UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

UNITED STATES OF AMERICA *ex rel.* SHANE LAGER,	)	
Plaintiff,	)	
vs.	)	Case No. 4:14-CV-841 (CEJ)
CSL BEHRING, LLC, *et al.*,	)	
Defendants.	)	

MEMORANDUM AND ORDER

This *qui tam* action is brought by relator Shane Lager pursuant to the False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (FCA). Relator alleges that drug manufacturer CSL Behring, LLC, and its parent corporation CSL Behring Limited (collectively, CSL Behring) conspired with specialty pharmacies Accredo Health, Inc., (Accredo) and Coram LLC (Coram) to submit false claims to the United States for reimbursement for prescription drugs. After a period of review, the government declined to intervene. Defendants move to dismiss the complaint pursuant to Fed.R.Civ.P. 12(b)(6) and 9(b). Defendant CSL Behring Limited additionally moves for dismissal for insufficient service of process, pursuant to Fed.R.Civ.P. 12(b)(5). Relator has filed responses in opposition and the issues are fully briefed.

I. Background

Relator worked for defendant CSL Behring for fourteen years in sales and sales management. He alleges that CSL Behring fraudulently reported inflated wholesale prices for the drugs Vibaglobin and Hizentra, causing government health

programs to reimburse to Coram and Accredo more than what they actually pay for the drugs.

CSL Behring manufactures protein-based therapies, including Vivaglobin and Hizentra. The drugs are classified as "DME infusion drugs" because they are self-administered by patients through a pump, which is "durable medical equipment" (DME). Vivaglobin was introduced in 2006 and was discontinued in 2011; Hizentra was introduced in 2010 and continues to be manufactured. According to relator, 70% of CSL Behring's sales of Vivaglobin and Hizentra are made to defendants Coram and Accredo. Complaint ¶¶ 34, 36.

Pharmacies that dispense drugs to beneficiaries of government healthcare programs (*e.g.*, Medicare) submit claims for reimbursement to the federal government. For most drugs, the government reimburses pharmacies based on a percentage of the average sales price (ASP). However, DME infusion drugs are reimbursed based on a percentage of the drug's average wholesale price (AWP).[1] Unlike the ASP, which is based on actual sales data, the AWP is based on figures the drug manufacturer reports to third-party publishers (*e.g.*, Red Book).[2] U.S.

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[1] Prior to 2005, Medicare used AWP as the basis for all drug reimbursements. In 2003, Congress made ASP the basis for of reimbursement for prescription drugs, effective January 1, 2005. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), 42 U.S.C. §§ 1395w–21–1395w–28. The MMA excluded DME infusion drugs from the new methodology and set their payment amount at 95% of the AWP in effect on October 1, 2003, or for drugs approved after that date, the first published AWP. See Suzanne Murrin, U.S. Dept. Health & Hum. Svces., Office of Insp. Gen'l, OEI-12-15-00110 *Recommendation Followup Memorandum Report: Implementing OIG Recommendation Could Have Reduced Payments for DME Infusion Drugs by Hundreds of Millions of Dollars,* (April 21, 2015) (2015 OIG Report) [Doc. #53-8].

[2] "Since the late 1960's, almost every brand and generic prescription drug sold in the United States has had an 'average wholesale price,' which is published in commercial compendia like Red Book, First DataBank, and Medispan." *In re* Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 32 (D. Mass. 2007). Initially, AWP was the average price paid by doctors and pharmacies to wholesalers, who added a 20 or 25% markup to the price they paid to manufacturers. Id. at 33. Due to "consolidation and competition among wholesalers, these standard markups on branded drugs no longer

Department of Health & Human Services, Office of Inspector General, OEI-12-12-00310, *Part B Payments for Drugs Infused Through Durable Medical Equipment* at 2-3 (Feb. 2013) (2013 OIG Report) [Doc. #53-1]. Also unlike ASP, AWP is not defined by law or regulation. U.S. Dept. of Health & Human Svcs., Office of Insp. Gen'l, OEI-03-05-00200, *Medicaid Drug Price Comparison: Average Sales Price to Average Wholesale Price* (June 2005) (2005 OIG Report) [Doc. #53-6]. The ASP is "substantially lower" than the AWP. Id. at 8 (in 2004, median percentage difference between ASP and AWP was 49%).

Relator alleges that CSL Behring reported inflated wholesale prices to the third-party publishers. As a result, the AWPs for Vivaglobin and Hizentra were established at $133 and $151,[3] respectively, while the pharmacies actually paid between $65 and $70. Relator alleges that the CSL Behring defendants use the "spread" between the actual cost and the AWP-based reimbursement rates to induce their customers, including Accredo and Coram, to buy their products. He further alleges that Accredo and Coram seek out patients covered by government health programs in order to take advantage of the spread. He alleges that the defendants conspired together to make, or cause to be made, false claims to the government. He claims that, as a result of the defendants' conduct, the federal government overpaid in excess of $100 million for Vivaglobin and in excess of $180 million for Hizentra.

II. Legal Standards

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reflect[] actual wholesaler margins, which were reduced to 2 to 3 percent. Therefore, the actual average wholesale price charged by wholesalers to providers [is] much lower than the 20 or 25 percent markup." Id.

[3] A drug's AWP does not change. See 2013 OIG Report at 7 n.14.

The purpose of a motion to dismiss under Rule 12(b)(6) is to test the legal sufficiency of the complaint. Fed. R. Civ. P. 12(b)(6). The factual allegations of a complaint are assumed true and construed in favor of the plaintiff, "even if it strikes a savvy judge that actual proof of those facts is improbable." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 556 (2007) (citing Swierkiewicz v. Sorema N.A., 534 U.S. 506, 508 n.1 (2002)); Neitzke v. Williams, 490 U.S. 319, 327 (1989) ("Rule 12(b)(6) does not countenance . . . dismissals based on a judge's disbelief of a complaint's factual allegations."); Scheuer v. Rhodes, 416 U.S. 232, 236 (1974) (stating that a well-pleaded complaint may proceed even if it appears "that a recovery is very remote and unlikely"). The issue is not whether the plaintiff will ultimately prevail, but whether the plaintiff is entitled to present evidence in support of his claim. Scheuer, 416 U.S. at 236. A viable complaint must include "enough facts to state a claim to relief that is plausible on its face." Twombly, 550 U.S. at 570; see id. at 563 (stating that the "no set of facts" language in Conley v. Gibson, 355 U.S. 41, 45–46 (1957), "has earned its retirement"); see also Ashcroft v. Iqbal, 556 U.S. 662, 678–84 (2009) (holding that the pleading standard set forth in Twombly applies to all civil actions). "Factual allegations must be enough to raise a right to relief above the speculative level." Twombly, 550 U.S. at 555.

Rule 9(b) provides that, "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting the fraud or mistake."

> Rule 9(b)'s particularity requirement demands a higher degree of notice than that required for other claims, and is intended to enable the defendant to respond specifically and quickly to the potentially damaging allegations. To satisfy the particularity requirement of Rule 9(b), the complaint must plead such facts as the time, place, and content of defendant's false representations, as well as the details of the defendant's fraudulent acts, including when the acts occurred, who engaged in them, and what was obtained as a result. Put another way,

> the complaint must identify the "who, what, where, when and how" of the alleged fraud.

U.S. *ex rel.* Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 556 (8th Cir. 2006) (internal citations omitted). A plaintiff must state an underlying basis for its assertions sufficient to provide an indicia of reliability. Id. at 557 (citation omitted). While a plaintiff need not allege specific details of every alleged fraud, the plaintiff must provide some representative examples of the alleged misconduct. Id.

III. Discussion

A. The Public Disclosure Bar

The FCA prohibits the knowing submission of false or fraudulent claims to the United States. 31 U.S.C. § 3729(a). The *qui tam* provisions of the FCA authorize private citizens to sue on behalf of the government and, as a bounty, to share in any recovery. U.S. *ex rel*. Newell v. City of St. Paul, Minn., 728 F.3d 791, 794 (8th Cir. 2013); see 31 U.S.C. § 3730(d) (setting forth amounts between 15 and 30% of the total recovery to be awarded to relators). "Although this financial incentive encourages would-be relators to expose fraud, it also serves to attract those looking to capitalize on fraud already exposed by others." U.S. *ex rel.* Poteet v. Bahler Med., Inc., 619 F.3d 104, 107 (1st Cir. 2010). "Seeking 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," Congress adopted the public disclosure bar "in an effort to strike a balance between encouraging private persons to root out fraud and stifling parasitic lawsuits." Graham Cty. Soil & Water Conservation Dist. v. U.S. *ex rel.* Wilson, 559 U.S. 280, 294-95 (2010) (citations omitted). The public disclosure bar prevents suits "by opportunistic late-comers who add nothing to the

exposure of the fraud." U.S. *ex rel*. Paulos v. Stryker Corp., 762 F.3d 688, 692 (8th Cir. 2014) (internal quotation and citation omitted).

A public disclosure reveals fraud if "the information is sufficient to put the government on notice of the likelihood of related fraudulent activity." U.S. *ex rel.* Poteet v. Medtronic, Inc., 552 F.3d 503, 512 (6th Cir. 2009) (citation omitted). The relator bears the burden of establishing that the public disclosure bar does not apply. U.S. *ex rel.* Ambrosecchia v. Paddock Labs., LLC, No. 4:12CV2164 RLW, 2015 WL 5605281, at *3 (E.D. Mo. Sept. 23, 2015) (citing U.S. *ex rel*. Ketroser v. Mayo Foundation, 729 F.3d 825, 828 (8th Cir. 2013)). In determining whether to dismiss a claim based on public disclosure, a court necessarily considers the alleged public documents. U.S. *ex rel.* Kraxberger v. Kansas City Power & Light Co., 756 F.3d 1075, 1083 (8th Cir. 2014).

The public disclosure bar is found at 31 U.S.C. § 3730(e)(4)(A) and states:

> The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed —
>
> > (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> >
> > (ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> >
> > (iii) from the news media,
>
> unless . . . the person bringing the action is an original source of the information.

31 U.S.C. § 3730(e)(4)(A) (emphasis added).[4]

[4] Until it was amended on March 23, 2010, the FCA's public disclosure bar eliminated jurisdiction over an action that was "based upon the public disclosure of allegations or transactions." Plaintiff applies the current version of the public-disclosure bar without

The statute defines "original source" as:

> an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the 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)(B) (emphasis added).

1. Prior Disclosures

Defendants identify a number of disclosures made in qualifying sources, a few of which are sampled here. See CSL Behring's Exs. A - T [Docs. #53-1 -#53-20]; Coram's Exs. 1 – 21; [Docs. #68-1 - #68-23]; Accredo's Ex. B [Doc. #59-2].

Multiple government sources have long disclosed that AWP does not represent the actual prices of drugs. "A 1984 OIG report . . . stated: 'AWP cannot be the best — or even an adequate — estimate of the prices providers generally are paying for drugs.'" *In re* Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d 20, 41 (D. Mass. 2007) (quoting report). In 1997, an OIG official testified before Congress that "the published wholesale prices that are currently being used . . . to determine [Medicare] reimbursement rates bear little or no resemblance to actual wholesale prices." *Health Care Waste, Fraud and Abuse: Hearing Before the S.Comm. on Health*, 105th Cong. 63 (1997) (statement of Michael F. Mangano); see also id. at 57 ("The AWP . . . is easily manipulated and greatly inflated.") [Doc. #53-3]. In 1997, the OIG "identified Medicare [payments made in 1995] that were 11 to 900 percent greater than drug prices available to the physician and supplier communities." U.S. Dept. of Health & Human Svcs., Office of Insp. Gen'l, OEI-03-

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discussion of the pre-2010 version. Thus, the Court assumes without deciding, that the current version applies. See Kraxberger, 756 F.3d 1075, 1078 n.2.

97-00290, *Excessive Medicare Payments for Prescription Drugs* at iii (Dec. 1997) (1997 OIG Report) [Doc. #68-2]; see also id. at 8 (bar graph showing reimbursement rates for 8 drugs).

Media outlets have also reported that AWPs do not reflect actual drug prices. See, e.g., Bill Alpert, *Hooked on Drugs: Why Do Insurers Pay Such Outrageous Prices for Pharmaceuticals?* Barrons, June 10, 1996 (stating AWP stands for "Ain't What's Paid") [Doc. #68-9]; Steve Bailey, *Profits vs. People*, Boston Globe, April 10, 2002, at C1 [Doc. #53-9]; Bill Brubaker, *Firms in Talks on Overbilling for Medicare, Medicaid Drugs*, Wash. Post, May 11, 2000, at E03 [Doc. #53-10]; Lisa Richwine, *Medicare Moves to Cut U.S. Drug Payments*, Reuters, June 1, 2000 [Doc. #53-11]; Alice Dembner*, Medicare Waste Raises Cost of Drugs By $1B, Congress To Hear Report on Overpayment Excess*, Boston Globe, Sept. 21, 2001 [Doc.#53-12].

Furthermore, there were multiple disclosures that manufacturers used the difference between actual costs and AWPs to influence sales. For example, during a congressional hearing in 2004, Representative Joe Barton observed that "the committee has uncovered evidence that several manufacturers either inflate their AWPs or actively market their products not based on the lowest price but on the difference between the price and the reimbursement amount, better known in the industry as the spread." *Medicaid Prescription Drug Reimbursement: Why the Government Pays Too Much: S.Comm. on Oversight & Investigations*, 108th Cong. 2 (Dec. 7, 2004) (statement of Chairperson Joe Barton) [Doc. 53-5]. Several sources also discussed the impact of this "spread" on physicians' decisions about which drugs to prescribe. See U.S. Dept. of Health & Hum. Svces., Office of Insp.

Gen'l, OEI-12-12-00310, *Part B Payments for Drugs Infused Through Durable Medical Equipment* 11 (Feb. 2013) (2013 OIG Report) [Doc. #53-1] (noting with respect to DME infusion drugs, "excessive payments could present incentives for providers to overutilize a particular product, while payments at below cost could contribute to an inability or unwillingness to provide a particular drug."); Edward Lotterman, *Insurance Firms Struggle to Avoid Moral Hazard*, St. Paul Pioneer Press, June 30, 2002, at D2 (a "doctor's professional judgment on the best drug or device is distorted by the financial incentive of which manufacturer offers the most lucrative 'spread' between the price charged . . . and the much higher 'average wholesale price'") [Doc. #53-17]; Am. Complaint ¶44, U.S. v. *ex rel.* Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, No. 95-CV-1354 (S.D. Fla.) ("grossly excessive" reimbursement rates acted as an inducement for physicians and suppliers to purchase specific drugs in order to "realize the greatest possible profit") [Doc. #68-3]; Complaint ¶5 U.S. *ex rel.* Sun v. Baxter Hemoglobin Therapeutics, et al., 05-736 (D. Colo.) (manufacturer "manipulated the AWP, knowing that health care providers . . . were . . . focused on the 'spread'") [Doc. #68-4]; see also First Am. Complaint ¶ 74 U.S. *ex rel.* Duxbury v. Ortho Biotech Products, L.P., 1:03-CV12189 (RWZ) (D. Mass.) (the "spread resulted in an illegal kickback to [healthcare] Providers funded by Medicare and Medicaid").

In 2007, a court summarized the negative effect of AWP-based reimbursements as follows:

> [T]he Medicare system created perverse incentives by pegging the nationwide reimbursement for billions of drug transactions a year to a price reported by the pharmaceutical industry without any oversight. Many pharmaceutical companies unscrupulously took advantage of that flawed AWP system by establishing secret mega-spreads between the fictitious reimbursement price they reported and the actual

> acquisition costs of doctors and pharmacies. These spreads grossly exceeded the standard industry markup. The publication of false, inflated AWPs caused real injuries to the government, insurers, and patients who were paying grossly inflated coinsurance payments for critically important, often life-sustaining, drugs.

In re Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 30-31.

As noted above, effective January 1, 2005, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) made ASP the basis for reimbursement for most prescription drugs. 2013 OIG Report at 1. However, DME infusion drugs were excluded from the new methodology and continue to be reimbursed using AWPs. Id. In February 2013, the OIG investigated how much money was paid to reimburse providers for DME infusion drugs under the AWP method. 2013 OIG Report. After comparing the ASP of all DME infusion drugs to the amounts Medicare reimbursed based on the AWP, the OIG found that, Medicare payment amounts for DME infusion drugs exceeded ASPs by 54 to 122 percent annually. Id. at 11. The OIG determined that, in 2011, Medicare would have saved $72 million using ASP-based reimbursement for DME infused drugs, leading the OIG to recommend the elimination of AWP-based pricing. Id. at 11. This recommendation was not adopted, however, and on reexamination in 2015, the OIG determined that there were $251 million in excessive expenditures on DME infusion drugs over just six quarters. 2015 OIG Report at 4, 6.

In addition to public disclosures regarding DME infusion drugs, generally, there have been public disclosures regarding the AWP and ASP for Vivaglobin and Hizentra. The third-party publications publish AWPs, while the Centers for Medicare & Medicaid Services (CMS) publishes ASPs for drugs on a quarterly basis. See, e.g., Accredo Ex. B (samples of Vivaglobin AWP figures) [Doc. #59-2]; Coram Exh. 19

(CMS report showing payment allowance limits based on ASP) [Doc. #68-21]. Based on these publicly available figures, Coram provides a table showing the significant spread between ASPs and AWPs for Vivaglobin and Hizentra for the years 2007 through 2013:

Quarter	Vivaglobin AWP	Vivaglobin ASP	Hizentra AWP	Hizentra ASP
2007Q4	$127.57	$66.75	N/A	N/A
2008Q4	$119.82	$66.06	N/A	N/A
2009Q4	$119.96	$67.85	N/A	N/A
2010Q4	$119.95	$68.42	N/A	$68.72
2011Q4	N/A	N/A	$151.07	$68.74
2012Q4	N/A	N/A	$150.66	$68.74
2013Q4	N/A	N/A	$150.96	$72.44

Coram Memorandum at 12 [Doc. # 59]. Relator does not dispute the accuracy of these figures.

2. Plaintiff's Claims

Relator argues that this action is not barred by § 3730(e)(4)(A) because none of the public disclosures contains all of the elements of the alleged fraudulent transactions. See Chart at Appendix A (indicating alleged omissions for each source) [Doc. #80 at 45-49]. The public disclosure bar applies to *qui tam* actions that are based on allegations that are "substantially the same" as publicly disclosed allegations. 31 U.S.C. § 3730(e)(4)(A). However, the prior public disclosures "need not contain every fact or legal consequence to trigger the public disclosure bar." U.S. *ex rel.* Winkelman v. CVS Caremark Corp., No. CV 11-11398-DJC, 2015 WL 4577341, at *8 (D. Mass. July 29, 2015) (citing Poteet, 619 F.3d at 115). "The fact that the information comes from different disclosures is irrelevant. All that is

required is that public disclosures put the government on notice to the possibility of fraud." Dingle v. Bioport Corp., 388 F.3d 209, 214 (6th Cir. 2004).

Relator also asserts that the disclosures do not specifically identify the defendants and drugs at issue here. This degree of specificity is not required, however, because the bar applies when the public disclosures are sufficient to alert the government to the likelihood of fraud by a particular actor. See U.S. *ex rel.* Fine v. Sandia Corp., 70 F.3d 568, 571 (10th Cir. 1995) (claims that Department of Energy laboratory misappropriated nuclear waste funds were barred by public disclosures that other labs engaged in same practices because "they sufficiently alerted the government to the likelihood that Sandia would also 'tax' nuclear waste funds in the future."); U.S. *ex rel*. Gear v. Emergency Med. Associates of Illinois, Inc., 436 F.3d 726, 729 (7th Cir. 2006) (where there are disclosures of industry-wide abuses, "[w]e are unpersuaded by an argument that . . . the specific defendants named in the lawsuit must have been identified in the public records). In 2007, the court overseeing the multidistrict litigation found that pharmaceutical companies submitted "false, inflated AWPs" that "caused real injuries." *In re* Pharm. Indus. Average Wholesale Price Litig., 491 F. Supp. 2d at 31. In 2013, the OIG disclosed the extreme spread between AWP and ASPs for DME infusion drugs, generally, while publications by the third-party publishers and CMS showed the spread for Viaglobin and Hizentra in particular.[5] These disclosures are sufficient to identify both the defendants and the drugs.

[5] Relator argues at some length that disclosures addressing industry-wide practices are not sufficient to bar his claims. This argument is immaterial, however, in light of the specific disclosures regarding the spread between ASP and AWP for Vivaglobin and Hizentra.

Relator attempts to avoid the import of the drug-specific disclosures by asserting that his allegations of fraud are not based on what he calls the "simple, irrelevant disparity between the ASPs and the reported AWPs" for the drugs. Memo. in Opposition at 20 [Doc. #80]. Rather, he asserts, his allegations of fraud are based on the difference between what he calls the "actual AWPs" and the "reported AWPs." Id. Relator does not explain what he means by "actual AWP." In any event, the term "actual AWP" is meaningless in the absence of any statutory or regulatory definitions. Furthermore, it is apparent from the complaint that the target of relator's allegations is the difference between the AWPs and what he calls the drugs' "true selling prices." Complaint ¶¶ 80, 83 ("true selling price" for Vivaglobin and Hizentra was $65 to $70); ¶¶ 81, 84 (the spread between "the reported AWP and the true selling price . . . ranged from approximately 190% to 204%" for Vivaglobin and "from approximately 215% and 232% for Hizenta). Relator's "true selling prices" of $65 to $70 are the same as the ASPs for the drugs. See Chart, *supra*. This is not a coincidence, because the ASP is intended to be a proxy for providers' acquisition costs.[6] 2013 OIG Report at 2. Thus, despite his attempts to recast his argument, relator's fraud claims are based on the difference between the ASP, or an equivalent price proxy, and the AWPs for the drugs.

All the essential elements of relator's claims were publicly disclosed before he filed suit: DME infusion drugs are reimbursed based on AWPs; AWPS are not based on actual sales data but are based on figures supplied by manufacturers to the

[6] The statute defines "average sales price" as "the manufacturer's sales to all purchasers" divided by "the total number of such units of such drug or biological sold by the manufacturer." 42 U.S.C. § 1395w-3a(c)(1). The average sales price "shall include volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates." Id. § 1395w-3a(c)(3).

third-party publishers; using AWP-based reimbursement results in inflated payments to providers; manufacturers and providers profit from the spread between AWP-based reimbursement rates and actual costs; providers seek out patients covered by federal programs in order to maximize their reimbursements; and the AWPs for Vivaglobin and Hizentra are approximately twice the ASPs for the drugs. This state of affairs has been labeled as a scam and fraud by the press and in multiple civil lawsuits. "[T]o raise the bar, the public disclosures must reveal both the true state of facts and that the defendant represented the facts to be something other than what they were." Newell, 728 F.3d at 796 (internal quotation and citation omitted). The public disclosure requirements of § 3730(e)(4)(A) have been satisfied. Thus, relator's claims succeed only if he is an "original source" under § 3730(e)(4)(B). Paulos, 762 F.3d at 693-94 (citation omitted).

B. Original Source

Relator qualifies as an original source if, (1) before the public disclosures, he "voluntarily disclosed to the Government the information on which" his claims' "allegations or transactions . . . are based," or (2) he "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and . . . has voluntarily provided the information to the Government before filing [this] action." Paulos, 762 F.3d at 694 (quoting 31 U.S.C. § 3730(e)(4)(B)).

Relator does not claim that he volunteered his information to the government before the public disclosures, but instead he relies on the second definition of "original source." Thus, he must show that (1) "before filing" suit, he "voluntarily

provided" to the government information that (2) "materially adds" to the publicly disclosed information. Relator cannot establish these elements.

In his declaration, relator states that he submitted a "written disclosure of the claims and substantially all material evidence and information" to the government "when [he] filed the instant action." [Doc. #80-5]. As he acknowledges, however, this disclosure was made in compliance with § 3730(b)(2), which requires relators to serve a "written disclosure of substantially all material evidence and information the person possesses" with a copy of the complaint to the government. Opposition at 25. The intention of the pre-filing disclosure requirement of § 3730(e)(4)(B) is to encourage "private individuals to come forward with their information of fraud 'at the earliest possible time and . . . discourage persons with relevant information from remaining silent.'" U.S. *ex rel.* King v. Hillcrest Health Ctr., Inc., 264 F.3d 1271, 1280-81 (10th Cir. 2001) (alteration in original; citation omitted) U.S. *ex rel.* Barth v. Ridgedale Elec., Inc., 44 F.3d 699, 704 (8th Cir. 1995) (stating that "clear intent" of § 3730(e)(4)(B) disclosure requirement is to "encourage private individuals who are aware of fraud against the government to bring such information forward at the earliest possible time and to discourage persons with relevant information from remaining silent").

Most courts addressing whether the mandatory disclosures of § 3730(b)(2) also satisfy the pre-filing disclosure requirement of § 3730(e)(4) have concluded that they do not. King, 264 F.3d at 1281; United States v. Bank of Farmington, 166 F.3d 853, 866 (7th Cir. 1999) overruled on other grounds by Glaser v. Wound Care Consultants, Inc., 570 F.3d 907 (7th Cir. 2009) (disclosure in compliance with § 3730(b)(2) does not satisfy § 3730(e)(4)); U.S. *ex rel.* Branch Consultants, L.L.C.

v. Allstate Ins. Co., 782 F. Supp. 2d 248, 268-69 (E.D. La. 2011) (pre-filing disclosure requirement is "distinct from" the requirements of § 3730(b)(2)); see also U.S. *ex rel.* Beauchamp v. Academi Training Ctr., Inc., 933 F. Supp. 2d 825, 846 (E.D. Va. 2013) (concluding that disclosures made to government two weeks before filing complaint were made to satisfy § 3730(b)(2) and thus were not voluntary).

Relator cites a case in which the Fifth Circuit wrote, in dicta, that the disclosure requirement of § 3730(e)(4) "is satisfied when, as directed by § 3730(b)(2), a relator serves the Government with a copy of the [*qui tam*] complaint and written disclosure of substantially all material evidence and information the person possesses." U.S. *ex rel.* Babalola v. Sharma, 746 F.3d 157, 163 (5th Cir. 2014) (alteration in original, citation omitted). Applying this interpretation here — where relator served his mandatory § 3730(b)(2) disclosures on the government when he filed his complaint — would vitiate the two requirements of § 3730(e)(4)(B)(2) that he make an original-source disclosure "voluntarily" and do so "before filing" suit. See Beauchamp, 933 F. Supp. 2d at 846 ("Courts that have addressed whether these mandatory disclosures under § 3730(b)(2) also qualify as voluntary disclosures under § 3730(e)(4) have held that they do not, as these are mandatory disclosures rather than voluntary disclosures.") (citations omitted).

Issues of timing aside, the allegations in this action do not "materially add[] to the publicly disclosed allegations or transactions." § 3730(e)(4)(B)(2). Relator claims to have firsthand knowledge relevant to pricing practices but "even 'independent' knowledge of allegedly fraudulent activity does not 'materially add' to publicly disclosed allegations unless it is 'qualitatively different' from information

already discovered and not 'merely the product and outgrowth of publicly disclosed information.'" U.S. *ex rel.* Hoggett v. Univ. of Phoenix, No. 2:10-CV-02478-MCE-KJ, 2014 WL 3689764, at *9 (E.D. Cal. July 24, 2014) (citation omitted). Relator claims that he knows the "actual sales prices" for Vivaglobin and Hizentra. Opposition at 26-27. However, these "actual sales prices" were readily available in publicly disclosed information. Relator's information does not materially add to the vast amounts of information available in public disclosures.

Relator's claims are barred by the public disclosure doctrine and he fails to satisfy the "original source" exception. The Court will dismiss relator's FCA claims pursuant to 31 U.S.C. § 3730(e)(4)(A), and his conspiracy claim pursuant to Rule 12(b)(6). The Court declines to address defendants' remaining arguments in any detail. The Court notes, however, that in order to satisfy Rule 9(b)'s particularity requirement, plaintiff "must provide some representative examples of [defendants'] alleged fraudulent conduct, specifying the time, place, and content of their acts and the identity of the actors." See U.S. *ex rel.* Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 557 (8th Cir. 2006). Plaintiff's "complaint is void of a single, specific instance of fraud, much less any representative examples," id., and thus he fails to satisfy Rule 9(b). Plaintiff's request that he be provided an opportunity to amend his complaint will be denied. Id. at 560 ("[A]llowing a *qui tam* relator to amend his or her complaint after conducting further discovery . . . is inconsistent with the relator's procedural obligations under the FCA and with the FCA's protections for the government, the real party in interest in a qui tam action.")

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For the foregoing reasons,

IT IS HEREBY ORDERED that defendants' motions to dismiss [Docs. #52, #56, #58, and #67] are **granted**.

IT IS FURTHER ORDERED that defendants' motions for hearing [Docs. #60 and #69] are **denied as moot**.

CAROL E. JACKSON
UNITED STATES DISTRICT JUDGE

Dated this 20th day of January, 2016.