

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE)
LITIGATION)
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THIS DOCUMENT RELATES TO:)
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UNITED STATES OF AMERICA, ex)
rel. LINNETTE SUN and GREG)
HAMILTON v. BAXTER HEMOGLOBIN)
THERAPEUTICS, et al.)
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MDL NO. 1456
CIVIL ACTION NO. 01-12257-PBS
SUBCATEGORY NO. 08-11200-PBS

MEMORANDUM AND ORDER

March 25, 2010

Saris, U.S.D.J.

I. INTRODUCTION

Relators Linnette Sun and Greg Hamilton bring this qui tam action under the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, alleging that Defendant pharmaceutical companies, Baxter Hemoglobin Therapeutics and Baxter International, Inc. (collectively "Baxter") reported inflated pricing information for certain drugs which caused the Medicaid and Medicare programs to make substantial overpayments.¹ Moving to dismiss, Baxter

¹ The Court has already dismissed without prejudice Count I (submitting false claims in violation of the federal False Claims Act) as to all drugs other than Advate and Recombinate, Count II (violations of the federal False Claims Act through violations of the Stark Act), Count III (violations of the federal False Claims Act through Best Prices violations), and Counts VII-XXI (violation of various state false claims acts) for the reasons

asserts that the Court does not have subject matter jurisdiction because the relators cannot satisfy the FCA's public disclosure/original source rule and that the Complaint fails to plead fraud with the requisite particularity under Fed. R. Civ. P. 9(b). After briefing and a hearing, Baxter's motion to dismiss [Docket No. 6371] is **DENIED**

II. BACKGROUND

This case comes as part of the massive AWP litigation currently in front of this Court. The Court assumes familiarity with the drug pricing schemes discussed in its previous AWP-related decisions.² The Relators allege that Baxter defrauded Medicaid, Medicare, and other programs that reimburse for drugs

discussed in court.

² See In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172 (D. Mass. 2003); In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196 (D. Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 321 F. Supp. 2d 187 (D. Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 339 F. Supp. 2d 165 (D. Mass. 2004); In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61 (D. Mass. 2005); In re Pharm. Indus. Average Wholesale Price Litig., 460 F. Supp. 2d 277 (D. Mass. 2006); In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d 164 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 12 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20 (D. Mass. 2007); In re Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d 367 (D. Mass. 2008); In re Pharm. Indus. Average Wholesale Price Litig., 252 F.R.D. 83 (D. Mass. 2008); In re Pharm. Indus. Average Wholesale Price Litig., No. 01-cv-12257, 2010 WL 582039 (D. Mass. Feb. 9, 2010); see also Massachusetts v. Mylan Labs., Inc., 357 F. Supp. 2d 314 (D. Mass. 2005); Massachusetts v. Mylan Labs., Inc., 608 F. Supp. 2d 127 (D. Mass. 2008).

on the basis of Average Wholesale Prices ("AWPs") published in various pharmaceutical industry compendia, including ones published by First DataBank ("FDB").

In May 2000, FDB entered into an agreement with the Department of Justice to cease reporting AWPs as published by manufacturers. FDB was instead required to report AWPs on the basis of market prices. In an attempt to do so, FDB compiled the Wholesale Acquisition Costs ("WACs") reported by the manufacturers and multiplied the reported WACs by 1.25 to calculate AWP.

Knowing how FDB now calculated AWP, Baxter reported only what it called a "list sales price" to FDB. Informed by FDB that FDB would be forced to consider Baxter's "list sales price" as its WAC if Baxter continued to refuse to provide any other information, Baxter persisted in reporting only its "list sales price." In light of these communications, FDB used Baxter's "list sales price" as Baxter's WAC and proceeded to calculate Baxter's AWP on the basis of that figure. In fact, fewer than 1% of Baxter's sales were made at its "list sales price."

According to the complaint, Baxter reported a price of \$1.30 for Recombinate, which FDB used to calculate an AWP of \$1.625. In fact, Recombinate was sold to providers for \$.89. Likewise, Baxter reported an AWP of \$1.60 for Advate, but Advate was sold to providers for \$.99.

Relator Greg Hamilton worked for Express Scripts, a pharmacy benefit manager which is a customer of Baxter and a large customer of FDB. Hamilton was contacted by Kay Morgan, a manager at FDB with whom he shared an ongoing business relationship. Morgan informed Hamilton that Baxter was insisting on reporting only a "list sales price" for Recombinate, even though Baxter knew that FDB needed a WAC. Morgan asked Hamilton if he had any ideas or advice concerning the problem.

Relator Linnette Sun was hired by Baxter in 2002 as Director of Medical Outcomes Research and Economics. Her primary responsibility was pricing Advate. She attended a meeting at Baxter where employees crafted a plan to set an AWP for Advate but to disguise it in reports to FDB as the "list sales price." When she discovered what was happening after Baxter's "list sales price" was reported to FDB, she notified her superiors, who ordered her to drop the matter. Her employment with Baxter ceased on July 22, 2003. Baxter began reporting pricing information on Advate to publications on July 28, 2003.

III. DISCUSSION

Baxter has moved to dismiss Count I as to Advate and Recombinate for failure to plead fraud with the requisite particularity under Fed. R. Civ. P. 9(b) and for lack of subject matter jurisdiction because the relators cannot satisfy the FCA's public disclosure/original source rule.

1. Rule 9(b)

This Court has ruled extensively on the required level of specificity for a complaint to satisfy Rule 9(b) under the circumstances of this MDL. See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., 538 F. Supp. 2d at 390-91; In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d at 171-72; In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d at 208-11; In re Pharm. Indus. Average Wholesale Price Litig., 263 F. Supp. 2d at 194; United States ex rel. Ven-A-Care v. Actavis Mid Atlantic LLC, 659 F. Supp. 2d 262, 271-72 (D. Mass. 2009). Specifically, this Court has held that a plaintiff must "state the specific drugs sold by each defendant by alleging the fraudulent scheme, specifying the alleged fraudulent [pricing] figures for each drug, and attaching exhibits to the complaint to demonstrate the spread for each drug." In re Pharm. Indus. Average Wholesale Price Litig., 478 F. Supp. 2d at 172. For both Advate and Recombinate, relators have alleged the fraudulent scheme and alleged both the fraudulent published prices and the actual prices, and thus the spread, for both drugs. This is sufficient to satisfy the pleading requirements of Fed. R. Civ. P. 9(b).

2. Public Disclosure/Original Source Rule

The Court may take into account documents beyond the complaint "when there is some doubt about a court's subject matter jurisdiction." Coyne v. Cronin, 386 F.3d 280, 286 (1st Cir. 2004) (citing Dynamic Image Techs., Inc. v. United States, 221 F.3d 34, 37-38 (1st Cir. 2000)). Review of documents outside the complaint is appropriate when such documents are "pertinent to the jurisdictional inquiries that the district court [is] obliged to conduct." Id. As such, the Court has considered the declarations of the relators.

Section 3730(e)(4) of the FCA provides:

(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). This operates as a jurisdictional bar when (1) there has been a "public disclosure," (2) the relator has "based" its suit on the disclosure, and (3) the relator was not the original source of the information on which its suit is based. See In re Pharm. Indus. Average Wholesale Price Litig.,

538 F. Supp. 2d at 375-79.

Whatever the merits of the Defendants' arguments regarding public disclosure, relators prevail on their argument that they both qualify as original sources. Satisfaction of the "original source" provision of the FCA turns on a relator having "direct and independent" knowledge of information underlying his allegations. Id. at 379. The relator need not have "direct and independent" knowledge of every detail or element of his complaint. United States ex rel. Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1050 (8th Cir. 2002) ("to qualify as an original source, a relator does not have to have personal knowledge of all elements of a cause of action."). A relator satisfies the requirement if he has "direct and independent knowledge of any essential element of the underlying fraud transaction." United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 657 (D.C. Cir. 1994). As numerous courts have noted, the statute requires only that the relator be "an" original source, not "the" original source. See, e.g., United States ex rel. Ervin & Assocs., Inc. v. Hamilton Sec. Group, Inc., 370 F. Supp. 2d 18, 40 n.11 (D.D.C. 2005) ("use of the word 'an,' . . . suggest[s] there may be more than one original source eligible to bring suit . . .").

For a relator's knowledge to be "independent" means that it is not derived from public disclosures. United States ex rel.

O'Keefe v. Sverdup Corp., 131 F. Supp. 2d 87, 93 (D. Mass. 2001). For a relator's knowledge to be "direct" generally means that the information was acquired by the relator through his own efforts. Id. "Direct and independent knowledge must be something more than 'secondhand information' or 'collateral research and investigations.'" United States ex rel. Montgomery v. St. Edward Mercy Med. Ctr., 2007 WL 2904111, at *10 (E.D. Ark. Sept. 28, 2007) (quoting United States ex rel. Barth v. Ridgedale Elec., Inc., 44 F.3d 699, 703 (8th Cir. 1995)). Direct knowledge is "'firsthand knowledge of the alleged fraud'" obtained through the relator's "'own labor unmediated by anything else.'" In re Average Wholesale Price Litig., 538 F. Supp. 2d at 384 (quoting United States ex rel. Aflatooni v. Kitsap Physicians Servs., 163 F.3d 516, 525 (9th Cir. 1999)).

The purpose behind the requirement of "direct" knowledge is to "strike a balance between 'encouraging people to come forward with information and . . . preventing parasitic lawsuits.'" United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1017 (7th Cir. 1999) (quoting False Claims Act Implementation: Hearing Before the Subcomm. on Admin. Law and Gov't Relations of the H. Comm. on the Judiciary, 101st Cong., 2d Sess. 3 (1990) (statement of Sen. Grassley)). The requirement serves to discourage lawsuits by "disinterested outsider[s] who simply stumble across an interesting court file," and encourage those by

people with "first-hand knowledge of fraudulent misconduct or those who are either close observers or otherwise involved in the fraudulent activity." Barth, 44 F.3d at 703 (quotation marks and citations omitted).

Here, Sun had direct and independent knowledge of essential information that she provided to the government before filing. Sun was intimately involved with the pricing of Baxter's drugs, specifically Advate. She was present when Baxter hatched its alleged plan to report its AWP disguised as its "list sales price" in the face of FDB's requirements. She saw documents which she said contained false prices. She also informed her superiors of the results of the false reporting, and was ordered to drop the issue. Although Sun did leave Baxter before Baxter began reporting information on Advate to FDB and other compendia, she left a mere week before, and thus was privy to much essential information. Sun has direct and independent knowledge of both the formation of Baxter's pricing scheme and Baxter's knowledge of its effects, "essential element[s] of the underlying fraud transaction." Springfield Terminal Ry. Co., 14 F.3d at 657. She thus qualifies as an original source.

Hamilton's case is a closer question. Hamilton has knowledge of an "essential element of the underlying fraud transaction," that Baxter was reporting only misleading "list sales prices" to FDB, specifically for Recombinate, even though

Baxter knew that FDB needed Baxter to report a WAC and would be forced to rely on Baxter's "list sales price" if Baxter continued to refuse to report anything else. Id. Hamilton's knowledge was derived from his conversation with Kay Morgan, and was thus "independent." O'Keefe, 131 F. Supp. 2d at 93.

Because Hamilton derived his knowledge primarily from a conversation with Morgan, Baxter attacks his knowledge as not "direct," pointing to cases where courts have held somewhat similar relators not to possess direct knowledge. One court held that a relator did not have "direct" knowledge when he acquired derivative or secondhand information from field auditors who had direct knowledge. United States ex rel. Fine v. MK-Ferguson Co., 99 F.3d 1538, 1548 (10th Cir. 1996). The court pointed out that the relator's allegations were not sufficiently direct because "[h]e did not himself discover the allegedly fraudulent practices" and "was not an observer of the purported fraud." Id.

Likewise, a relator's knowledge is not direct if it is derived from analyzing existing data and conducting interviews with individuals who have direct knowledge of the fraud. O'Keefe, 131 F. Supp. 2d at 96.

An analysis of the caselaw illuminates no bright line as to when a relator's knowledge is sufficiently "direct" to elevate him to original source status. Focusing on concepts such as the relator's "own labor unmediated by anything else," Aflatooni, 163

F.3d at 525, is somewhat unhelpful, especially considering that the parasitic Sherlock Holmes relators that the statute attempts to exclude often extend significantly more actual "labor" than those who simply happen to witness a fraud as it occurs. See, e.g., O'Keefe, 131 F. Supp. 2d at 96. Likewise, the distinction between "secondhand information," Barth, 44 F.3d at 703, and "firsthand knowledge," Aflatooni, 163 F.3d at 525, is less than fully enlightening as only the Moriarty behind the fraud brings entirely firsthand knowledge, with no reliance on secondhand information at all.

The Court thus takes as its touchstone the purpose behind the statute, to encourage suits by those who are "close observers or otherwise involved in the fraudulent activity." Barth, 44 F.3d at 703 (quoting S. Rep. No. 345, 99th Cong., 2d Sess. 4 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5269). Those who are "close observers" of the fraud stand in stark contrast to those whose knowledge is based merely on "collateral research and investigations." Id. (quoting United States ex rel. Kreindler & Kreindler v. United Techs. Corp., 985 F.2d 1148, 1159 (2d Cir. 1993)).

Even so, Hamilton's case is a close one. He is neither a Sherlock Holmes nor a Moriarty. Importantly, Hamilton did not get his information after the fact through collateral research and investigation. Hamilton, as an employee of Express Scripts,

a large customer of FDB, was contacted by Kay Morgan, a manager at FDB, as part of their ongoing business relationship. Morgan did not only tell Hamilton what Baxter was doing, but also came to him specifically for his ideas and advice for solving an ongoing problem, which was at the very heart of Baxter's alleged fraud. Hamilton was consulted as part of a professional relationship by one of the critical players in the alleged fraud regarding the fraud's very nature as the fraud was occurring. This suffices to make him a "close observer" of the fraud, and thus to make his knowledge of an essential element of the fraud "direct." As such, he qualifies as an original source.

As both Sun and Hamilton are original sources, the Court has subject matter jurisdiction over this action, and thus denies Baxter's motion as to Recombinate and Advate under Count I.

ORDER

Baxter's motion [Docket No. 6371] is **DENIED**.

/s/ Patti B. Saris
Patti B. Saris
United States District Judge