NOT FOR PUBLICATION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. (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.)

The Court granted Cephalon's motion to dismiss the Complaint pursuant to Federal Rule of Civil Procedure ("Rule") 12(b)(6) on October 7, 2009, and closed the action, granting the plaintiffs leave to move to reopen the action and file an amended complaint. (Dkt. entry nos. 8 & 9, 10-7-09 Mem. Op. & Order.) The

plaintiffs have so moved. (Dkt. entry no. 11, Mot. to Reopen Case and File Am. Compl.) Cephalon opposes the motion. (Dkt. entry no. 12, Cephalon Br.) The Court decides the motion on the papers without an oral hearing, pursuant to Rule 78(b). For the following reasons, the plaintiffs' motion will be denied.

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 opioid-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.)[1] The plaintiffs 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.)

The proposed amended complaint seeks to add as a defendant Express Scripts, Inc. ("ESI"), a Pharmacy Benefits Manager for plaintiffs that pays for prescription medication for employees of the plaintiffs and bills the plaintiffs for handling the prescription benefit plan. (Dkt. entry no. 11-2, Proposed Am. Compl. at 7, ¶¶ 14-17.) The plaintiffs also seek to add Dr. Lauren Shaiova ("Shaiova"), a "speaker" for Cephalon, and "Jane Doe," a dependent of an employee member of the plaintiffs, alleging that Shaiova prescribed Actiq to Jane Doe for off-label purposes. (Id. at 7, ¶¶ 18-22 & 17, ¶¶ 69-70.) The plaintiffs

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[1] "The term 'off-label' refers to the use of a prescription drug for any purposes–any indication, dosage form, dosage regimen, or 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) ("In re Schering-Plough"). (See also Compl. at 7, ¶ 11.)

allege that ESI failed to monitor patient drug use as to Jane Doe and allowed Jane Doe to fill prescriptions for Actiq, charging the plaintiffs $2,312.50 per 30-dose pack of the narcotic lozenges. (Id. at 17, ¶ 71 & 77.) The plaintiffs allege that Shaiova prescribed to Jane Doe, and ESI approved, 960 days' worth of Actiq over a 365-day period. (Id. at 19, ¶ 80.) The plaintiffs contend that ESI profited over $144,000 in a single year by approving Actiq for Doe. (Id. at 19, ¶ 82.)

The proposed amended complaint is styled as a putative class action and contains the following claims: violation of the New Jersey Racketeer Influenced and Corrupt Organizations Act ("NJ RICO"), N.J.S.A. § 2C:41-1 (Count I); fraudulent concealment (Count II); "illegal fraud" (Count III); "unjust enrichman" [sic] (Count IV); and violation of the covenant of good faith and fair dealing (Count V). (Proposed Am. Compl. at 23-32.)

DISCUSSION

I. Applicable Legal Standards

A. Motion to Reopen & Leave to Amend Standard

The plaintiffs' motion to reopen the action and for leave to file an amended complaint is governed by Rule 15(a), which provides that "[t]he court should freely give leave when justice so requires." Fed.R.Civ.P. 15(a)(2). Leave to amend is properly denied for reasons including bad faith, dilatory motive, undue delay, futility, repeated failure to cure deficiencies by

previously allowed amendments, or prejudice to the party opposing the amendment. See Hill v. Scranton, 411 F.3d 118, 134 (3d Cir. 2005); Long v. Wilson, 393 F.3d 390, 400 (3d Cir. 2004).

Leave to file an amended complaint may be denied as futile if it appears that the complaint as amended would fail to state a claim upon which relief could be granted. See In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1434 (3d Cir. 1997).

B. Motion to Dismiss Standard

In addressing a motion to dismiss a complaint under Rule 12(b)(6), the court must "accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine, whether under any reasonable reading of the complaint, the plaintiff may be entitled to relief." Phillips v. County of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008). At this stage, a "complaint must contain sufficient factual matter, accepted as true to 'state a claim to relief that is plausible on its face.' A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 129 S.Ct. 1937, 1949 (2009)(quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 556 (2007)). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show[n]'- that the 'pleader

is entitled to relief.'" Iqbal, 129 S.Ct. at 1950 (quoting Rule 8(a)(2)).

The plaintiffs' common law fraud and NJ RICO claims are subject to the heightened pleading standards of Rule 9(b): "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." 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. Legal Standards Applied Here

A. Count I – NJ RICO Claim

The plaintiffs do not specify the manner in which the defendants allegedly violated NJ RICO, N.J.S.A. § 2C:41-2. (See Proposed Am. Compl. at 23-25.) The plaintiffs conclusorily allege that each of the defendants constituted an "enterprise" as

defined in N.J.S.A. § 2C:41-1(c) ("[A]ny individual . . . or group of individuals associated in fact . . . includ[ing] illicit as well as licit enterprises") and engaged in a "pattern of racketeering activity" as defined in N.J.S.A. § 2C:41-1(d) (requiring a "showing that the incidents of racketeering activity embrace criminal conduct that has either the same or similar purposes, results, participants or victims . . . and are not isolated incidents").

To state a claim under NJ RICO or its federal counterpart, 18 U.S.C. § 1962, a plaintiff must allege (1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity, and an injury to property or business resulting from the offensive conduct. In re Schering-Plough, 2009 WL 2043604, at *7.[2]

An allegation that the plaintiffs were caused to pay for more prescription drugs than would have otherwise been prescribed but for off-label marketing does not constitute a cognizable injury under NJ RICO. See id. at *9-*10. Off-label marketing activities, including Cephalon's alleged payment to Shaiova for "studies," are "not inherently fraudulent." In re Actimmune Mktg. Litig., 614 F.Supp.2d 1037, 1051 n.6 (N.D. Cal. 2009) (emphasis added). (See Proposed Am. Compl. at 17, ¶ 74 (alleging

[2] NJ RICO claims are subject to the same standards of proof as those required by the federal RICO statute. In re Schering-Plough, 2009 WL 2043604, at *7 (citing Cetel v. Kirwan Fin. Group, 460 F.3d 494, 510 (3d Cir. 2006)).

that "Shaiova was paid by Cephalon to conduct 'studies' regarding the use of Cephalon drugs for 'off label' treatments while Shaiova was also a 'speaker' for Cephalon").) The plaintiffs do not allege any specific facts as to Shaiova's alleged "studies" that would support an inference that such studies conveyed fraudulent misrepresentations to the plaintiffs or doctors who prescribed prescription medications to members of the plaintiffs. See In re Actimmune Mktg. Litig., 614 F.Supp.2d at 1051 ("A RICO violation is not focused on the drug's label, but rather whether the promoted assertion was knowingly false as to a material matter about the drug, i.e., if it constituted actionable fraud.").

The plaintiffs do not allege that any of the pharmaceutical products at issue here were ineffective even for off-label uses or that Cephalon itself made misrepresentations directly to the plaintiffs. See Williams v. Purdue Pharma Co., 297 F.Supp.2d 171, 176 (D.D.C. 2003) (dismissing pharmaceutical product liability action brought under District of Columbia Consumer Protection Procedures Act for failure to allege an injury-in-fact).[3] Thus, the plaintiffs have failed to plead the type of

[3] See also In re Actimmune Mktg. Litig., 614 F.Supp.2d at 1052:

> Plaintiffs need to allege what specific information the individual plaintiffs or their physicians had about the drug, the extent to which they relied upon that information, and that the information relied upon was false, misleading or otherwise fraudulent. Plaintiffs also need to allege when the drug was prescribed,

injury necessary to pursue an NJ RICO claim. See In re Schering-Plough, 2009 WL 2043604, at *13 ("Plaintiffs' allegations of insufficient evidence [of efficacy] and lack of FDA approval are not adequate to plead RICO injury because they fail to assert that the Subject Drugs were ineffective, unsafe, or somehow worth less than what Plaintiffs paid for the drugs. . . . As the Court has already held, there is a clear and decisive difference between allegations that actually contest the safety or effectiveness of the Subject Drugs and claims that merely recite violations of the [Federal Food, Drug, and Cosmetic Act], for which there is no private cause of action.") (emphasis added).

B. Counts II and III – Common Law Fraud Claims

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 another rely on it; (4) reasonable reliance thereon by another; 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

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> purchased and administered, and whether these actions would have been taken if not for the concealment/misrepresentations of facts made regarding the efficacy or lack thereof about [the drug for the off-label treatment].

Gennari standard to both fraud and fraudulent concealment claims).

The plaintiffs' common law fraud claims for "fraudulent concealment" and "illegal fraud" fail to meet the pleading requirements set forth in Twombly, Iqbal, and Rule 9(b). In support of their fraudulent concealment claim the plaintiffs allege, inter alia, that Cephalon "concealed its off label promotion of the various drugs as well as its financial 'arrangement' with Shaiova." (Proposed Am. Compl. at 27 ¶ 3.) The plaintiffs do not allege any material misrepresentation or omission by Cephalon that the plaintiffs relied on, only that Cephalon engaged in off-label marketing and that Shaiova was a "speaker" for Cephalon and prescribed large quantities of Actiq to Jane Doe, which ESI paid for. Here, as in In re Schering-Plough, "Plaintiffs do not plead a single instance in which they, themselves, or any of their prescribing doctors received a misrepresentation of fact from Defendants and relied upon that misrepresentation in deciding to prescribe one of the Subject Drugs to Plaintiffs." 2009 WL 2043604, at *33. The plaintiffs allege, e.g., that "Cephalon, through its sales representatives, targeted neurologists, primary care physicians, rehabilitation centers and others as markets for Actiq" and that its off-label marketing activities included "training representatives to make false statements about the dosing and/or efficacy of the

prescription drugs . . . [and] conducting training seminars with false and misleading information." (Proposed Am. Compl. at 10, ¶ 28 & 11, ¶ 33.) Such allegations do not specify the how the content of the representations was false or, significantly, how this generalized activity affected the plaintiffs in particular.

As noted above, 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 at 1051 n.6; see also In re Schering-Plough, 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."). To the extent that the plaintiffs allege that Cephalon's off-label marketing efforts including "provid[ing] information which was known to be inaccurate and/or misleading," none of those factual allegations contain any nexus at all to the plaintiffs from which the Court could infer reliance by the plaintiffs or causation of the plaintiffs' alleged damages. (See Proposed Am. Compl. at 12, ¶¶ 35-43.) The Court finds that the plaintiffs' proposed amended complaint fails to state a claim for common law fraud in the form of either fraudulent concealment or "illegal fraud."

C. Count IV - Unjust Enrichment

"Unjust enrichment is an equitable theory of recovery centered on the principle that a person shall not be allowed to enrich himself unjustly at the expense of another." Boyko v. Am. Int'l Group, Inc., No. 08-2214, 2009 WL 5194425, at *5 (D.N.J. Dec. 23, 2009) (citation and quotation omitted). To state a claim for unjust enrichment in New Jersey, a plaintiff must allege that (1) the defendant received a benefit, and (2) retention of that benefit by defendant would work an injustice. VRG Corp. v. GKN Realty Corp., 641 A.2d 519, 526 (N.J. 1994). The plaintiff must further show "that it expected remuneration from the defendant at the time it performed or conferred a benefit on defendant and that the failure of remuneration enriched defendant beyond its contractual rights." Id. In cases where an unjust enrichment claim is predicated on underlying tort claims, the unjust enrichment claim should be dismissed if the accompanying traditional tort claims fail for failure to establish a proximate connection between the defendants' conduct and the plaintiffs' injuries. Steamfitters Local Union No. 420 Welfare Fund v. Philip Morris, Inc., 171 F.3d 912, 936-37 & n.23 (3d Cir. 1999).

The plaintiffs allege that the "fraudulent acts and omissions" of Cephalon, ESI, and Shaiova have allowed those defendants to gain significant "profits that would not have been

gained" but for the allegedly fraudulent acts and omissions. (Proposed Am. Compl. at 30, ¶¶ 2-7.) However, the plaintiffs' proposed amendment does not allege with sufficient specificity the underlying "fraudulent acts" of each of the defendants to state a claim for unjust enrichment. See Steamfitters, 171 F.3d at 937; Boyko, 2009 WL 5194425, at *5 (dismissing unjust enrichment claim where plaintiff did not allege that he expected defendants to give him anything in return for an insurance premium paid "under protest"); Blystra v. Fiber Tech Group, Inc., 407 F.Supp.2d 636, 645 n.11 (D.N.J. 2005) (treating unjust enrichment claim as subsumed by plaintiffs' other tort claims, and not an independent cause of action).

D. Count V - Breach of the Covenant of Good Faith and Fair Dealing

"A covenant of good faith and fair dealing is implied in every contract in New Jersey." Wilson v. Amerada Hess Corp., 773 A.2d 1121, 1126 (N.J. 2001). "[T]here can be no claim for breach of the implied covenant of good faith and fair dealing without identifying a contract, the performance or non-performance of which may serve as the predicate for the claim." Ferraioli v. City of Hackensack Police Dep't, No. 09-2663, 2010 WL 421098, at *12 (D.N.J. Feb. 2, 2010).

The proposed amended complaint does not identify any contract, express or implied, to which Cephalon is a party. Thus, the proposed amended complaint in no way states a claim for

breach of the implied covenant of good faith and fair dealing as against Cephalon. See id. The only contract referred to in the proposed amended complaint is ESI's "standard contract," which the plaintiffs contend required ESI "to monitor patient drug use pursuant to the 'Concurrent Drug Utilization Review System'." (Proposed Am. Compl. at 17, ¶ 71.) Apparently unrelated to the "standard contract," plaintiffs then allege that "ESI did not investigate, nor question, the relationship between Cephalon and/or Cima and Shaiova." (Id. at 17, ¶ 72.) As Cephalon points out, the plaintiffs merely refer to, but "do not actually allege that they were parties to," ESI's "standard contract." (Cephalon Br. at 26 n. 17.) This passing reference to a "standard contract," without more, does not satisfy the plaintiffs' pleading burden to establish the existence of a contract between the parties in order state a claim for either breach of contract or breach of the implied covenant of good faith and fair dealing.

CONCLUSION

As discussed above, off-label marketing and promotion of prescription drugs is not inherently fraudulent. It is apparent to the Court that the proposed amended complaint constitutes yet another legally unsupportable attempt to bring a private cause of action against Cephalon for its "misbranding" and off-label

promotion violations of the Federal Food, Drug and Cosmetics Act ("FDCA") and implementing regulations.[4]

To the extent that the proposed amended complaint adds allegations regarding ESI, Shaiova, and Jane Doe, those allegations appear factually remote from the plaintiffs' assertions of wrongdoing on Cephalon's part, which remain limited to allegations that Cephalon engaged in off-label marketing. Thus, the Court finds that to reopen the action and grant the plaintiffs leave to file the proposed amended complaint, requiring Cephalon to respond, would unfairly prejudice Cephalon at this juncture after the plaintiffs have been afforded the opportunity to cure the defects of their fraud claims against Cephalon.

Because amendment would be futile, and would prejudice Cephalon, the Court will deny the plaintiffs' motion to reopen

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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 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).

the action and file an amended complaint. The action will remain closed.

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

Dated: March 29, 2010