**UNITED STATES DISTRICT COURT**
**DISTRICT OF MINNESOTA**

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In Re: BAYCOL PRODUCTS LITIGATION MDL No. 1431

This Document Relates to:

United States ex rel. Simpson,

**MEMORANDUM OPINION AND ORDER**

Relator, Case No. 08-5758 (MJD/SER)

v.

Bayer Healthcare d/b/a Bayer Healthcare Pharmaceuticals; Bayer Pharmaceuticals Corp.; Bayer Corporation; and Bayer A.G.,

Defendants.

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Robert W. Sadowski and Raphael Katz, Diamond McCarthy LLP and Edward Normand, Boies, Schiller & Flexner LLP, Counsel for Relator Laurie Simpson.

Philip S. Beck and Adam Hoeflich, Bartlit Beck Herman Palenchar & Scott LLP, Susan A. Weber, James R.M. Hemmings, Ryan C. Morris and Kristin Graham Koehler, Sidley Austin LLP and Peter W. Sipkins, Dorsey & Whitney LLP, Counsel for Defendants.

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This matter is before the Court upon Defendants Bayer Healthcare d/b/a Bayer Healthcare Pharmaceuticals, Bayer Pharmaceuticals Corp., Bayer

Corporation and Bayer A.G.'s (collectively "Bayer") motion to dismiss pursuant to Federal Rules of Civil Procedure 8(a), 9(b), 12(b)(1) and 12(b)(6).

## I. Introduction

Relator Laurie Simpson originally filed this action on October 5, 2006 in the United States District Court, District of New Jersey on behalf of the United States of America, eleven states and the District of Columbia, alleging claims under the False Claims Act, 31 U.S.C. § 3729 et seq. (the "FCA") and various state laws concerning the statin drug Baycol, also known as cerivistatin. Thereafter, the case transferred to this Court as part of the Baycol MDL.

In January 2009, Relator filed a First Amended Complaint ("FAC") in which she alleged that Bayer's marketing and sale of the drug Baycol violated the FCA, and that the false and fraudulent statements at issue involve payments made by federal government-funded health insurance programs and by state funded programs including Medicare, Medicaid, the Federal Employees Health Benefits Program ("FEHBP"), TRICARE/CHAMPUS and the Department of Defense ("DOD") for prescription drugs. (FAC ¶ 1.)

By Memorandum Opinion and Order dated September 30, 2010 [Doc. No. 50], this Court granted Bayer's motion to dismiss the FAC. The Court dismissed

with prejudice any FCA claims premised on false claims asserted prior to October 5, 2000. The Court also dismissed, with prejudice, claims asserted pursuant to § 3729(a)(3)[1] and (7)[2] and 42 U.S.C. § 1320a-7.[3] The remaining claims were dismissed without prejudice pursuant to Rule 9(b) of the Federal Rules of Civil Procedure, for failing to plead fraud with particularity. Relator was given leave to amend her complaint with respect to those allegations for which the Relator was found to be an original source, as defined in Part I.D. of the Court's Memorandum Opinion. (Mem. Op. at 35.)

On the original source issue, the Court found that Relator was the original source of allegations concerning misleading and deceptive marketing as asserted in paragraphs 40-82 and 94-112 of the FAC; mislabeling as asserted in paragraphs 88-93 of the FAC; and kickbacks, as asserted in paragraphs 113-129. (Mem. Op. at 22-24.) The Court further held that Relator was not an original source of allegations concerning clinical trials involved a plan to develop a fixed-dose

[1]This subsection addresses false or fraudulent claims paid by the United States and performed one or more acts to effect payment of false or fraudulent claims.

[2]This subsection addressed false certifications made or caused to be made to conceal, avoid or decrease an obligation to pay or transmit money or property to the United States.

[3]This statute defines those persons who can be excluded from participation in Medicare and State health care programs, including those who engage in fraud, kickbacks and other prohibited activities as defined in §§ 1320a-7a, 7b and 8.

combination with a fenofibrate asserted in paragraphs 83-87 of the FAC and for allegations concerning kickbacks involving individual physician-level, as well as in managed care and institutional settings asserted in paragraph 130 of the FCA. (Mem. Op. at 24.)

On November 23, 2010, Relator filed a Second Amended Complaint ("SAC").

## II. Factual Allegations Contained in the Second Amended Complaint

Relator alleges that between January 1998 and August 8, 2001, Baycol was one of the most important pharmaceutical products manufactured, marketed and sold by Bayer. (SAC ¶ 3.) Baycol was removed from the market in August 2001, however, after multiple deaths were linked to the drug. (Id. ¶ 4.)

Among other government funded agencies, the DOD had a contract with Bayer for Baycol, and paid Bayer millions of dollars for Baycol during the relevant time period. (Id. ¶ 5.) Relator alleges that through illegal kickbacks and misbranding, Bayer caused false claims to be filed, which claims would not have been paid had the truth been known. (Id. ¶ 6.)

Relator was a Senior Market Research Analyst for Bayer and during the relevant time period was assigned to the Baycol marketing team. (Id. ¶ 7.)

Relator alleges that she participated in the development and refinement of marketing messages, assessed product perceptions of Baycol and its competitors, evaluated communications to physicians and the public, conducted product pricing studies, participated in assessing sample requirements and attended copy approval meetings as well as the Baycol product team and Joint Marketing team meetings devoted to Baycol promotion. (Id. ¶ 8.) Relator further alleges that she routinely translated clinical trial information into potential marketing material, and she routinely participated in discussions with other team members about the design and status of Baycol clinical trials. (Id. ¶¶ 9 and 10.) In 1998, Relator began to conduct competitive intelligence activities, and developed and maintained a clinical trial database, as well as provided input to clinical trial designs. (Id. ¶¶ 11 and 13.) Because of her position and duties, Relator asserts that she is uniquely positioned to detail Bayer's knowledge concerning the risks attendant with Baycol, when those risks became known, and Bayer's steps to conceal those risks. (Id. ¶ 14.)

Relator alleges that Bayer engaged in improper and unlawful marketing strategies, including kickbacks and downplaying the risks of Baycol to physicians through defective and inadequate warnings. (Id. ¶¶ 15-16.) Bayer is also alleged

to have intentionally misrepresented, concealed or omitted facts and refrained from taking steps to learn facts about Baycol in connection with its communications to the public, government representatives and to physicians. (Id. ¶ 16.) It is Relator's position that had government representatives known of the foregoing deceptive, misleading and improper conduct, they would not have contracted to purchase Baycol. (Id. ¶ 17.) Further, because of Bayer's alleged misbranding of Baycol, false claims were submitted to the government when physicians prescribed Baycol without knowing the risks associated with Baycol. (Id. ¶ 265.)

The remaining allegations included in the SAC are addressed to descriptions of the government funded programs involved, to the relevant statutes and regulations and to the alleged fraudulent schemes carried out by Bayer.

**III. Motion to Dismiss**

Bayer argues that the SAC should be dismissed as Relator has failed to cure the fundamental deficiencies that led to the dismissal of the FAC. Bayer argues that the new factual allegations do not provide the type of particularized allegations needed to sufficiently state a claim for fraud under the FCA. In

addition, some of the new allegations concern events that took place prior to October 5, 2000 - the cut off date for a timely claim as set forth in the Court's prior order.

Bayer further argues certain FCA claims must be dismissed for lack of subject matter jurisdiction, as Relator is not the original source of the publicly disclosed allegations contained in the SAC. Bayer next argues that Relator cannot base a claim on the DOD contract, because in settlement, the government released all liability against Bayer based on that contract. Finally, Bayer argues that the new PacifiCare and DOD allegations are time-barred because they do not share a common core of operative facts with those in the FAC, and thus do not relate back.

## IV. The False Claim Act

### A. Specificity Requirements

In Count I, Relator asserts that Bayer presented a false or fraudulent claim for payment or approval to the United States Government, in violation of 31 U.S.C. § 3729(a)(1). Count II asserts a claim that Bayer knowingly made or used false records or statements to get false or fraudulent claims paid or approved by the Government, and knowingly caused physicians and other healthcare

providers to submit bills to the Government and to Medicaid as a result of illegal kickbacks, in violation of § 3729 (a)(2)[4].

The FCA is concerned with "protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money." United States ex rel. Vigil v. Nelnet, Inc., 639 F.3d 791, 796 (8th Cir. 2011). "Without sufficient allegations of materially false claims, an FCA complaint fails to state a claim on which relief can be granted." Id. The focus is thus on the alleged false claims, as the FCA "attaches liability, not to the underlying fraudulent activity, but to the 'claim for payment.'" Costner v. URS Consultants, Inc., 153 F.3d 667, 677 (8th Cir. 1998) (quoting United States ex rel. Hopper v. Anton, 91 F.3d 1261, 1266 (9th Cir. 1996) cert. denied, 519 U.S. 1115 (1997)).

As the FCA is an anti-fraud statute, any claims asserted thereunder must comply with Rule 9(b) of the Federal Rules of Civil Procedure. United States ex rel. Joshi v. St. Luke's Hosp., 441 F.3d 552, 556 (8th Cir. 2006). Rule 9(b) provides that the circumstances constituting fraud must be stated with particularity, in

[4]In 2009, Congress amended the FCA, but as the alleged false claims described in the SAC were resolved prior to the effective date set forth in the amendment, the amendment does not apply here. See United States v. Hawley, 619 F.3d 886, 894 (8th Cir. 2010).

order to allow "the defendant to respond specifically and quickly to the potentially damaging allegations." Id. (citation omitted). To meet the requirements of Rule 9(b), the relator "must plead such facts as the time, place, and content of the defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result." Id. In a *qui tam* action under the FCA, the relator need not allege specific details of every alleged false claim, but must provide some representative examples of false claims. Id. at 557.

Relying on Joshi, this Court found that Relator failed to provide the requisite particularity as to representative false claims, and dismissed the false claims act claims pursuant to Rule 9(b). (Mem. Op. at 30-31.) In response to the Court's dismissal order, Relator asserts that she added numerous allegations in the SAC concerning actual Baycol claims made to the government and that the government paid claims for Baycol. (SAC ¶¶ 243-54.) Relator also included lists of expenditures made in 2001 by various Tricare divisions to pay Baycol claims, as well as the Federal and State Medicare expenditures made in 2000 for Baycol. (Id.) In response to Bayer's current motion to dismiss, Relator has also submitted a spreadsheet detailing over 30,000 examples of specific claims made through the

Medicaid programs in Florida, Georgia, Texas, Maine, North Carolina, Michigan and New York.

Relator asserts that she also added allegations in the SAC concerning specific examples of DOD patient level claims from adverse event reports. (Id. ¶¶ 237-42.) Relator has also added allegations concerning her core allegations that Bayer embarked on a deceptive marketing scheme which rendered false each claim for reimbursement for Baycol made to the government. (Id. ¶¶ 56-85, 125-38.) Relator also added allegations concerning how her position in marketing provided her direct and independent knowledge of her allegations concerning clinical trials and certain kickbacks. (Id. ¶¶ 9-13, 230-36.) Finally, Relator added allegations explaining how Bayer's violation of the Anti-Kickback Statute is a further basis for a False Claim Act claim. (Id. ¶¶ 48, 208, 272-75.)

Before addressing whether the SAC satisfies Rule 9(b), the Court finds that with respect to the claims based on the Anti-Kickback Statute, the Court has already determined that Relator is not the original source of kickback claims involving clinical trials involved a plan to develop a fixed dose combination with a fenofibrate and for allegations concerning kickbacks involving individual physician-level, as well as in managed care and institutional settings as described

in paragraphs 83-87 and 130 of the FAC. Relator was only given leave to amend her complaint with respect to kickback allegations set forth in paragraphs 113-129 of the FAC. To the extent that Relator bases any of her current kickback-based FCA claims on kickbacks unrelated to those described in paragraphs 113-129 of the FAC, such claims must be dismissed as beyond the scope of this Court's prior order.

The Court further finds that adding allegations concerning certain patient-level claims and representative summaries of amounts paid by the government for Baycol does not cure the pleading deficiencies of her FCA claims. As with the FAC, what is missing from the SAC are allegations that particular claims made to the government for payment of Baycol were false or fraudulent, and what part of the claim is false or fraudulent. In addition, there are no allegations as to when purchases for Baycol occurred, or who submitted the claim.

Relator argues that pursuant to her theory of the case, if the government had known of Bayer's deceptive marketing schemes, such as the concealment of safety issues, the government would not have paid any claims for Baycol. Thus, each Baycol claim submitted to the government was a false claim. In support, Relator cites to United States ex rel. Repko v. Guthrie Clinic, P.C., 557 F. Supp.2d

522 (M.D. Pa. 2008). In that case, the relator alleged that in exchange for financial incentives, the defendant clinic referred patients to the defendant hospital in violation of federal law. Based on this alleged scheme, all claims submitted to the hospital for those patients amounted to false claims. Id. 557 F. Supp.2d at 527. The district court denied the motion to dismiss, finding:

> Relator has alleged that every claim submitted to the government by Hospital during the relevant time period was fraudulent. This is because each of these claims was the result of a referral that was allegedly illegal under the Stark and Anti-Kickback laws. Thus, the theory is that the certification of compliance with the Stark and Anti-Kickback laws that was on each claim rendered each claim false. Furthermore, relator has discussed in great detail why each referral was illegal under these statutes, having discussed various agreements entered into by Hospital, Clinic, and GHS from paragraphs 33 to 108, which spans a total of twenty-eight pages in the third amended complaint and includes various attachments. Therefore, we find that attachment of some or all of the allegedly fraudulent claims would serve no further purpose consistent with Rule 9(b) because defendants are on notice that the basis of the alleged fraud in each claim is the relationship between defendants, not anything unique to a particular claim, that has caused these claims to be allegedly fraudulent. Therefore, we believe defendants are on notice of the conduct that is alleged to have occurred, and will deny defendants' motion to the extent it seeks dismissal based on a failure to plead fraud with particularity.

Id. (internal citation omitted). See also, U.S. ex rel. Fry v. The Health Alliance of Greater Cincinnati, No. 1:03-CV-00167, 2008 WL 5282139 at *13 (S.D. Ohio Dec. 18, 2008) (relying on Repko).

The cases cited by Relator are not controlling in the Eighth Circuit, and actually contradict controlling Eighth Circuit precedent, as well as the controlling precedent within their respective circuits. See, e.g., U.S. ex rel. Quinn v. Omnicare Inc., 382 F.3d 432, 434 (3d Cir. 2004) (finding that evidence of the actual submission of a false claim is necessary to prove an FCA claim based on the theory that defendant pharmacy was not properly reimbursing Medicare); United States ex rel. Snapp, Inc. v. Ford Motor Co., 532 F.3d 496, 506 (6th Cir. 2008) (finding that relator needed to identify with particularity a fraudulent claim for payment in scheme by automobile company to fraudulently induce government to contract with company by inflating company's dealings with small and minority owned businesses).

Cases decided by the Eighth Circuit post-Joshi reaffirm this Court's previous finding that particularized allegations of representative false claims are required to properly assert a claim under the FCA.

For example, in United States ex rel. Roop v. Hypoguard USA, Inc., the Eighth Circuit affirmed the district court's dismissal of a *qui tam* action for failing to plead claims of fraud with particularity. 559 F.3d 818, 822 (8th Cir. 2009). In that case, the relator alleged that the defendant manufactured and sold defective

glucose monitors and test strips, and that the defendant knew of the defects and failed to file reports required by the FDA, which caused Medicare to pay countless fraudulent reimbursement claims submitted by defendant distributors. Id. at 820. The court found that even where a relator alleges a systematic practice of submitting fraudulent claims, the FCA complaint must nonetheless include representative examples of the alleged fraudulent conduct. The court further found that additional allegations of product defects and consumer injury would not cure the deficiencies in the pleadings "because sales of a defective product do not give rise to FCA liability absent proof that a party 'knowingly or with deliberate ignorance charged the government for worthless service.'" Id. at 824 (quoting United States ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1053 (9th Cir. 2001)). The court further found that relator had failed to include particularized allegations of how any product defect or failure to submit required reports was material to - that is capable of influencing - the government's decisions to pay countless unidentified Medicare reimbursement claims submitted by defendant's distributors. Id. at 825. See also Vigil, 639 F.3d at 797-99 (dismissing FCA claims where relator failed to provide allegations as to specific materially false claims and did not link alleged false statements to the

government's decision to pay false claims).

The claims alleged in the SAC are similarly deficient. Relator's theory in this case is that through fraudulent marketing schemes involving misrepresentations, omissions, mislabeling and kickbacks, Baycol was included in the military formulary, as well as the formularies for certain federal and state funded health care programs, causing the submission of a claim for payment for Baycol when Baycol was prescribed to a patient covered under such a program. Relator then asserts that had the government known of Bayer's misrepresentations and omissions concerning the risks associated with Baycol, the government would not have paid any claims submitted under the DOD contract or to federal and state health insurance programs.

First, the Court finds there are no allegations in the SAC linking the government's decision to pay Baycol to any alleged fraud. Second, the fact that a patient covered by a federal or state funded health care program was prescribed Baycol to lower his/her cholesterol is not, in and of itself, false or fraudulent. Relator does not allege that Baycol did not work for all patients. Thus, assuming that a patient was prescribed Baycol to reduce his/her cholesterol levels, and assuming Baycol successfully lowered the patient's cholesterol, there would be

nothing false or fraudulent about the claim for payment for that patient. A claim under the FCA focuses on the claims, not the underlying fraudulent activity. Costner, 153 F.3d at 677. Because there are no allegations in the SAC that a claim submitted to the government for payment for Baycol, was - in and of itself - fraudulent or false, Relator has failed to sufficiently plead a claim under the FCA.

Accordingly, the Court finds that the FCA claims must be dismissed pursuant to Rule 9(b). As Relator has filed three complaints in this case, she will not be given leave to amend.

**V. State False Claim Act Claims**

The Court previously held that Relator's state false claim act claims must also be plead with particularity. Accordingly, for the same reasons Relator's FCA claims do not meet the requirements of Fed. R. Civ. P. 9(b), the state claims must also be dismissed.

**IT IS HEREBY ORDERED** that Defendants' Motion to Dismiss [Doc. No. 55] is **GRANTED.** The Second Amended Complaint is **DISMISSED WITH PREJUDICE.**

**LET JUDGMENT BE ENTERED ACCORDINGLY.**

Date: July 18, 2012

s/ Michael J. Davis
Michael J. Davis
Chief Judge
United States District Court

Civil No. 08-5758