UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In Re: BAYCOL PRODUCTS LITIGATION MDL No. 1431

This Document Relates to:

United States ex rel. Simpson,

MEMORANDUM OF LAW & 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.

Gerald C. Robinson, Gerald Robinson Law Firm, PLLC, Counsel for Relator Laurie Simpson.

Philip S. Beck and Adam Hoeflich, Bartlit Beck Herman Palenchar & Scott LLP, Susan A. Weber, Bradley Arant Boult Cummings LLP, Ryan C. Morris and Kristin Graham Koehler, Sidley Austin LLP and Paul Dieseth and Annie M. Trimberger, Dorsey & Whitney LLP, Counsel for Defendants.

This matter is before the Court following remand from the Eighth Circuit Court of Appeals. In re Baycol Prod. Litig., 732 F.3d 869, 876-77 (8th Cir. 2013).

Defendants Bayer Healthcare d/b/a Bayer Healthcare Pharmaceuticals,

Bayer Pharmaceuticals Corp., Bayer Corporation and Bayer A.G.'s (collectively "Bayer") move to dismiss the claim for fraudulent inducement asserted in the Second Amended Complaint pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6).

I. Background

A. Allegations in the Complaint and Amended Complaint

Relator Laurie Simpson filed this action in the United States District Court, District of New Jersey on October 5, 2006 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 false claim act statutes concerning the statin drug Baycol. Generally, Relator alleged that Baycol was removed from the market in August 2001 after multiple deaths and injuries were linked to the drug. (Complaint ¶ 4.) She further alleged that "[a]mong other government funded agencies, the Department of Defense had a contract with Bayer for Baycol, and paid millions of dollars to purchase the drug during the relevant time period." (Id. ¶ 5.) As a former member of Bayer's marketing team for Baycol, Relator alleged that she participated in the development and refinement of marketing messages, and evaluated

communications to physicians and the public about Baycol. (Id. ¶¶ 6 and 7.) Relator further alleged "that from April 1998 through August 8, 2001, Bayer engaged in numerous improper and unlawful marketing strategies, including paying kickbacks, to increase the market share of its drug." (Id. ¶ 9.) Relator alleged that Bayer marketed Baycol with defective, inadequate and deceptive warnings in order to downplay the risks that Baycol posed. (Id. ¶ 10.) She further alleged that "Bayer intentionally misrepresented, concealed or omitted facts and refrained from taking necessary steps to learn facts about the drug in connection with its communications with physician, representatives of the Government, and the public." (Id.) Relator alleged that if the Government knew of the deceptive, misleading and/or improper conduct, they would not have contracted for and/or purchased Baycol. (Id. ¶ 11.)

On March 31, 2008, Relator filed an Amended Complaint in which she included additional factual allegations to support her claims, including the allegation that through illegal kickbacks and misbranding, Bayer caused false claims to be filed which would not have been paid had the full truth been known and that Bayer engaged in this deceptive and misleading conduct to increase its overall market share of Baycol by inducing physicians to prescribe Baycol who

otherwise would have not done so. (Amended Complaint ¶ 6.) The matter was thereafter transferred to the District of Minnesota by the Judicial Panel on Multidistrict Litigation ("JPML") in October 2008.

By Memorandum Opinion and Order dated September 30, 2010, the Court granted Bayer's motion to dismiss the Amended Complaint. (Doc. No. 50.) The Court dismissed certain claims with prejudice, and the remaining claims were dismissed without prejudice based on the Court's determination that Relator had failed to plead the fraud claims with particularity as required by Rule 9(b) of the Federal Rules of Civil Procedure. The Court granted Relator leave to amend her complaint to comply with Rule 9, and held that if Relator did file an amended complaint, any claim arising prior to October 5, 2000 would be time-barred. On November 23, 2010, Relator filed the Second Amended Complaint ("SAC").

B. Allegations in the Second Amended Complaint and Second Dismissal Order

In the SAC, Relator again alleges that 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. (SAC ¶ 5.) Relator also 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.) She further alleges that Bayer engaged in deceptive and misleading conduct in order to increase the overall market share of Baycol by inducing physicians to prescribe Baycol who otherwise may not have done so. (Id.)

In the SAC, Relator added allegations concerning the contract with the DoD, including the allegation that the original contract with the DoD was for a term of 18 months, with an option for two additional years, extended one year at a time. (SAC ¶ 70.) Relator alleges that on January 11, 2001, the DoD contract was renewed. (Id. ¶ 80.) Thereafter, in February 2001, Bayer and the DoD entered into a Blanket Purchase Agreement ("BPA") whereby Bayer supplied bottles of 0.8 mg tablets for certain prices. (Id. ¶ 96.)

Relator further alleges that Bayer, in response to specific inquiries by personnel from the DoD, misrepresented the efficacy of Baycol and the known risks associated with Baycol in a number of communications in November and December 1999 and January 2000 to induce the DoD into entering into the January 2001 renewal and the February 2001 BPA. (SAC ¶¶ 105-112, 116-120.)

By Order dated July 18, 2012, this Court granted Bayer's motion to dismiss the SAC, and dismissed all claims with prejudice. (Doc. No. 71.) The Court again

found that Relator had failed to demonstrate that she is the original source of the kickback claims and that dismissal of the remaining claims was warranted as Relator again failed to comply with the particularity requirements of Fed. R. Civ. P. 9(b).

C. Eighth Circuit Opinion

On appeal, the Eighth Circuit affirmed this Court's dismissal of Relator's claims relating to federal health insurance reimbursements, but reversed as to Relator's claim that the DoD was fraudulently induced to enter into the January 2001 renewal contract and the February 2001 BPA. In re Baycol Prod. Litig., 732 F.3d at 876-77. The Eighth Circuit found that Relator had sufficiently alleged facts to support a fraudulent inducement claim and that such allegations satisfied the particularity requirements of Rule 9(b), and remanded the case for further proceedings consistent with its opinion. The Eighth Circuit declined to address Bayer's alternative grounds for dismissal, finding instead that this Court should address such arguments in the first instance. Id. at 877 n. 6.

D. Third Motion to Dismiss

Bayer moves to dismiss the fraudulent inducement claim asserted in the SAC for lack of subject matter jurisdiction as Relator has not demonstrated that

she is the original source of the allegations supporting such claim. Bayer further argues that the fraudulent inducement allegations are time-barred because they do not share a common core of operative facts with those in the original complaint, and thus do not relate back.

II. The False Claim Act

The FCA makes it unlawful to knowingly present or cause to be presented a false or fraudulent claim for payment to the government. 31 U.S.C. § 3729(a)(1)(A). Although the FCA focuses on false claims submitted to the government for payment, courts have recognized a fraudulent inducement theory to establish liability for each claim submitted under a contract that was procured by fraud, even if the claim itself was not fraudulent. United States ex rel. Marcus v. Hess, 317 U.S. 537 (1943). To prevail on a claim of fraudulent inducement, a plaintiff must show a material false statement caused the government to pay out money or to forfeit moneys due. United States ex rel. Thomas v. Siemens AG, __ F. App'x __, 2014 WL 6657058 (3d Cir. Nov. 25, 2014) (citing United States es rel. Schmidt v. Zimmer, Inc., 386 F.3d 235, 242 (3d Cir. 2004)).

Here, the Eighth Circuit found that Relator sufficiently alleged a claim of

fraudulent inducement under the FCA. In re Baycol Prod. Litig., 732 F.3d at 876-77. Specifically, that Bayer fraudulently induced the DoD to agree to a contract extension in January 2001 and to enter into the February 2001 BPA for a higher dosage for Baycol by misrepresenting the risks associated with Baycol in particular communications sent in November and December 1999 and January 2000. Id.

A. Subject Matter Jurisdiction

Bayer argues that this Court does not have subject matter jurisdiction over the fraudulent inducement claim because Relator cannot demonstrate that the jurisdictional requirements of 31 U.S.C. § 3730(e)(4) have been met.

When determining whether it has subject matter jurisdiction over an action, the Court must keep in mind that "no presumptive truthfulness attaches to the plaintiff's allegations, and the existence of disputed material facts will not preclude the trial court from evaluating for itself the merits of jurisdictional claims." Osborn v. United States 918 F.2d 724, 730 (8th Cir. 1990) (quoting Mortensen v. First Fed. Sav. & Loan Ass'n, 549 F.2d 884, 891 (3rd Cir. 1977)). The plaintiff bears the burden of proving that jurisdiction exists. Id. "Once evidence is submitted, the district court must decide the jurisdictional issue, not simply

rule that there is or is not enough evidence to have a trial on the issue." Id.

1. Section 3730(e)(4) Requirements

The FCA specifically authorizes a private party to bring an action on behalf of the government "to promote private citizen involvement in exposing fraud against the government, while at the same time prevent parasitic suits by opportunistic late-comers who add nothing to the exposure of the fraud." United States ex. rel. Rabushka v. Crane Co., 40 F.3d 1509, 1511 (8th Cir. 1995). To achieve this balance, the FCA provides that:

> (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 Government 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.

31 U.S.C. § 3730(e)(4)[1].

[1]In 2010, Congress amended the definition of "original source" as follows: "For purposes of this paragraph, 'original source' means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the

In order to determine whether the FCA's jurisdictional requirements have been met, the Eighth Circuit has adopted the following test:

> (1) Have allegations made by the relator been "publicly disclosed" before the qui tam suit was brought? (2) If so, is the qui tam suit "based upon" the public disclosure? and (3) If so, was the relator an "original source" of the information on which the allegations were based?

Mn. Assoc. of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1042 (8th Cir. 2002). "Jurisdiction exists only if the answer to one of the first two questions is "no" or the answer to the third question is "yes." Id.

2. Whether Allegations Are Based Upon Public Disclosures

"A *qui tam* action will be deemed 'based upon' public disclosures when the allegations in the action and those in the public disclosures are substantially similar, regardless of whether the relator may have had independent knowledge of the fraud." United States ex. rel. Newell v. City of St. Paul, 728 F.3d 791, 797 (8th Cir. 2013). Bayer argues that Relator's fraudulent inducement claim concerning the January 2001 renewal of the DoD contract and the February 2001

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information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(2010). Because this action was originally filed in 2006, the Court will apply the previous version of § 3730(e)(4). The parties do not argue otherwise.

BPA are based upon public disclosures. The Court agrees.

First, this Court previously found that the allegations that Bayer concealed the risks and dangers of Baycol in its marketing efforts contained in the Amended Complaint were publicly disclosed in the many lawsuits filed prior to this case, as well as the many articles published in the news media. (Doc. No. 50 (Order at 8-15).) Relator's fraudulent inducement claim concerning the DoD contract renewal and BPA are based in part on these allegations.

The Court further finds that the contracts between Bayer and the DoD were public knowledge prior to the filing of this action, and were widely discussed in medical literature beginning in 2000. (Bayer Exs. 15, 16, 17 and 18 (Doc Nos. 95-16, 95-17, 95-18 and 95-19).) Further, after Baycol was withdrawn from the market in August 2001, the DoD launched an investigation into Baycol and subpoenaed Bayer. Bayer disclosed this investigation long ago in public filings that were reported on by the media. (Bayer Exs. 19 at 4 (Doc. No. 95-18); 12 (Doc. No. 95-11); and 13 (Doc. No. 95-12).) Also, the allegation that Bayer enticed the DoD into entering into the initial contract by offering deep discounts is based on similar allegations that have been alleged in many other Baycol lawsuits throughout the country. See, e.g., Second Am. Master Class Action Comp. ¶ 29,

In re Baycol Prod. Litig., MDL No. 1431 (D. Minn. Jan. 27, 2005) (Doc. No. 95-2) ("Defendants attained their market share by selling Baycol at a price significantly below that of other statins . . "); Fourth Consolidated Amended Class Action Complaint ¶ 23, Lewis v. Bayer AG, Case No. 002353 (Ct. C.P. Phila. Cnty. Pa. Jan. 17, 2003) (Doc. No. 95-3) ("Baycol was a relatively late entry into the statin market, and was less effective than other statins but was heavily promoted by the pharmaceutical defendants as a less expensive alternative to the other statins.").

Because the Court finds that the fraudulent inducement claim is based upon public disclosures, Relator can only proceed if she can demonstrate direct and independent knowledge of the allegations supporting the fraudulent inducement claim.[2]

3. Original Source

a. Direct and Independent Knowledge

Relator is deemed to be an original source pursuant to § 3730(e)(4)(B) if she

[2]In her opposition brief, Relator did not challenge Bayer's position that the fraudulent inducement claim is based on public disclosures. At oral argument, however, Relator's counsel raised for the first time the argument that certain exhibits that are e-mail communications between Bayer and the DoD were not publicly disclosed, and that Bayer conceded in its briefing that these documents were only produced in discovery. Contrary to counsel's argument, Bayer has not conceded such documents were not publicly disclosed. It is Relator's burden to demonstrate that this Court has subject matter jurisdiction, and arguments of counsel are simply not evidence.

has 1) direct or independent knowledge of the information on which the allegations are based; and 2) she voluntarily provided the information to the government prior to bringing suit. Independent knowledge is knowledge "not derived from public disclosure." Mn. Assoc. of Nurse Anesthetists, 276 F.3d at 1048. Direct knowledge is knowledge "marked by absence of an intervening agency" or "unmediated by anything but [the plaintiff's] own labor." United States ex rel. Barth v. Ridgedale Elec. Inc., 44 F.3d 699, 703 (8th Cir. 1995). Thus, one "who obtains secondhand information from an individual who has direct knowledge of the alleged fraud" is not considered an original source under the FCA. Barth 44 F.3d at 703 (further finding that collateral research and investigation does not establish direct and independent knowledge). See also United States ex rel. Stinson, Lyons, Gelin & Bustamanze, P.A. v. Prudential Ins. Co., 944 F.2d 1149, 1160 (3d Cir. 1991) (finding that "relator must possess substantive information about the particular fraud, rather than merely background information which enables a putative relator to understand the significance of a publicly disclosed transaction or allegation.")

The relator must also have direct and independent knowledge of the allegations in the complaint *"as amended*." Rockwell Intern. Corp. v. United

States 127 S.Ct. 1397, 1408 (2007) (emphasis in the original). The requirement of direct and independent knowledge of the new allegations in an amended complaint is to prevent a relator from "plead[ing] a trivial theory of fraud for which he had some direct and independent knowledge and later amend the complaint to include theories copied from the public domain or from materials in the Government's possession." Id.

Relator asserts that the Court has already found her the original source of allegations concerning the increased number of cases of rhabdomyolysis reported for patients taking Baycol in early 1999; concerning an article in a medical journal addressing rhabdomyolysis involving Baycol and Gemfibrozil; that Bayer solicited opinion leaders to sign an article to allay concerns about such adverse events; and through a FOIA request, Relator discovered data concerning adverse events concerning Baycol which suggested that Baycol was more dangerous than other statins. Relator argues that these allegations underlie the allegations that Bayer made misrepresentations to the DoD, when, for example, Casimir Zygmunt told a DoD contact that there is no evidence to suggest that Baycol causes more rhabdomyolysis than other statins.

Relator further asserts that she directly participated in developing and

refining market strategy for Baycol, which guided Bayer's contract discussions with the DoD. (Supp. Simpson Decl. ¶ 13.) She further asserts she was involved in discussions on strategy to be used in obtaining the initial DoD contract in 1999 as well as planning the launch of the 0.4 mg dose of Baycol, which included plans for communications to the DoD. (Id. ¶¶ 4-9.)

She asserts that in late 1998 and early 1999, Relator was involved in multiple discussions regarding an ongoing clinical trial for a 1.6 mg dose of Baycol. (Supp. Simpson Decl. ¶ 7.) Relator was involved in discussions about the high rate of adverse events seen in this trial, and the ultimate conclusion that Bayer would not be able to market that dose. (Id.) Relator also participated in discussions regarding the decision to conceal this study from the public, and also the DoD. (Id.)

Relator asserts that Zygmunt contacted Relator and requested details of the adverse events analysis she had done. (Id. ¶ 10 & Ex. A.) This analysis suggested that there was very likely a material difference in adverse event rates between Baycol and other statins. (SAC ¶¶ 157-59.) Relator asserts she is one of the few at Bayer who would have known that Zygmunt's subsequent communications to the DoD, that there was no evidence to suggest that Baycol

causes more rhabdomyolysis than other statins, was a knowingly false statement. (Supp. Simpson Decl. ¶ 10.)

Relator also asserts that she had discussions with others that the DoD had raised questions regarding Baycol's safety prior to the launch of the 0.8 mg dose in August 2000. (Id. ¶ 13.) She also participated in discussions regarding the pricing of the 0.8 mg dose to the DoD. (Id. ¶ 14.) She also reviewed drafts of documents which included contracting strategy, positioning and main messages for Baycol, which were used to sell Baycol into federal accounts, including the DoD, and that such documents included false and misleading information. (Id. ¶ 16.) She further asserts that on multiple occasions, she discussed the DoD contract with Baycol Product Manager Paul Fletcher and others, including promotional efforts, and in early 2001, she participated in discussions about creating a DoD "sell sheet" using approved Baycol messages. (Id. ¶ 19.) During these discussions, the concerns over the potential loss of the DoD contract and how to address these concerns were raised, including concerns of the perception of Baycol's safety within the DoD and its effect on the contract. (Id.)

To be deemed an original source as defined by the FCA, Relator argues that she need not have knowledge of the actual fraudulent conduct itself or

knowledge of every element of her fraud claims. See Minn. Assoc. of Nurse Anesthetists, 276 F.3d at 1050 ("If the relator has direct knowledge of the true state of the facts, it can be an original source even though its knowledge of the misrepresentation is not first-hand."); United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 656 (D.C. Cir. 1994) (finding that relator need only have direct and independent knowledge of the information underlying the allegation, rather than of the transaction itself); Kennard v. Comstock Resources, Inc., 363 F.3d 1039, 1044 (10th Cir. 2004) (finding that relator need only have knowledge underlying or supporting the fraud allegation).

Despite the fact that she did not claim direct and independent knowledge of the communications that form the basis of the fraudulent inducement claim, Relator argues that she qualifies as an original source of the allegations supporting such claim because she was one of a few at Bayer that would have known such communications were false and misleading.

The applicable law is clear that Relator need not demonstrate knowledge of every aspect of the asserted FCA claim. See United States ex. rel. Newell, 728 F.3d at 797 (finding that the "relator does not have to have personal knowledge of all elements of a false claim cause of action" it is enough if the relator has

knowledge of the true state of the facts). As applied here, the only claim remaining in this action is one for fraudulent inducement of a contract; that through direct communications to persons at the DoD, Bayer used false and misleading information to induce the DoD to enter into the January 2001 renewal contract and the February 2001 BPA.

Thus, to demonstrate that she has direct and independent knowledge of the "true state of the facts" underlying the fraudulent inducement claim, Relator must demonstrate knowledge that Bayer actually sent false and misleading communications to persons with the DoD with the intent to fraudulently induce the DoD to execute the January 2001 renewal and the February 2001 BPA. It is not enough to show knowledge of Baycol's efficacy, the reported injuries related to Baycol and the marketing efforts to downplay such risks. See United States ex. rel. Mistick PBT v. Housing Auth. of City of Pittsburgh, 186 F.3d 376, 389 (3d Cir. 1999) ("While 'it is not necessary for a relator to have all the relevant information in order to qualify as "independent," a relator cannot be said to have 'direct and independent knowledge of the information on which [its fraud] allegations are based,' if the relator has no direct and independent knowledge of the allegedly fraudulent statements.") Instead, she must demonstrate direct and independent

knowledge that Bayer sent false and misleading communications to the DoD to induce the DoD to enter into the two contracts. Relator has not met this burden. There is no reference in her declaration or in any of the allegations in the SAC, or the underlying documents to such allegations, to demonstrate that Relator had direct or independent knowledge of **any** communication between Bayer and the DoD that form the basis of the fraudulent inducement claim.

For example, in paragraph 105 of the SAC, Relator discusses a letter from Casimir Zygmunt, in which he responds to concerns of Lt. Richerson regarding the safety of Baycol. (Doc. No. 94 (Ex. 25).) This letter does not reference Relator, and Relator was not copied on such letter. (Id.) Relator claims that this letter is a "version[] of standard letters Bayer used in communicating with prescribers about Baycol" (Supp. Simpson Decl. ¶ 6) yet she does not claim knowledge that such form letter was used to provide information to the DoD, or that the particular letter was sent.

In paragraph 107 of the SAC, Relator alleges that Zygmunt reported to a DoD contact in November 1999 that there is no evidence to suggest that Baycol causes more rhabdomyolysis than other statins. (Id. (Ex. 20).) Again, Relator is not referenced in this communication, and she has claimed no knowledge that

such communication was sent.

As in Rockwell, the Court finds that Relator cannot demonstrate that she is an original source of the factual allegations underlying the fraudulent inducement claim asserted in the SAC. While she may have knowledge as to background facts that Bayer engaged in fraudulent or misleading marketing efforts, she has not demonstrated that she has any direct and independent knowledge of the alleged false or misleading communications between Bayer and the government that provide the basis for the fraudulent inducement claims involving the DoD contracts.

Relator's reliance on the Minn. Assoc. of Nurse Anesthetists decision is misplaced, as the cases are factually distinguishable. In Minn. Assoc. of Nurse Anesthetists, the FCA claim at issue involved anesthesiologists submitting billing forms for procedures they did not perform. The Eighth Circuit determined that the nurse anesthetists had direct and independent knowledge of the true state of the facts supporting the claim because they had direct and independent knowledge that the anesthesiologists were not performing the procedure at issue, and because they knew the anesthesiologists were filling out forms used for billing with misleading information. By contrast, the claim at issue here is a

fraudulent inducement claim and Relator has provided no evidence that she had direct and independent knowledge of the alleged fraudulent communications used to induce the DoD to enter into the 2001 contracts.

As Relator has not demonstrated that she is an original source of the allegations supporting the fraudulent inducement claim, the Court lacks subject matter jurisdiction over this claim.

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: March 31, 2015

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