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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

Case No.	MDL 08-1934 PSG (AGRx)	Date	December 17, 2008
Title	In re: Epogen & Aranesp Off-Label Marketing & 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 on Defendants' Motions to Dismiss

Before the Court are Defendants' separate motions to dismiss the Complaint. The Court heard oral argument on the matter on November 3, 2008. For the reasons set forth below, the Court DISMISSES the complaint with leave to amend.

I. Background

A. The Parties

Plaintiff Sheet Metal Workers National Health Fund ("SMW") 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, as well as to their dependents. Plaintiff Painters District Counsel 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 Linda A. Watters, Commissioner, Offices of Financial and Insurance Services for the State of Michigan, has sued in her capacity as liquidator of Michigan Health Maintenance Organization Plans, Inc., formerly known as Omnicare Health Plan, Inc. ("Omnicare"). Omnicare was a private third-party payor who assumed the risk of payment for

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medical and prescription costs on behalf of the participants in its plan. Collectively, the foregoing parties are referred to as "Plaintiffs." Plaintiffs seek to represent a proposed class ("the Class") consisting of all persons and entities that paid any portion of the purchase price of Epogen and Aranesp when the drugs were prescribed for purposes not specified on their FDA-approved labels between May 21, 2002 and March 9, 2007 ("the Class Period").

Defendants are Amgen, Inc. ("Amgen"), one of the largest pharmaceutical companies in the United States; DaVita, Inc. ("DaVita"), a provider of dialysis services for patients suffering from chronic kidney failure, or end stage renal disease; and Fresenius Medical Care Holdings, Inc. ("Fresenius"), a wholly owned subsidiary of Fresenius Medical Care AG & Co., which operates dialysis services in the United States (collectively, "Defendants").

B. Factual Background

This action arises out of Defendants' allegedly unlawful promotion of two drugs: epoetin alfa, which Amgen markets in the United States as Epogen, and darbepoetin alfa, which Amgen markets in the United States as Aranesp (jointly referred to as "EPO"). *Consolidated Class Action Complaint* ("*Compl.*") ¶ 3. Both of these drugs are known as erythropepoiesis-stimulating agents, or ESAs, because they stimulate the production of red blood cells. *Compl.* ¶ 4.

The Food and Drug Administration ("FDA") approved Epogen in 1989 for the treatment of anemia in chronic renal failure patients (whether or not they are on dialysis), HIV-infected patients, cancer patients on chemotherapy, and for surgery patients to reduce allogeneic blood transfusion. *Compl.* ¶¶ 40, 42. Epogen's 2005 FDA-approved package insert regarding dosage and administration for patients with chronic renal failure states that "EPOGEN® may be given either as an IV or SC injection. In patients on hemodialysis, the IV route is recommended."[1] *Compl.* ¶ 47. The insert further states that "the dose should be adjusted for each patient to achieve and maintain a target hemoglobin not to exceed 12 g/dL." *Id.* In 2001, the FDA approved a similar drug, Aranesp, for the treatment of anemia associated with chronic renal failure. *Compl.* ¶ 48. In July 2002, the FDA approved Aranesp for the treatment of chemotherapy-induced anemia. *Compl.* ¶ 48.

From 2002 to at least 2007, Amgen issued a number of press releases touting the positive

[1] IV refers to intravenous injection, and SC refers to subcutaneous injection.

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results of clinical studies on the off-label use of Aranesp. *Compl.* ¶¶ 54-56, 59-60, 62-63, 65-70.) Many of these press releases did not reveal that the studies were not conducted by independent researchers and instead were funded by Amgen. *Compl.* ¶¶ 56, 59, 60, 62. According to the Complaint, Amgen also promoted off-label uses of EPO to physicians and the public by funding third-party organizations that provided educational materials, Continuing Medical Education ("CME") programs, and physician brochures highlighting the off-label uses of EPO. *Compl.* ¶¶ 71-87. 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. *Compl.* ¶¶ 88-90, 92-93. Plaintiffs refer to this allegedly fraudulent scheme as the "Off-Label Marketing Enterprise" ("OLME").

Additionally, Amgen entered into drug supply contracts with Defendants DaVita and Fresenius that provided volume-based discounts and other incentives for increased use of EPO. *Compl.* ¶¶ 7, 125. The Complaint alleges that Defendants engaged in a scheme to boost profits by unlawfully 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. *Compl.* ¶¶ 7, 128. Plaintiffs refer to this scheme as the "Kidney Dialysis Enterprise" ("KDE").

On February 16, 2007, *The Cancer Letter* published an article about the results of an October 2006 study regarding Aranesp's effectiveness on patients with head and neck cancer which had been closed early due to increased mortality rates. *Compl.* ¶¶ 10, 104. On March 9, 2007, the Food and Drug Administration ("FDA") mandated a "black box" warning for the off-label use of EPO. *Compl.* ¶¶ 11, 109. The warning cautioned that use of ESAs 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 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." *Compl.* ¶ 109. 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. *Compl.* ¶ 110.

C. Procedural Background

Initially, Plaintiffs in this MDL proceeding brought separate cases in the Central District

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of California. At various times, 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 Defendants engaged in a fraudulent scheme that caused Plaintiffs and the Class to pay millions of dollars for EPO prescribed for ineffective and unsafe off-label uses. *Compl.* ¶ 151. Presently before this Court are Amgen, DaVita, and Fresenius's separate motions to dismiss the Complaint. With leave of the Court, Plaintiffs filed a single brief in opposition to Defendants' motions.

II. Legal Standard

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 do." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1965, 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 Dept.*, 901 F.2d 696, 699 (9th Cir. 1990).

III. Requests for Judicial Notice

As a threshold matter, the Court considers DaVita's requests for judicial notice. On a motion to dismiss, the Court may take judicial notice of facts that are not "subject to reasonable dispute." *Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001). Under Fed. R. Evid. 201, a fact is not subject to reasonable dispute when it is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." The Court grants DaVita's request as to Exhibits 1-4, labels for Epogen that are publicly available on the FDA website, finding that the labels are documents not subject to reasonable dispute. *See In re Amgen Inc. Secs. Litig.*, 544 F. Supp. 2d 1009, 1023 (C.D. Cal. 2008).

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IV. Discussion

Plaintiffs allege four causes of action: (1) violation of 18 U.S.C. § 1962(c) against Amgen in connection with the OLME, (2) violation of 18 U.S.C. § 1962(c) against all Defendants in connection with the KDE, (3) violation of California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200 *et seq*., and (4) violation of California's Fair Advertising Law, Cal. Bus. & Prof. Code §§ 17500 *et seq*.

In Counts 1 and 2, Plaintiffs allege that Defendants violated section 1962(c) of the Racketeer Influenced and Corrupt Organizations Act ("RICO"), which makes it "unlawful for any person employed by or associated with" an enterprise engaged in or affecting interstate commerce "to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c). The term "racketeering activity" includes a number of so-called "predicate acts," including mail and wire fraud. *See* 18 U.S.C. § 1961(1). In this case, Plaintiffs allege that Defendants' unlawful promotion of EPO for unsafe, off-label uses constituted a pattern of racketeering activity, including mail and wire fraud.

The Complaint also alleges that Defendants engaged in unfair, deceptive, and fraudulent business practices which violated California's consumer fraud laws. Specifically, Plaintiffs claim that these practices included:

> (1) Fostering the false belief that EPO was safe for off-label uses and at doses exceeding the FDA-approved label;
>
> (2) Marketing and promoting use of EPO outside of the approved FDA indication, i.e., for off-label use;
>
> (3) Concealing adverse results of clinical trials and selectively disclosing positive study results; and
>
> (4) Encouraging unnecessary intravenous administration of EPO in dialysis patients that risked raising hemoglobin to dangerously high levels.

See Compl. ¶¶ 177(a)-(c), 184(a)-(c).

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Defendants argue that each of Plaintiffs' causes of action constitutes an impermissible attempt to bring a private cause of action under the Food, Drug, and Cosmetics Act ("FDCA" or "the Act"), 21 U.S.C. § 301 *et seq.*, and its implementing regulations. Defendants contend that the action should be dismissed in its entirety on this ground.

The FDCA, which grants the FDA authority to oversee the safety of drugs, provides that "all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States." 21 U.S.C. § 337(a). "Courts have generally interpreted this provision to mean that no private right of action exists to redress alleged violations of the FDCA." *Summit Tech., Inc. v. High-Line Med. Instruments, Co., Inc.*, 922 F. Supp. 299, 305 (C.D. Cal. 1996) (hereinafter "*Summit I*") (citations omitted). Instead, "the right to enforce the provisions of the FDCA lies exclusively within the federal government's domain, by way of either the FDA or the Department of Justice." *Id.*

In the present case, the Court finds that Plaintiffs' suit is largely an attempt to bring a private cause of action for violations of the FDCA. Under FDA regulations, drug manufacturers are prohibited from promoting off-label uses of prescription drugs. 21 C.F.R. § 202.1(e)(6); *see also United States v. Caronia*, 576 F. Supp. 2d 385, 389 (E.D.N.Y. 2008). Dissemination of an advertisement not in compliance with FDA regulations causes a drug to be "misbranded" in violation of the FDCA. 21 C.F.R. § 202.1(j)(3); 21 U.S.C. § 352(n). The Complaint outlines in detail a number of relevant provisions of the FDCA:

> All advertisements for an FDA-approved prescription drug must present a 'true and brief summary' relating to the drug's side effects, contraindications and effectiveness. 21 C.F.R. § 202.1(e)(1). *Advertisements may not recommend or suggest any unapproved use.* 21 C.F.R. § 202.1(e)(4).
>
> An advertisement does not satisfy the requirement that it present a true statement of information in brief summary relating to side effects, contraindications, and effectiveness if: (i) it is false or misleading with respect to side effects, contraindications, and effectiveness; or (ii) if it fails to present a fair balance between information relating to side effects and contraindications and information relating to effectiveness; or (iii) it fails to reveal facts material in the light of its representations or material with respect to consequences that may result from the use of the drug as

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recommended or suggested in the advertisement. 21 C.F.R. § 202.1(e)(5).

Pursuant to applicable regulations, an advertisement for a prescription drug is false, lacking in fair balance, or otherwise misleading, among other reasons, if it: (I) *contains a representation or suggestion, not approved or permitted for use in the labeling, that a drug is useful in a broader range of conditions or patients than has been demonstrated by substantial evidence or substantial clinical experience*; (ii) contains favorable information or opinions about a drug previously regarded as valid but which have been rendered invalid by contrary and more credible recent information; or (iii) contains a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience. 21 C.F. R. § 202.1(e)(6).

No advertisement concerning a particular prescription drug may be disseminated without the approval of the FDA if the sponsor has received information that has not been widely publicized in medical literature that the use of the drug may cause fatalities or serious damage. 21 C.F.R. § 202.1(j)(1)(I). *Dissemination of an advertisement not in compliance with this requirement is deemed to be an act that causes the drug to be misbranded in violation of the FDCA.*

Although the FDCA allows a manufacturer to disseminate to health care practitioners and third-party payors written information concerning the safety, effectiveness or benefits of an unapproved use of a drug . . . the information disseminated may not be false or misleading or pose a significant risk to the public health. 21 U.S.C. § 360aaa-1(a)(2). Moreover, a manufacturer that disseminates information on unapproved uses to health care practitioners and third-party payors pursuant to these regulations is required to notify the FDA of any additional knowledge the manufacturer obtains on clinical research or other data that related to the safety or effectiveness of the new use involved. 21 U.S.C. § 360aaa-4(a)(2). The FDCA prohibits the dissemination of information concerning unapproved uses in violation of these provisions. 21 U.S.C. § 331(z).

Compl. ¶¶ 31-34, 37 (emphasis added.)

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Although Plaintiffs have avoided explicit references to "misbranding" in their Complaint, their RICO and state law claims are primarily based on allegations that Defendants promoted EPO for off-label uses. For example, Plaintiffs allege that Defendants "engaged in a massive scheme to defraud Plaintiffs and the Class . . . and substantially increase sales of [EPO] by unlawfully promoting the use of these drugs for unsafe purposes and at dangerous doses not specified on the drugs' [FDA-]approved labels (i.e., off label promotion)." *Compl.* ¶ 3. The Complaint is rife with similar references to illegal off-label promotion, *see, e.g.*, *Compl.* ¶¶ 5, 7, 14, 54, 71, 80, 85, 119, 123, and Plaintiffs seek to enjoin the illegal promotion. These allegations of off-label promotion are, in essence, misbranding claims that should be reviewed by the FDA. *See Healthpoint, Ltd. v. Stratus Pharms., Inc.*, 273 F. Supp. 2d 769, 786 (W.D. Tex. 2001).

Moreover, although Plaintiffs' RICO claims are purportedly based on predicate acts of mail and wire fraud, the main thrust of their allegations is that Defendants illegally promoted EPO for off-label uses, *not* that Defendants promoted EPO through false, misleading, or otherwise fraudulent statements. Notably, Plaintiffs identify the purpose of the RICO enterprises as: (1) "to profit from the unlawful marketing and sale of EPO for off-label use and to extract excessive and illegal payments from Plaintiffs and Class Members," and (2) "to profit from increased sales of EPO by promoting wasteful dispensing and administration practices that had the effect of achieving a hemoglobin level of 13 g/dL and above - an unlawful off-label use of these drugs - and thereby extract excessive and illegal payments from Plaintiffs and Class Members." *Compl.* ¶¶ 119, 123. Thus, Plaintiffs seem to assume that off-label promotion is inherently fraudulent.

For example, the Complaint alleges that DaVita unlawfully promoted the intravenous administration of EPO by posting an article on its website that stated: "Most patients with anemia due to chronic kidney disease who are not yet on dialysis will receive it as an injection - directly under the skin. Most patients with renal failure on hemodialysis will get the hormone during each treatment by intravenous injection into the return dialysis tubing." *Compl.* ¶ 129. Even assuming that DaVita's statement did constitute an off-label promotion of EPO, Plaintiffs have not alleged that the statement was fraudulent. "Promotion of off-label uses is not inherently misleading simply because the use is off-label." *Caronia*, 576 F. Supp. 2d at 397; *see also United States v. Caputo*, 288 F. Supp. 2d 912, 921 (N.D. Ill. 2003) (manufacturer promotion of off-label uses was potentially misleading, but not inherently so). Plaintiffs have not alleged that the statement on DaVita's website is literally false, misleading, or contains a material omission. Because Plaintiffs fail to set forth how the statement on DaVita's website is fraudulent, it cannot support a charge of wire fraud. As to Fresenius, Plaintiffs' allegations are

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even more inadequate. The Complaint merely alleges generally that Fresenius "has a long history of promoting off-label usage of EPO." *Compl*. ¶ 130. The Complaint does not identify a single statement made by Fresenius that Plaintiffs claim was 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 1130, 1139 (4th Cir. 1993); *Summit I*, 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. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990).

For the foregoing reasons, the Court finds that this lawsuit largely constitutes an attempt to shoehorn allegations that Defendants have engaged in off-label promotion in violation of the FDCA into RICO and state consumer fraud causes of action. However, Plaintiffs *may* bring a RICO claim that is truly based on allegations of mail or wire fraud (in the form of deceptive advertising). This distinction, although perhaps difficult to grasp, is crucial. To the extent that Plaintiffs allege that Defendants made false statements or deliberately concealed material facts in order to mislead health care professionals and consumers about the safety of EPO, those claims are viable under RICO. *See In re Zyprexa Products Liability Litigation*, 493 F. Supp. 2d 571, (E.D.N.Y. 2007) (denying summary judgment for manufacturer where plaintiffs alleged that defendant's misrepresentation of drug's safety misled plaintiffs to pay more for the drug than they would have absent defendant's fraud).

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 Pharms. v. Richardson-Vicks, Inc*., 902

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F.2d 222, 230 (3d Cir. 1990)). 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." *Caronia*, 576 F. Supp. 2d at 401 (citing *Wash. Legal Found. v. Friedman*, 13 F. Supp. 2d 51, 72 (D.D.C. 1998)); *see also Caputo*, 288 F. Supp. at 921 (vacated on other grounds).

As discussed above, plaintiffs may not use other federal statutes or state unfair competition laws as a vehicle to bring a private cause of action that is based on violations of the FDCA. *Mut. Pharm.*, 459 F. Supp. 2d at 935. Nonetheless, some false statements made in connection with prescription drug marketing are actionable under state or federal law, "even if their truth may be generally within the purview of the FDA." *Summit Technology, Inc. v. High-Line Med. Instruments*, 933 F. Supp. 2d at 918, 935 (C.D. Cal. 1996) ("*Summit II*"). For example, in *Mylan Laboratories, Inc. v. Matkari*, the plaintiff brought a Lanham Act claim for false advertising based on the defendant's allegedly false representation that its product was "bioequivalent" to plaintiff's product. 7 F.3d 1130, 1137-38 (4th Cir. 1993). The Court found that although FDA regulations define "bioequivalence," the claim could proceed because the plaintiff had alleged that the defendant's statement was literally false. *Id*. at 1138. Similarly, in *Grove Fresh Distrib., Inc. v. The Flavor Fresh Foods, Inc*., the plaintiff based Lanham Act and RICO claims on the defendant's purported misrepresentation that its product was 100% orange juice from concentrate. 720 F. Supp. 714, 715 (N.D. Ill. 1989). The court rejected defendants' argument that the suit was an attempt to circumvent the prohibition on private causes of action under the FDCA. It stated:

> The fact that Grove Fresh refers to or relies on a FDA regulation defining orange juice to support its Lanham Act claim is not grounds for dismissal. Although courts have held that there is no private cause of action under the FDCA, Grove Fresh has not brought suit directly under the FDCA or its accompanying regulations. Grove Fresh relies on the FDA regulation merely to establish the standard of duty which defendants allegedly failed to meet. Nothing prohibits Grove Fresh from using the FDCA or its

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accompanying regulations in that fashion.

Id. at 716.

Accordingly, here, to the extent that Plaintiffs have alleged that Defendants made statements that were fraudulent (i.e., literally false, misleading, or omitted material facts), their claims are actionable. *See United States v. Beecroft*, 608 F.2d 753, 757 (9th Cir. 1979) (deliberate concealment of material facts constitutes mail fraud). It is of no matter that the deceptive statements may have been made in order to promote off-label uses of EPO. "[T]he simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim" of fraud under another federal statute, such as RICO. *See Mut. Pharm.*, 459 F. Supp. 2d at 935; *see also Summit II*, 933 F. Supp. 2d at 935 ("If the allegedly false or misleading nature of a statement can be easily verified, then the fact that the determination of the truth of that statement was made by the FDA is immaterial so long as the party can also show the other requirements for establishing a [false advertising] claim.")

For example, Plaintiffs allege that Amgen issued a "Dear Health Care Professional" letter which warned that of the risk of pure red cell aplasia in patients with chronic renal failure receiving EPO by SC administration. *Compl.* ¶ 64. The Complaint further alleges that Amgen issued "this deceptive letter" despite its awareness of a study that demonstrated that SC administration of EPO was not the primary cause of increased incidence of pure red cell aplasia; rather, it was attributable to contamination of the drug from uncoated rubber syringe stoppers. *Id.* A fact-finder could determine whether this alleged omission was misleading or otherwise fraudulent without reference to FDA regulations governing the advertisement of prescription drugs. *See Summit II*, 933 F. Supp. at 933; *Grove Fresh*, 720 F. Supp. 2d at 716. Moreover, the FDA does not have special expertise that the Court should defer to in resolving this question. Therefore, Plaintiffs' RICO and state law causes of action, to the extent which they allege fraud *not* dependent on the FDCA's prohibition on off-label promotion, are valid. *See Summit II*, 933 F. Supp. at 943 (California UCL and FAL claims were not preempted by federal law so long as they were not merely vehicles for claims under the FDCA or FDA regulations). To hold to the contrary would mean that the FDA, not courts, would be responsible for resolving all questions of whether a statement made in connection with prescription drug advertising was false, misleading, or omitted a material fact. This Court would not extend the FDA's primary jurisdiction so far. *See Healthpoint*, 273 F. Supp. 2d at 792-93.

In sum, insofar as Plaintiffs' claims are based solely on allegations that Defendants

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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.

V. Conclusion

For the foregoing reasons, the Complaint is DISMISSED in its entirety with leave to amend.

IT IS SO ORDERED.