**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

| | | |
|---|---|---|
| UNITED STATES OF AMERICA ex rel. PETER ROST, | ) | |
| Plaintiff, | ) | Docket No. 03-CV-11084-PBS |
| v. | ) | The Honorable Patti B. Saris |
| PFIZER, INC., et al., | ) | |
| Defendants | ) | |

**UNITED STATES' STATEMENT OF INTEREST**
**IN RESPONSE TO DEFENDANT'S MOTION TO DISMISS**
**PLAINTIFF'S FIRST AMENDED COMPLAINT**

The United States, real party in interest in this action, hereby moves to submit this Statement of Interest pursuant to 28 U.S.C. § 517 to respond to certain arguments raised in the context of defendants' Motion to Dismiss Relator's First Amended Complaint. The United States remains a real party in interest in this matter, even where it has not intervened in the action. United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 231 (1st Cir. 2004). The False Claims Act (FCA), 31 U.S.C. § 3729 et seq., is the United States' primary tool used to redress fraud on the government. As such, the statute should be read broadly to reach all fraudulent attempts to cause the government to pay out sums of money. United States v. Neifert-White, 390 U.S. 228, 233 (1968). Thus, the United States has a keen interest in the development of the law in this area and in the correct application of the law in this, and similar, cases.[4]

[4] The brief of *amicus* Washington Legal Foundation (WLF) offers this Court its views as to what information manufacturers of medical devices and drugs may lawfully disseminate about the off-label uses of their products. Defendants, however, do not seek dismissal of this case on the grounds that the off-label marketing alleged in the First Amended Complaint was lawful.

The United States submits this brief to make four points. First, the fact that an off-label use is *listed in* a statutorily recognized compendium does not necessarily mean that the use is *supported by* the compendium citation, so that, in some circumstances, a use that is listed may not qualify as a "medically accepted indication" that is covered by law. Second, even if an off-label use is supported by a citation in a compendium, a claim nevertheless may be false for any other number of reasons (if sufficiently plead) and thus present an alternative ground for FCA liability. Third, as to section (a)(2) of the FCA, which requires the existence of a false record or statement to get a false or fraudulent claim paid or approved, a complaint need not allege that the defendants themselves made a false statement – the defendants may be liable if they caused a third party to make a false statement to get a false claim paid. In addition, false statements include not only affirmative misrepresentations but also material omissions so that the existence of either one may suffice to satisfy the false statement requirement of section (a)(2). Fourth, the identification of specific false claims is not an absolute prerequisite to satisfying the particularity requirement of Rule 9(b) in FCA cases. So long as the complaint as a whole is sufficiently particular to strengthen the inference of fraud beyond possibility, a court may conclude, as this one has in other cases, that Rule 9(b) is satisfied. Nonetheless, the United States submits that if

---

WLF's arguments have not been raised or briefed by the parties, are not relevant to the instant motion to dismiss, and need not be addressed by this Court.

Indeed, WLF's assertion that it "successfully challenged the constitutionality of certain FDA restrictions on speech about off-label uses and has in place a permanent injunction against enforcement of those restrictions" is incorrect. There is no permanent injunction against the enforcement of FDA's guidance as WLF asserts. Washington Legal Foundation v. Henney, 128 F. Supp. 2d 11, 15-16 (D.D.C. 2000) (denying WLF's motion to confirm and enforce injunction, stating that the Court of Appeals "vacated all of this Court's previous constitutional rulings on the matter").

the Court finds that relator's complaint fails to meet that test and is subject to dismissal under Rule 9(b), then it need not reach the other issues addressed herein.

## BACKGROUND

In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by the Centers for Medicare and Medicaid Services (CMS), which administers the program on behalf of the Secretary of Health and Human Services. The state plan must specify, among other things, the specific kinds of medical care and services that will be covered. 42 U.S.C. § 1396a(a)(10) and (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation, *i.e.*, reimbursement by the federal government for a specified percentage of the amounts that qualify as medical assistance under the state plan. *Id.* at §§ 1396b(a)(1), 1396d(b).

States are accorded a broad measure of flexibility in tailoring the scope and coverage of their plans to meet the particular needs of their residents and their own budgetary and other circumstances. While the Medicaid Act requires States to provide certain basic services, the Act permits, but does not require, States to cover prescription drugs, although most States choose to do so. 42 U.S.C. § 1396d(a)(12).

In 1990, Congress enacted the Medicaid Drug Rebate Statute, codified at 42 U.S.C. §1396r-8, to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990). That statute prohibits federal financial participation for covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8. See 42 U.S.C. §§ 1396b(i)(10)(A) and 1396r-8(a)(1). Once a drug manufacturer has entered into

a rebate agreement for a covered outpatient drug, a State is generally required to cover that drug under the state plan. However, there are several provisions of the Medicaid Act that permit a State to exclude or restrict coverage, at least two of which are potentially implicated in this case. 42 U.S.C. § 1396a(a)(54); H.R. Rep. No. 881 at 97, 98. A State may restrict from coverage or exclude altogether certain drugs or classes of drugs, or certain medical uses, such as drugs used for, among other things, cosmetic purposes. 42 U.S.C. § 1396r-8(d)(1)(B)(ii). A State also may exclude or restrict coverage of a drug where "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).[5]

Under the statute, a "covered outpatient drug" includes a drug dispensed by prescription and approved as safe and effective under the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 355 & 357, but does not include "a drug or biological used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(2), (3). The statute defines "medically accepted indication" as:

> any use for a covered outpatient drug which is approved under the [FDCA], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

Id. at § 1396r-8(k)(6). The three compendia described in subsection (g)(1)(B)(i) are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the Drugdex Information System. Id. at § 1396r-8(g)(1)(B)(i).

[5] In addition, under the terms set forth in the Medicaid Act, a State also may adopt a prior authorization program, maintain a formulary, impose limits on prescription quantities to discourage waste, and address instances of fraud or abuse by individuals. 42 U.S.C. § 1396r-8(d)(4)-(6). It does not appear that any of these potential restrictions are at issue in this matter.

## I. The Term "Supported By" Requires That a Compendium Citation Corroborate a Particular Use.

One question raised by the parties here is what is necessary to satisfy the statutory requirement that a use is "supported by one or more citations" in a compendium. See id. at § 1396r-8(k)(6) (defining "medically accepted indication"). As both relator and defendants recognize, the mere existence of a compendium citation is not sufficient to meet this standard. Common usage of the term "supported by" generally requires some form of corroboration or validation. See American Heritage Dictionary of the English Language, 4th ed. (2000) ("to furnish corroborating evidence for"); Cambridge Dictionary of American English, 2d ed. (2006) ("to show (something) to be true . . . New evidence *supports* his theory"); see, e.g., In re Pharmaceutical Indus. Average Wholesale Price Litig., 460 F. Supp. 2d 277, 284 (D. Mass. 2006) ("Dictionaries of the English language are a fundamental tool in ascertaining the plain meaning of terms used in statutes and regulations."). Interpreting the definition of medically accepted indication to require only "citation in the compendia" would be problematic because it would fail to give meaning to the words "supported by," and would render that phrase superfluous. See United States v. Flores, 968 F.2d 1366, 1371 (1st Cir. 1992). Furthermore, CMS, the agency with responsibility to administer the statute at issue, has reiterated that the statutory definition of medically accepted indication "requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia." See CMS Release No. 141 (emphasis added) (Attached to Relator Brief as Ex. 4). Because the agency's interpretation of this statutory provision is reasonable, it is entitled to deference by this Court. See Federal Express Corp. v. Holowecki, et al., 128 Sup. Ct. 1147, 1156 (2008).

Moreover, a basic practical consideration is that Drugdex, the compendium relied on by

defendants here, classifies some indications as "not effective" and describes others as "controversial." See Def. Brief at Ex. A. Accordingly, whether a particular use is "supported by" a compendium citation may depend on a variety of factors, including the type of drug and indication at issue, the compendium's assessment of the drug's efficacy in treating the indication, the content of the compendium citation, and the scope and outcome of the studies as described in the compendium.

The only other case to have considered this provision, Edmonds v. Levine, 417 F. Supp. 2d 1323, 1339 (S.D. Fla. 2006), is distinguishable because of the circumstances in which the case was presented, and in particular because the decision predated CMS Release 141, which was released three months after the decision in Edmonds. The Edmonds case arose out of certain Medicaid beneficiaries challenging the State of Florida's adoption of a policy to make an independent evaluation of off-label uses for the drug Neurontin that resulted in the State's denying reimbursement for certain uses of the drug that were listed as effective in Drugdex, but allowing reimbursement for other uses listed as ineffective. The Court need not address the various issues raised in Edmonds stemming from whether the State's action was permissible. The relevant point here is that, as both relator and defendants recognize and CMS Release 141 has made clear, the statutory language of "supported by" means something other than merely "listed in."

As a final issue relating to coverage, it should be noted that the Medicaid statute permits a State to exclude or restrict reimbursement of an otherwise "covered outpatient drug" in certain circumstances.[6] See 42 U.S.C. § 1396r-8(d); supra at 3 & n. 1.

**II. Coverage of an Off-label Indication Does Not Negate All Potential FCA Liability.**

A claim may be false for any number of reasons regardless of whether it is submitted for a use supported by a citation in a compendium. For example, a claim may be ineligible for payment if a physician submitted a claim for reimbursement for which he received a kickback in exchange for prescribing a particular drug. See, e.g., United States v. Rogan, 517 F.3d 449 (7th Cir. 2008); Parke-Davis, 2003 WL 22048255, at *7. Likewise, a claim may be ineligible for payment if the prescription were signed by a person without a medical license or for a patient that did not exist. See, e.g., United States ex rel. Riley v. St. Luke's Episcopal Hosp., 355 F.3d 370, 378-79 (5th Cir. 2004) (allegation that services were performed by an unlicensed and unsupervised physician states a claim under FCA). Finally, a claim may be rendered false if a drug manufacturer falsified studies or engaged in other unlawful, fraudulent conduct in the promotion of a drug or to procure FDA approval or inclusion in a compendium. See, e.g., United States v. Dynamics Research Corp., 2008 WL 886035, *10 (D. Mass. Mar. 31, 2008) ("[W]here a claim for payment is the result of a fraudulent process-bid rigging, self-dealing, etc. such that the reliability and trustworthiness of a claim is compromised, the claim may be

---

[6] Notably, this case does not present – at least not at this time – the question this Court left open in Parke-Davis as to whether States have discretion to cover off-label uses that are not supported by a citation in the compendia. See United States ex rel. Franklin v. Parke-Davis et al., 2003 WL 22048255, at *3 (D. Mass. Aug. 22, 2003). The Parke-Davis defendants argued that States are *permitted* to cover prescriptions for off-label uses even if those uses are *not* supported by a citation in the compendia. In this case, defendants contend that the off-label indication of "short stature" *is* supported by compendium citations.

considered false under the FCA despite its facial accuracy."); United States v. Incorporated Village of Island Park, 888 F. Supp. 419, 439 (E.D.N.Y. 1995) ("[T]he [FCA] is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money."). Thus, the mere fact that a particular use is a "medically accepted indication" does not eliminate the possibility of fraudulent conduct or abuse that could render the claim false and ineligible for payment.

**III. False Statements Under Section (a)(2) of the FCA.**

This Court has held that illegal off-label marketing that results in the submission of impermissible claims for reimbursement states a claim under the FCA. Parke-Davis, 2003 WL 22048255, at *2. FCA liability exists so long as the defendants knowingly cause a false claim to be submitted by a provider to the United States. Id. Proof of falsity could entail a showing that the provider sought payment from a federal health care program for a use that was off-label and not covered by that program. Id. at *3. It is not necessary also to show (or allege) an express falsehood from the defendant to the provider to satisfy the "falsity" element of section (a)(1). Id. at *1.

Defendants correctly observe that to state a claim under section (a)(2), there must be a false record or statement. To satisfy this requirement, defendants assert that relator needed to allege "both that Pharmacia made a false statement and that this false statement was made to get a false claim paid by the government." See Def. Brief at 11. However, requiring a false statement to be made by the defendant drug company is contrary to the plain language of the FCA. Although section (a)(2) requires the existence of a false statement, it does not require the

false statement to be made *by the defendant*. Section (a)(2) imposes liability on a defendant so long as it "caused" another, such as a hired consultant, to make a false statement.

Contrary to what defendants' brief implies (Def. Br. at 11-12), for a statement to be "false," it need not be an affirmative misrepresentation; a material omission will suffice: "[H]alf the truth may obviously amount to a lie, if it is understood to be the whole." W. Page Keeton, Prosser & Keeton on the Law of Torts § 106, at 738 (5th ed. 1984); see Luckey v. Baxter Healthcare Corp., 183 F.3d 730, 732 (7th Cir. 1999) (observing that a half-truth may amount to a false statement under the FCA in certain circumstances); United States ex rel. Schwedt v. Planning Research Corp., 59 F.3d 196, 199 (D.C. Cir. 1995) (finding that false progress reports may constitute false statements under the FCA); United States ex rel. Fry v. Guidant Corp., 2006 WL 2633740, at *10-11 (M.D. Tenn. Sept. 3, 2006) (finding representation was rendered false by concealment of material information); United States ex rel. Kneepkins v. Gambro Healthcare, Inc., 115 F. Supp. 2d 35, 43 (D. Mass. 2000) (an "omitted material fact," such as the existence of illegal kickbacks, may be actionable under the FCA). Thus, a statement urging a physician to prescribe a drug for an unapproved, off-label use could well amount to a half-truth and satisfy the false statement requirement of section (a)(2), where, for example, the drug sales representative fails to mention that the evidence does not support the drug's efficacy for the use he or she is promoting or the FDA has specifically concluded that the drug is not safe or effective for that use.[7]

---

[7] Notably, despite defendants' suggestion to the contrary (Def. Br. at 11, n. 8), the fact that the Medicaid Act provides for coverage for off-label uses that are supported by citation in certain compendia is irrelevant to whether a drug company made a false statement. To the extent that the FDA Modernization Act, 21 U.S.C. § 360aaa, provided a safe harbor for the dissemination of certain scientific information if a manufacturer complied with the requirements

## IV. FCA Pleading Requirements.

Of course, if a relator is claiming that the defendant drug company *caused* the providers to submit these false claims, the relator must adequately allege such causation. See Parke-Davis, 2003 WL 22048255, at *4-5; United States ex rel. Cantekin v. University of Pittsburgh, 192 F.3d 402, 416 (3d Cir. 1999). The relator need not allege an express false statement to satisfy the causation element, though such evidence would be one way the relator could do so.[8]

Defendants argue that relator's complaint fails to set forth with sufficient particularity that conduct by defendants caused false claims to be submitted to federal health care programs. Defendants also argue the complaint does not sufficiently allege that the two off-label uses raised by relator (adult anti-aging and pediatric short stature) resulted in claims being submitted to federal health care programs that were false. Finally, Defendants further assert that relator has failed to identify specific adult anti-aging claims and that regardless of whether relator has identified specific pediatric short-stature claims submitted to federal health care programs, he

---

set forth in the statute, the provision expired on September 30, 2006, and Congress has not renewed it. Moreover, the FDA draft guidance on *Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices* states that it contains "Nonbinding Recommendation, Draft – Not for Implementation" and that the FDA is accepting comments on the draft.

[8] WLF wrongly suggests that the defendant must have instructed or directed that claims be submitted or how to do so in order for liability to exist for "causing" the submission of a false or fraudulent claim. As the Supreme Court has recognized, the prototypical FCA case involving the "causing" of the submission of a false claim – when a subcontractor submits a false invoice to a prime contractor which, in turn, submits the invoice to the United States – rarely involves a subcontractor affirmatively instructing or directing the prime contractor to submit a false claim. See United States v. Bornstein, 423 U.S. 303, 309 (1976); Marcus v. Hess, 317 U.S.537, 544-45 (1943).

has failed to provide sufficient details about those claims.[9] To the extent that defendants contend that relator's complaint must fail because it did not identify specific false claims or do so with sufficient particularity, defendants seek to impose too rigid a pleading standard in FCA cases.

As a general matter, the allegation of a specific false claim is not an absolute prerequisite to pleading a viable FCA claim. Although FCA liability attaches to the claim for payment, the First Circuit and this Court have held that whether specific claims must be identified for a complaint to satisfy Rule 9(b)'s particularity requirement will depend on the circumstances of each case. See United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 732 (1st Cir. 2007); United States ex rel. West v. Ortho-McNeil Pharm., Inc., 2008 WL 435497, at *18 (D. Mass. Feb. 19, 2008). Thus, in off-label cases, where the alleged false claims were submitted not by the defendant, but instead by a third party, a relator "need not allege the details of particular claims, so long as 'the complaint as a whole is sufficiently particular to pass muster under the FCA.'" See Rost, 507 F.3d at 732 (quoting Karvelas, 360 F.3d at 225).[10] In evaluating such

---

[9] Whether the requisite knowledge under the FCA was sufficiently plead does not appear to be a focus of defendants' brief and, in any event, questions relating to a defendant's knowledge typically cannot be resolved at the pleadings stage of a case. Accordingly, the Court need not address this issue. It bears noting here, however, that if a defendant knew or acted with reckless disregard as to the truth or falsity of claims that they caused to be submitted, "any possible ambiguity in the regulations is water under the bridge." Minnesota Ass'n of Nurse Anesthetists v. Allina Health System Corp., 276 F.3d 1032, 1053 (8th Cir. 2002).

[10] Such an analysis is consistent with FCA cases in which courts have found that when a complaint sets forth with particularity allegations of a fraudulent scheme or course of conduct, it is not also necessary to identify specific claims because doing so adds little to the sufficiency of the complaint as a whole. See, e.g., United States ex rel. Singh v. Bradford Regional Medical Center, 2006 WL 2642518, at *7 (W.D. Pa. 2006) ("[T]he falsity of the instant claims does not turn on anything unique to any individual claim or that would be revealed from an examination of any claim, but rather the claims 'are false because of the improper financial arrangements

matters, "the strength of the inference of fraud on the government" may be measured by, for example, factual or statistical evidence tending to show fraud beyond possibility. See West, 2008 WL 435497, at *18. Given the posture of this matter, the unique circumstances of the drug at issue in this case, and to assist the Court in applying the standard here, the United States submits that it is not aware of any billable diagnosis code for an anti-aging use that would be recognized or reimbursable by federal health care programs.

**Conclusion**

The United States submits this brief regarding how to interpret and apply certain aspects of the Medicaid Act and the FCA. The United States takes no position on the sufficiency of the complaint herein.

Respectfully submitted,

GREGORY G. KATSAS
ACTING ASSISTANT ATTORNEY GENERAL

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

/s/ *Sara Miron Bloom*
SARA MIRON BLOOM
Assistant U.S. Attorney
Suite 9200, One Courthouse Way
Boston, MA 02210
Phone: (617) 748-3265

JOYCE R. BRANDA
MICHAEL D. GRANSTON
JAMIE ANN YAVELBERG
EDWARD C. CROOKE
Civil Division, Commercial Litigation Branch
P. O. Box 261, Ben Franklin Station

---

between [defendant] and the physicians.'").

Washington, D.C. 20004
Phone: (202) 353-0426

Dated: May 12, 2008