. Iqbal, 129 S.Ct. at 1949.

The plaintiffs' allegations pertaining to Count III of the Complaint, "illegal fraud," contain no specific facts at all. (See, e.g., Compl. at 19, ¶ 3 ("Cephalon made material misrepresentations and/or omitted facts with a duty and/or obligation to disclose the presently existing or past facts.").) Rather, paragraphs 1-7 of Count III merely state the elements of common law fraud, with no specific supporting facts as to what "misrepresentations" Cephalon allegedly made.

Assuming that the plaintiffs intend for Cephalon's alleged off-label marketing and promotion scheme, as described in minimal detail in the Complaint (Compl. at 9, ¶ 30), to adequately allege "fraud" or "misrepresentations," it is well-established that "off-label marketing of an approved drug is itself not inherently fraudulent." In re Actimmune Mktg. Litig., 614 F.Supp.2d 1037,

1051 n.6 (N.D. Cal. 2009); see also In re Schering-Plough Corp. Intron/Temodar Consumer Class Action, 2009 WL 2043604, at *10; United States v. Caronia, 576 F.Supp.2d 385, 397 (E.D.N.Y. 2008) ("[P]romotion of off-label usage does not promote unlawful activity. . . . Promotion of off-label uses is not inherently misleading simply because the use is off-label."). Merely alleging that Cephalon marketed the drugs at issue for off-label purposes does not state a claim for fraud. To the extent that the plaintiffs state in the "Class Action Allegations" section of the Complaint that one of the issues to be determined in the case is "whether the defendants misrepresented the efficacy and/or cost effectiveness and/or economic efficiency of" the drugs, that statement contains no factual allegations, which are required under Twombly and Iqbal. (Compl. at 13, ¶ 5(c).)

The plaintiffs attempt to rely on a reference in the Complaint to a proceeding in the United States District Court for the Eastern District of Pennsylvania in 2003, brought pursuant to the False Claims Act, 31 U.S.C. § 3729 et seq., wherein Cephalon was alleged to have engaged in "misbranding" of its products. (Compl. at 9, ¶ 32; Pl. Br. at 14.) That proceeding allegedly resulted in a plea agreement and criminal fine of $50 million, and a civil settlement of $375 million, to be paid to the United States and various states. (Compl. at 9-10, ¶¶ 32-42.)

Referring to a plea agreement and civil settlement in another action, however, does not satisfy the plaintiffs' burden

of pleading fraud with specificity under Rule 9(b) in this case, nor does such a reference "raise a right to relief above the speculative level." Twombly, 550 U.S. at 555. That separate proceeding appears to have concerned "off label" promotional activities and "misbranding" of drugs by Cephalon. (Compl. at 10, ¶¶ 37, 40.) As discussed above, off-label marketing and promotion is not inherently fraudulent, and the plaintiffs may not rely on Cephalon's alleged past statutory or regulatory violations to state a common law claim for fraud.[4] In the absence of any specific allegations of fraud, as opposed to the mere fact of off-label marketing, the plaintiffs' common law fraud claims must be dismissed.[5]

CONCLUSION

For the reasons discussed supra, the Court will dismiss the Complaint. Count I will be dismissed with prejudice. Counts II

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[4] FDA regulations prohibit drug manufacturers from marketing or promoting prescription drugs for off-label uses. 21 C.F.R. § 202.1(e)(6). Enforcement of FDA regulations, as well as the Federal Food, Drug, and Cosmetic Act ("FDCA") statutory provision prohibiting "misbranding" of drugs, 21 U.S.C. § 352(n), "lies exclusively within the federal government's domain, by way of either the FDA or the Department of Justice." Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc., 922 F.Supp. 299, 305 (C.D. Cal. 1996); see 21 U.S.C. § 337(a). No private cause of action exists under the FDCA. Merrell Dow Pharms., Inc. v. Thompson, 478 U.S. 804, 810-12 (1986); Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994); Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA, 145 F.Supp.2d 565, 570-71 (D.N.J. 2001).

[5] The Court will, sua sponte, dismiss these claims insofar as they are asserted against Cima as well.

and III will be dismissed without prejudice. The Court will issue an appropriate Order and Judgment.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: October 7, 2009