

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)	
ex rel. DR. PETER ROST)	
Plaintiff,)	
)	
v.)	CIVIL ACTION NO. 03-11084-PBS
)	
PFIZER, INC., and PHARMACIA)	
CORPORATION)	
Defendants.)	

MEMORANDUM AND ORDER

September 18, 2008

Saris, U.S.D.J.

I. INTRODUCTION

Whistleblower Plaintiff Dr. Peter Rost, a former Vice President of Defendant Pharmacia, alleges that Pharmacia, a subsidiary of Defendant Pfizer, violated the federal False Claims Act ("FCA"), 31 U.S.C. §3729 et seq., and state law¹ by unlawfully promoting the off-label use of the growth hormone medication Genotropin. Defendants have moved to dismiss the First Amended Complaint pursuant to Fed. R. Civ. P. 12(b)(6) and 9(b). After hearing, the motion is **ALLOWED in part.**

¹Plaintiff asserts violations of the false claims acts in California, Delaware, Florida, Hawaii, Illinois, Massachusetts, Nevada, Tennessee, Texas, Virginia, District of Columbia, and New York.

II. FACTS

The following facts are taken from the Amended Complaint and are treated as undisputed for purposes of this motion. Dr. Rost, a physician in the pharmaceutical industry since 1992, was employed by Pharmacia in June 2001 as Vice President in charge of the Endocrine Care Unit in Peapack, New Jersey. (Am. Compl. ¶ 9). In April 2003, Pharmacia was acquired by Pfizer, Inc. (Am. Compl. ¶ 10). Rost alleges that beginning in 1997, and continuing to this day, Defendants unlawfully promoted the use of Genotropin for off-label indications. (Am. Compl. ¶ 2).

a. Genotropin

Genotropin is a recombinant human growth hormone that was manufactured and marketed by Pharmacia. (Am. Compl. ¶ 18). The FDA has approved the use of Genotropin in children for three indications: (1) the treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (approved for this indication in August 1995); (2) treatment of pediatric patients who have growth failure due to Prader-Willi syndrome, a rare genetic disorder that causes short stature and other disabilities (approved June 2000); and (3) treatment of growth failure in children born small for gestational age and who fail to manifest catch-up growth by age two (approved July 2001). (Am. Compl. ¶ 21). The FDA has approved the use of Genotropin for only one indication in adults:

growth hormone deficiency (approved November 1997). (Am. Compl. ¶ 22).

Genotropin is an extremely expensive drug, costing from several thousand dollars per year for limited supplemental use to \$35,000 per year for a child who completely lacks growth hormone. (Am. Compl. ¶ 19). The market for Genotropin for FDA-approved, on-label indications is limited, however, with fewer than 50,000 adults currently diagnosed with human growth deficiencies and approximately 6,000 new cases reported a year. (Am. Compl. ¶ 55). Similarly, very few pediatric patients suffer from any of the three FDA approved indications. (Am. Compl. ¶ 55).

The market for non-FDA approved, off-label uses of Genotropin, including anti-aging and body improvement in adults and treatment of short stature unrelated to growth hormone deficiency in children, is considerably larger. (Am. Compl. ¶ 55).

b. The Off-Label Marketing Campaign

To increase sales, Pharmacia promoted Genotropin's use in a broad range of these off-label treatments. (Am. Compl. ¶¶ 55-56). As a result of Pharmacia's off-label marketing, United States sales revenues for Genotropin tripled. (Am. Compl. ¶ 2). Now, sixty-percent of all adult sales and twenty-five percent of all pediatric sales of Genotropin are off-label. (Am. Compl. ¶ 3).

During Rost's employment, Pharmacia engaged in illegal

practices in order to tap into the off-label Genotropin market. (Am. Compl. ¶ 56). Genotropin sales and marketing efforts were undertaken by Pharmacia's Endocrine Care Division. (Am. Compl. ¶ 24). Rost was VP of that division after he joined Pharmacia in 2001. (Am. Compl. ¶ 24). Pharmacia's Genotropin sales and marketing are organized by regions and each region is organized into numerous sales districts. (Am. Compl. ¶ 26). The company communicated to the sales team a desire to promote Genotropin for off-label use in violation of Pharmacia's formal policy. (Am. Compl. ¶ 62(a)). In order to increase their bonuses, sales representatives offered doctors and distributors price discounts and rebates and other financial incentives. (Am. Compl. ¶ 61). For example, the sales director in Florida gave direct payments as inducements to prescribe Genotropin. (Am. Compl. ¶ 62(f)). Pharmacia also conducted adult and child growth hormone "clinical research programs" which were, in Plaintiff's view, marketing tools used by Pharmacia designed to provide financial incentives (\$200 per patient) to prescribe Genotropin for off-label uses. (Am. Compl. ¶¶ 65-67).

Pharmacia understood that "Pediatric Endocrinology practices depend on funding from growth hormone manufacturers to survive." (Am. Compl. ¶ 68) (quoting marketing plan for 2003). Pharmacia took advantage of this fact to increase the sales of Genotropin, making payments to physicians that prescribed Genotropin despite knowing that approximately 25 percent of pediatric patients and

approximately 60 percent of adult patients prescribed Genotropin were prescribed the drug for off-label indications. (Am. Compl. ¶¶ 68-69).

c. Medicaid

Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r-8(k)(3), (6); 42 U.S.C. § 1396r-8(g)(1)(B)(I). State Medicaid programs will not authorize reimbursement for other uses. (Am. Compl. ¶¶ 42, 43). Further, each prospective Medicaid provider must agree that he will comply with all Medicaid requirements which include the anti-kickback provisions of the Anti-Kickback statute, 42 U.S.C. § 1320a-7b(b). (Am. Compl. ¶ 52).

In April 2007, Defendants pleaded guilty to one count of offering "kickbacks" in connection with their outsourcing contract for the administration and distribution of Genotropin. (Am. Compl. ¶¶ 116, 118, 121). Pharmacia paid a \$34.7 million fine. (Am. Compl. ¶ 114). As part of their plea agreement, Defendants admitted to the unlawful promotion of Genotropin for off-label uses, specifically as an anti-aging medication for adults. (Am. Compl. ¶ 122). The plea agreement did not, however, discuss any off-label promotion of Genotropin for pediatric uses. (Am. Compl. ¶ 123).

Dr. Rost alleges that as a result of Pharmacia's practices

hundreds and possibly thousands of false claims based on off-label prescriptions were reimbursed by federal Medicaid and other federal health care programs in violation of the FCA. (Am. Compl. ¶ 89). According to claims data from Indiana, the Medicaid and CHIP federal programs reimbursed for over 200 prescriptions there for off-label uses of Genotropin, such as for short stature without growth hormone deficiency and for "small for date" (Am. Compl. ¶¶ 90, 97, 101). Plaintiff contends neither of these is a "medically accepted indication" supported by citations in the drug compendia during the time period covered by this action. (Am. Compl. ¶¶ 43, 97)

d. DRUGDEX

Defendants have submitted the "DRUGDEX Drug Evaluations" from 2000 to 2002 and 2004 which they claim support the use of Genotropin (also called Somatropin) for short stature (Def.'s Mem. Supp. Dismiss Am. Compl. Ex. A-D). DRUGDEX is one of the compendia on which the Medicaid programs rely to determine whether to reimburse for a drug. See 42 U.S.C. § 1396r-8(k)(3), (6); 42 U.S.C. § 1396r-8(g)(1)(B)(I). In December 2000, DRUGDEX stated that the FDA had not approved Somatropin for adult or pediatric use for short stature. With respect to efficacy, it states, "Adult, possibly effective." With respect to pediatric treatment, it summarizes: "The use of exogenous Somatropin therapy in children with idiopathic short stature is

controversial." (Def.'s Mem. Supp. Dismiss Am. Compl. Ex. A at 4). The report was substantially similar the following year. (Def.'s Mem. Supp. Dismiss Am. Compl. Ex. B at 5). In December 2002, however, DRUGDEX changed its report on efficacy to: "Pediatric, possibly effective," but still noted that "[t]he use of exogenous Somatropin therapy in children with idiopathic short stature is controversial." (Def.'s Mem. Supp. Dismiss Am. Compl. Ex. C at 5).

By March 2004, the FDA had approved the use of human growth hormone for "Idiopathic short stature," summarizing: "Indicated for non-growth, hormone-deficient short stature." (Def.'s Mem. Supp. Dismiss Am. Compl. Ex. D at 6).

III. PROCEDURAL BACKGROUND

Dr. Rost brought his *qui tam* action against Pfizer and Pharmacia on June 5, 2003. United States ex rel. Rost v. Pfizer Inc., 446 F. Supp. 2d 6, 11 (D. Mass. 2006). On November 8, 2005, after nearly three years of investigation, the government declined to intervene in the case. Id. Pfizer moved to dismiss Dr. Rost's complaint for lack of subject matter jurisdiction under Rule 12(b)(1) because it was jurisdictionally barred by the FCA's public disclosure bar; it was "based upon" Defendants' disclosure to the government; and Plaintiff was not an "original source". Id. at 11, 15, 19, 22. Pfizer also moved to dismiss the complaint because it failed to meet the heightened pleading

requirements of Rule 9(b). Id. at 25. The district court (Tauro, J.) ruled that it had jurisdiction to hear the complaint, but it dismissed the First Complaint solely on the grounds that Plaintiff's failure to identify a single false claim submitted to the government for reimbursement constituted a deficient pleading under Rule 9(b). Id. at 24-25, 27-28.

Plaintiff appealed and the First Circuit affirmed the district court's ruling, but remanded the decision whether or not to allow Plaintiff to amend. United States ex rel. Rost v. Pfizer Inc., 507 F.3d 720, 723 (1st Cir. 2007). After Plaintiff filed an amended complaint on January 25, 2008, the Defendants renewed their motion to dismiss.

IV. DISCUSSION

A. Standard of Review

When considering a motion to dismiss under 12(b)(6) 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)). The Supreme Court "recently altered the Rule 12(b)(6) standard in a manner which gives it more heft." ACA Fin. Guar. Corp. v. Advest, Inc., 512 F.3d 46, 58 (1st Cir. 2008). Now, "to survive a motion to dismiss, a complaint must allege 'a plausible entitlement to relief.'" Id.

(quoting Bell Atl. Corp. v. Twombly, --- U.S. ----, 127 S.Ct. 1955, 1967-69 (2007)); see also Rodríguez-Ortiz v. Margo Caribe, Inc., 490 F.3d 92, 95-96 (1st Cir. 2007).

Dismissal for failure to state a claim is appropriate if the complaint fails to set forth "factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery under some actionable legal theory." Gagliardi v. Sullivan, 513 F.3d 301, 305 (1st Cir. 2008) (quoting Centro Medico del Turabo, Inc. v. Feliciano de Melecio, 406 F.3d 1, 6 (1st Cir. 2005)) (citation omitted). The Court need not consider "bald assertions [or] unsupportable conclusions." Doyle v. Hasbro, Inc., 103 F.3 186, 190 (1st Cir. 1996) (citation omitted).

Although ordinarily the Court must not look beyond "the four corners of the complaint" when evaluating a motion to dismiss, the Court may look to "documents the authenticity of which are not disputed by the parties." Watterson v. Page, 987 F.2d 1, 3 (1st Cir. 1993). Accordingly, the Court considers the DRUGDEX documents.

B. Rule 9(b).

Defendants argue that in the Amended Complaint, Rost failed to plead his FCA claims with particularity, as required under Rule 9(b). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances

constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) applies to FCA claims. See United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 228 (1st Cir. 2004). The particularity requirement "means that a complaint must specify the time, place, and content of an alleged false representation." Rost, 507 F.3d at 731 (citation and internal quotation marks omitted). The heightened standard of Rule 9(b) is necessary to give the defendant notice as to the nature of the fraud claims and to protect defendants from the filing of weak fraud claims due to the reputation harms resulting from such accusations. See Id., at 733.

Not all fraudulent activity is actionable under the FCA. "[T]he statute attaches liability, not to the underlying fraudulent activity or the government's wrongful payment, but to the claim for payment. Evidence of an actual false claim is the sine qua non of a False Claims Act Violation". Karvelas, 360 F.3d at 225 (citations and internal quotation marks omitted). Affirming the dismissal of Dr. Rost's first complaint, the First Circuit explained "Rost's complaint amply describes illegal practices in which Pfizer allegedly engaged. But those practices, while illegal, are not a sufficient basis for an FCA action because they do not involve claims for government reimbursement". Rost, 507 F.3d at 732 (citation omitted). The First Circuit dismissed Dr. Rost's first complaint because "the

complaint does not give notice to Pfizer of false claims submitted by others for federal reimbursement of off-label uses, only of illegal practices in promotion of the drug... At most, Rost raises facts that suggest fraud was possible; but the complaint contained no factual or statistical evidence to strengthen the inference of fraud beyond possibility." Rost, 570 F.3d at 733.

To correct the deficiencies in his first complaint, Dr. Rost alleges more than 200 false claims were submitted to both Medicaid and other federal programs from citizens of Indiana. (Am. Compl. ¶ 90). For each of these claims, Dr. Rost has listed codes which reveal a) the drug for which reimbursement was sought from CHIP and Medicaid; b) the medical diagnosis accompanying the claim; c) both the diagnosis and dispensation dates; and d) the prescription dosage. (Am. Compl. ¶ 94). Dr. Rost alleges that claims submitted to federal agencies for reimbursement were for off-label, non-FDA approved uses of Genotropin such as for "short stature" and "small for date". (Am. Compl. ¶ 97). Dr. Rost's Amended Complaint satisfies Rule 9(b)'s heightened pleading requirement.

C. Falseness of Claim

Defendants argue that because DRUGDEX supports the off-label use of Genotropin for short stature in children, the Medicaid and CHIP claims listed in the complaint are medically accepted

indications and therefore cannot be false claims as a matter of law. Defendants go one step further, audaciously insisting that the Medicaid program "require[d] [s]tates... to reimburse" Genotropin claims for "short stature." (Def.'s Mem. Supp. Dismiss Am. Compl. 7-8 (emphasis in original)). Plaintiff disagrees. In his view, DRUGDEX does not "support" the use of the drug for short stature.

In the years 2000 and 2001, DRUGDEX refers to using the drug to treat short stature as "possibly effective" in adults and "controversial" for children; in 2002, DRUGDEX refers to it as "possibly effective" but still "controversial" for children. For support, the Defendants look to Edmonds v. Levine, 417 F. Supp. 2d 1323 (S.D. Fla. 2006), which rejected a state Medicaid agency interpretation that the statutory term "supported" by citation in the compendia means "only those uses that are supported by double-blind, placebo-controlled, randomized clinical trials." Id. at 1337. The Court went on to hold that whenever a drug is listed for a particular therapeutic use in DRUGDEX, even if it is rated only "possibly effective" or even "ineffective," it is "'supported by citation' as defined in 42 U.S.C. § 1396r-8(k)(6)." Id. at 1340-1341. A more recent statement of the Center for Medicaid and State Operations undermines this holding, by explaining that "[t]he statute requires coverage of off-label uses of FDA-approved drugs for indications that are *supported* (as

opposed to listed) in the compendia." Ctr. for Medicaid and State Operations, Medicaid Drug Rebate Program Release No. 141, For State Medicaid Directors: Compendia Clarification (emphasis added); (Pl.'s Mem. Opp. Def.'s Mot. Dismiss Am. Compl. Ex. 4). The preliminary record is insufficient to determine whether the citations included in DRUGDEX discussing "short stature" can be read to "support" its off-label use.

Defendants' stronger argument is that off-label claims that were approved by the Drug Utilization Review Board under Indiana law are not false. Under Indiana law, a Drug Utilization Review Board must "[e]nsure that any prior approval program or restriction on the use of a single source drug is not applied to prevent acceptable medical use for appropriate off-label indications." Ind. Code § 12-15-35-35(a)(6). Defendants contend that this mechanism -- prior authorization -- ensures that Medicaid would not reimburse for Genotropin, which is on the DUR Board's Preferred Drug list, unless it had been determined to be medically appropriate for the listed use. Ind. Health Coverage Programs, Ind. Medicaid Preferred Drug List, <http://www.indianapbm.com/Downloads/Master%20Preferred%20Drug%20List%20updated%2007-01-2008.pdf>. This argument is forceful because the Drug Utilization Board was intended "to ensure that the prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes." Ind. Code § 12-

15-35-37. Defendants have a compelling position that state approval undermines the assertion of a "false claim." Thus, for example, if a state knowingly chose to reimburse for a drug, even for an off-label use, after a prior authorization review, liability would not attach because extensive government knowledge would "negate the intent requirement under the FCA as a matter of law." See Shaw v. AAA Eng'g & Drafting, Inc., 213 F.3d 519, 534 (10th Cir. 2000) (explaining government knowledge defense).

Defendants do not win the day with this argument, however, because Plaintiff also alleges that the claims are false if they were caused by unlawful kickbacks. See 42 U.S.C. § 1320a-7b(b). Merely alleging off-label marketing, a criminal act, is not sufficient, without more, to plead a false claims act violation. Rost, 507 F.3d at 727. To state a cause of action, Plaintiff must allege that Defendants "caused" the submission of a "false claim" by a doctor. 31 U.S.C. § 3729(a)(1)-(2). Plaintiff has generally alleged that Defendants have engaged in marketing tactics (like provision of financial incentives, direct payments, travel boondoggles, phony consultant fees, or other "kickbacks") and this marketing campaign has caused the submission of false claims by doctors. To prevail, Plaintiff will have to demonstrate that the financial incentives were unlawful kickbacks which foreseeably caused the submission of a false claim for federal reimbursement under the FCA. See United States v. Roqan,

517 F.3d 449, 452-453 (7th Cir. 2008) (affirming a finding of liability under the FCA for claims based on the payment of illegal kickbacks).

Whether there are facts which support Plaintiff's position that Defendants paid unlawful financial incentives to cause the prescription of Gentotropin for "short stature" and "short for date" is a challenge more appropriate for summary judgment. It is true that Plaintiff has not alleged that any improper financial incentives were paid to any of the doctors in Indiana who made the prescriptions. However, that information is not within Plaintiff's possession. See Rost, 507 F.3d at 732 ("Rule 9(b) may be satisfied where, although some questions remain unanswered, the complaint as a whole is sufficiently particular to pass muster under the FCA) (citation omitted); See also In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164, 171-172 (D. Mass. 2007) (noting that in certain complex circumstances, "Rule 9(b) will be satisfied if the complaint alleges the basic framework, procedures, and the nature of [the] fraudulent scheme..."). Accordingly, for the time being, the Court will permit discovery only relating to the sales and marketing region that includes Indiana. If the discovery shows that kickbacks were paid to the doctors who then made off-label prescriptions, and that this sales region was following national directives, the Court will expand the scope of discovery

nationwide.

D. Aging

The Court agrees with Defendants that Plaintiff's allegations of false claims for adult anti-aging use are deficient, and they will be dismissed.

V. CONCLUSION

Defendants' motion to dismiss is **DENIED** with respect to allegations of false claims for off-label pediatric uses. However, it is **ALLOWED** with respect to allegations of false claims for anti-aging off-label uses. All fact discovery relating to the Indiana sales region shall be completed by February 15, 2009. Plaintiff's expert report shall be filed by March 15, 2009. Defendants' expert report shall be filed by April 15, 2009. All expert depositions shall be taken by May 15, 2009. Any motion for summary judgment shall be filed by June 15, 2009.

S/PATTI B. SARIS
United States District Judge