

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

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| <i>In re: PHARMACEUTICAL INDUSTRY</i> |) | |
| AVERAGE WHOLESale PRICE |) | |
| LITIGATION |) | MDL No. 1456 |
| <hr/> |) | |
| |) | Civil No. 01-12257-PBS |
| |) | |
| THIS DOCUMENT RELATES TO: |) | |
| <i>United States ex rel. Edward</i> |) | |
| <i>West, et al., v. Ortho-McNeil</i> |) | |
| <i>Pharmaceutical, Inc. and</i> |) | |
| <i>Johnson & Johnson.</i> |) | |
| |) | |
| CIVIL ACTION NO. 06-12299-PBS |) | |
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MEMORANDUM AND ORDER

February 19, 2008

Saris, U.S.D.J.

I. INTRODUCTION

This is a *qui tam* action brought by Relator Edward West pursuant to the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-33, and state law. Relator claims that Ortho-McNeil Pharmaceutical and its parent corporation, Johnson & Johnson, pursued a marketing strategy that gave kickbacks and unlawful remuneration to hospitals. Relator brings this action on behalf of the United States, nine states,¹ and the District of Columbia. The United

¹ West originally filed on behalf of ten states, but subsequently has voluntarily dismissed his claims on behalf of the State of Illinois (Count VII). He claims violations of the false claims statutes of California, Delaware, Florida, Hawaii, Massachusetts, Nevada, Tennessee, Texas, Virginia and the District of Columbia.

States declined to intervene, but filed two statements of interest.

Defendants move to dismiss the complaint for lack of subject matter jurisdiction, pursuant to Fed. R. Civ. P. 12(b)(1).

(Docket No. 4307.) Defendants argue that this Court lacks subject matter jurisdiction over Relator's claims brought (1) under the federal False Claims Act and similar state statutes because they are based upon publicly disclosed allegations or transactions and West is not an original source; (2) under the Nevada False Claims Act because they are based on the same allegations as those being pursued by the State of Nevada in a separate lawsuit; and (3) under the Hawaii False Claims Act because they are based on the same allegations being pursued by the State of Hawaii in a separate lawsuit.

Also before this Court are Defendants' prior motions to dismiss pursuant to Fed. R. Civ. P. 9(b) for failure to plead fraud with particularity, and Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

For the reasons stated below, the Defendants' motions to dismiss are **ALLOWED-IN-PART** and **DENIED-IN-PART**.

II. Background

From 1997 to 1999, Relator Edward West was an employee of Innovex, a company that provides pharmaceutical companies with sales representatives. He was assigned as a contract sales

representative to Defendant Ortho-McNeil. In July 1999, Ortho-McNeil hired West as an employee sales representative.

A. West's Allegations²

One of Ortho-McNeil's many drug products is Levaquin, an antibiotic that is used to treat pneumonia, upper respiratory tract infections, and urinary tract infections. In 1999, the introduction of the newer, cheaper competitor drug Tequin by Bristol-Myers Squibb threatened to encroach upon Levaquin's market share. Prompted to pursue more aggressive marketing tactics, Ortho-McNeil resorted to illegal kickback schemes designed to gain and maintain a competitive edge.

When West was employed as an Ortho-McNeil sales representative, his manager instructed him to make a \$5,000 payment to Holy Cross Hospital in Chicago. He was told that four other Ortho-McNeil employees would make equivalent payments, for a combined total of \$25,000. Earlier that year, Holy Cross indicated that it planned to drop Levaquin from its formulary and exclusively carry the cheaper competitor drug, Tequin. The cash payment scheme was designed, West understood, to convince Holy Cross to abandon its plan to drop Levaquin from the formulary. In fact, his supervisor told him that a regional manager had, with the permission of the Ortho-McNeil home office, executed a similar payment to a different Chicago hospital (Rush-

²Most of these allegations are hotly contested.

Presbyterian-St. Lukes) for the same purpose of inducing the hospital to retain Levaquin on its formulary. West states that he refused to participate in the payment scheme. (First Am. Compl. ¶¶ 65-69.) (hereinafter "Complaint").³

According to West, cash bribes were not the only fraudulent marketing practice implemented by Ortho-McNeil. Ortho-McNeil sales representatives also offered conditional price discounts; that is, purchasers would receive a discount only if they agreed to drop competitor drugs from their formulary. Specifically, West alleges that, in 2002, an Ortho-McNeil sales representative offered a price discount on Levaquin to Holy Cross Hospital on the "condition that the hospital 'no longer stock Cipro,'" even though, according to West, Cipro was approved for treatment of several illnesses for which Levaquin was not. (Compl. ¶ 71.)

West also alleges that Ortho-McNeil cut rebate checks running into "the tens of thousands of dollars" payable to hospitals that purchased Levaquin. (Compl. ¶ 74.) When Ortho-McNeil sales representatives delivered these checks to the hospitals, they were instructed to tell the hospitals that hospitals could easily hide these rebates from Medicare and Medicaid - and thus make a "hidden profit" on Levaquin. (Compl. ¶ 75.) According to Relator, Ortho-McNeil also marketed another "hidden profit" mechanism to hospitals by encouraging them to

³ The First Amended Complaint ("Complaint") can be found at case number 06-cv-12299-PBS, Docket No. 49-3.

divide and re-use single use premix bags of Levaquin in order to create a secret discount and increase hospital profits and Levaquin sales. (Compl. ¶¶ 78-87.) Finally, West alleges that Ortho-McNeil created other kickbacks under the guise of "speaker fees," "research grants," and other gifts to particular doctors who regularly prescribed Levaquin. (Compl. ¶¶ 88-99.)

West was fired by Ortho-McNeil in July 2000. According to West, he was fired after he refused to participate in providing Holy Cross Hospital with cash payments as part of the scheme described above.⁴ (Compl. ¶ 69.)

B. Procedural History

In September 2003, three years after he was dismissed from Ortho-McNeil, West contacted the Office of the United States Attorney for the Northern District of Illinois and reported that Defendants had engaged in fraudulent marketing activities in order to increase sales of two of their drugs. (West Aff. ¶ 5.) West subsequently documented his allegations on a form provided by the United States Attorney's Office and through additional written communications. (West Aff. ¶¶ 6, 8.) Also in September 2003, West contacted the Illinois Attorney General's office and reported similar fraudulent marketing activities. (West Aff. ¶¶

⁴ After he was fired, West filed a complaint with the Equal Employment Opportunity Commission and with the Illinois Department of Human Rights alleging race, sex, and age discrimination. He was issued a right-to-sue letter by the EEOC and subsequently filed a civil action against Ortho-McNeil.

7, 9.) Finally, in November 2003, West met with the FBI to discuss his allegations of wrongdoing by Defendants. (West Aff. ¶ 11.)

On November 17, 2003, Relator commenced this *qui tam* action by filing a complaint in the United States District Court for the Northern District of Illinois. As is required for *qui tam* actions under the FCA, the complaint was sealed. See 31 U.S.C. § 3730(b)(2). He filed a First Amended Complaint ("Complaint") under seal on March 14, 2004. In 2006, the United States, the states involved, and the District of Columbia each notified the court that it would not intervene, and, in June 2006, the Complaint was unsealed and served on Defendants.

Defendants then filed a motion to dismiss the Complaint pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6). After this motion was briefed, but before any decision was rendered, the Joint Panel on Multidistrict Litigation ("JPML") transferred the case to this Court. The multi-district litigation involves multiple suits against pharmaceutical companies for allegedly fraudulently inflating the "average wholesale price" ("AWP") reported to drug pricing compendia. This memorandum assumes familiarity with the basic concepts underlying AWP and related litigation handled by this Court. For a detailed description, see In re Pharmaceutical Industry Average Wholesale Price Litigation, 491 F. Supp. 2d 20 (D. Mass. 2007).

Defendants moved to vacate this order, and, on December 20, 2006, their motion was granted in part and denied in part. The JPML ultimately transferred the case to this Court, but separated Relator's claims related to off-label marketing, which were remanded to the Northern District of Illinois. After the case was transferred to this Court, Defendants filed a second motion to dismiss for lack of subject matter jurisdiction, pursuant to Fed. R. Civ. P. 12(b)(1).

III. DISCUSSION

A. Jurisdiction Under the Federal False Claims Act

Defendants argue that the case should be dismissed under the "public disclosure bar" of the FCA, 31 U.S.C. § 3730(e)(4)(A) and (B), and similar state statutes. Specifically, Defendants assert that Relator's claims are based upon publicly disclosed transactions and West is not an original source.

Because the public disclosure bar in § 3730(e)(4)(A) and (B) of the FCA is jurisdictional, the Court must first satisfy itself that the statute does not bar jurisdiction. See Rockwell Int'l Corp. v. United States, ___ U.S. ___, 127 S. Ct. 1397, 1405-07 (2007); United States ex rel. Rost v. Pfizer, 507 F.3d 720, 727 (1st Cir. 2007) ("The threshold question in a False Claims Act case is whether the statute bars jurisdiction."). Jurisdiction is based upon Relator's amended complaint. Rockwell, 127 S. Ct. at 1408.

When evaluating a 12(b)(1) motion to dismiss, the court may

conduct a "broad inquiry" and may consider extrinsic materials, including exhibits attached to the pleadings and the evidentiary materials submitted by the parties. Hernandez-Santiago v. Ecolab, Inc., 397 F.3d 30, 33 (1st Cir. 2005); see generally Torres-Negrón v. J&N Records, LLC, 504 F.3d 151, 162-63 (1st Cir. 2007) (explaining the difference between a facial and a factual challenge to a court's subject matter jurisdiction). The Relator carries the burden of proving jurisdiction. Murphy v. United States, 45 F.3d 520, 522 (1st Cir. 1995).

The "public disclosure bar" contained within Section 3730(e)(4)(A) and (B) of the FCA provides:

(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).

The public disclosure bar was added to the statute as part of the False Claim Amendments Act of 1986. See Pub. L. No. 99-562, § 3, 100 Stat. 3153 (1986). This new jurisdictional bar

supplanted a previous, more restrictive provision that barred a *qui tam* suit "based on evidence or information the Government had when the action was brought." 31 U.S.C. § 3730(b)(4) (1982) (superseded); see also United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 650 (D.C. Cir. 1994). In passing the 1986 amendments, Congress sought to "discourag[e] 'parasitic' or 'free-loading' *qui tam* suits while also encouraging productive private enforcement suits." Rost, 507 F.3d at 727. Congress has frequently altered the FCA, "[s]eeking the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own." Springfield Terminal Ry., 14 F.3d at 649; see United States ex rel. Precision Co. v. Koch Indus., Inc., 971 F.2d 548, 552 (10th Cir. 1992) (concluding that the dual purposes of the FCA suggest that the "threshold 'based upon' analysis is intended to be a quick trigger for the more exacting original source analysis.").

To determine whether jurisdiction is barred by Section 3730(e)(4), courts must make several inquiries:

- (1) whether there has been public disclosure of the allegations or transactions in the relator's complaint;
- (2) if so, whether the public disclosure occurred in the manner specified in the statute;
- (3) if so, whether the relator's suit is "based upon" those publicly disclosed allegations or transactions;
- and (4) if the answers to these

questions are in the affirmative, whether the relator falls within the "original source" exception as defined in § 3730(e)(4)(B).

Rost, 507 F.3d at 728.

1. "Publicly Disclosed"

For the jurisdictional bar of § 3730(e)(4) to apply, an "allegation or transaction" must have been publicly disclosed in one of the sources explicitly identified by the statute. United States ex rel. LeBlanc v. Raytheon Co., 913 F.2d 17, 20 (1st Cir. 1990). Thus, only those public disclosures made in "a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing audit, or investigation, or [in] the news media" will trigger the bar. 31 U.S.C. § 3730(e)(4)(A). To be considered "public," disclosure need not be widespread or reach "all members of the community," but there must be "some act of disclosure to the public outside of the government." Rost, 507 F.3d at 728, 728 n.6.

Although the First Circuit has not addressed the issue, it is generally accepted that publicly available documents, such as a complaint filed in conjunction with a civil lawsuit, qualify as public disclosures under the statute. See 1 John T. Boese, Civil False Claims and Qui Tam Actions, § 4.02[B][1][a] (3d ed. 2005) (noting that "civil complaints . . . can constitute a 'public disclosure' within the meaning of Section 3730(e)(4)(A)"); see

also Rost, 507 F.3d at 728 n.5 ("It could be that disclosure in the form of a filing to a . . . court (not under seal) where all records are public could be public disclosure [But, this is] not our case."). It follows that any information disclosed through civil litigation and electronically filed on the docket or otherwise publicly available in the clerk's office should be considered a public disclosure for purposes of section 3730(e)(4)(A). See Kennard v. Comstock Res., Inc., 363 F.3d 1039, 1042 (10th Cir. 2004).

2. "Based Upon"

If a court determines that allegations or transactions in the relator's complaint are in the public domain as specified by 31 U.S.C. § 3730(e)(4)(A), it must then determine whether the relator's suit is "based upon" those publicly disclosed allegations or transactions. Courts have differed in determining whether a particular action is "based upon" publicly disclosed allegations or transactions. Under the majority view, eight circuits have held that an action is "based upon" a public disclosure when the allegations in the relator's complaint are similar to, supported by, or "the same as those that have been publicly disclosed . . . *regardless of where the relator obtained his information.*"⁵ United States ex rel. Doe v. John Doe Corp.,

⁵ Accord United States ex rel. Paranich v. Sorqnard, 396 F.3d 326, 334-35 (3d Cir. 2005) ("We have held, consistent with the majority of our sister courts of appeals, that the term 'based

960 F.2d 318, 324 (2d Cir. 1992) (emphasis added). A minority of courts, relying primarily on a "plain language" argument, apply the jurisdictional bar to a *qui tam* suit only when the relator's complaint is actually "derived from" the publicly disclosed allegations or transactions.⁶ In its statement of interest, the

upon' means 'supported by' or 'substantially similar to,' not 'actually derived from.'"); Walburn v. Lockheed Martin Corp., 431 F.3d 966, 975 (6th Cir. 2005) ("In line with the reasoning of the majority of circuits, we have construed 'based upon' broadly to mean 'supported by' information previously disclosed."); Minn. Ass'n of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032, 1047 (8th Cir. 2002) (endorsing the majority rule because it "makes better sense of the 1986 Amendments Act and better effectuates the [Act's] policy goals"), cert. denied, 537 U.S. 944 (2002); United States ex rel. Biddle v. Bd. of Trs. of Leland Stanford, Jr. Univ., 161 F.3d 533, 536-40 (9th Cir. 1998), cert. denied, 526 U.S. 1066 (1999); United States ex rel. King v. Hillcrest Health Ctr., Inc., 264 F.3d 1271, 1279 (10th Cir. 2001) ("[A] *qui tam* action is based on a public disclosure when its allegations share a substantial identity with the allegations in prior litigation."), cert. denied, 535 U.S. 905 (2002); Cooper v. Blue Cross & Blue Shield of Fla., 19 F.3d 562, 567 (11th Cir. 1994) (stating that "based on" is generally defined as "supported by" and that the statutory language is "most naturally read to preclude suits based in any part on publicly disclosed information"); United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 682-85 (D.C. Cir. 1997), cert. denied, 522 U.S. 865 (1997). See United States ex rel. Duxbury v. Ortho-Biotech Prods., L.P., No. 03-12189, 2008 WL 244304, at *5 (D. Mass. Jan. 25, 2008) (Zobel, J.) ("I adopt the majority view, which I believe better comports with both the policies underlying the provision and the Supreme Court's recent Rockwell decision."); United States ex rel. O'Keefe v. Sverdup Corp., 131 F. Supp. 2d. 87, 92-93 (D. Mass. 2001) (Saris, J.) ("I take the majority view because its reading of "based upon" is consonant with the structure and policies of the FCA.").

⁶ See, e.g., United States ex rel. Siller v. Becton Dickinson & Co., 21 F.3d 1339, 1348 (4th Cir. 1994) ("Rather plainly, therefore, a relator's action is 'based upon' a public disclosure of allegations only where the relator has actually derived from that disclosure the allegations upon which his *qui tam* action is

United States espouses the majority position. The First Circuit has not yet addressed the question.⁷

The Supreme Court has recently issued a talmudic decision parsing the language of the public disclosure bar. See Rockwell Int'l Corp. v. United States, __ U.S. __, 127 S. Ct. 1397 (2007). As background, in June 1987, the relator had gone to the FBI with allegations that Rockwell had committed environmental crimes. Relator provided the FBI with thousands of pages of documents, "buried among which was his 1982 engineering report" predicting

based."), cert. denied, 513 U.S. 928 (1994); United States ex rel. Mathews v. Bank of Farmington, 166 F.3d 853, 864 (7th Cir. 1999) ("[A] claim which both depends essentially upon publicly disclosed information and is actually derived from such information is 'based upon' a public disclosure for purposes of § 3730(e)(4)(A)."). Three courts in this district have taken the minority view. See United States ex rel. Rost v. Pfizer Inc., 446 F. Supp. 2d 6, 19 (D. Mass. 2006) (Tauro, J.) ("This court adopts the minority rule and holds that a *qui tam* action is 'based upon' a public disclosure only when the allegations supporting the action are 'derived from' the public disclosure."), vacated on other grounds, Rost, 507 F.3d at 734; United States ex rel. LeBlanc v. Raytheon Co., 874 F. Supp. 35, 41 (D. Mass. 1995) (Lindsay, J.) (noting in dicta that the court was "inclined to agree" with the minority interpretation of "based upon"); United States ex rel. LaValley v. First Nat'l. Bank of Boston, 707 F. Supp. 1351, 1366-67 (D. Mass. 1988) (Wolf, J.) (finding jurisdiction where the "information and knowledge upon which [the *qui tam*] action [was] based did not originate from" the public disclosure and was, instead, derived from "the ongoing monitoring and investigation" by the relators).

⁷ In its most recent decision involving the public disclosure bar, United States ex rel. Rost v. Pfizer, Inc., 507 F.3d 720 (1st Cir. 2007), the First Circuit did not specifically review the district court's adoption of the minority view. See id. at 728 (noting that the court reaches only the question of whether there was a public disclosure of the allegations or transactions).

that a piping system proposed by Rockwell was faulty and would produce "pondcrete blocks" that would ultimately disintegrate, leaking toxic wastes into the environment. Id. at 1402 n.1. The blocks did ultimately leak, but for a reason different from and unrelated to that which the relator had predicted. Id. at 1402. In May 1988, the Department of Energy became aware of the problem and the media reported on the leaking blocks. Id. As the dissent pointed out, it was not at all clear whether the relator was the original source of the allegations publicly disclosed by the media. Id. at 1413.

Assessing the original source subparagraph, the Supreme Court held, inter alia, that the original source provision is jurisdictional and that the statutory phrase "information on which the allegations are based," contained within the "original source" provision, refers to the relator's allegations, not the publicly disclosed allegations. Id., at 1406-07. The Supreme Court stated:

The sense of the matter offers strong additional support for this interpretation. Section 3730(e)(4)(A) bars actions based on publicly disclosed allegations whether or not the information on which those allegations are based has been made public. It is difficult to understand why Congress would care whether a relator knows about the information underlying a publicly disclosed allegation (e.g., what a confidential source told a newspaper reporter about insolid pondcrete) when the relator has direct and independent knowledge of different information supporting the same allegation

(e.g., that a defective process would inevitably lead to insolid pondcrete). Not only would that make little sense, it would raise nettlesome procedural problems, placing courts in the position of comparing the relator's information with the often *unknowable* information on which the public disclosure was based. Where that latter information has not been disclosed (by reason, for example of a reporter's desire to protect his source), the relator would presumably be out of court. To bar a relator with direct and independent knowledge of information underlying his allegations just because no one can know what information underlies the similar allegations of some other person simply makes no sense.

Id. at 1407-08. The Supreme Court did not directly address the interpretation of the "based upon" language in 31 U.S.C. § 3730(e)(4)(A) because it was conceded that the claims upon which the relator prevailed "were based upon publicly disclosed allegations within the meaning of § 3730(e)(4)(A)." Id. at 1405. Still, throughout Rockwell, the Supreme Court was vigilant in satisfying itself that it had subject matter jurisdiction even where parties made concessions about jurisdictional facts. See, e.g., id. at 1406-1407. Despite the lack of any evidence that the relator derived his allegations from the media, the Court accepted the parties' agreement that his allegations were based upon the public disclosures in the sense that they were similar to the publicly disclosed allegations. Id. at 1405. Thus, under one fair reading of Rockwell, a private citizen may not bring an action to enforce the False Claims Act where *similar* allegations

have been publicly disclosed unless he proves he is an original source of his own allegations under the exacting standard of 31 U.S.C. § 3730(e)(4)(B). Accord United States ex rel. Duxbury v. Ortho-Biotech Prods., L.P., No. 03-12189, 2008 WL 244304, at *5 (D. Mass. Jan. 25, 2008) (Zobel, J.) (“[T]he Court’s discussion [in Rockwell] presupposes that a relator’s allegation which is similar to or the same as the publicly disclosed allegation is subject to the public disclosure bar.”). This reading is consistent with the majority view of the meaning of “based upon” which I continue to follow.

3. Original Source

An original source is defined to be “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 [a suit] which is based on the information.” 31 U.S.C. § 3730(e)(4)(B). Courts have construed this statutory definition as conjunctive, requiring the relator to have both “direct” and “independent” knowledge. See United States ex rel. O’Keeffe v. Sverdup Corp., 131 F. Supp. 2d. 87, 93 (D. Mass. 2001) (Saris, J.) (citing Springfield Terminal Ry., 14 F.3d at 656). “A relator’s knowledge is ‘direct’ if she acquired it through her own efforts without an intervening agency, and it is ‘independent’ if her knowledge is not dependent on the public disclosure.” Id.

Thus, the jurisdictional inquiry here is whether Relator has proven that he has direct and independent knowledge of the information underlying his own specific allegations. This must be a claim-by-claim analysis. Rockwell, 127 S. Ct. at 1410.

4. Application of the Standard to Relator's Claims

Relator generally alleges that Ortho-McNeil engaged in an unlawful marketing strategy in order to increase sales of its drugs Levaquin and Ultram in violation of the federal False Claims Act (and similar state statutes) and the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). (Compl. ¶ 63.)

Relator has described his allegations in the notice of related action filed with the Judicial Panel on Multidistrict Litigation:

This is a 'tag-along' action per Panel Rule 1.1 because it involves common questions of fact with actions previously transferred in this MDL [West] alleges that Ortho-McNeil used fraudulent marketing and billing schemes to inflate the average wholesale price that hospitals could charge to government programs, including Medicare and Medicaid, including hidden kickbacks, "grants" and "speaker's fees." He also alleges that Ortho-McNeil sales representatives were instructed on how to advise the hospital to hide rebates and to alter their billing methods on Levaquin in order to bill Medicare at a higher AWP than they should have. See, eg., Amended Complaint paragraphs 67, 71, 72-77, 79-87.

(Defs.' Mem. Supp. Mot. Dismiss Ex. 3, Docket No. 4308-2.)

Specifically, Defendants' alleged actions, as articulated in Relator's complaint, include:

- 1) providing rebates to hospitals and providers in order to increase the spread - and thus the profit for providers - between the Medicare and Medicaid reimbursement level and the actual cost to the provider;
- 2) providing price discounts to hospitals and providers that agreed not to carry competing drugs on their formularies;
- 3) making cash payments to hospitals to keep Levaquin on their formulary;
- 4) encouraging hospitals to divide single use premix bags of Levaquin in order to create a secret discount and increase hospital profits and Levaquin sales;
- 5) creating kickbacks under the guise of "speaker fees" and "research grants"; and
- 6) giving improper gifts to physicians.

(Compl. ¶¶ 65-99.)

a. Possible Sources of Public Disclosure

Defendants assert that allegations of fraud nearly identical to Relator's were publicly disclosed in previously-filed lawsuits, media reports, government reports and investigations, and the Medicare Modernization Act. See, e.g., Master Consolidated Class Action Complaint, Docket No. 148, Sept. 6, 2002 ("MACC"); State of Nevada's Amended Complaint, Docket No. 922, Sept. 30, 2003 ("Nevada Complaint"); Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. As a result, Defendants argue, all of Relator's claims are "based upon" publicly disclosed allegations or transactions and, unless he is an original source, Relator's

qui tam action cannot survive.

Defendants point to complaints (the MACC and the Nevada Complaint) in two AWP fraud lawsuits filed before Relator commenced the action.⁸ These complaints generally allege that a multitude of pharmaceutical companies, including Johnson & Johnson and some of its subsidiaries, intentionally perpetrated a fraudulent scheme to inflate AWPs and then market the spread to boost sales of their products.⁹ See MACC ¶ 294; Nevada Compl. ¶¶ 7-10. According to the complaints, the companies "manipulated the spread" in two different ways. See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 36 (D. Mass. 2007) (explaining the two ways that pharmaceutical companies manipulated the spread). First, drug manufacturers would report artificially high AWPs to publishers, which would

⁸ Defendants do not suggest that this Court consider public disclosures made during the period between the initial and amended complaints, and this Court is not aware of any public disclosures in that period that would alter this Court's conclusions.

⁹ It is difficult to discern whether Defendant Ortho-McNeil was specifically implicated in these complaints. The MACC named, among others, Johnson & Johnson and its subsidiaries, Centocor, Inc., and Ortho-Biotech. The Nevada Complaint named Johnson & Johnson and several of its subsidiaries (Centocor, Inc.; Janssen Pharmaceutica Products, L.P.; McNeil-PPC, Inc.; and OrthoBiotech) as defendants. Defendant Ortho-McNeil is not specifically named, but is a subsidiary of Johnson & Johnson. The Amended Master Consolidated Class Action Complaint ("AMACC"), however, does name Levaquin, a drug that is manufactured by Ortho-McNeil, Inc., according to the Johnson & Johnson website. (See Docket No. 443, ¶ 436.)

increase the spread and provide an incentive for a provider to choose the product with the larger spread. (MACC ¶ 6.) Second, pharmaceutical manufacturers would also provide a variety of improper financial inducements to stimulate drug sales. (MACC ¶¶ 162-165.) These inducements decreased the actual acquisition cost of the drug to providers while the AWP reimbursement rate remained steady, thereby increasing the spread. See In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 36.

According to the complaints, these inducements included:

- “volume discounts, rebates, off-invoice pricing, free goods, credit memos, consulting fees, debt forgiveness and grants . . . [a]ll of [which] were designed to lower the providers’ net cost of purchasing the Defendant Drug Manufacturers’ Covered Drugs” (MACC ¶ 165);
- “a pattern and practice of paying illegal kickbacks, disguised as free goods, rebates, consulting fees, junkets and education grants to providers and other intermediaries” (MACC ¶ 340(g));
- “providing the providers with . . . unlawful financial incentives, including kickbacks and bribes, to induce use of the Covered Drugs” (MACC ¶ 361);
- “chargebacks, credits, rebates, hidden price discounts and/or other unlawful financial inducements, including free samples, that are not included in the AWPs reported by defendants, which consequently further increase the provider’s spread and their incentive to prescribe a particular defendant’s product” (Nevada Compl. ¶ 9); and
- “free goods, volume discounts, credits, rebates, educational grants and other programs that lower the providers’ actual cost of the drugs” (Nevada Compl. ¶ 12.)

Importantly, the Amended Master Consolidated Class Action

Complaint ("AMACC"), filed in June 2003, specifically alleges that Johnson & Johnson inflated the AWP's for the drugs Levaquin and Ultram, the two drugs implicated in Relator's allegations. (Docket No. 443, ¶ 436.) Similarly, Levaquin and Ultram are both included in the Nevada complaint. (¶ 302.)

Nevada's complaint goes one step further by alleging Medicaid fraud. In addition to alleging that Defendants perpetrated an illegal "AWP-inflation" scheme, Nevada alleges that manufacturers, including Johnson & Johnson and several of its subsidiaries, also failed to account for these cost-lowering practices when they reported their "best prices" to state Medicaid programs, as they are required to do by law. See 42 U.S.C. § 1396r-8(c)(1)(C)(ii) ("The term 'best price' . . . shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and [non-exempted] rebates.").

A brief description of Medicaid reimbursement is warranted. In order to ensure that Medicaid is able to access the same price concessions and deals received by commercial customers, Congress created a program that requires drug manufacturers, on a quarterly basis, to remit rebates to state Medicaid offices that have subsidized the purchase of that manufacturer's drugs. See 42 U.S.C. § 1396r-8. The required rebate is calculated by multiplying the difference between the "average manufacturer price" ("AMP") and "best price" for the covered drug by the total

number of units each state paid for during that rebate period. The AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1)(A). "Best price" is defined as "the lowest price available from the manufacturer during the rebate period" and "shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and [non-exempted] rebates." 42 U.S.C. § 1396r-8(c)(1)(C)(I)-(ii). Each manufacturer is required to report both the "AMP" and the "best price" for each of its covered drugs. The system therefore depends on accurate reporting by the drug manufacturers.

Thus, by not accounting for these cost-lowering programs in their "best price" reports, the Defendants allegedly paid the state Medicaid programs less than what they truly owed in rebates. See Nevada Compl. ¶¶ 12, 383-403 (alleging, on information and belief, that each defendant identified as having inflated AWP's also failed to pay the "best price," but providing only two examples of such misconduct).

Defendants also argue that media reports about the lawsuits - and therefore the underlying fraud alleged within the suits - constitute public disclosures. For example, a December 2001 Boston Globe article reporting on one of several AWP lawsuits spoke generally about the manufacturers' practice of discounts and rebates to doctors and specifically reported allegations that

TAP Pharmaceuticals "gave doctors ski trips and VCRs to prescribe its prostate cancer drug Lupron, and sold the drug to them at prices far lower than the AWP it reported to Medicare." (Defs.' Mem. Supp. Mot. Dismiss Ex. 5.) In June 2002, the Philadelphia Inquirer reported that a lawsuit accused Johnson & Johnson of "pa[ying] unspecified illegal bribes and kickbacks to doctors to induce them to prescribe" one of Johnson & Johnson's drugs. Id. Finally, Defendants contend that the Medicare Modernization Act and various government reports and investigations also qualify as public disclosures under the FCA.

The Court must determine whether the allegations or transactions in the Relator's complaint were publicly disclosed by these sources.

b. Rebates

Relator alleges the following fraudulent rebate scheme. Ortho-McNeil presented hospitals with rebate checks that "typically ran into the tens of thousands of dollars." (Compl. ¶ 74.) When delivering these checks, Ortho-McNeil sales representatives were instructed to inform the hospitals that hospitals could easily hide these rebates from Medicare and Medicaid and, as a result, make a "hidden profit on Levaquin." (Id. ¶ 75.) Finally, "on information and belief," Relator alleges that "Ortho-McNeil did not accurately and fully report the lower prices resulting from Ortho-McNeil's hospital rebate

program as required by the Medicaid and other government funded programs." (Id. ¶ 77.) In essence, Relator accuses Defendants of using rebates to "market the spread" between what the hospital paid for the drug and what it would be reimbursed by Medicare and Medicaid. By not accounting for these rebates in either their AWP or "best price" reports, Relator contends that the Defendants caused several states and the federal health care programs to pay false or fraudulent reimbursement claims and miss out on rebates that they were owed by the manufacturers.

In Springfield Terminal Railway, the Court of Appeals for the District of Columbia Circuit articulated a helpful, straightforward, and widely accepted framework for determining whether a public disclosure of the allegations or transactions has occurred. 14 F.3d at 654. According to that framework, "if $X + Y = Z$, Z represents the *allegation* of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, *i.e.*, the conclusion that fraud has been committed." Id. Under the framework:

X stands for the allegedly false set of facts set forth in the claim at issue, and Y is a proxy for the allegedly true set of facts. Thus, 'when X [the false set of facts] and Y [the true set of facts] surface publicly, or when Z is broadcast . . . , there is little need for *qui tam* actions,' and the claim will be barred unless the relator qualifies as an

original source. However, where only one element of the fraudulent transaction is in the public domain (e.g., X), the *qui tam* plaintiff may mount a case by coming forward with either the additional elements necessary to state a case of fraud (e.g., Y) or allegations of fraud itself (e.g., Z)."

O'Keefe, 131 F. Supp. 2d at 94 (quoting Springfield Terminal Ry., 14 F.3d at 654) (citations omitted). The outcome of this analysis determines whether a court proceeds to the next and final step of the jurisdictional inquiry: determining whether the relator qualifies as an "original source."

In the Springfield Terminal Railway terminology, Relator's rebate allegation includes two distinct (albeit related) "Z's." First, in alleging that Defendants failed to account for rebates when reporting AWP, Relator alleges an "AWP fraud Z." The Court concludes that this "Z" was publicly disclosed before Relator commenced this action. Each of the civil complaints cited above specifically identifies rebates as a means by which Johnson & Johnson and its subsidiaries increased the spread between the drug price actually paid by providers and their reimbursement price. Second, in alleging that Defendants failed to account for rebates when reporting their "best prices" for the Medicaid program, Relator alleges a "best price Z." Like the AWP fraud allegation, this "Z" was also publicly disclosed in the Nevada Complaint prior to Relator's commencement of this action. Accordingly, both of Relator's rebate allegations are based upon

publicly disclosed allegations or transactions, and each claim will be barred unless he qualifies as an "original source" for that particular allegation.¹⁰

To qualify as an original source, Relator must 1) have direct and independent knowledge of the Defendants' use of rebates to perpetuate the fraud and 2) have voluntarily provided the information to the government before filing suit. See 31 U.S.C. § 3730(e)(4)(B).

For a Relator to possess direct knowledge, he must establish that he had "firsthand knowledge of the alleged fraud, and that he obtained this knowledge through his own labor unmediated by anything else." United States ex rel. Aflatooni v. Kitsap Physicians Servs., 163 F.3d 516, 525 (9th Cir. 1999) (internal quotation marks omitted); see also Wang v. FMC Corp., 975 F.2d 1412, 1417 (9th Cir. 1992) (holding that a relator had "direct"

¹⁰As discussed above, it is unclear whether Ortho-McNeil was specifically named as a defendant in the earlier complaints. However, even assuming Defendant was not named, the jurisdictional bar can still apply. See United States ex rel. Gear v. Emergency Med. Assoc. of Ill., Inc., 436 F.3d 726, 729 (7th Cir. 2006) ("We are unpersuaded by an argument that for there to be public disclosure, the specific defendants named in the lawsuit must have been identified in the public records."). Moreover, the previous complaints "set the government squarely on the trail of fraud" such that it would not have been difficult for the government to identify Ortho-McNeil as a potential wrongdoer. United States ex rel. Fine v. Sandia Corp., 70 F.3d 568, 571-72 (10th Cir. 1995) (affirming the dismissal of a *qui tam* suit for lack of jurisdiction where the public disclosures had "detailed the mechanics of the practices" and the possible perpetrators were a small number of "easily identifiable . . . and government-owned laboratories").

knowledge of a problem because "he saw [it] with his own eyes" and his knowledge was "unmediated by anything but [his] own labor.").

i. Original Source of the AWP-fraud "Z"?

In the Complaint, West speaks generally of Ortho-McNeil sales representatives being instructed to market the spread created by rebate checks. In his affidavit dated July 7, 2007, West states that the allegations in the Complaint "were based solely upon information [he] learned and saw with [his] own eyes during the time [he] was employed by [Defendant Ortho-McNeil]." (West Aff. ¶ 12.) Defendants have not requested jurisdictional discovery. At this preliminary stage of the litigation, when all reasonable inferences are drawn in favor of the plaintiff (here, the Relator), this affidavit is sufficient to establish that it is likely that West, a salesman, has "direct and independent" knowledge of the AWP fraud rebate scheme. However, Rockwell has made it clear that the Court's inquiry into subject matter jurisdiction is an ongoing one. A later demonstration, after discovery, that Relator's surviving allegations are not based on direct and independent knowledge will ultimately defeat jurisdiction. Rockwell, 127 S. Ct. at 1403-05, 1408-09 (conducting inquiry into relator's original source status after a jury verdict and using the allegations as stated in the final pretrial order as the basis for the evaluation).

Defendants further contend that Relator has not established that he has "direct and independent" knowledge that the rebates were not reflected in the reported AWP's. It is disingenuous for Defendants to argue that West lacked direct and independent knowledge that AWP was not the true price that wholesalers charge providers, as Defendants have argued throughout the MDL litigation that the fact that AWP was not the true price charged to providers was known throughout the industry. In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 40.

The conclusion that Relator has "direct and independent" knowledge of his AWP-based rebate allegation leads to the final step of the "original source" inquiry: whether Relator "voluntarily provided the information to the Government before filing an action." 31 U.S.C. § 3730(e)(4)(B). Relator has satisfied this requirement, stating in his affidavit that he voluntarily contacted the Office of the United States Attorney for the Northern District of Illinois in September 2003 - two months prior to filing this *qui tam* action - and provided the office with the same information that underlies the allegations in the Complaint. See West Aff. ¶ 5, 6, 8. Relator also stated that he voluntarily met with an FBI agent and discussed the same information that underlies the allegations in the Complaint. Id. ¶ 11. Accordingly, Relator has demonstrated that this Court has jurisdiction over his allegation that Defendants used rebates to

"market the spread" between what a hospital paid for the drug and what it would be reimbursed by Medicare and Medicaid and failed to account for these rebates when reporting AWP.

ii. Original Source of the Best Price "Z"?

The situation for "best price" reporting is different. Relator does not provide direct and independent information that Ortho-McNeil did not fully incorporate these rebates into their "best price" reports. Instead, Relator alleges "on information and belief" that Defendant "did not accurately and fully report the lower prices resulting from Ortho-McNeil's hospital rebate program as required by the Medicaid and other government funded programs." (Compl. ¶ 77.) An allegation "on information and belief" is insufficient to meet the burden of demonstrating "direct and independent" knowledge. Unlike the AWP fraud allegation, it is not self-evident that a sales representative would know whether a company accounted for such rebates in its "best price" reports. As such, Relator is not an original source of any FCA claim alleging that Defendants failed to accurately and fully account for rebates when reporting the "best price" of Levaquin for a given quarter. The Court therefore does not have jurisdiction over these claims. Further, even if Relator's "information and belief" allegation were considered sufficient here, it would still fail to satisfy the specificity requirements under Fed. R. Civ. P. 9(b), as Relator does not

specify any grounds for such belief. See United States ex rel. Karvelas v. Melrose-Wakefield Hosp., 360 F.3d 220, 226 n.8 (1st Cir. 2004) (clarifying that information and belief pleading is permissible under Rule 9(b), but stating that such pleadings must "set forth the facts on which the belief is founded").

Accordingly, this aspect of Relator's rebate claim is dismissed.

c. Discounts

Relator alleges that Ortho-McNeil sales representatives gave price discounts for the drug Levaquin to hospitals and other institutional providers that agreed not to carry competing drugs on their formularies. (Compl. ¶ 70.) Relator alleges a specific instance, in March 2002, of an Ortho-McNeil sales representative "lower[ing] the price of Levaquin to Holy Cross Hospital on the condition that the hospital 'no longer stock Cipro for MD's requesting the drug.'" (Id. ¶ 71.) In contrast to his rebate allegation, Relator does not specifically allege that Defendants failed to report accurately these discounts in either the AWP or "best price" context.¹¹

The first inquiry is whether Relator's discount allegation

¹¹ Even if this omission is an oversight and Relator had included an allegation that Defendants did not accurately and fully report the lower prices created by the discounts in the AWP or "best price" context, the public disclosure bar analysis would be identical to that relating to the rebate allegation. The same holds true for each of Relator's remaining allegations, none of which specifically allege AWP or "best price"-based claims.

was publicly disclosed prior to his complaint. The publicly disclosed MACC spoke of "volume discounts . . . designed to lower the providers' net cost of purchasing the Defendant Drug Manufacturers' Covered Drugs," (MACC ¶ 165), and "unlawful financial incentives . . . [designed] to induce use of the Covered Drugs." (MACC ¶ 361.) The publicly disclosed Nevada Complaint alleged that pharmaceutical companies used "hidden price discounts . . . which consequently further increase[d] the provider's spread and their incentive to prescribe a particular defendant's product." (Nevada Compl. ¶ 9; see also id. ¶ 12 ("volume discounts")).

Like the publicly disclosed complaints, Relator's complaint speaks of drug manufacturers' practice of giving volume discounts. (Compl. ¶ 70) ("[T]he most important factor in setting price was the market share that Levaquin carried at the particular institution."). The crux of Relator's allegation, however, is that Defendants provided discounts with the intent to restrict hospital formularies by excluding competitor drugs, and that the discounts led to a violation of the False Claims Act.

This allegation is not contained within the publicly disclosed complaints. Essentially, such an allegation is a different "Z" than that alleged in the earlier lawsuits and public disclosures. In the previous lawsuits, the "Z" was the use of discounts to increase the spread and thus cause doctors to submit false claims for drug reimbursement under a fraudulent

AWP. Here, the "Z" is the use of discounts to induce providers to prescribe only Defendants' drug. This legal theory relies upon the federal health care Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). This second scheme has an element - the quid pro quo that a hospital will only receive the discount if it refuses to carry a competitor drug - that was absent from the scheme described in the publicly disclosed allegations. It is therefore an entirely separate fraudulent scheme and not "substantially similar" to the publicly disclosed allegations. Because Relator's allegation of this second scheme is not "based upon" a publicly disclosed transaction, this Court need not determine whether Relator is an independent source. Jurisdiction is proper.

d. Cash Payments as Bribes

Relator alleges that Ortho-McNeil offered monetary inducements to persuade hospitals not to switch from Levaquin to a less expensive competitor drug, Tequin. (Compl. ¶ 66.) Relator contends that although some of the payments were labeled "'educational grants' they had one, and only one purpose - to indirectly lower the cost of Levaquin to the hospital, and thereby induce the hospital to continue to purchase Levaquin." (Id.) Relator alleges that, in the summer of 2000, "[he] was directed by his district manager to participate in offering a \$25,000 payment to Holy Cross Hospital" in Chicago. (Id. ¶ 67.)

This payment was to consist of five separate \$5000 payments made to the hospital, each by a different Ortho-McNeil employee.

(Id.) This cash payment scheme was designed, West believed, to convince Holy Cross to abandon its plan to drop Levaquin from the formulary and replace it with the competitor drug Tequin. (Id. ¶¶ 67-68.) Relator also alleges that he was told that similar payments had been made to a nearby hospital and that Ortho-McNeil's home office had approved the payment. (Id. ¶ 68.) From this, Relator states that he understood such payments to be part of an overall marketing plan to compete with Tequin. (Id.)

Relator is not the first to accuse pharmaceutical companies of bribery. The MACC alleges the pharmaceutical companies "provid[ed] the providers with . . . unlawful financial incentives, including kickbacks and bribes, to induce use of the Covered Drugs." (MACC ¶ 361.) The MACC also references improper "consulting fees" and "education grants" (¶ 340(g)), while the Nevada complaint alleges that "educational grants" (¶ 12) were part of the pharmaceutical companies' improper marketing schemes. A 2002 Philadelphia Inquirer article detailed a New Jersey lawsuit that accused Johnson & Johnson of "pa[ying] unspecified illegal bribes and kickbacks to doctors to induce them to prescribe" one of its drugs. (Defs.' Mem. Supp. Mot. Dismiss Ex. 5.)

It is a close call whether these public disclosures trigger the jurisdictional bar. Relator's cash bribe allegation is

arguably a different "Z" than found within the prior disclosures. The earlier lawsuits alleged a long-term, industry-wide practice of providing various financial incentives, including bribes, to doctors and hospitals, marketing the spread created by the incentives, and failing to account accurately for these incentives in the reported AWP's and "best prices" of drugs.

Here, however, Relator alleges a very specific fraudulent scheme: that Defendants paid (or planned to pay) a specific bribe to two specific hospitals for a specific purpose (persuading them not to drop Levaquin from the formulary) in a specific time period.¹² Even if the scheme Relator alleges is viewed, as Defendants suggest it should be, as part and parcel of the industry-wide scheme alleged in the public disclosures, the bar is not triggered because the public disclosures were not "adequate to set the government squarely on the trail of fraud." United States ex rel. Fine v. Sandia Corp., 70 F.3d 568, 571-72 (10th Cir. 1995). Compare United States ex rel. Findley v. FPC-Boron Employees' Club, 105 F.3d 675, 687 (D.C. Cir. 1997) (concluding that the specific wrongdoers were "easily identifiable federal employee organizations" and upholding the dismissal of a *qui tam* action) and Sandia, 70 F.3d at 571-72 (affirming the dismissal of a *qui tam* suit for lack of

¹² To the extent that Relator seeks to pursue a nationwide claim based on this cash bribe allegation, that claim will have to satisfy the requirements of Rule 9(b).

jurisdiction because the public disclosures had "detailed the mechanics of the practices" and the possible perpetrators of fraud were limited to nine, "easily identifiable . . . and government-owned laboratories") with Cooper v. Blue Cross & Blue Shield of Fla., Inc., 19 F.3d 562, 566 (11th Cir. 1994) (holding that public allegations of widespread fraud within the insurance industry were insufficient to trigger the public disclosure bar) and Friedman v. Rite Aid Corp., 152 F. Supp. 2d 766, 769 (E.D. Pa. 2001) (concluding that a *qui tam* suit against Rite Aid "more closely approximates Cooper" than Sandia because "[a]ny fraudulent acts that occurred at Rite Aid are not of the type that are easily discoverable from public disclosures as were those under the circumstances in Sandia"). For these reasons, this Court has jurisdiction over Relator's cash bribe allegations.

Even if this Court were to hold that Relator's cash bribe allegations were publicly disclosed, Relator would qualify as an original source. Relator maintains that, when employed as a sales representative by Defendant Ortho-McNeil, he was personally asked to participate in a bribery scheme. This qualifies as "direct" knowledge because "he saw [it] with his own eyes." Wang, 975 F.2d at 1417. It also is independent because, as someone with personal experience, Relator need not rely upon the public disclosure for his knowledge of the alleged bribery

scheme. Because Relator also satisfied the "voluntary disclosure" requirement, he would qualify as an "original source" and this Court would have jurisdiction over any cash bribes for which Relator could establish "original source" status.

e. Dividing Single Use Premix to Increase Profit

Relator alleges that Ortho-McNeil instructed its sales representatives to inform hospitals that they could save money by ordering 500 mg containers of Levaquin, rather than 250 mg containers. Purchasing the larger bag and dividing it into two doses decreased the actual cost of the drug to the hospitals, yet the Medicare Part B reimbursement amount remained constant. As a result, hospitals would be reimbursed at an amount higher than what they had paid - a feature that Ortho-McNeil sales representatives were to emphasize to hospitals. (Compl. ¶ 84.) According to Relator, dividing 500 mg bags of Levaquin into two 250 mg doses violated the FDA single use labeling restriction and "endangered the patient who received the second-use of the single use package." (Id. ¶ 85.)

Applying the Springfield Terminal Railway terminology, the "Z" of this allegation is that, by encouraging hospitals to improperly divide single use premix bags of Levaquin, Defendants caused the submission of false claims or statements to the government. This particular "Z" was not publicly disclosed prior to the Relator's complaint. The civil complaints discussed above

contain laundry lists of "inducements" allegedly used by pharmaceutical companies in their quest to "market the spread" and perpetrate AWP fraud. None, however, mentions the improper marketing of single use premix bags of any drug. Accordingly, because there has not been a public disclosure of Relator's single use premix allegation, the jurisdictional bar does not apply, and this Court has jurisdiction over Relator's dividing single use premix claim. Therefore, this Court need not determine whether Relator is an original source. Jurisdiction is proper.

f. Improper Speaker Fees, Research Grants, and Gifts

Relator alleges that, under the guise of "speaker fees" and "research grants," Ortho-McNeil provided illegal inducements to physicians, pharmacists, and Pharm.D.'s with the goal of increasing prescriptions of Levaquin and Ultram. (Compl. ¶ 88.) Relator provides the names of several doctors that he claims were "paid thousands of dollars" to speak about Levaquin and Ultram at organized lunches and dinners. (Id. ¶¶ 89-90.) Ortho-McNeil, according to Relator, also tracked the prescribing practices of these speakers, "so that the speakers would understand that their continued service as paid speakers was dependent on their own prescribing practices." (Id. ¶ 89.)

Relator also alleges that Ortho-McNeil made "sizeable payments" to physicians to conduct "research studies." (Id. ¶

91.) Relator contends that, although "the research studies had impressive names, in reality the studies involved such 'research' as giving the consultant doctors free samples of Levaquin to provide their patients, and then asking doctors to fill in a form for each patient who received the free sample." (Id.) On information and belief, Relator alleges that Ortho-McNeil engaged in this practice across the country to influence prescribing practices with respect to Levaquin and Ultram. (Id. ¶ 92.)

Finally, Relator alleges that Ortho-McNeil offered and provided physicians with a variety of improper gifts and inducements to encourage them to prescribe Levaquin and Ultram. Specifically, Relator alleges that Ortho-McNeil had two separate programs offering physicians and practice groups free websites and website maintenance. (Id. ¶¶ 93-98.) According to Relator, Ortho-McNeil sales representatives would make sure that doctors in the program knew that Ortho-McNeil was tracking their ordering practices. (Id. ¶ 94.) Relator provides the names of several practices in Illinois that allegedly accepted the free website offer. (Id. ¶ 95.) Relator also alleges that "Ortho-McNeil often provided physicians with free trips to conferences, expensive dinners, golf outings, tickets to amusement parks and other similar gratuities." (Id. ¶ 99.)

Relator's allegations of speaker fees, research grants, and improper gifts were publicly disclosed prior to Relator's filing of the complaint. As discussed above, the previous lawsuits

contained allegations of "a pattern and practice of paying illegal kickbacks, disguised as free goods, rebates, consulting fees, junkets and education grants to providers." (MACC ¶ 340(g).) Accordingly, Relator's allegations are based upon publicly disclosed allegations, and therefore he must qualify as an "original source" in order for this Court to have jurisdiction over his claim.

Here, Relator's statement, in his affidavit, that all of the allegations in his complaint "were based solely upon information [he] learned and saw with [his] own eyes during the time [he] was employed by [Defendant Ortho-McNeil]," is enough to establish that West has "direct and independent" knowledge of the alleged speaker fees, research grants, and improper gifts specifically listed in his complaint. It is not enough, however, to qualify him as an original source for a nationwide claim. Re-evaluation after discovery may be warranted.

This Court has already concluded that Relator satisfied the "voluntary disclosure" requirement, the final step in the "original source" test. Accordingly, Relator has demonstrated that this Court has jurisdiction over allegations of illegal inducements in the form of speaker fees, research grants, and improper gifts.

B. The State False Claims Acts

1. Nevada False Claims Act and Hawaii False Claims Act

Defendants move to dismiss West's claims under the Nevada False Claims Act (Count IX) and the Hawaii False Claims Act (Count VI) for lack of subject matter jurisdiction. The Relator did not dispute this ground for dismissal.

Each state's false claims act bars private suits when the state is pursuing its own action. The Nevada False Claims Act states that "[a]n action may not be maintained by a private plaintiff pursuant to this chapter . . . (b) [i]f the action is based upon allegations or transactions that are the subject of a civil action or an administrative proceeding for a monetary penalty to which the State or political subdivision is already a party." Nev. Rev. Stat. § 357.080(3). Similarly, the Hawaii False Claims Act states that a person may not bring an action "[t]hat is based upon allegations or transactions that are the subject of a civil or criminal investigation by the State, civil suit, or an administrative civil money penalty proceeding in which the State is already a party." Haw. Rev. Stat. § 661-27(e)(3).

Both the State of Nevada and the State of Hawaii are pursuing their own claims against Defendants. Accordingly, Relator's claims under the False Claims Acts of Nevada and Hawaii are dismissed.

2. Additional Requirements to Qualify as an "Original Source"

The False Claims Acts of California, Hawaii, Nevada, and the

District of Columbia each require a relator whose allegations are based upon public disclosures to prove that he is the person "[w]hose information provided the basis or caused the making of the investigation, hearing, audit or report that led to the public disclosure" in order to qualify as an original source and proceed with the claim. Nev. Rev. Stat. § 357.100(2)(c). See also Cal. Gov't Code § 12652(d)(3)(B); Haw. Rev. Stat. § 661-28; D.C. Code § 2-308.15(c)(2)(B). Defendant asserts, and West does not dispute, that West cannot prove that he was the person whose information provided the basis for the public disclosures. Accordingly, each of Relator's allegations that this Court has determined to be based upon "public disclosures" is dismissed from Relator's claims under the False Claims Acts of California, Hawaii, Nevada, and the District of Columbia.

C. Motions to Dismiss Pursuant to Rule 9(b)

Relator's claims that have survived the jurisdictional inquiries face yet another challenge: sufficiency under Rule 9(b).

Fed. R. Civ. P. 9(b) mandates that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." "Conclusory allegations and references to plans and schemes are not sufficient." Rost, 507 F.3d at 731 (internal quotation marks omitted). Generally, "the

particularity requirement means that a complaint must specify the time, place, and content of an alleged false representation."

Id. (internal quotation marks omitted). Rule 9(b) applies to *qui tam* actions under the federal FCA and similar state statutes.

Id. at 731, 731 n.8 (concluding that the district court did not err in applying Rule 9(b) to relator's federal and state claims because "[t]he heightened pleading standard of Rule 9(b) generally applies to state law fraud claims brought in federal court").

In two recent cases, the First Circuit has analyzed *qui tam* complaints involving allegations of false claims being submitted to federal health insurance programs such as Medicare and Medicaid under Rule 9(b). See Rost, 507 F.3d at 731-33; Karvelas, 360 F.3d at 232-35. The First Circuit anchored its analyses in the principle that the FCA "attaches liability not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." Rost, 507 F.3d at 731-32, 727 ("FCA liability attaches to a false or fraudulent claim for payment or to a false record or statement [made] to get a false or fraudulent claim paid by the government.") (internal quotation marks omitted); see also Karvelas, 360 F.3d at 225.

The First Circuit has recognized that the specific requirements to satisfy 9(b) will depend upon the circumstances of the case. In Karvelas, which involved a defendant who

submitted claims directly to government programs, the First Circuit held that a relator "must provide details that identify particular false claims for payment that were submitted to the government." Karvelas, 360 F.3d at 232. However, in Rost, where the alleged false claims were submitted not by the defendant, but by a third party instead, the First Circuit explained that the relator need not allege the details of particular claims, so long as "the complaint as a whole is sufficiently particular to pass muster under the FCA." Rost, 507 F.3d at 732. A complaint, for example, must include "factual or statistical evidence to strengthen the inference of fraud beyond possibility." Id. at 733. In Rost, where there was evidence that actually "undercut the strength of the inference that fraud on the government in fact occurred," the First Circuit ultimately concluded that the complaint failed to satisfy this standard. Id. at 732-33.

1. AWP-based allegations

At the hearing on September 10, 2007, Relator conceded that, under the standard set forth by this Court in previous AWP cases, he had not pled the fraudulent AWPs with the specificity required to pass muster under Rule 9(b). See, e.g., In re Pharm. Indus. Average Wholesale Price Litig., 307 F. Supp. 2d 196, 208 (D. Mass. 2004) (articulating the requirement that each drug named in the complaint be accompanied by the allegedly fraudulent AWP published for that drug by a named defendant).

2. Relator's Other Allegations

Relator's remaining allegations pass muster under Karvelas and Rost. The discount, cash bribe, premix bag, and improper fees, grants, and gifts allegations are each sufficiently particular. For example, Relator identifies a particular time (March 2002) when a particular Ortho-McNeil sales representative (Cheryl Janicek) allegedly discounted the price of Levaquin for a specific hospital (Holy Cross Hospital) on the condition that the hospital "no longer stock Cipro for MD's requesting the drug." (Compl. ¶ 71.) Relator's other allegations include sufficient descriptions of the alleged schemes, including names of particular doctors and hospitals, to satisfy the particularity requirement. Moreover, the circumstances of the alleged bribes (i.e., serial cash payments) and other alleged kickbacks are sufficiently clandestine that it is probable that the payments were not disclosed in reported prices and/or that they led to the submission of false certifications of compliance with the Anti-Kickback statute. Because the Defendants here, as in Rost, do not directly submit reimbursement claims, Relator need not plead the details of specific false claims.

Accordingly, this Court holds that Relator's complaint satisfies Rule 9(b) for the specific instances of fraud described in his discount, cash bribe, premix bag, and improper fees, grants, and gifts allegations for the regional office and for the

years in which he worked. Relator has not pleaded his case with specificity on a nationwide level for all years.

D. Motions to Dismiss Pursuant to Rule 12(b)(6)

Defendants argue that West has failed to state a claim against Defendant Johnson & Johnson. Each wrongful act alleged by the Relator implicates only Ortho-McNeil, not Johnson & Johnson, the corporate parent. Although West implies that Johnson & Johnson might be liable under a "piercing the corporate veil" theory, he has not pled facts to support such a theory. Because West has not set forth facts that support a cause of action against Johnson & Johnson, the claims against Johnson & Johnson are dismissed. Accord United States ex rel. West v. Ortho-McNeil Pharm., Inc., No. 03-C-8239, 2007 WL 2091185, at *5 (N.D. Ill. July 20, 2007) (dismissing West's off-label marketing claims against Johnson & Johnson and noting that West has "pleaded no facts" to support a "piercing the corporate veil" theory).

The motion to dismiss on other grounds is **DENIED**.

E. Leave to Amend

The Court allows the Relator the requested leave to amend the complaint to allege the AWP spread with specificity. Relator should so within 30 days.

ORDER

The Court dismisses the claims under the False Claims Acts

of Nevada and Hawaii (Counts VI and IX). The Court dismisses the claims based on rebates and improper speaker fees, grants, and gifts, under the False Claims Acts of California and the District of Columbia (Counts III and XIII). The Court dismisses the claims against Johnson & Johnson. The Court dismisses the allegations under the False Claims Act under state and federal law to the extent they relate to best price violations. The Court will dismiss the AWP claims unless the complaint is amended to state with specificity the allegedly fraudulent spread within 30 days. The Court dismisses all claims under Fed. R. Civ. P. 9(b) except with respect to the years and region in which the relator worked. Otherwise **DENIED**.

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