UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF MASSACHUSETTS, STATE OF ILLINOIS, ex rel. JAMES HOPPER and COLIN HUTTO,

Plaintiffs and Relators,

v. CASE No. 8:04-CV-2356-T-23TGW

SOLVAY PHARMACEUTICALS, INC., et al.,

Defendants.

REPORT AND RECOMMENDATION

Qui tam relators allege violations of the False Claims Act, 31 U.S.C. 3729, et seq., and several analogous state statutes, arising from the defendants' alleged illegal marketing of the prescription drug Marinol for uses not approved by the U.S. Food and Drug Administration ("FDA"). They contend that the defendants' marketing campaign caused physicians to prescribe Marinol for off-label uses to government healthcare beneficiaries, which resulted in the submission of false or fraudulent claims to the government for reimbursement of Marinol's cost. The defendants have

moved to dismiss the second amended complaint on the ground that the relators failed to plead the submission of specific false claims to the government with the particularity required by Rule 9(b), F.R.Civ.P. (Doc. 88). The law of the Eleventh Circuit clearly holds that, in the circumstances presented here, the failure to allege the actual submission of a specific false claim is fatal. I therefore recommend that the motion to dismiss be granted.

I.

Relator James Hopper worked as a sales representative for defendant Solvay Pharmaceutical, Inc.'s Mental Health Division from 1999 until December 2005 (Doc. 84, ¶14).[1] Relator Colin Hutto was a sales representative for Solvay from 1999 until late 2003 (id., ¶15). Hopper and Hutto allege that, as sales representatives, they were required to implement an illegal marketing plan for the prescription drug Marinol, which is distributed by Solvay (id., ¶¶ 14, 15).[2]

[1]During 2002, Hopper was a Solvay district sales trainer (Doc. 84, ¶14).

[2]Defendant Unimed Pharmaceuticals, Inc. has held the FDA drug application for Marinol since 1985 (Doc. 84, ¶41). Unimed was acquired by Solvay in July 1999 and is its wholly-owned subsidiary (id., ¶18). Since 2001, Marinol has been marketed and distributed exclusively by Solvay (id., ¶58).

Marinol is a synthetic form of delta-9-tetrahydrocannbinol ("THC"), which is the major active component of marijuana (id., ¶36). The FDA first approved Marinol in 1985 for the treatment of "nausea and vomiting associated with cancer in chemotherapy patients who have failed to respond adequately to conventional antiemetic treatments" (id., ¶38). In 1991 the FDA also approved Marinol for anorexia associated with weight loss in patients with AIDS (id., ¶39).

The relators claim that, through the 1990s, the market for Marinol was small because it was not generally viewed as a useful product for its on-label use (id., ¶¶ 57-60). Consequently, despite Marinol's limited approval as an appetite stimulant in certain AIDS patients, Solvay allegedly developed in 2001 an aggressive off-label marketing campaign for Marinol, promoting it to physicians as an appetite stimulant in patients with appetite loss due to a variety of conditions, including cancer and aging (id., ¶¶ 62, 64, 65). It also allegedly marketed Marinol as a drug that could collectively treat appetite, nausea, and mood in cancer and HIV/AIDS patients (id., ¶¶ 84, 117, 139).

The FDA regulates the sales and marketing activities of pharmaceutical manufacturers in the United States (id., ¶21). After the FDA approves a drug for a particular use, it does not regulate how the drug is prescribed (id.). Thus, a physician may lawfully prescribe a drug to a patient for a use other than that for which it was approved by the FDA, and this is known as "off-label" use (id.).

However, the FDA prohibits a drug manufacturer from marketing or promoting a drug for non-approved use (id., ¶23). For example, a drug manufacturer may not initiate discussions with, or disseminate materials to, a medical professional regarding off-label use of a drug (id., ¶¶ 23, 24, 31, 32). Furthermore, federal healthcare programs, including Medicaid and Medicare, do not knowingly pay for medications that are not prescribed for a medically acceptable indication, or that are prescribed as a result of false or misleading information provided by the drug manufacturer (id., ¶¶ 34, 35).[3] In addition, the federal programs do not pay for drugs that

[3]The federal government pays prescription drug benefits under a variety of health care programs, including Medicare, Medicaid, CHAMPUS/Tricare, the Veteran's Health Administration, Federal Employees Health Benefits Program, and the Indian Health Bureau (id., ¶34).

were prescribed as a result of unlawful inducements or unlawful marketing activities by the manufacturer (id.).

The relators allege that Solvay spent millions of dollars to train its sales representatives, and educate health care providers, about the use of Marinol for off-label purposes (see, e.g., id., ¶¶ 113, 114, 125, 126, 131, 140-43, 169, 170, 179, 190, 222-28). Further, the relators allege that a Solvay sales representative arranged for lunches, ice cream, and Starbucks coffee to be brought to the offices of specifically targeted physicians in order to induce physicians to prescribe Marinol for off-label uses (id., ¶¶ 107, 108). The relators, moreover, allege that the defendants paid physicians for preceptorships, and attendance at meetings and events, which were intended to induce the physicians to prescribe Marinol for off-label uses (id., ¶¶ 193-221).[4]

After the implementation of the alleged illegal marketing program, the number of prescriptions for Marinol increased substantially, from 10,367 in 2000 to 124,208 in 2004 (id., ¶249). Concomitantly, payment for Marinol by public funding sources, such as Medicaid, increased (id., ¶95).

[4]During a preceptorship, a sales representative is allowed to "shadow" a physician ostensibly to learn about the physician's medical practices (see Doc. 84, ¶195).

Thus, Medicaid payments for Marinol during the years of the illegal off-label marketing campaigns increased from about $15 million in 1999 to over $69 million in 2005 (id., ¶237).

The relators allege that the majority of the Medicaid claims for Marinol were made as a result of prescriptions written for off-label uses that were not medically indicated or necessary, and the issuance of which were influenced by the defendants' alleged illegal marketing campaign (see id., ¶¶ 238-44). Therefore, they allege that, when claims were submitted to the government for reimbursement of the cost of Marinol, they were false because these off-label uses were not eligible for federal financial participation or covered by state Medicaid programs (id., ¶¶ 239, 241).[5]

On November 22, 2004, the relators filed a complaint under seal against the defendants pursuant to the qui tam provisions of the False Claims Act ("FCA"), 31 U.S.C. 3729, et seq., alleging that the illegal marketing campaign caused the filing of false claims for reimbursement of the cost of

[5]Pursuant to the Medicaid program, the federal government pays to states a portion of medical expenses incurred for health care provided to low-income individuals (Doc. 84. ¶230). The states submit quarterly Medicaid Statements of Expenditures to the federal government and they receive some reimbursement from the federal government for drugs that have been prescribed for a medically acceptable use (id., ¶¶ 230-32). The relators contend that the defendant's alleged illegal marketing activities also resulted in false claims to Medicare and other government health care programs (see id., ¶¶ 260-69).

Marinol (Doc. 3). The United States was served with the complaint and commenced its investigation of the allegations (see Doc. 5). It sought, and received, several extensions of time to notify the court whether it would intervene in the case (Docs. 5, 7, 13, 14, 17, 18). During its investigation, Solvay produced to the government hundreds of thousands of documents pursuant to government subpoenas (see Doc. 89-2).

The relators filed their first amended complaint on July 7, 2005 (Doc. 11). In July 2006, the United States requested a fourth six-month extension of time in which to decide whether to intervene in the case, but the court ordered the United States to decide whether it would intervene by October 27, 2006 (Docs. 21, 24). On that date, the United States notified the court that it was "not able to decide by the Court's deadline whether to proceed with the action" and it was therefore "not intervening at this time" (Doc. 25).

On November 17, 2006, the court ordered this lawsuit unsealed (Doc. 28). The relators subsequently moved to file a second amended complaint (Doc. 65), and the motion was granted (Doc. 83). The second amended complaint alleges violations of the FCA and analogous Illinois, California, and Massachusetts state statutes (Doc. 84, pp. 61-73).

The relators state in the second amended complaint that the "gravamen of [their] claims is that the Defendants developed and successfully executed a sophisticated marketing plan with the purpose of inducing physicians to prescribe the prescription drug Marinol ... for uses which are neither FDA approved nor demonstrated to be safe and effective" (id., p. 2, ¶3). The relators allege further that the defendants' conduct "has caused submission for reimbursement by Government Healthcare Programs of millions of dollars worth of prescriptions which were ineligible for such reimbursement" (id., ¶4). The second amended complaint also alleges kickbacks to physicians and other healthcare providers, such as remuneration under the guises of preceptorships, speaker programs, gifts, free entertainment and food, in order to induce them to prescribe Marinol for off-label appetite stimulation (id., p. 3, ¶¶ 7, 8).

The defendants have filed a motion to dismiss the second amended complaint pursuant to Rules 9(b), and 12(b)(1), (6), F.R.Civ.P. (Doc. 88). They allege that the relators have failed to plead their allegations of fraud with particularity, as required by Rule 9(b), F.R.Civ.P. (id.). Further, the defendants argue that the court lacks subject matter jurisdiction over the second amended complaint because some of its allegations are based on

publicly disclosed information for which the relators are not the original source of the information (id.).

The relators filed a memorandum in opposition to this motion, arguing that their allegations of fraud satisfy Rule 9(b)'s particularity requirement (Doc. 92). The relators also dispute the defendants' challenge to subject matter jurisdiction, contending that the allegations in the second complaint are not based upon publicly disclosed information and that they were the original sources of that information (id.). The defendants, with leave of court, filed a reply (Doc. 97).

The motion was referred to me for disposition, if it was to be denied, and for a report and recommendation, if the case was to be dismissed (Doc. 98). Oral argument was subsequently conducted on the motion (Doc. 100).

II.

As indicated, the relators' second amended complaint alleges violations of two provisions of the FCA (see Doc. 84, ¶273). Pursuant to 31 U.S.C. 3729(a), civil liability arises when a person:

> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of

> the United States a false or fraudulent claim for payment or approval; [or]
>
> (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[.][6]
>
> . . .

Statutory sanctions for FCA violations include civil penalties and treble damages. 31 U.S.C. 3729(a).

To assist the government in uncovering fraud, the FCA authorizes qui tam actions, in which a private citizen, or "relator," brings a lawsuit for violations of the FCA on behalf of the United States government. 31 U.S.C. 3730(b). After filing a complaint in camera, the relator provides the federal government with a copy of the complaint and a written disclosure of substantially all material evidence and information possessed by the relator. 31 U.S.C. 3730(b)(2).[7] The government has sixty days to intervene

---

[6]For purposes of the FCA, a "'claim' includes any request or demand ... for money ... which is made to a contractor, grantee or other recipient if the United States Government provides any portion of the money ... which is requested or demanded, or if the Government will reimburse such contractor, grantee or other recipient for any portion of the money ... which is requested or demanded." 31 U.S.C. 3729(c).

[7]Pursuant to §3730(b)(2), the relator's complaint is filed in camera. and remains under seal for at least sixty days and is not served upon the defendant until the court so orders.

in the case. Id. If the government elects not to proceed with the action, the relator has the right to conduct the lawsuit. 31 U.S.C. 3730(c)(3).

The relator stands to gain significantly from bringing a qui tam action. Thus, where, as here, the government does not assert its statutory right to take over the case from the relators, they can recover between twenty-five and thirty percent of any monies recovered from a settlement or judgment, plus reasonable expenses and reasonable attorneys' fees and costs. 31 U.S.C. 3730(d)(2).

III.

A. The defendants have asserted, as a secondary argument, that this lawsuit must be dismissed for lack of subject matter jurisdiction. See Rule 12(b)(1), F.R.Civ.P. Although the defendants did not press this argument at the hearing, the suggestion that subject matter jurisdiction is absent must be addressed first because if "the court determines at any time that it lacks subject-matter jurisdiction, the court must dismiss the action." Rule 12(h)(3), F.R.Civ.P.; see also U.S. ex rel. Atkins v. McInteer, 470 F.3d 1350, 1356 n. 10 (11th Cir. 2006)("A district court must examine its subject matter jurisdiction even though the parties do not challenge it.").

The defendants contend that the FCA bars jurisdiction over the second amended complaint because it purportedly contains allegations from publicly disclosed documents, and the relators were not the original source of that information (Doc. 88, pp. 29-40). In this regard, the FCA provides (31 U.S.C. 3730(e)(4)):

> (A) No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

The purpose of this jurisdictional bar is to prevent opportunistic lawsuits by individuals with no personal knowledge of fraud who gathered their information from the public domain. See Cooper v. Blue Cross and Blue Shield of Florida, Inc., 19 F.3d 562, 565 (11th Cir. 1994).

It is the relators' burden to establish subject matter jurisdiction. See McElmurray v. Consolidated Gov't of Augusta-Richmond Cty., 501 F.3d 1244, 1251 (11th Cir. 2007). A motion to dismiss for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), F.R.Civ.P., can be based upon either a facial or a factual challenge to the complaint. Id. If the challenge is facial, the court considers the allegations in the plaintiff's complaint as true. Id. Factual attacks challenge the existence of subject matter jurisdiction in fact, irrespective of the pleadings, and matters outside the pleadings, such as testimony and affidavits, are considered. Id. In the event of a factual challenge, "the district court must give the plaintiff an opportunity for discovery and for a hearing that is appropriate to the nature of the motion to dismiss." Williamson v. Tucker, 645 F.2d 404, 414 (5th Cir. 1981), cert. denied, 454 U.S. 897 (1981).

A facial challenge clearly fails in this case. The relators have specifically alleged that "[n]one of the actionable allegations set forth in this Complaint are based on a public disclosure as set forth in 31 U.S.C. 3730(e)(4), and Relators are an original source of the facts alleged in this Complaint" (Doc. 84, ¶16). This allegation defeats a contention that the

second amended complaint, on its face, shows that §3730(e)(4) forecloses subject matter jurisdiction.

Further, a factual challenge is premature, particularly since no discovery has been conducted in this case. A factual challenge, moreover, raises the unsettled question of whether production of documents pursuant to a Department of Justice subpoena and the subsequent sharing of those documents with the relators constitutes a public disclosure under §3730(e)(4). Compare U.S. ex rel. Fowler v. Caremark Rx, L.L.C., 496 F.3d 730, 736-37 (7th Cir. 2007), cert. denied, 128 S.Ct. 1246 (2008) (public disclosure); U.S. ex rel. Rost v. Pfizer, Inc., 507 F.3d 720, 728 (1st Cir. 2007) (no public disclosure). There is no justification for proceeding toward a difficult and burdensome factual challenge when the Rule 12(b)(6) contention is easily resolved and disposes of the case.

B. The defendants' primary argument is that the second amended complaint should be dismissed for failure to plead with particularity the contention that the defendants' alleged illegal marketing campaign caused the submission of false or fraudulent claims to the government (Docs. 88, 97). This contention is predicated upon Rule 9(b), F.R.Civ.P., which requires a

party alleging fraud to "state with particularity the circumstances constituting fraud."

The relators have alleged that the "[d]efendants, through their illegal off-label marketing campaigns, knowingly caused the submission of hundreds of thousands of false ... claims" for off-label Marinol prescriptions, which resulted in the government's improper reimbursement of millions of dollars (Doc. 84, ¶¶ 4, 250, 275). The defendants argue that Eleventh Circuit caselaw requires that such a count must include specific allegations of an actual false claim that was submitted to the government (Doc. 88, p. 13). The defendants argue that the relators have instead asked the court to infer the existence of an actual false claim. In this respect, the defendants say that "[t]he [second amended complaint] points to no actual off-label prescription resulting from the alleged off-label marketing campaign, when or where such a prescription would have been written, or for which patient" (id., p. 7). They add that the second amended complaint does not identify "any alleged false claim actually submitted for reimbursement, ... let alone who submitted such a claim, when the claim was submitted ... [or] the content of the claim" (id., p. 20) (emphasis omitted).

The relators concede that they have no evidence of a false claim. Rather, they argued at the hearing that the Eleventh Circuit's pleading requirements are not as limiting as the defendants suggest (see also Doc. 92, p. 12, n.14). Specifically, they contend that the Eleventh Circuit's requirement that allegations of false or fraudulent claims be supported by "indicia of reliability" is satisfied by allegations in the second amended complaint from which it can be inferred that a false claim was submitted to the government.

That is not the law of the Eleventh Circuit. There are three binding decisions, as well as an unpublished decision, that hold that, in qui tam actions like this one, a False Claims Act count must, in order to satisfy Rule 9(b)'s particularity requirement, allege a false claim that was actually submitted to the government. U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc., 290 F.3d 1301 (11th Cir. 2002), cert. denied, 537 U.S. 1105 (2003); Corsello v. Lincare, Inc., 428 F.3d 1008 (11th Cir. 2005), cert. denied, 127 S.Ct. 42 (2006); U.S. ex rel. Atkins v. McInteer, supra, 470 F.3d 1350; Mitchell v. Beverly Enterprises, Inc., 248 Fed.Appx. 73, 2007 WL 2551404 (11th Cir. 2007)(unpub. dec.), reh'g en banc denied, 255 Fed.Appx. 504 (11th Cir. 2007).

In Clausen, the qui tam relator, who worked in the medical testing industry and was a competitor of the defendant, alleged that the defendant was billing the government for unnecessary laboratory tests for patients who participated in government-funded health insurance programs. 290 F.3d at 1303. He identified patients allegedly subjected to improper testing, set forth the improper tests, and stated the dates on which those procedures were performed. Id. at 1304-05.

Although the relator in Clausen described in detail the defendant's alleged scheme to defraud the government, the Eleventh Circuit affirmed the dismissal of the complaint for failure to plead fraud with specificity because it did not contain "any billing information to support [the plaintiff's] allegation that actual false claims were submitted for payment." Id. at 1306. The Eleventh Circuit explained that the relator did not include a copy of a single actual bill or claim, he did not identify the amounts of any charges or dates of claims, and he did not provide a single completed reimbursement form. Id. In sum, the relator in Clausen "failed to provide any ... information linking the testing schemes to the submission of any actual claims or any actual charges." 290 F.3d at 1313.

The Eleventh Circuit followed Clausen in Corsello v. Lincare, supra. In that qui tam suit, the relator, who had been a salesman for two of the defendants, alleged that the defendants had "engaged in various fraudulent schemes, including paying illegal kickbacks to physicians to induce referrals, falsifying certificates of medical necessity to provide unnecessary treatment, and billing for unnecessary or non-existent treatment to obtain Medicare payments unlawfully." 428 F.3d at 1011. A dismissal of the second amended complaint was upheld on appeal because the pleading "failed to allege when, where, and what violations of the False Claims Act occurred." Id. at 1013.

The Eleventh Circuit in Corsello said that, in order "[t]o state a claim under the False Claims Act with particularity, the complaint must allege 'facts as to time, place, and substance of the defendant's alleged fraud,' and 'the details of the defendants' allegedly fraudulent acts, when they occurred, and who engaged in them." Id. at 1012 (quoting U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc., supra, 290 F.3d at 1310). It explained that "[l]iability under the False Claims Act arises from the submission of a fraudulent claim to the government, not the disregard of government regulations." 428 F.3d at 1012.

Clausen was again followed in U.S. ex rel. Atkins v. McInteer, supra, 470 F.3d 1350. There, the qui tam relator was a psychiatrist who alleged that two other psychiatrists and associated businesses had improperly sought reimbursement for services from Medicare and Medicaid. Id. at 1354. The court of appeals stated that, "[a]s the plaintiff did in Clausen, Atkins has described in detail what he believes is an elaborate scheme for defrauding the government by submitting false claims." Id. at 1359. "Just like the Clausen plaintiff, though, Atkins fails to provide the next link in the FCA liability chain: showing that the defendants actually submitted reimbursement claims for the services he describes." Id. (emphasis in original). Accordingly, the court upheld the dismissal of the complaint because Rule 9(b)'s particularity requirement was not satisfied.

The Eleventh Circuit most recently reiterated its construction of Rule 9(b) in an FCA case in Mitchell v. Beverly Enterprises, Inc., supra, 2007 WL 2551404. In Mitchell, the Eleventh Circuit affirmed the dismissal of a qui tam complaint for failure to meet the particularity requirement because, although the relator included specific allegations of the defendant's illegal policies, he "fail[ed] to make specific allegations about [false] claims actually submitted to Medicare." Id. at *2. The short shrift given to the issue in

Mitchell's unpublished decision demonstrates that the Eleventh Circuit views the law as well-settled.

In this case, the relators have provided detailed allegations of various schemes to promote Marinol's off-label use, but their allegations that the defendants' alleged illegal marketing campaign caused the submission of false claims for government reimbursement totaling millions of dollars are not supported by any facts concerning false claims actually submitted to the government for reimbursement. The relators concede that they cannot identify a specific false claim. Further, they have no information about the contents, or processing, of a false claim, such as who created a false claim or when false claims were created, the substance of the false representations, or alleged improper billing practices. In short, the relators lack knowledge of any false claim that was submitted to the government.

The relators speculate that a false claim must have been submitted to the government, arguing that "it is possible to draw a strong inference that false claims to Medicaid resulted from Solvay's off-label marketing campaign, because over the life of that illegal campaign, prescriptions for Marinol rose from 10,367 in 2000 to 124,208 in 2004, and Medicaid reimbursements for Marinol rose from $21.6 million in 2000 to $62

million in 2005" (Doc. 92, p. 9). However, the Eleventh Circuit will not infer that a false claim was submitted to the government, even when the relator provides detailed allegations of the fraudulent scheme that purportedly gave rise to the false claim. The court explained in U.S. ex rel. Atkins v. McInteer, supra, 470 F.3d at 1357(citation omitted):

> We cannot make assumptions about a False Claims Act defendant's submission of actual claims to the Government without stripping all meaning from Rule 9(b)'s requirement of specificity or ignoring that the "true essence of fraud" of a False Claims Act action involves an actual claim for payment and not just a preparatory scheme.

See also U.S. ex rel. Clausen v. Laboratory Corp. of America, Inc., supra, 290 F.3d at 1313, n.23 (the court cannot presume billing policies or assume claims were actually billed to the government); Corsello v. Lincare, Inc., supra, 428 F.3d at 1013 ("Because it is the submission of a fraudulent claim that gives rise to liability under the False Claims Act, that submission must be pleaded with particularity and not inferred from the circumstances.").[8]

---

[8]The defendants argue that an inference of wrongdoing under the FCA is further attenuated in this circumstance, as it requires the court to assume the existence of an off-label prescription which was written as a result of the defendants' illegal marketing campaign for a beneficiary of a government health care program, and that reimbursement for the cost of the drug was sought from the government on a claim form that falsified the fact that the prescription was for an off-label use (see Doc. 97, pp. 5-6).

Therefore, while the defendants' allegations may state a regulatory violation, they have not stated with particularity an FCA violation. Under Clausen, Corsello, and Atkins, the relators' second amended complaint is clearly insufficient and should be dismissed.

Notably, the relators in their memorandum make no meaningful attempt to distinguish these three decisions. At the outset of their argument, the relators point to proposed legislation that would eliminate a requirement that a person identify specific claims (Doc. 92, pp. 3-4). That unenacted proposal not only does not assist the relators, but it confirms the Eleventh Circuit's requirement that specific claims must be identified.

Next, the relators urge a fresh reading of Judge Barkett's dissent in Clausen. Id., p. 4. Obviously, a dissent does not reflect the law of the Eleventh Circuit.

The relators then seek support from Tellabs, Inc. v. Makor Issues & Rights, Ltd., ___ U.S. ___, 127 S.Ct. 2499 (2007) (Doc. 92, pp. 4-10). That decision construed a scienter requirement under the Private Securities Litigation Reform Act. It did not address the FCA. Consequently, it provides no basis for this court to disregard the Eleventh Circuit's binding precedent in Clausen, Corsello, and Atkins.

At the hearing, relators' counsel emphasized the Eleventh Circuit's decisions in Hill v. Morehouse Medical Associates, Inc., 2003 WL 22019936 (11th Cir. 2003)(unpub. dec.) and U.S. ex rel. Walker v. R&F Properties of Lake County, Inc., 433 F.3d 1349 (11th Cir. 2005), cert. denied, 127 S.Ct. 554 (2006). Those decisions do not call Clausen, Corsello, and Atkins into question, and they certainly do not override them.

In Hill, the qui tam relator alleged that the defendant violated the FCA by routinely submitting claims for payment to the government for tests that it did not perform. 2003 WL 22019936 at *1. The relator, who worked in the defendant's billing and coding department, supported her allegations with details of fraudulent billing, including, for example, her personal observations of employees changing diagnosis codes, after claims were rejected, to codes that would support Medicare reimbursement, and then resubmitting the claims for payment. Id. She also identified the employees who were responsible for the improprieties and how often they occurred. Id. at *1, *2. Despite the absence of an allegation of a specific false claim, the Eleventh Circuit found that the relator's complaint met the particularity requirement, as it included facts about the alleged fraudulent billing, the

reliability of which were buttressed by the relator's firsthand observation of false claims in her role as a billing department employee. Id. at *5.

There is arguably some tension between Hill and Clausen. Corsello and Atkins.[9] In any event, Hill is clearly distinguishable from Clausen, Corsello, and Atkins, since Hill's allegations of false billing were based upon personal knowledge and did not require any inference regarding the submission of false claims. There are no comparable allegations in this case and, thus, Hill provides the relators no support.

Similarly, U.S. ex rel. Walker v. R&F Properties of Lake County, Inc., supra, is inapposite. In Walker, the qui tam relator worked as a nurse practitioner for the defendant. She alleged that the defendant submitted false claims in violation of the FCA by improperly billing Medicare for nursing services as "incident to the service of a physician" even though no physician was present.[10] 433 F.3d at 1353-54. In her complaint, Walker alleged

[9]The Eleventh Circuit noted in Atkins that Hill, as an unpublished opinion, is not binding precedent. 470 F.3d at 1358 n.15. Further, the court added that, even if Hill were a published opinion, the prior panel rule would dictate that Clausen supercedes Hill to the extent that Hill is inconsistent with Clausen. Id.

[10]The Walker complaint alleged that, when a nurse works largely unsupervised, the treatment should be billed under the nurse's own identification number, for which the medical care provider would receive only eighty-five percent of the rate otherwise paid by the government. U.S. ex rel. Walker v. R&F Properties of Lake County, Inc., supra, 433 F.3d.3d at 1352-53.

firsthand knowledge of actual false claims. Thus, she had no billing number and her nursing services were improperly billed at a higher rate through a physician's billing number even though she saw patients without physician supervision. Id. at 1360. Further, the complaint alleged that the office administrator confirmed to her that the defendant never billed nurse and nurse practitioner services in another manner. Id.

The relator's personal knowledge of the billing situation distinguishes Walker from Clausen and Corsello, as the Eleventh Circuit expressly pointed out. Id. As noted in Atkins, even if there were any inconsistency between Walker, on the one hand, and Clausen and Corsello, on the other – and there does not appear to be any – Clausen and Corsello would be the controlling decisions under the prior panel rule.

In all events, Walker does not support the relators' position in this case. There are no allegations in this case that are similar to the allegations in Walker based upon personal knowledge regarding the submission of false claims.

Consequently, Clausen, Corsello, and Atkins control the outcome in this case. Those cases require in an FCA case like this one allegations of the actual presentment of false claims. Because in this case the

second amended complaint contains no such allegations, the complaint should be dismissed.

C. There are two ancillary matters that are appropriately addressed, even though the parties have not done so.

First, the relators have alleged claims on behalf of Illinois (Count II), California (Count III) and Massachusetts (Count IV) (Doc. 84, pp. 63-73). They have made no request that those counts remain pending if the FCA count is dismissed, and they certainly have not developed any argument supporting such a result. In particular, they have provided no basis for concluding that these state law claims could be considered on some type of supplemental jurisdiction after dismissal of the federal claim. In any event, in order to proceed in federal court, the state law claims would have to satisfy Rule 9(b)'s requirements, and, for the same reason that the federal claim is deficient under that rule, the state law claims are deficient as well.

Second, the relators have made no request to file another amended complaint. See Wagner v. Daewoo Heavy Industries America Corp., 314 F.3d 541, 542 (11th Cir. 2002)(en banc). This is understandable since the relators acknowledge that they do not have the information

necessary to cure the Rule 9(b) insufficiency. In other words, any attempt to remedy the deficiency would be futile.

IV.

For the foregoing reasons, I recommend that the motion to dismiss (Doc. 88) be denied to the extent that it challenges subject matter jurisdiction. The motion should be granted, however, pursuant to Rule 12(b)(6), F.R.Civ.P., because the relators failed to state with particularity their FCA allegation that the defendants' illegal marketing scheme caused the submission of false or fraudulent claims to the government.

Respectfully submitted,

THOMAS G. WILSON
UNITED STATES MAGISTRATE JUDGE

DATED: AUGUST 1, 2008

NOTICE TO PARTIES

Failure to file written objections to the proposed findings and recommendations contained in this report within ten days from the date of its service shall bar an aggrieved party from attacking the factual findings on appeal. 28 U.S.C. 636(b)(1).