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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

#55 / JS-6

CIVIL MINUTES - GENERAL

Case No.	MDL 08-1934 PSG (AGR _x)	Date	June 17, 2009
Title	In re Epogen and Aranesp Off-Label Marketing and Sales Practices Litigation		

Present: The Honorable Philip S. Gutierrez, United States District Judge

Wendy K. Hernandez	Not Present	n/a
Deputy Clerk	Court Reporter	Tape No.

Attorneys Present for Plaintiff(s):

Attorneys Present for Defendant(s):

Not Present

Not Present

Proceedings: (In Chambers) Order Granting Motion to Dismiss With Prejudice

Before the Court is Amgen's motion to dismiss the Corrected Amended Class Action Complaint. After considering the moving and opposing papers, as well as oral argument at the June 1, 2009 hearing, the Court GRANTS the motion.

I. Background

A. The Parties

Plaintiff Sheet Metal Workers National Health Fund is a welfare plan that provides post-retirement health benefits to approximately 17,000 retired members of the Sheet Metal Workers International Association. Plaintiff United Food & Commercial Workers Central Pennsylvania & Regional Health & Welfare Fund ("UFCW") is a not-for-profit trust established and maintained to provide health care benefits to participant-workers who are employed under various collective bargaining agreements and their dependents. Plaintiff Painters District Council No. 30 Health & Welfare Fund is a not-for-profit trust established and maintained to provide health care benefits to participant-workers and their dependents. Plaintiffs Ironworkers Local Union No. 68 and Participating Employers Health and Welfare Funds, Ironworkers Local Union No. 399 and Participating Employers Health and Welfare Funds, and Ironworkers District Council of Philadelphia and Vicinity Benefit and Pension Plan are health and welfare funds. Plaintiff Kenneth Ross is Commissioner of the Offices of Financial and Insurance Services for the State of Michigan and sues in his capacity as liquidator of Michigan Health Maintenance

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Organization Plans, Inc., formerly known as Omnicare Health Plan, Inc. (“Omnicare”).¹ Omnicare was a private third-party payor who assumed the risk of payment for medical and prescription costs on behalf of the participants in its plan. Collectively, the foregoing parties are referred to as “Plaintiffs.”

Plaintiffs charge Defendant Amgen, Inc. (“Amgen”) with fraudulently promoting two drugs (sometimes jointly referred to as “EPO”): epoetin alfa, which Amgen markets in the United States as Epogen, and darbepoetin alfa, which Amgen markets in the United States as Aranesp. Plaintiffs seek to represent a nationwide class consisting of “[a]ll persons or entities that paid for EPO when EPO was administered for anemia of cancer and/or heart failure and/or for treatment of cancer (“the Fraudulent Marketing Class” or “the Class”). The Class includes one subclass consisting of “[a]ll persons or entities that paid for EPO when EPO was administered through intravenous administration and/or at dosages that achieved a hemoglobin of 13 g/dL and above” (“The Kidney Dialysis Subclass”). The Class Period is May 21, 2002 through March 9, 2007.

B. Factual Background

Amgen manufactures and sells Epogen and Aranesp, both of which are erythropoiesis-stimulating agents (“ESAs”), meaning that they encourage the creation of oxygen-carrying red blood cells. *Am. Compl.* ¶ 4. The Food and Drug Administration (“FDA”) first approved Epogen in 1989. *Am. Compl.* ¶ 25. The current FDA-approved indications for Epogen include the treatment of anemia in chronic renal failure patients (including patients on dialysis and those not on dialysis), HIV-infected patients, and cancer patients on chemotherapy, and the reduction of allogeneic blood transfusion in surgery patients. *Am. Compl.* ¶ 27. In 2001, the FDA approved Aranesp, a similar drug, for the treatment of anemia associated with chronic renal failure. *Am. Compl.* ¶ 33. In July 2002, the FDA also approved Aranesp for the treatment of chemotherapy-induced anemia. *Am. Compl.* ¶ 33-34.

From 2002 until 2007, Amgen issued a number of press releases touting the positive results of clinical studies on “unproven and unsafe” off-label uses of EPO.² *Am. Compl.* ¶¶ 39-

¹ Ross was substituted for formerly named Plaintiff Linda A. Watters.

² “Off-label” refers to those uses of a drug that are not FDA-approved. While it is illegal for drug companies to market drugs for off-label uses, physicians may prescribe a legal

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53. According to Plaintiffs, many of these press releases did not reveal that the studies were funded by Amgen, rather than conducted by independent researchers. *Am. Compl.* ¶¶ 41, 44, 45, 47, 49. The Amended Complaint alleges that Amgen also promoted off-label uses of EPO to physicians and the public by funding third-party organizations, including the National Anemia Action Council (“NAAC”) and CancerCare, which provided educational materials, Continuing Medical Education (“CME”) programs, and physician brochures highlighting the off-label uses of EPO. *Am. Compl.* ¶ 54; *see also generally id.* at ¶¶ 55-76. While engaging in this promotion, Amgen allegedly concealed or minimized the results of studies that showed risks associated with off-label uses of EPO, such as higher incidence of heart attacks, strokes, tumor growth, and death. *E.g., Am. Compl.* ¶¶ 6, 77. Plaintiffs refer to this allegedly fraudulent scheme as the “False Marketing Enterprise.” *Am. Compl.* ¶ 5.

Additionally, Amgen entered into drug supply contracts with dialysis providers, including DaVita, Inc. (“DaVita”) and Fresenius Medical Care Holdings, Inc. (“Fresenius”), that provided volume-based discounts and other incentives for increased use of EPO. *Am. Compl.* ¶¶ 105, 111. The Amended Complaint alleges that Amgen sought to boost profits by promoting the intravenous administration of EPO to treat anemia in kidney dialysis patients, even though this route of administration had the effect of achieving a dangerously high hemoglobin level of 13g/dL or above. *Id.*

Eventually, the dangers of certain off-label uses of EPO became publicly known. On February 16, 2007, *The Cancer Letter* published an article about the results of an October 2006 study relating to Aranesp’s effectiveness in treating patients with head and neck cancer that had been closed early due to increased mortality rates. *Am. Compl.* ¶¶ 81-82. On February 27, 2007, it was widely reported that a meta-analysis of clinical trial data had shown a statistically significant increase in the risk of death for cancer patients who took EPO. *Am. Compl.* ¶ 84. Aranesp was quickly de-listed as an accepted treatment for anemia of cancer by the publishers of the United States Pharmacopeia-Drug Information (“USP-DI”), an authoritative industry reference guide for on- and off-label uses of prescription drugs. *Am. Compl.* ¶ 85. On March 9, 2007, the FDA mandated a “black box” warning for the off-label use of EPO. *Am. Compl.* ¶ 87. The warning cautioned that use of EPO to achieve a target hemoglobin of 12/dL or greater in cancer patients: (1) “shortened the time to tumor progression in patients with advanced head and neck cancer receiving radiation therapy;” (2) “shortened overall survival and increased deaths

medication for any purpose, regardless of whether the drug has been approved for that use by the FDA. *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000).

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attributed to disease progression in patients with metastatic breast cancer receiving chemotherapy;” and (3) “increased the risk of death in patients with active malignant disease not under treatment with chemotherapy or radiation therapy.” *Am. Compl.* ¶ 87. The FDA alert also included the results of a December 2003 study which indicated that anemia patients with non-small cell lung cancer receiving EPO died in half the time of patients given placebos; as a result, the study was cut short. *Am. Compl.* ¶ 88.

C. Procedural History

Initially, Plaintiffs in this MDL proceeding brought separate cases in the Central District of California. Several cases were transferred to other districts around the country. Upon UFCW’s motion, the Judicial Panel for Multidistrict Litigation ordered all cases transferred to this Court on April 8, 2008. On July 2, 2008, Plaintiffs filed a Consolidated Class Action Complaint alleging that Amgen, in conjunction with former Defendants DaVita and Fresenius, engaged in a fraudulent scheme that caused members of the Class to pay millions of dollars for EPO prescribed for ineffective and unsafe off-label uses.

On December 17, 2008, the Court dismissed the complaint with leave to amend, finding that Plaintiffs’ suit was, primarily, an impermissible attempt to bring a private cause of action for violations of the Food, Drug, and Cosmetics Act (“FDCA”), 21 U.S.C. §§ 301, *et seq.*, and its implementing regulations. Plaintiffs filed an Amended Class Action Complaint on January 30, 2009. On February 24, 2009, Plaintiffs filed the operative Corrected Amended Class Action Complaint (“Amended Complaint”), which terminated Fresenius as a party, leaving Amgen as the only remaining Defendant. Amgen now moves to dismiss the Amended Complaint.

II. Legal Standard

A. Motion to Dismiss

Rule 12(b)(6) of the Federal Rules of Civil Procedure provides a mechanism for a party to dismiss a claim if the claimant fails to state a claim upon which relief can be granted. In evaluating the sufficiency of a complaint under Rule 12(b)(6), courts must be mindful that the Federal Rules require only that the complaint contain “a short and plain statement of the claim showing that the pleader is entitled to relief.” Fed. R. Civ. P. 8(a). Even though a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, “a plaintiff’s obligation to provide the grounds of his entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not

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do.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) (internal citations omitted). The complaint must allege facts sufficient to raise a right to relief above the speculative level. *Id.* (citing 5 C. Wright & A. Miller, Federal Practice and Procedure § 1216, pp. 235-236 (3d ed. 2004)). The Court must accept as true all factual allegations in the complaint and must draw all reasonable inferences from those allegations, construing the complaint in the light most favorable to the plaintiff. *Guerrero v. Gates*, 442 F.3d 697, 703 (9th Cir. 2006); *Balistreri v. Pacifica Police Dep’t*, 901 F.2d 696, 699 (9th Cir. 1988).

B. Fraud-Based Claims: Rule 9(b)

Federal Rule of Civil Procedure 9(b) requires a plaintiff to plead all claims of fraud with particularity. This requirement applies equally to all fraud-based causes of action, including civil RICO claims predicated on mail or wire fraud. Therefore, “the pleader must state the time, place, and specific content of the false misrepresentations as well as the identities of the parties to the misrepresentation.” *Odom v. Microsoft Corp.*, 486 F.3d 541, 553 (9th Cir. 2007) (citation omitted). Furthermore, the plaintiff must “set forth an explanation as to why the statement or omission complained of was false and misleading.” *In re GlenFed, Inc. Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994) (en banc), *superseded by statute on other grounds*.

III. Discussion

The Court dismissed Plaintiffs’ previous complaint based on its conclusion that the lawsuit was essentially an attempt to bring a private cause of action for violations of the FDCA and related regulations. The power to enforce the FDCA lies exclusively with the federal government. *Summit Tech., Inc. v. High-Line Med. Instruments Co., Inc.*, 922 F. Supp. 299, 305 (C.D. Cal. 1996). Although Plaintiffs cast their suit as a RICO and state law consumer fraud action based on false marketing, the Court found that Plaintiffs had failed to point to statements made by Amgen that were false, misleading, or contained a material omission:

Instead, the existence of federal enactments—i.e., the FDCA and accompanying regulations—making off-label promotion illegal is central to many of Plaintiffs’ claims that Defendants engaged in wrongful conduct. Allowing Plaintiffs to proceed on a theory that Defendants violated RICO by engaging in off-label promotion, without specific allegations that Defendants made false or misleading statements, would, in effect, permit Plaintiffs to use RICO as a vehicle to enforce the FDCA and the regulations promulgated thereunder. *See Mylan Laboratories, Inc. v. Matkari*, 7 F.3d

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1130, 1139 (4th Cir. 1993); *Summit*, 922 F. Supp. at 306. Differently put, (truthful) off-label promotion of a drug does not violate RICO. Rather, it violates the FDCA. But the FDCA provides no private right of action for violations thereof, and what the FDCA does not create directly, RICO cannot create indirectly. *See Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990).

In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig., 590 F. Supp. 2d 1282, 1289-90 (C.D. Cal. 2008). The Court concluded:

[I]nsofar as Plaintiffs' claims are based solely on allegations that Defendants promoted EPO for off-label purposes, they constitute an impermissible attempt to bring a private suit for violations of the FDCA. However, insofar as Plaintiffs can identify specific representations by Defendants that are literally false, misleading, or contain material omissions, the claims are actionable under RICO and California consumer fraud laws. As currently pled, however, Plaintiffs' allegations of fraud (i.e., deceptive advertising) are so intertwined with allegations that Defendants engaged in illegal off-label promotion that the Court must dismiss the Complaint in its entirety. The Court grants Plaintiffs leave to amend their complaint to allege, with the specificity required by Rule 9(b) of the Federal Rules of Civil Procedure, that Defendants violated RICO and state consumer fraud laws by engaging in deceptive advertising that fraudulently misrepresented the safety of off-label uses of EPO. To be clear, the Court emphasizes that Plaintiffs may *not* rely on allegations that Defendants engaged in off-label promotion of EPO; instead, Plaintiffs must point to specific misrepresentations made by Defendants.

Id. at 1292.

Amgen contends that the Amended Complaint should be dismissed because Plaintiffs have failed to cure the deficiencies previously identified by the Court. The Amended Complaint includes four causes of action: (1) violation of 18 U.S.C. § 1962(c) in connection with the activities of the Fraudulent Marketing Enterprise ("FME"); (2) violation of California's Unfair Competition Law ("UCL"), Cal. Bus. & Prof. Code §§ 17200, *et seq.*, in connection with the FME; (3) violation of California's Fair Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*; and (4) violation of the UCL in connection with "Amgen's 'Kidney Dialysis' Conduct."

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Although Plaintiffs have liberally incorporated the modifiers “false” and “deceptive” into their Amended Complaint, they have not added any substantive allegations or adequately fleshed out their claims of fraud. Plaintiffs have deleted the “Regulatory Framework” section of their previous pleading and substituted the terms “falsely” for “unlawfully” and “unsafe and unproven” for “off-label” throughout their Amended Complaint. These changes, however, are purely cosmetic. The Court finds that the Amended Complaint constitutes yet another attempt to shoehorn allegations that Amgen engaged in off-label promotion in violation of the FDCA into RICO and state consumer fraud causes of action.

Plaintiffs point to a number of paragraphs which, they argue, satisfy the requirement that they allege that Amgen engaged in deceptive promotion or other fraudulent conduct. The Court will explain why Plaintiff’s latest attempt to plead a cognizable fraud-based claim remains insufficient.

First, Plaintiffs maintain that paragraphs 39-53 “allege that Amgen falsely promoted EPO for unproven and unsafe uses.” In these paragraphs, Plaintiffs aver that Amgen issued a number of press releases pertaining to clinical research on the effectiveness of Aranesp in treating anemia in cancer patients not receiving chemotherapy (an off-label use), but they do not identify any particular affirmative statements that were false or misleading. Plaintiffs insinuate that the press releases were deceptive or otherwise improper because Amgen did not disclose that it sponsored many of the clinical studies which reported positive findings on unapproved uses of EPO. However, these allegations are not actionable as fraud because Plaintiffs do not claim that Amgen had a duty to disclose its sponsorship of the studies. *See Chiarella v. United States*, 445 U.S. 222, 227-28, 100 S. Ct. 1108, 63 L. Ed. 2d 348 (1980) (mere failure to disclose information constitutes fraud only when there is a duty to disclose).

Next, Plaintiffs direct the Court’s attention to paragraphs 54-70, maintaining that they “allege that Amgen also used third parties to deceptively promote unsafe and unsubstantiated uses of EPO to physicians.” Significantly, these paragraphs are nearly identical to the previous pleading, except for the fact that Plaintiffs have swapped the terms “unsubstantiated” and “unsafe and unproven” for “off-label.” Amgen argues that these “new” allegations are nothing more than a proxy for allegations of off-label promotion. The Court agrees; the only standard of proof of efficacy that Plaintiffs point to is FDA approval. *See, e.g., Am. Compl.* ¶ 63 (“EPO has not been *approved* to effectively treat cancer-related anemia.”); *Id.* at ¶ 64 (“EPO has not been proven to be effective in the treatment of anemia in MDS patients *as the FDA has not approved it for such use.*”); *Id.* at ¶ 69 (“This statement is false and misleading, *evidenced in part by the*

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FDA's refusal to approve such use."); *Id.* at ¶ 70 (The use of EPO in patients with anemia of cancer (as opposed to chemotherapy-induced anemia), and in patients with MDS, have not been proven to be effective and/or safe and *were not among the FDA-approved uses of EPO.*") (all emphasis added). These allegations clearly demonstrate that Plaintiffs' asserted causes of action remain claims of misbranding (*i.e.*, promotion of non-FDA-approved uses) in disguise, not claims of false advertising or other fraudulent conduct.³

Furthermore, as the Court noted in its previous order of dismissal, Rule 9(b) requires Plaintiffs to explain how specific information booklets, CME programs, and promotional materials that Amgen provided to physicians were false or deceptive. To merely assert that Amgen promoted EPO for "ineffective" or "unapproved" uses, without more, will not pass muster under Fed. R. Civ. P. 9(b). *See In re Actimmune Mktg. Litig.*, – F. Supp. 2d – , 2009 WL 1139585, at *16 (N.D. Cal. Apr. 28, 2009) (generalized allegations that drugmaker promoted false belief that drug was effective in treating particular condition and concealed adverse study results while releasing positive findings insufficient to state a fraud claim). Many of the statements which Plaintiffs point to appear to be simple statements of fact—or perhaps nonactionable puffery—about beneficial uses of EPO. *See, e.g., Am. Compl.* ¶ 60 ("One [email to physicians] highlighted an article suggesting that off-label use of EPO may be beneficial in treating critically ill patients by decreasing hospital stays and reducing the need for transfusions."); *Id.* at ¶ 61 ("[T]his brochure contained extensive coverage of studies suggesting that EPO was beneficial for many uses, including anemia of cancer."). To survive a motion to dismiss, Plaintiffs must show that Amgen's actions went beyond presenting its drugs in the best light possible and crossed the line into actionable fraud. *See In re Actimmune*, 2009 WL 1139585, at *16 (noting distinction between mere puffery and actionable fraud). By way of example, if Amgen had falsely represented in its informational materials that EPO was FDA-approved for an off-label use, such conduct would almost certainly be fraudulent. Similarly, if Plaintiffs alleged that Amgen made untrue statements about the results of a particular study, this would likely support a fraud-based RICO and/or state consumer law claim. As currently pled,

³ As the Court previously explained, off-label promotion is not inherently fraudulent. *See In re Epogen*, 590 F. Supp. 2d at 1289; *see also Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 67-68 (D.D.C. 1998) (claims of drug's effectiveness are not untruthful or inherently misleading simply because a use is not an FDA-approved indication), *vacated in part on other grounds*; *United States v. Caputo*, 288 F. Supp. 2d 912, 921 (N.D. Ill. 2003) (sophistication of audience is taken into account when evaluating whether off-label promotion to physicians was misleading).

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however, Plaintiffs have not stated any particularized facts which, if true, establish that Amgen fraudulently misrepresented the effectiveness of EPO. The inclusion of conclusory adjectives (“false” and “deceptive”), without more, is insufficient to cure the deficiencies of the previous pleading.

Plaintiffs next point to paragraphs 71-76, which purportedly “explain that Amgen concealed and minimized the results of tests showing higher incidents [sic] of heart attacks, strokes, tumor growth, and death from off-label uses of EPO,” and paragraphs 77 and 78, which “explain that Amgen concealed and denied the truth about the dangers of its products.” Plaintiffs have identified two studies, one in 2003 and one in 2006, which found higher incidence of death and tumor growth in cancer patients being treated with EPO. *Am. Compl.* ¶¶ 72, 75. The Amended Complaint avers that Amgen was aware of the adverse findings but did not publicly disclose them. Again, however, Plaintiffs have failed to state a claim for fraud because they have not alleged that Amgen had a duty to disclose these study results, much less such a duty to Plaintiffs. *See Chiarella*, 445 U.S. at 227-28; *Am. United Life Ins. Co. v. Martinez*, 480 F.3d 1043, 1065 (11th Cir. 2007) (to state a RICO claim for fraudulent concealment, plaintiff must allege a duty to disclose).

Finally, Plaintiffs highlight paragraphs 79 through 91, which, according to them, “allege that Amgen eventually was forced to admit EPO’s health risks.” These paragraphs describe the public release of adverse study results pertaining to EPO, various reactions thereto, and the events that followed, including the de-listing of Aranesp as an accepted treatment for anemia of cancer by the publishers of USP-DI and the new “black box” FDA warning for off-label uses of EPO. There are no allegations here which could arguably support a RICO or state consumer fraud claim. Indeed, most of these paragraphs describe actions by individuals and entities other than Amgen.

Plaintiffs also argue that “their claims for violations of FDA regulations are not preempted by section 337, and this Court should reverse its decision to the contrary.” Plaintiffs misunderstand the law and the Court’s previous order. The Court never held that Plaintiffs’ claims were *preempted* by the FDCA. Rather, it found that Plaintiffs could not predicate RICO and state consumer fraud claims on what are, in essence, misbranding claims, absent allegations that Amgen made false or deceptive statements. This is because off-label promotion is not inherently fraudulent; *truthful* off-label promotion of drugs does not violate RICO or state consumer protection laws. Rather, it violates the FDCA. But the law is very clear in that only the federal government, and not a private plaintiff, may enforce the FDCA. In other words, the Court dismissed Plaintiff’s previous pleading because it failed to state a cognizable fraud

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claim—not because it stated a fraud claim that was preempted by the FDCA.⁴ (Indeed, the Court explicitly recognized that Plaintiffs could state a claim by identifying specific representations by Amgen that were literally false, misleading, or contained material omissions, *even if* those

⁴ In its previous order, this Court implicitly held that the FDCA does not preempt state law claims of fraud or false advertising:

The existence of the FDCA does not completely preclude injured parties from asserting claims of fraud or false advertising. Other legislation, state and federal, remains in effect to protect consumers from false and deceptive prescription drug advertising. *See, e.g., Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 934 (C.D. Cal. 2006) (discussing the interplay of the Lanham Act and the FDCA). “The FDCA is not focused on the truth or falsity of advertising claims, but is instead directed to protect the public by ensuring that drugs sold in the marketplace are safe, effective and not misbranded, a task vested in the FDA to implement and enforce.” *Id.* at 933 (internal quotation marks omitted) (citing *Sandoz*, 902 F.2d at 230). As the Second Circuit has explained, “[t]he FDA’s authority in th[e] field [of advertising] derives from the requirement that no drug may be sold in the United States unless it has FDA approval, and then only within the standards set by the FDA.” *Sandoz*, 902 F.2d at 226. In other words, the main purpose of the advertising restrictions set forth in the FDCA and its accompanying regulations is not to protect consumers from deceptive advertising, but rather to further the FDCA’s underlying goal of ensuring the safety of prescription drugs. “[C]onstraining the marketing options of manufacturers is one of the few mechanisms available to the FDA to ensure that manufacturers will not seek approval only for certain limited uses of drugs, then promote that same drug for off-label uses, effectively circumventing the FDA’s new drug requirements.” *United States v. Caronia*, 576 F. Supp. 2d 385, 401 (E.D.N.Y. 2008) (citing *Wash. Legal Found.*, 13 F. Supp. 2d at 72); *see also Caputo*, 288 F. Supp. 2d at 921 (vacated on other grounds).

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representations involved off-label promotion or otherwise fell within the purview of the FDCA.⁵

In support of its fourth cause of action for violation of California's UCL, Plaintiffs allege additional "wrongful conduct" which led to the "extraction of excessive and illegal payments from Plaintiffs and Class members." *Am. Compl.* ¶ 105. According to the Amended Complaint, Amgen "promoted intravenous administration of EPO though false statements regarding the necessity of intravenous administration of EPO to dialysis patients, on the basis that subcutaneous injections resulted in greater risk of pure red cell aplasia." *Am. Compl.* ¶ 111. Plaintiffs point to only one specific statement that was allegedly fraudulent: In November 2005, Amgen issued a "Dear Health Care Professional" letter which warned health care providers of the risk of pure red cell aplasia in patients treated with Aranesp. *Am. Compl.* ¶ 112. "[S]ignificantly, the letter notes that reports of pure red cell aplasia were 'predominantly in patients with [chronic renal failure] receiving Aranesp by subcutaneous administration.'" *Id.* According to Plaintiffs, this letter was deceptive because increased incidence of pure red cell aplasia was largely attributable to contamination of the drug from uncoated rubber syringe stoppers during the dispensing and administration of EPO. *Id.*

These allegations fail to meet the heightened pleading standard for fraud because Plaintiffs have not adequately explained how the letter was false or deceptive. *See In re GlenFed, Inc. Sec. Litig.*, 42 F.3d at 1548. Plaintiffs simply quote the letter as stating that "reports of pure red cell aplasia were 'predominantly in patients with [chronic renal failure] receiving Aranesp by subcutaneous administration.'" *Id.* There is no indication that this statement was untrue at the time it was made; that is, Plaintiffs have not averred that reports of pure red cell aplasia were *not* predominantly in patients with chronic renal failure receiving Aranesp by subcutaneous administration. The Amended Complaint suggests that the letter was deceptive because Amgen failed to reveal that the predominant *cause* of pure red cell aplasia in these patients was contamination from syringe stoppers. However, Plaintiffs have not suggested that Amgen fraudulently misrepresented the cause of pure red cell aplasia or had a duty to disclose information beyond that contained in the letter.

Plaintiff's remaining allegations are too generalized to state a fraud claim. They repeatedly refer to Amgen's alleged promotion of "the misconception that it was safer for patients on dialysis to receive Aranesp intravenously rather than through smaller doses received

⁵ The Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. —, 128 S. Ct. 999, 169 L. Ed. 2d 892 (2008) and *Wyeth v. Levine*, 555 U.S. —, 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), do not effect this Court's holding.

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subcutaneously.” *E.g., Am. Compl.* ¶ 113. Plaintiffs seem to infer that Amgen’s conduct was fraudulent in pushing intravenous administration over subcutaneous administration because the former is more profitable for the drugmaker, since subcutaneous administration requires a lower dose of the medication. However, “the mere objective of a company . . . to maximize profits is not in and of itself evidence of fraud.” *In re Actimmune*, 2009 WL 1139559, at *15. It does not follow that, by pointing out risks involved in the cheaper method of administration, Amgen was necessarily engaging in fraud.

IV. Conclusion

For the foregoing reasons, the Court GRANTS Amgen’s motion to dismiss. Although Fed. R. Civ. P. 15(a) requires that leave to amend be freely given “when justice so requires,” a court has broad discretion to deny leave to amend where a plaintiff has previously amended the complaint. *Allen v. City of Beverly Hills*, 911 F.2d 367, 373 (9th Cir. 1990). In the instant case, the Court previously identified, in detail, the deficiencies in the complaint and granted leave to amend. However, Plaintiffs have made few substantive changes and added no new facts in support of their allegations of fraud. Instead, they filed an Amended Complaint with semantic changes that did nothing to cure the previous fatal defects. Accordingly, dismissal is with prejudice.

The Clerk is directed to close the following cases: CV 07-3623 PSG (AGR_x), CV 07-3880 PSG (AGR_x), CV 07-5157 PSG (AGR_x), CV 07-5332 PSG (AGR_x), and CV 07-5620 PSG (AGR_x).

IT IS SO ORDERED.

NOTICE PARTY SERVICE LIST

Case No. _____ Case Title _____

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ADR
BAP (Bankruptcy Appellate Panel)
BOP (Bureau of Prisons)
CA St Pub Defender (Calif. State PD)
CAAG (California Attorney General's Office - Keith H. Borjon, L.A. Death Penalty Coordinator)
Case Asgmt Admin (Case Assignment Administrator)
Chief Deputy Admin
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Clerk of Court
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Dep In Chg E Div
Dep In Chg So Div
Federal Public Defender
Fiscal Section
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Intake Section, Criminal SA
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MDL Panel
Ninth Circuit Court of Appeal
PIA Clerk - Los Angeles (PIALA)
PIA Clerk - Riverside (PIAED)
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PSA - Los Angeles (PSALA)
PSA - Riverside (PSAED)
PSA - Santa Ana (PSASA)
Schnack, Randall (CJA Supervising Attorney)
Statistics Clerk

US Attorneys Office - Civil Division -L.A.
US Attorneys Office - Civil Division - S.A.
US Attorneys Office - Criminal Division -L.A.
US Attorneys Office - Criminal Division -S.A.
US Bankruptcy Court
US Marshal Service - Los Angeles (USMLA)
US Marshal Service - Riverside (USMED)
US Marshal Service -Santa Ana (USMSA)
US Probation Office (USPO)
US Trustee's Office
Warden, San Quentin State Prison, CA

	ADD NEW NOTICE PARTY (if sending by fax, mailing address must also be provided)
Name:	
Firm:	
Address (include suite or floor):	
*E-mail:	
*Fax No.:	

* For CIVIL cases only

	JUDGE / MAGISTRATE JUDGE (list below):

Initials of Deputy Clerk _____