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UNITED STATES OF AMERICA ex rel. DAVID FRANKLIN, Plaintiff, v. PARKE-DAVIS, DIVISION OF WARNER-LAMBERT COMPANY, Defendant.

No. 96-CV-11651-PBS

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

147 F. Supp. 2d 39; 2001 U.S. Dist. LEXIS 9663

June 25, 2001, Decided

DISPOSITION:
[1]** Defendant's motion to dismiss DENIED in part and ALLOWED in part.

COUNSEL:
For DAVID FRANKLIN, Plaintiff: Thomas G. Hoffman, Thomas M. **Greene, Greene** & Hoffman, P.C., Boston, MA.

For PARKE-DAVIS, DIVISION OF WARNER-LAMBERT COMPANY, Defendant: Robert B. Fiske, Jr., James P. Rouhandeh, James E. Murray, Barbara D. Diggs, Davis Polk & Wardwell, New York, NY.

For PARKE-DAVIS, DIVISION OF WARNER-LAMBERT COMPANY, Defendant: David B. Chaffin, Hare & Chaffin, Boston, MA.

For UNITED STATES OF AMERICA, interested party: Thomas E. Kanwit, United States Attorney's Office, Boston, MA.

JUDGES:
PATTI B. **SARIS,** United States District Judge.

OPINIONBY:
PATTI B. **SARIS**

OPINION:

[*43]

MEMORANDUM AND ORDER

June 25, 2001

Saris, U.S.D.J.

In this *qui tam* action under the False Claims Act ("FCA"), *31 U.S.C. § 3729*-33, Relator Dr. David Franklin alleges, among other things, that his former employer engaged in a fraudulent scheme to promote the sale of the drug **Neurontin** for "off-label" uses (i.e., uses other than those approved by the Food and Drug Administration) and that this illegal marketing campaign caused the submission of false claims to the Veterans Administration and to **[**2]** the federal government for Medicaid reimbursement. n1 The Defendant has moved for dismissal based on Relator's failure to plead a claim of fraud with particularity pursuant to Fed. R. Civ. P. 9(b) and his failure **[*44]** to state a claim upon which relief may be granted pursuant to Fed. R. Civ. P. 12(b)(6).

n1 The complaint asserts the following counts: direct sales to the Veterans Administration (Count I); deliberate avoidance of FDA regulations/medicare and Medicaid financed sales (Count II); avoiding price controls/experimental use of drug (Count III); violating state formularies/Medicare and Medicaid (Count IV); illegal kickbacks (Count V); false statements to physician (Count VI); avoiding price controls based on therapeutic equivalency (Count VII); frustration of federal policy (Count VIII); illegal promotion of accupril (Count IX). The Relator has agreed to drop Count VII and VIII.

After hearing, Defendant's motion to dismiss is **DENIED** in part and **ALLOWED** in part.

I. BACKGROUND

As it **[**3]** must on a motion to dismiss, the Court takes the facts alleged in the complaint and disclosure as true:

A. The Parties

Relator David Franklin ("Franklin" or "Relator") is a former employee of Defendant Parke-Davis, a division of Warner-Lambert Company. Franklin, who holds a doctorate degree in biology, was employed by Parke-Davis as a "medical liaison" for a period of approximately five months during 1996. He has co-authored five scientific publications, is an author of a pending patent application, and received a two-year research fellowship with Harvard Medical School and the Dana Farber Cancer Institute in Boston in 1992.

At the time of the events in question, Warner-Lambert Company was a corporation engaged in the manufacture and sale of pharmaceutical and consumer products. Defendant Parke-Davis was the company's pharmaceutical products division, which manufactured, marketed, and conducted research relating to prescription drugs. n2

> n2 In June 2000, Warner-Lambert, including the Parke-Davis division, was acquired by Pfizer, Inc., another pharmaceutical manufacturer.

[4]**

B. "Off-label" usage of pharmaceuticals

Under the Food, Drug, and Cosmetics Act ("FDCA"), *21 U.S.C. § § 301*-97, new pharmaceutical drugs cannot be distributed in interstate commerce unless the sponsor of the drug demonstrates to the satisfaction of the Food and Drug Administration ("FDA") that the drug is safe and effective for each of its intended uses. See *21 U.S.C. § 355*(a) & (d). Once a drug is approved for a particular use, however, the FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA. Allowing physicians to prescribe drugs for such "off-label" usage "is an accepted and necessary corollary of the FDA's mission to regulate [pharmaceuticals] without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 121 S. Ct. 1012, 1018, 148 L. Ed. 2d 854 (2001).* Though physicians may prescribe drugs for off-label usage, the FDA prohibits drug manufacturers from marketing or promoting a drug for a use that the FDA has not approved. See *21 U.S.C. § 331*(d) (prohibiting distribution **[**5]** of drug for non-approved uses); id. § 331(a) (prohibiting distribution of a "misbranded" drug). A manufacturer illegally "misbrands" a drug if the drug's labeling includes information about its unapproved uses. See *Washington Legal Foundation v. Henney, 340 U.S. App. D.C. 108, 202 F.3d 331, 333 (D.C. Cir. 2000).* If the manufacturer intends to promote the drug for new uses in addition to than those already approved, the materials on off-label uses must meet certain stringent requirements and the manufacturer must resubmit the drug to the FDA testing and approval process. *202 F.3d at 334* (setting forth the requirements in the Food and Drug Administration Modernization Act of 1997, *21 U.S.C. § 360aaa, et seq.*)

Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program. Reimbursement under **[*45]** Medicaid is, in most circumstances, n3 available only for "covered outpatient drugs." *42 U.S.C. § 1396b*(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not **[**6]** a medically accepted indication." Id. § 1396r-8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. Id. § 1396r-8(k)(6). See also id. § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

> n3 Payment for certain drugs that are not otherwise covered may be allowed where the drugs have been determined to be "essential to the health of beneficiaries." *42 U.S.C. § 1396r-8*(a)(3). This narrow exception has no application in this case.

C. Defendant's products

Neurontin, which is the brand name for the drug gabapentin, was approved by the FDA in 1994 for use as an adjunctive treatment for epilepsy in doses from 900 to 1800 mg per day. **[**7]** **Neurontin** is also used for a number of off-label purposes. For example, **Neurontin** is prescribed for pain control, as mono-therapy for epilepsy, for control of bipolar disease, and as treatment for attention deficit disorder. According to Relator, 50% of **Neurontin's** sales in 1996 are attributable to off-label uses. Of those sales, Relator estimates that 50% (or 25% of **Neurontin's** total sales) were reimbursed by the government either indirectly through Medicaid or

directly through purchases by the Veterans Administration.

Accupril, which is the brand name for the drug quinipril, is an angiotensin converting enzyme (ACE) inhibitor that has been approved for the control of hypertension and as a treatment for heart failure.

During the events in question, neither **Neurontin** nor Accupril were eligible for reimbursement from Medicaid when prescribed for an off-label use because neither drug's off-label uses were included in one of the compendia specified by *42 U.S.C. § 1396r-8*(g)(1)(B)(i).

D. Allegations regarding marketing of Neurontin and Accupril

The crux of Relator's allegations is that the Defendant engaged in an extensive and far-reaching campaign **[**8]** to use false statements to promote increased prescriptions of **Neurontin** and Accupril for off-label uses which caused the filing of false claims for reimbursement by the federal government.

Relator alleges that he was hired by Parke-Davis onto a team of "medical liaisons." While medical liaisons are ordinarily connected to the research divisions of the manufacturer, Parke-Davis's medical liaisons were exclusively employed as sales and promotion personnel.

Parke-Davis's medical liaisons, including Relator, were instructed to make exaggerated or false claims concerning the safety and efficacy of Parke-Davis drugs for off-label uses. They were also trained to convey that **Neurontin** could be prescribed for its various off-label uses in amounts of up to 4800 mg per day--far above the maximum dosage of 1800 mg per day approved by the FDA. To bolster their representations to physicians, medical liaisons were encouraged to misrepresent their scientific credentials and to pose as research personnel, rather than as sales representatives.

Relator also alleges the doctors were rewarded with kickbacks for prescribing large quantities of Parke-Davis drugs. **[*46]** These alleged kick-backs took various **[**9]** forms. For instance, some doctors were allegedly paid sums of money which were ostensibly compensation for drug studies. However, Relator alleges these studies were shams and had no scientific value. Other doctors were allegedly paid sums of money under the guise of being compensated for their services as "consultants" or "preceptors" or for participating in a "speakers bureau." Doctors were also allegedly given cash payments for small record-keeping tasks, such as allowing Parke-Davis access to information about the doctors' patients who were receiving **Neurontin.** There are also allegations that doctors prescribing large amounts of Parke-Davis drugs were given gifts such as travel and tickets to the Olympics.

According to Relator, when questions arose concerning the availability of reimbursement for prescriptions for off-label uses of Parke-Davis drugs, medical liaisons were instructed to coach doctors on how to conceal the off-label nature of the prescription. Relator also alleges that Parke-Davis took numerous actions to conceal its activities from the FDA, including shredding documents, falsifying documents, and encouraging medical liaisons to conduct their marketing activities **[**10]** without leaving a "paper trail" that might be discovered by the FDA.

E. Present action

Relator filed this nine-count *qui tam* action under seal on August 13, 1996. The case remained in limbo and under seal for several years while the United States mulled over its option to intervene. The seal on the complaint was finally lifted on December 21, 1999, and the litigation began in earnest. To date, the government has elected to participate only in the capacity of *amicus curiae* while reserving its right to intervene as a plaintiff at a later point.

II. ANALYSIS

A. Failure to plead fraud with particularity

1. Application of Rule 9(b) to FCA *qui tam* claims

Qui tam actions under the FCA must comply with Fed. R. Civ. P. 9(b), which requires that "the circumstances constituting fraud ... shall be stated with particularity." See United States *ex rel. Walsh v. Eastman Kodak Co., 98 F. Supp. 2d 141, 147 (D. Mass. 2000)* (applying heightened pleading requirement of Rule 9(b) to relator's *qui tam* claim). Relator must, at a minimum, set forth the "'who, what, when, where, and how' of the alleged fraud." Id. (quoting **[**11]** United States *ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997))*. To pass Rule 9(b) muster, the complaint must plead with particularity the time, place and contents of the false representations as well as the identity of the person making the false representations and what he obtained with them. See *Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 783-84 (4th Cir. 1999).* The particularity requirement of Rule 9(b) serves the purposes of enabling defendants to prepare meaningful defenses to charges of fraud, preventing conclusory allegations of fraud from serving as a basis for strike suits and fishing expeditions, and protecting defendants from groundless charges that may damage their reputations. See *New England Data Servs., Inc. v. Becher, 829 F.2d 286, 292 (1st Cir. 1987).*

The requirements of Rule 9(b), however, must be read in conjunction with Fed. R. Civ. P. 8(a), which requests "a short and plain statement of the claim" for relief. Thus, while Relator must allege the **[*47]** circumstances of the fraud, he is not required to plead all of the evidence or facts supporting it. See 5 Wright **[**12]** & Miller, Federal Practice and Procedure § 1298, at 625-26 (2nd ed. 1990) (stating that Rule 9(b) does not require plaintiff to resort to "fact pleading").

In addition, strict application of requirements of Rule 9(b) may be relaxed in certain circumstances. For instance, where facts underlying the fraud are "peculiarly within the defendants' control," a plaintiff may be excused from pleading the circumstances of the fraud with a high degree of precision. *Boston & Me. Corp. v. Hampton, 987 F.2d 855, 866 (1st Cir. 1993).* See also Wilkins *ex rel. United States v. Ohio, 885 F. Supp. 1055, 1061 (S.D. Ohio 1995)* (allowing *qui tam* relator to plead certain facts on information and belief). In other instances, the alleged scheme of fraud may involve numerous transactions or transactions that occur over a long period of time, and pleading the specifics with regard to every instance of fraudulent conduct may be impractical. See *Corley v. Rosewood Care Ctr., Inc., 142 F.3d 1041, 1050 (7th Cir. 1998)* (applying relaxed standard to allegations of fraud in plaintiff's racketeering complaint); see also United States *ex rel. Johnson v. Shell Oil Co., 183 F.R.D. 204, 206-07 (E.D. Tex. 1998)* **[**13]** (collecting cases that apply relaxed standard).

2. The Disclosure

Although Relator's complaint alleges a general framework of what might be actionable FCA claims, those allegations standing alone lack the specificity required under Rule 9(b). The complaint does not disclose the "who, what, when, where, and how" of the alleged fraud. Recognizing the likely faults of the complaint, Relator has urged this Court to consider the more specific information concerning Parke-Davis's alleged FCA violations contained in Relator's disclosure to the government pursuant to *31 U.S.C. § 3730*(b)(2). n4 The disclosure essentially recounts Franklin's experience as a "medical liaison" employed by Parke-Davis and is supported by approximately twenty exhibits. The disclosure is referenced in the complaint, and Relator has provided copies to both the Court and Defendant.

n4 Section 3730(b)(2) provides: "A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the government pursuant to Rule 4(d)(2) of the Federal Rules of Civil Procedure."

[14]**

Although Section 3730(b)(2) does not displace the pleading requirements in Fed. R. Civ. P. 9(b), it does serve many of the same salutary policy objectives (i.e., precluding strike suits, permitting the preparation of meaningful defenses, etc.). "A court should hesitate to dismiss a complaint under Rule 9(b) if the Court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts." *Harrison, 176 F.3d at 784.* In light of this admonition, it is appropriate to look to disclosure to determine whether the Relator has supplied sufficient allegations concerning the circumstances of the fraud to permit this action to go forward. This approach makes sense because the disclosure is referenced in the complaint, and documents referenced in the complaint are routinely considered as part of the pleadings. See, e.g., United States *ex rel. Wilkins v. North Am. Constr. Corp., 101 F. Supp. 2d 500, 513 (S.D. Tex. 2000)* (considering facts in documents attached to qui tam relator's complaint). Cf. also Fed. **[**15]** R. Civ. P. 10(c) ("A copy of any written instrument **[*48]** which is an exhibit to a pleading is a part thereof for all purposes."). Although the Court will consider the allegations in the disclosure for purposes of evaluating Defendant's motion to dismiss, the disclosure is a thirty-one page single spaced document in narrative form with attached documents. An answer pursuant to Fed. R. Civ. P. 8(b) and Fed. R. Civ. P. 11 is impracticable. Accordingly, the Court will require plaintiff to amend the complaint to meet the pleading requirements of Fed. R. Civ. P. 9(b).

3. Sufficiency of the Allegations

a. Neurontin

Viewed in light of the disclosure, Relator's complaint contains allegations of fraud sufficient to satisfy Rule 9(b): Counts II and IV describe a scheme of fraud designed to increase the submission of off-label prescriptions for **Neurontin** for payment by Medicaid; and Count VI describes false statements made to physicians to induce off-label prescriptions for **Neurontin.** As far as the "who" in these counts is concerned, the disclosure identifies by name the individuals at Parke-Davis who instructed the medical liaisons on how to fraudulently promote off-label use of **Neurontin. [**16]** It also lists the medical liaisons by name. In addition, the disclosures and exhibits identify the physicians who were contacted and allegedly given false information and kickbacks in return for increasing their off-label use of **Neurontin.** Relator adequately identifies the "what" by alleging that Defendant's

conduct resulted in the submission of numerous **Neurontin** prescriptions that were ineligible for reimbursement under Medicaid because they were prescribed for an off-label use. The "when" of Relator's complaint is confined to the time-frame during which Relator was employed as a Parke-Davis medical liaison in its Northeast Customer Business Unit. Finally, the "how" of the alleged fraud is detailed in the portions of the complaint and disclosure that describe a fraudulent marketing campaign conducted by Parke-Davis in which kickbacks and unlawful and misleading marketing were allegedly used to encourage doctors to increase their use of **Neurontin** for unapproved purposes.

Dr. Franklin cites at least eleven specific examples of fraudulent statements which medical liaisons (including himself) were trained to give to physicians, and did give to physicians, to induce the purchase of **Neurontin [**17]** for off-label uses, including the following:

. Upon order of the company and as a result of training of medical liaisons, Dr. Franklin "deliberately contrived reports to mislead physicians into believing that a body of data existed that demonstrated the effectiveness of **Neurontin** in the treatment of bipolar disease." In fact, no data existed at all to support the use of **Neurontin** in bipolar disease. (Disclosure at 22-23).

. Dr. Franklin was trained and instructed to actively deceive physicians with contrived data, falsified "leaks" from clinical trials, scientifically flawed reports, or "success stories" that stated that **Neurontin** was highly effective in the treatment of a variety of pain syndromes. No such body of evidence existed. (Id. at 23.)

. He was instructed to advise physicians that Parke-Davis had developed a large body of data to support the use of **Neurontin** as mono-therapy. This was an "outright lie" and left patients unknowingly without good seizure control. (Id. at 24.)

. Medical liaisons were instructed to tell physicians that a great deal of data existed that supported the safe use of **Neurontin** at levels that exceed 4800 mg **[*49]** per day. However, **[**18]** clinically significant safety data existed at dosing levels at only 1800 mg per day. (Id. at 25.)

. Parke-Davis provided medical liaisons with slides that stated that **Neurontin** was effective for the treatment of Attention Deficit Disorders but no data existed to support that claim (Id.)

Defendant contends that the pleading of the basic scheme of fraud or the identification of certain instances of fraudulent conduct does not satisfy Rule 9(b). Indeed, Defendant goes so far as to argue that Rule 9(b) requires no less than the identification of every ineligible prescription submitted to the government for payment. This view of Relator's pleading obligation may fit a scenario where the alleged fraud is confined to a small number of transactions about which Relator had knowledge. However, where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible. Courts facing similar claims under the FCA have not placed the bar so high as to require pleading with total insight. See United States *ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1049 (S.D. Tex. 1998)* **[**19]** (holding relator satisfied Rule 9(b) by alleging the "basic framework, procedures, the nature of fraudulent scheme, and the financial arrangements and inducements among the parties and physicians that give rise to Relator's belief that fraud has occurred"); *United States v. Kensington Hosp., 760 F. Supp. 1120, 1125 (E.D. Pa. 1991)* (requiring government in FCA action to plead only the time-frame, the clinics involved, and the types of kickbacks involved); United States *ex rel. Pogue v. American Healthcare Corp., 977 F. Supp. 1329, 1332-33 (M.D. Tenn. 1997)* (permitting relator to omit allegations concerning each instance of fraudulent conduct); United States *ex rel. Downy v. Corning, Inc., 118 F. Supp. 2d 1160, 1172-73 (D.N.M. 2000)* (allowing relator to plead general scheme of fraud where information concerning individual instances of fraud could be sought during discovery).

To be sure, when a relator has access to the information regarding the alleged false claims, merely alleging a fraudulent scheme may not be sufficient. See, e.g., *Eastman Kodak Co., 98 F. Supp. 2d at 147-178* (holding that the chief financial **[**20]** officer of a hospital had sufficient access to the allegedly false cost reports resulting from the false invoices to require him to plead at least one example of a false claim with particularity). Although the Relator here does not identify specific prescriptions for Medicaid patients for off-label uses made by doctors in reliance on the fraudulent representations, Franklin (unlike the relator in Eastman Kodak) does not reasonably have pre-discovery access to that patient-specific information. n5

n5 That lacuna will have to be addressed at the summary judgment stage.

When considered alongside the disclosure, the complaint amply details both a general framework of the purported Medicaid fraud and provides more specific information on the individuals, locations, the precise

statements alleged to be false and time-frames involved. The complaint therefore satisfies the requirements of Rule 9(b) with respect to the off-label sale of **Neurontin** for Medicaid reimbursement (Counts II, IV, and VI).

b. Veterans [21] Administration**

Even when read alongside Relator's disclosure, Count I, which generally describes an FCA claim for promoting-label **[*50]** uses of **Neurontin** in direct sales to the Veterans Administration, is deficient. Relator's allegations do not specify which Parke-Davis personnel engaged in this conduct, where such conduct took place, which VA personnel were involved, or any specific fraudulent statements made to personnel at the Veterans Administration. It is dismissed.

c. Accupril

Count IX alleges the illegal promotion of Accupril. According to Franklin, the medical liaisons were told to tell physicians, including those at the Veterans Administration, that if a patient is on any other ACE inhibitor but Accupril, the studies showed that these patients would have more heart attacks, require more procedures, and die sooner. Relator alleges there was no credible scientific data to support these claims. (Disclosure at 28.) However, unlike the claims involving **Neurontin,** the Disclosure does not identify the liaisons involved in the fraud, the doctors who were given false information, or any false claims made. It is dismissed.

B. Failure to state a claim

1. Motion to [22] dismiss standard**

"Like a battlefield surgeon sorting the hopeful from the hopeless, a motion to dismiss invokes a form of legal triage, a paring of viable claims from those doomed by law." *Iacampo v. Hasbro, Inc., 929 F. Supp. 562, 567 (D.R.I. 1996)*. For purposes of this motion, the Court takes as true "the well-pleaded facts as they appear in the complaint, extending [the] plaintiff every reasonable inference in his favor." *Coyne v. City of Somerville, 972 F.2d 440, 442-43 (1st Cir. 1992)* (citing *Correa-Martinez v. Arrillaga-Belendez, 903 F.2d 49, 51 (1st Cir 1990)*. A complaint should not be dismissed under Fed. R. Civ. P. 12(b)(6) unless "'it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Roeder v. Alpha Indus., Inc., 814 F.2d 22, 25 (1st Cir. 1987)* (quoting *Conley v. Gibson, 355 U.S. 41, 45-46, 2 L. Ed. 2d 80, 78 S. Ct. 99 (1957))*.

2. Causing submission of false Medicaid claims

The FCA provides:

> Any person who--
> (1) knowingly presents, or causes to be presented, to an officer of employee of the **[**23]** United States Government a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government; is liable to the United States Government for a civil penalty ..., plus 3 times the amount of damages which the Government sustains because of the act of that person ....

31 U.S.C. § 3729(a) (emphasis added). An action may be brought under the False Claims Act only if there is "(1) ... a false statement or fraudulent course of conduct; (2) made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a 'claim')." *Harrison, 176 F.3d at 788*. As stated in *United States v. Neifert-White Co., 390 U.S. 228, 19 L. Ed. 2d 1061, 88 S. Ct. 959 (1968):*

> [The False Claims Act is] intended to reach all types of fraud, without qualification, that might result in financial loss to the Government .... The Act is broadly phrased to reach any person who makes or causes to be made any claim **[**24]** upon or against the United States .... The Court has consistently refused **[*51]** to accept a rigid, restrictive reading [of the Act] .... This remedial statute reaches beyond "claims" which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.

Id. at 232-33 (quotations and footnote omitted).

Here, the Relator has alleged in Counts II, IV, and VI that Parke-Davis has caused the submission of numerous off-label prescription for **Neurontin** to the Medicaid program through both its fraudulent statements about the safety and efficacy of **Neurontin** and its system of unlawful financial incentives and kickbacks to doctors who prescribe **Neurontin.**

Defendant does not dispute that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA. Cf. *Peterson v. Weinberger, 508 F.2d 45, 52* (5th Cir.) (holding that knowing submission of Medicare claims for services that are not covered and payable under the Medicare Act is a violation of the FCA), cert. denied sub nom. *Peterson v. Mathews, 423 U.S. 830, 46 L. Ed. 2d 47, 96 S. Ct. 50 (1975)*. Instead, **[**25]** Defendant's response is a four-fold attack on the viability of a claim under the FCA against a pharmaceutical manufacturer that did not itself submit false claims in the form of off-label prescriptions directly to the government.

First, Defendant argues that Relator cannot use the FCA as an end-run around the enforcement provisions of the FDCA by creating a cause of action for money damages. Although the FDCA forbids the marketing of drugs for off-label uses, see *21 U.S.C. § 331*(a)&(d), it does not provide the government with a civil damage remedy to enforce the ban on off-label marketing. n6 The FDCA provides for enforcement of the off-label marketing prohibition only by the FDA and only through certain channels. The FDA may take administrative actions against a manufacturer such as seizing the violative drugs or seeking a court order enjoining the unlawful promotional activities. See id. § 332(a) (permitting FDA to seek injunction against unlawful conduct); id. § 334(a) (permitting seizure of drugs). The FDA may also institute criminal proceedings for off-label marketing violations. See id. § 333(a).

n6 Likewise, the FDCA does not contain a provision creating private enforcement of the off-label marketing ban by way of a civil damages action.

[26]**

It is true that the FCA cannot be used to enforce compliance with every federal law or regulation. See United States *ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402, 416 (3d Cir. 1999)* ("Not every regulatory violation is tantamount to making a knowingly false statement to the government."), cert. denied, *531 U.S. 880, 148 L. Ed. 2d 133, 121 S. Ct. 192 (2000).* Accord *Thompson, 125 F.3d at 902* ("claims for services rendered in violation of a statute do not necessarily constitute false or fraudulent claims under the FCA."); United States *ex rel. Hopper v. Anton, 91 F.3d 1261, 1266-67 (9th Cir. 1996)* ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA.") cert. denied, *519 U.S. 1115, 136 L. Ed. 2d 844, 117 S. Ct. 958 (1997).*

Nonetheless, the FCA *can* be used to create liability where failure to abide by a rule or regulation amounts to a material misrepresentations made to obtain a government benefit. See, e.g., *United States v. White, 765 F.2d 1469, 1479-80 (11th Cir. 1985)* (involving FCA case based on altered time cards submitted in violation **[**27]** of the Truth in Negotiations Act); **[*52]** *Pickens v. Kanawha River Towing, 916 F. Supp. 702, 705-06 (S.D. Ohio 1996)* (rejecting defendant's argument that remedies under federal Clean Water Act preempted relator's action under the FCA); United States *ex rel. Fallon v. Accudyne Corp., 880 F. Supp. 636, 638 (W.D. Wis. 1995)* (allowing FCA action based on failure to comply with environmental standards); *United States v. Incorporated Village of Island Park, 888 F. Supp. 419 434-36 (E.D.N.Y. 1996)* (same with regard to failure to comply with non-discrimination requirements). Thus, the failure of Congress to provide a cause action for money damages against a pharmaceutical manufacturer for marketing off-label drugs does not preclude on FCA claim where the manufacturer has knowingly caused a false statement to be made to get a false claim paid or approved by the government in violation of *31 U.S.C. § 3729*(a).

Second, Defendant argues that an impermissible off-label promotion does not necessarily include a false statement or fraudulent conduct. For example, it points out, off-label promotion of a drug might simply consist **[**28]** of a representative of a pharmaceutical company distributing the finding of one doctor's experience with an off-label use of a particular drug to other physicians. However, Relator alleges more than a mere technical violation of the FDA's prohibition on off-label marketing. The gravamen of Relator's claim is that Parke-Davis engaged in an unlawful course of fraudulent conduct including knowingly making false statements to doctors that caused them to submit claims that were not eligible for payment by the government under Medicaid. Thus, the alleged FCA violation arises--not from unlawful off-label marketing activity itself--but from the submission of Medicaid claims for uncovered off-label uses induced by Defendant's fraudulent conduct. Cf. United States *ex rel. Marcus v. Hess, 317 U.S. 537, 543-544, 87 L. Ed. 443, 63 S. Ct. 379 (1943)* (payments under government contract that was executed as a result of collusive bid constituted actionable false claims). A much closer question would be presented if the allegations involved only the unlawful--yet truthful--promotion of off-label uses to physicians who provide services to patients who are covered by Medicaid, as **[**29]** well as patients who are not, without any fraudulent representations by the manufacturer.

Third, Defendant argues that Relator has not stated a claim because he has not accounted for the independent actions of the physicians who wrote the off-label prescriptions and the pharmacists who accepted and filled the off-label prescriptions. In other words, Defendant argues that--as a matter of law--Relator's allegations cannot establish the causation requirement of the FCA because the actions of these professionals were an intervening force that breaks the chain of legal causation. See *Cantekin, 192 F.3d at 416* (applying intervening cause analysis to claim under the FCA). Under black letter law, however, such an intervening force only breaks the causal connection when it is unforeseeable. See id. Accord D. Dobbs, et al., Prosser and Keeton on Torts § 44, at 303-04 (5th ed. 1984) ("The courts are quite generally agreed that [foreseeable

intervening forces] will not supersede the defendant's responsibility."); Restatement (Second) of Torts § 443 (1965) ("The intervention of a force which is a normal consequence of a situation created by the actor's ... conduct **[**30]** is not a superseding cause of harm which such conduct has been a substantial factor in bringing about."). In this case, when all reasonable inferences are drawn in favor of the Relator, the participation of doctors and **[*53]** pharmacists in the submission of false Medicaid claims was not only foreseeable, it was an intended consequence of the alleged scheme of fraud.

Finally, Defendant argues that Relator's claim fails because he does not allege that false statements made by Parke-Davis to doctors were material to the government's decision to pay the claim for off-label prescriptions of **Neurontin.** Liability under the FCA, however, is not limited only to false statements or claims made directly by the Defendant to the government. The Act "reaches beyond claims which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money." *Neifert-White Co., 390 U.S. at 233* (internal quotations omitted). Relator has adequately alleged that Parke-Davis knowingly *caused* the submission of these false claims through a fraudulent course of conduct in violation of *31 U.S.C. § 3729*(a). The fact that such prescriptions **[**31]** are for an off-label use is material because, as the Defendant does not dispute, the government would not have paid the claims if it had known of the use for which they were being submitted. See S. Rep. No. 99-345, at 9 (1986) (stating that "claims may be false even though the services are provided as claimed if, for example, the claimant is ineligible to participate in the program").

To be sure, Relator's theory of liability takes the parties into territory that is not well charted by the existing decisional law. Nonetheless, the statutory language--which-must provide the touchstone for the Court's analysis--supports Relator's somewhat expansive claim. See *31 U.S.C. § 3729*(a) ("Any person who ... knowingly ... *causes to be presented*, to... the United States Government ... a false or fraudulent claim for payment or approval [or] ... knowingly ... *causes to be made or used*, a false record or statement to get a false or fraudulent claim paid or approved by the Government ... is liable") (emphasis added). Moreover, the terms of the FCA must be read liberally in accordance with their remedial purpose. See *Neifert-White Co., 390 U.S. at 232-33* **[**32]** (noting that "the Court has consistently refused to accept a rigid, restrictive reading" of the FCA and that "this remedial statute reaches beyond 'claims' which might be legally enforced, to all fraudulent attempts to cause the Government to pay out sums of money.").

3. Kickback claim

Count V of the complaint alleges a FCA claim based on violations of the Medicaid Antikickback provision, *42 U.S.C. § 1320a-7b*(b). Under the antikickback provision:

> Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person --
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> (B) to purchase, lease, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more **[**33]** than $ 25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b)(2).

Relator contends that Parke-Davis violated the antikickback provision **[*54]** by, *inter alia*: paying doctors for inconsequential drug "studies"; paying doctors for minimal participation as "consultants" or "preceptors" or for participating in a "speakers bureau"; giving doctors cash payments for small record-keeping tasks, such as allowing Parke-Davis access to information about the doctors' patients who were receiving **Neurontin;** and giving gifts such as travel and Olympics tickets to doctors prescribing large amounts of Parke-Davis drugs. n7 Relator further asserts that a violation of the federal antikickback provision has been recognized as a *per se* violation of the FCA because any claims "tainted" by the kickbacks were ineligible for payment by the government. Thus, under Relator's kickback theory, Parke-Davis is liable for both approved and off-label **Neurontin** prescriptions submitted to the government by doctors who received kickbacks if "one purpose" of the remuneration was to induce the submission of prescriptions for **Neurontin** that are reimbursable **[**34]** by Medicaid. See *United States v. McClatchey, 217 F.3d 823, 835* (10th Cir.) ("a person who offers or pays remuneration to another person violates the [Anti-Kickback] Act so long *as one purpose* of the offer or payment is to induce Medicare or Medicaid patient referrals.") (emphasis added), cert. denied, *531 U.S. 1015, 148 L. Ed. 2d 492, 121 S. Ct. 574 (2000).* Defendant, on the other hand, contends that the cases equating violations of the antikickback law with a violation of the FCA are inapplicable where, as is the case here, the Defendant did not itself submit the allegedly "tainted" claim.

n7 Similar allegations have not escaped the notice of the Office of the Inspector General of the Department of Health and Human Services. See *Special Fraud Alert: Prescription Drug Marketing Schemes*, *59 Fed. Reg. 65,376* (Dec. 19, 1994) (discussing use of "research grant programs" to promote prescription drugs as potential violations of federal antikickback statute).

Contrary to **[**35]** Relator's argument, a violation of the federal antikickback provision is not a *per se* violation of the FCA. In order for the antikickback violation to be transformed into an actionable FCA claim, the government must have conditioned payment of a claim upon the claimant's certification of compliance with the antikickback provision. See *Thompson, 125 F.3d at 902*. That certification may be proven by evidence showing the claimant expressly agreed to abide by the law as a condition of payment. See United States *ex rel. Gublo v. Novacare, Inc., 62 F. Supp. 2d 347, 355 (D. Mass. 1999)* (holding relator stated FCA claim where defendants submitted annual cost reports that included a certification of compliance).

In the absence of an affirmative certification, some courts have found "implied certification" by virtue of the defendant's participation in the federal program. See, e.g., United State *ex rel. Pogue v. American Healthcorp, Inc., 914 F. Supp. 1507, 1513 (M.D. Tenn. 1996)*. The implied certification theory has not gone without criticism. See *Thompson, 125 F.3d at 902* (requiring that defendant affirmatively **[**36]** certify compliance); *Thompson, 20 F. Supp. 2d at 1048 n.33* (referring to the implied certification theory as Pogue's "Achilles heel"); see also Lisa Michelle Phelps, Note, *Calling Off the Bounty Hunters: Discrediting the Use of Alleged Anti-Kickback Violations to Support Civil False Claims Actions*, *51 Vand. L. Rev. 1003 (1998)*. Nonetheless, at least one court in this district has accepted it as a valid basis for an action under the FCA. See United States *ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 43 (D. Mass. 2000)* (O'Toole, J.) (accepting theory of FCA liability based on violation of the Anti-Kickback Law, but noting **[*55]** that other cases "have generally involved some evidence, lacking here, of express certification of compliance with applicable law.").

At this point, Relator has not provided allegations regarding two crucial components of its theory. Relator has failed to allege that physicians either expressly certified or, through their participation in a federally funded program, impliedly certified their compliance with the federal anti-kickback statute as a prerequisite to participating in the **[**37]** federal program. This Count fails for a different reason as well. Parke-Davis argues that no False Claims Act anti-kickback case has ever extended the "false certification" or the "false implied certification" theory to cover claims filed, not by the defendant, but by third parties. While Defendant's payment of kickbacks may well be illegal, a claim under the FCA will fail unless Relator alleges that Parke-Davis caused or induced a doctor and/or pharmacist to file a false or fraudulent certification regarding compliance with the anti-kickback statute.

4. Clinical Trials

Count IV alleges that Defendant engaged doctors to perform clinical trials using Parke-Davis drugs in violation of FDA regulations requiring that the drugs for such trials be provided at no cost. Cf. *21 C.F.R. § 312.7* (prohibiting manufacturer from charging for an investigational new drug in a clinical trial without the prior written approval of the FDA). This count is an example of the Relator improperly seeking to use the FCA as a means to enforce various regulatory proscriptions of the FDA. See *Pogue, 914 F. Supp. at 1513* (The FCA "was not intended to operate **[**38]** as a stalking horse for enforcement of every statute, rule, or regulation."). It is dismissed. While Parke-Davis may well have violated this regulatory provision, there is no allegation that in doing so it fraudulently caused the submission of a false claim for reimbursement.

III. CONCLUSION AND ORDER

The Defendant's Motion to Dismiss (Docket No. 58) is **ALLOWED** with regard to Counts I, III, V and IX of the complaint. Pursuant Fed. R. Civ. P. 15(a), the Relator is allowed leave to amend the complaint within thirty (30) days of the issuance of this order to incorporate the allegations of the disclosure. Counts VII and VIII are also dismissed without objection of the Relator.

PATTI B. **SARIS**

United States District Judge

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