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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ALASKA

UNITED STATES OF AMERICA Ex rel. Law Project for Psychiatric Rights, an Alaskan non-profit corp., Plaintiff, vs. OSAMU H. MATSUTANI, MD., et al., Defendants.	Case No. 3:09-cv-0080-TMB
UNITED STATES OF AMERICA, Ex rel. Daniel I. Griffin Plaintiff, vs. RONALD A. MARTINO, MD., FAMILY CENTERED SERVICES OF ALASKA, INC., an Alaska corporation, and SAFEWAY, INC., a Delaware corporation, Defendants.	Case No. 3:09-CV-246-RRB (CONSOLIDATED) **DEFENDANT SAFEWAY, INC.'S MEMORANDUM IN SUPPORT OF MOTION TO DISMISS RELATOR GRIFFIN'S COMPLAINT PURSUANT TO FEDERAL RULES OF CIVIL PROCEDURE 9(B), 12(B)(1) AND 12(B)(6) AND 31 U.S.C. § 3730(b)(5)**

I. INTRODUCTION

Defendant Safeway, Inc. ("Safeway") moves to dismiss Daniel Griffin's ("Relator's") complaint with prejudice on the following grounds: (1) pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction; (2) pursuant to 31 U.S.C. § 3730(b)(5) because Relator's complaint is barred under the first-to-file rule; (3) pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted; and (4) pursuant to Federal Rule of Civil Procedure 9(b) for failure to allege fraud with the requisite particularity. Relator filed this *qui tam* lawsuit accusing Safeway of defrauding the United States government by knowingly submitting claims to "Medicaid" for the cost of psychotropic drugs prescribed to minors, including Relator, for uses not approved by the Food & Drug Administration ("FDA"), allegedly in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729(a)(1) & (2).

Relator's complaint should be dismissed under Rule 12(b)(1) because the FCA's public disclosure bar deprives this Court of subject matter jurisdiction over this lawsuit. Relator's claim against Safeway is based upon information that was previously disclosed to the public, including a prior complaint filed by Relator's own attorney in Alaska state court. Moreover, Relator is not an "original source" of the information under the Ninth Circuit's well-settled interpretation of that term. Therefore, pursuant to Rule 12(b)(1), the court should dismiss this case with prejudice.

Relator's complaint should also be dismissed under 31 U.S.C. § 3730(b)(5). That statute establishes a first-to-file bar, preventing successive plaintiffs, like Relator, from bringing related actions based on the same underlying facts as a previously filed lawsuit.

More fundamentally, the court should dismiss Relator's claim with prejudice under Rule 12(b)(6) for his failure to state a claim upon which relief can be granted; his FCA claim relies on an erroneous interpretation of the Social Security Act that cannot be sustained as a matter of law.

Finally, Relator's complaint should be dismissed with prejudice pursuant to Rule 9(b). Although Relator accuses Safeway of defrauding Medicaid by knowingly submitting false claims for reimbursement, he fails to identify facts supporting his claim that Safeway has presented to the United States government for reimbursement with the requisite particularity under Rule 9(b).

Because Relator's complaint fails to contain particularized allegations of fraud, the complaint should be dismissed.

II. BACKGROUND AND RELEVANT FACTS

On December 14, 2009, Relator filed the instant *qui tam* lawsuit, naming as Defendants Dr. Ronald Martino, Family Centered Services of Alaska, Inc. ("FCSA"), and Safeway. The Relator complained that Safeway, in its pharmacy operations, sought payment from "Medicaid" for prescription drugs dispensed to Medicaid beneficiaries for drugs not prescribed for a medically-accepted indication, as defined by the FDA, or supported by one of three compendia (that is, prescribed for an "off-label" use). According to Relator, federal law prohibits the federal government from paying for these "off-label" uses.[1] Thus, according to Relator, merely submitting these Medicaid claims, without more, constitutes a violation of the False Claims Act, 31 U.S.C. § 3729(a)(1) & (2).[2]

On July 12, 2010, this Court issued an order consolidating Relator's instant action with the federal action commenced by the Law Project for Psychiatric Rights ("PsychRights") in April 2009.[3] PsychRights filed an amended complaint on May 6, 2010.[4] In that case—just like the instant case—PsychRights claimed that Safeway, along with 31 other defendants comprising much of the Alaska mental healthcare community—violated the False Claims Act by submitting or causing to be submitted to Medicaid claims for drugs prescribed for an off-label use.[5] In

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1 See Compl., ¶¶ 14-18. (Docket #1, Case No. 3:09-CV-00246-RRB)

2 Id., ¶¶ 22-28.

3 See United States of America ex rel. Law Project for Psychiatric Rights v. Matsutani, et al., No. 3:09-CV-0080-TMB (D. Alaska). Pursuant to the Amended Clerk's Notice, dated July 14, 2010 (Docket # 25, Case No. 3:09-cv-246-RRB) all further filings in both consolidated cases are to proceed under Case No. 3:09-cv-00080-TMB.

4 See Am. Compl. (Docket #106, Case No. 3:09-cv-00080-TMB)

5 Id.

particular, PsychRights asserted that Safeway "ha[s] submitted millions of false Medicaid claims for reimbursement of pediatric psychotropic medications[.]"[6] All of the defendants in the PsychRights case, including Safeway, have filed joint motions to dismiss the PsychRights' complaint based on Rules 9(b), 12(b)(1), and 12(b)(6).[7] [8]

III. ARGUMENT

A. Relator's Complaint Should Be Dismissed Pursuant to Rule 12(b)(1).

Relator's complaint should be dismissed under Rule 12(b)(1) because the FCA's public disclosure bar deprives this Court of subject matter jurisdiction where, as here, the lawsuit is based on "allegations or transactions" that have been "publicly disclosed," and the relator is not "an original source of the information."[9] The "threshold question in a False Claims Act case is whether the statute bars jurisdiction."[10] This is a two-tiered inquiry: (1) the court must first determine whether there has been a public disclosure; and (2) if there has been a public

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6 Id., ¶ 205.

7 See United States of America ex rel. Law Project for Psychiatric Rights v. Matsutani, et al., No. 3:09-CV-0080-TMB (D. Alaska) (Docket #s 84, 91, 93).

8 Prior to filing the federal case, PsychRights had filed a complaint in Alaska superior court against the State of Alaska seeking declaratory and injunctive relief to prevent the administration of psychotropic drugs to Alaskan children. See Am. Compl. in Law Project for Psychiatric Rights v. State of Alaska, et al., No. 3AN 08-10115 CI (Sept. 29, 2008), Ex. 5 to Defs.' Mot. to Dismiss for Lack of Subj. Matter Jsd., Case No 3:09-cv-00080-TMB, ¶ 1. In an amendment to its initial complaint, PsychRights made precisely the same allegation that Relator makes in this case; namely, that it is unlawful for "[t]he State [to] approve[] and appl[y] for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth" unless those medications were prescribed for indications approved by the FDA, or included one of three compendia. See Mot. for Leave to Amend. ¶ 236 of Complaint (Apr. 3, 2009); see also Am. Compl., ¶ 22. PsychRights' state court case was dismissed by the Superior Court because PsychRights lacked standing to assert the cause of action. See Order Granting State of Alaska's Mot. for Judg. on the Pleadings (May 27, 2009). PsychRights appealed the dismissal, and the appeal is currently fully briefed and pending before the Alaska Supreme Court. See Law Project for Psychiatric Rights v. State of Alaska, et al., No. S-13558 (Alaska).

9 31 U.S.C. § 3730(e)(4)(A).

10 U.S. ex. rel. Duxbury v. Ortho Biotech Prods., L.P., 579 F.3d 13, 20 (1st Cir. 2009).

disclosure, the court must determine whether the relator is an "original source" of each public disclosure within the meaning of Section 3730(e)(4)(B).[11] The relator bears the burden of establishing subject matter jurisdiction.[12]

1. The Complaint's Allegations Were Publicly Disclosed.

As noted above, the allegations contained in Relator's complaint regarding Safeway's alleged submission of false or fraudulent claims to Medicaid is virtually indistinguishable from the allegations made by PsychRights in the consolidated case. As a result, the public disclosure arguments set forth in "All Defendants' Motion to Dismiss under Rules 12(b)(1) and 12(h)(3) for Lack of Subject Matter Jurisdiction Under the False Claims Act's Public Disclosure Bar, 31 U.S.C. § 3730(e)(4)(A)"[13] in the PsychRights' case are equally applicable to this case. Safeway hereby adopts those arguments in support of this Motion. In short, the allegations in Relator's complaint are based on public disclosures made prior to the time Relator filed his complaint in this case.

2. Relator Is Not an "Original Source" of the Publicly Disclosed Allegations.

Because the allegations in the complaint were publicly disclosed, this Court has no jurisdiction over this case unless Relator can demonstrate that he was an "original source" of the public disclosures.[14] To qualify as an "original source," "a relator must . . . [have] 'direct and independent knowledge of the information on which the allegations are based,' 'voluntarily

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11 See Meyer, 565 F.3d at 1199.

12 Id.

13 See Mem. in Supp. of Mot. to Dismiss under Rules 12(b)(1) and 12(h)(3) for Lack of Subject Matter Jurisdiction at 5-15 (Docket #91, Case No. 3:09-cv-00080-TMB); Reply in Support of Motion to Dismiss Under Rules 12(b)(1) and 12(h)(3) for Lack of Subject Matter Jurisdiction (Docket #111, Case No. 3:09-cv-00080-TMB).

14 See 31 U.S.C. § 3730(e)(4).

provided the information to the government . . . ,' and 'had a hand in the public disclosure of allegations that are a part of . . . the suit." [15]

Here, Realtor cannot show that he is an "original source" of the information contained in the complaint because he lacks the requisite "hand in the public disclosure of the allegations that are part of [his] suit." Relator fails to allege any facts that demonstrate that he had a hand in the initial public disclosures of the allegations upon which his complaint is based, nor could he allege such a claim. Merely specifying of a handful of his own prescriptions in support of his claim does not give Relator "original source" status when those prescriptions are a mere subset of the thousands of prescriptions described in the numerous public disclosures predating Relator's complaint.[16] Therefore, Relator has failed to plead facts essential to establish subject matter jurisdiction under the FCA.

As a result, the FCA's public-disclosure bar deprives this Court of subject matter jurisdiction in this case. The Court should dismiss the case with prejudice under Rule 12(b)(1).

B. The First-to-File Bar Requires Dismissal of Relator's Complaint.

Section 3730(b)(5) of the FCA provides that: "When a person brings an action under this subsection, no person *other than the Government* may intervene or bring a related action based on the facts underlying the pending action."[17] The Ninth Circuit has interpreted this Section to mean that "subsequent complaints filed after a complaint that fulfills the jurisdictional prerequisites of § 3730(e)(4)" are barred by the first-to-file rule.[18] Thus, the first-to-file rule "precludes a subsequent relator's claim that alleges the defendant engaged in the same type of

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15 Lujan v. Hughes Aircraft Co., 162 F.3d 1027, 1033 (9th Cir. 1998) (internal quotation marks omitted and emphasis added).

16 See Mem. in Supp. of Mot. to Dismiss under Rules 12(b)(1) and 12(h)(3) at 5-15 (Case No. 3:09-cv-00080-TMB) (Docket #91) at 5-15 (identifying public disclosures).

17 31 U.S.C. § 3730(b)(5) (emphasis added).

18 Campbell v. Redding Med. Ctr., 421 F.3d 817, 825 (9th Cir. 2005).

wrongdoing as that claimed in a prior action even if the allegations cover a different time period or location within the company."[19]

Here, Relator's complaint is barred by the prior federal case filed by PsychRights. That case indisputably qualifies as a "related action" because PsychRights alleged the "same type of wrongdoing" on the part of Safeway as Relator alleges here; namely, that Safeway in the District of Alaska submitted false claims to Medicaid for reimbursement of psychotropic drugs prescribed to minors for off-label uses, and that Medicaid authorized payment of those claims.

Moreover, the action was "pending" within the meaning of Section 3730(b)(5). PsychRights' federal case was filed prior to the filing of Relator's case. Although the first-to-file rule would not bar Relator's complaint if the Court concludes that PsychRights' federal complaint is jurisdictionally barred[20] (as the defendants in that case have argued), the rule would bar Relator's case should the Court dismiss PsychRights' case on the merits.[21] [22]

C. Relator's Complaint Should Be Dismissed Under Rule 12(b)(6).

Relator's complaint should be dismissed under Rule 12(b)(6) for failure to state a claim upon which relief may be granted because his entire case relies on an erroneous interpretation of

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19 United States ex rel. Lujan, 243 F.3d at 1188; see also United States v. Apollo Group, Inc., 2009 WL 3756623, *3 (S.D. Cal. Nov. 6, 2009) (a "related action" "need not assert facts identical to those in the prior complaint. . . . Rather, the current action need only 'allege the same material elements of fraud described in an earlier suit.").

20 See Campbell, 421 F.3d at 822-25; United States v. Poteet, 552 F.3d 503, 516 (6th Cir. 2009) ("One important caveat to this first-to-file rule, however, is that in order to preclude later-filed *qui tam* actions, the allegedly first-filed *qui tam* complaint must not itself be jurisdictionally or otherwise barred.")

21 Lujan, 243 F.3d at 1188-89 (holding first-to-file bar precluded filing of subsequent suit where earlier complaint dismissed on the merits); Poteet, 552 F.3d at 516-17 ("[I]f the first-filed *qui tam* action has been dismissed on the merits or on some other grounds not relating to its viability as a federal action, it can still preclude a later-filed, but possibly more meritorious, *qui tam* complaint under the first-to-file rule.").

22 Counsel for Relator is faced with the dilemma of arguing that PsychRights' complaint is not jurisdictionally barred in order to defeat the motions to dismiss filed in PsychRights' case, which, if successful, will necessarily mean dismissal of Relator's complaint by operation of the first-to-file rule.

the Medicaid provisions of the Social Security Act.[23] Relator's FCA claim—just like PsychRights' FCA claim—is based on the legal assertion that federal reimbursement for prescription drugs under Medicaid is "limited to 'medically accepted indications,'" approved by the FDA or supported by one of three compendia.[24] Relying on this erroneous interpretation, Relator posits a "per se" theory of FCA liability; he claims that simply seeking reimbursement for off-label, non-compendia prescriptions, without other actions or intentions, is a violation of the FCA. [25] But this "per se" theory of liability, in addition to its other flaws as pointed out in the motion practice in these consolidated cases, must fail most fundamentally because it is based on an incorrect reading of the Social Security Act.

The analysis demonstrating Relator is simply wrong in his statutory interpretation is set out in the pleadings supporting "All Defendants' Motion to Dismiss Under Rule 12(b)(6)" in the

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[23] Social Security Act Amendments of 1965, Pub. L. No. 89-97, § 121, 79 Stat. 343-353 (July 30, 1965).

[24] Compl., ¶ 15 (citing 42 U.S.C. 1396R-8(k)(3); 42 U.S.C. 1396R-8(k)(6); 42 U.S.C. 1396R-8(g)(1)(B)(i)).

[25] "Off-label" prescribing is entirely lawful, extremely common, and for many conditions and populations – including children – essential for effective medical care. See e.g., Weaver v. Reagen, 886 F.2d 194, 199 (8th Cir. 1989); David C. Radley, et al., Off-label prescribing among office-based physicians, 166 Arch. Intern. Med 1021 (2006) (21% of drugs prescribed by office-based physicians are for off-label uses). Off-label prescriptions are especially common in pediatric practice, in part because, as PsychRights correctly notes, FDA "on-label" approval requires successful clinical trials supporting the use, and the pediatric patients are usually the last to be included in clinical trials. Compl. ¶¶ 46-49; see also Oklahoma Chapter of the American Acad. of Pediatrics (OKAAP) v. Fogarty, 366 F.Supp.2d 1050, 1093 (N.D. Okla. 2005); American Academy of Pediatrics Committee on Drugs, Uses of Drugs Not Described in the Package Insert (Off-Label Uses), 110 Pediatrics No. 1 (July 2002), available on-line at http://www.pediatrics.org/cgi.cntent/full/110/1/181; reaffirmed October 2005, *AAP Publications Reaffirmed, October 2005*, Pediatrics 2006; 117; 577, available on-line at http://www.pediatrics.org/cgi/content/full/117/2/577; Final Report on the Activities of the House Comm. on Government and Oversight, 104th Cong. 2d Sess., 104 H. Rep. 874 (Section 2), (January 2, 1997) at 114 (General Accounting Office estimating that approximately *80 percent* of drugs prescribed for pediatric use are off-label). Given the lengthy and costly process of modifying the FDA labeling of a medication, off-label prescribing is often the only way to ensure that patients receive the medication they need, when they need it. Any State plan that failed to cover off-label prescriptions would be woefully inadequate to meet the health needs of many, if not most, Medicaid patients, especially children.

PsychRights' case,[26] Those pleadings are hereby adopted for purposes of this Motion and summarized in the following paragraphs.

Basically, Relator's theory of liability ignores the structure of the Medicaid program, overlooks critical provisions of the Social Security Act, and takes certain rebate provisions of that statute out of context.

The Medicaid program is a joint federal-state public insurance program created by Congress in 1965 to finance the health needs of children from low-income families, single parents with dependent children, and the aged, blind or disabled.[27] The Medicaid program is administered by each State through a single state Medicaid agency, and the federal government participates by providing federal matching grants if certain statutory criteria are satisfied.[28] In order to qualify for federal financial participation, the state must obtain federal approval of its State Medicaid Plan through the Federal Centers for Medicare and Medicaid Services ("CMS"),[29] which Alaska has done.

Rules applicable to claim coverage and reimbursement methodologies for any given state's Medicaid program are promulgated by the States, consistent with federal guidelines. 42 U.S.C. § 1396a(a)(30); 42 C.F.R. § 42, Part 447. Those rules are incorporated at least by reference in its State Medicaid Plan. Federal financial participation in the State's Medicaid program is a match of state expenditures for covered services provided to Medicaid recipients. See 42 U.S.C. § 1396b(a). Nowhere does federal Medicaid law forbid the State of Alaska, or any state, from covering claims for which it does not or will not get federal financial participation.

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26 See Mem. of Law in Support of Mot. to Dismiss Under Rule 12(b)(6) (Case No. 3:09-cv-00080-TMB) (Docket #93), Reply in Support of Motion to Dismiss Under Rule 12(b)(6) (Docket #120).

27 See Social Security Act Amendments of 1965, Pub. L. No. 89-97, §121, 79 Stat. 343-353 (July 30, 1965).

28 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10.

29 See generally, 42 U.S.C. § 1396a.

The drug rebate law was enacted as an enhancement of the Social Security Act in 1990 to "establish a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser."[30] To that end, the Act prohibits Medicaid federal financial participation for "covered outpatient drugs" unless the manufacturer has entered into an agreement to rebate a percentage of the drug's purchase price back to the government (a "rebate agreement").[31] Once a drug manufacturer has entered into a rebate agreement for a drug, however, a *quid pro quo* applies: States that offer a prescription drug Medicaid benefit are generally *required* to cover that drug under their plans.[32]

Finally, and most relevant here, a state "may" – and by implication is not *required to* – exclude or otherwise restrict coverage of a covered outpatient drug for off-label uses not supported by the compendia.[33]

The Medicaid rebate law, then, includes extensive provisions designed to ensure that rebated drugs are generally covered by State Medicaid programs, while allowing the state programs to exclude or restrict coverage only in limited circumstances, including when an off-label use is not supported by the compendia. Contrary to Relator's principal contention, the Act contains no provision saying that States may only provide reimbursements for "covered outpatient drugs." As used in the rebate law, "covered outpatient drug" establishes a floor or minimum on the drugs that States generally must cover, not a ceiling or maximum on the drugs they may cover. Although other sections of the Medicaid law do establish some coverage

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30 H.R. Rep. No. 881, 101st Cong., 2d Sess. 96 (1990).

31 42 U.S.C. §§ 1396b(i)(10(A), 1396r-8(a)(1).

32 See 42 U.S.C. §§ 1396a-(a)(10), 1396d-(a)(12), 1396r-8(d)(4) ("include[] the covered outpatient drugs of any manufacturer which has entered into and complies with [a rebate agreement]").

33 42 U.S.C. § 1396r-8(d)(1)(B)(i). The use of the permissive term "may," as opposed to the mandatory terms "must" or "shall" makes clear that States have the option, but not the obligation, to prohibit coverage of non-compendia off-label uses. See Fernandez v. Brock, 840 F.2d 622, 632 (9th Cir. 1988) ("'May' is a permissive word, and we will construe it to vest discretionary power absent a clear indication from the context that Congress used the word in a mandatory sense.").

ceilings, none limits coverage only to "covered outpatient drugs" as defined by the rebate statute.[34]

Relator's argument stands the purpose of the rebate provisions on their head: instead of expanding coverage for the disadvantaged as intended, Relator would contract it dramatically by making off-label prescriptions, an important part of medical treatment, unavailable to Alaska's most vulnerable citizens.

Even more fundamentally, Relator has failed to state a plausible cause of action for the simple reason that Alaska law and Alaska's Medicaid Plan, which was approved by CMS, unambiguously allow providers to submit Medicaid claims to the State for off-label non-compendium uses. Ultimately, whether the state and CMS have correctly intepreted federal law does not matter, because there can be no FCA liability for submitting a Medicaid claim that state law *does* allow.[35] Accordingly, no false claims have been made, Relator has failed to allege a violation of the FCA, and the Court should dismiss the case with prejudice under Rule 12(b)(6).[36]

D. Relator's Complaint Should Be Dismissed Under Rule 9(b).

Finally, Relator's complaint should be dismissed with prejudice pursuant to Rule 9(b) because Relator failed to plead fraud with particularity. Relator alleges that Safeway "presented false claims to Medicaid for reimbursement of the psychotropic drugs prescribed to Relator that

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[34] 42 U.S.C. § 1396d(a) lists the services that States either may or must include in their Medicaid plans. These include "prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select." Id. § 1396d(a)(12). Notably, this section does not include the term "covered outpatient drug" or reference the rebate statute.

[35] United States ex rel Quinn v. Omnicare, 382 F.3d 432, 441 (3d Cir. 2004). PsychRights does not challenge Defendants' description of the Alaska laws.

[36] While, for purposes of a Rule 12(b)(6) motion, a court will accept as true the *facts* plead in the complaint, the court need not, and indeed should not, accept as true statements of *law*. See Western Min. Council v. Watt, 643 F.2d 618, 624 (9th Cir. 1981) (noting that, even for the purposes of 12(b)(6), the court was not required to "assume the truth of legal conclusions merely because they are cast in the form of factual allegations"). Relator's interpretation of the Act is incorrect as a matter of law, and cannot be used to escape dismissal under Rule 12(b)(6).

were not for a medically accepted indication," in violation of the False Claims Act, and lists a number of prescriptions by type of drug, date and dollar amount that Safeway allegedly filled for Relator's use.[37] Despite these allegations, Relator fails to identify any particularized allegations of fraud as required by Rule 9(b), and his complaint should be dismissed with prejudice under that Rule.

Indeed, Relator's claim is based entirely on the mistaken assumption that submitting a claim to Medicaid for a drug prescribed for an off-label use establishes some sort of "per se" FCA liability. There is, however, no such thing as a "per se false claim" and Relator's identification of claims for drugs that were allegedly not covered by Medicaid is insufficient to state an FCA violation. Stated differently, a claim that is allegedly not payable under the Medicaid scheme does not make the submission of that claim "false;" more is needed to establish a false claim, and Relator fails to allege anything more.

1. Rule 9(b)'s Heightened Pleading Standard Applies to Relator's Complaint.

The False Claims Act is an anti-fraud statute; complaints brought under the Act are subject to Rule 9(b)'s the heightened pleading requirements, which require that "in all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."[38] To comply with Rule 9(b), allegations of fraud must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong."[39] Courts have construed this language to require allegations of fraud to "specify such facts as the times, dates, places, benefits received, and other details of the alleged fraudulent activity";

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37 Compl., ¶¶ 19-21.

38 Fed. R. Civ. P. 9(b); Bly-Magee v. California, 236 F.3d 1014, 1018 (9th Cir. 2001); United States ex rel. Lee v. Smithkline Beecham, Inc., 245 F.3d 1048, 1051 (9th Cir. 2001).

39 Bly-Magee, 236 F.3d at 1019 (citing Neubronner v. Milken, 6 F.3d 666, 672 (9th Cir. 1993)).

namely, the who, what, when, where and how of the alleged fraud.[40] Stated differently, broad or conclusory allegations of fraud, absent particularized supporting detail, are insufficient to withstand challenge under Rule 9(b).[41]

2. Relator Has Not Identified Sufficient Particularized Facts or Details Supporting Its FCA Claim Against Safeway.

Relator has failed to identify sufficient particularized facts to withstand a motion to dismiss under Rule 9(b). In order to satisfy Rule 9(b), "a party alleging fraud must 'set forth *more* than neutral facts necessary to identify the transaction.'"[42] As the Eleventh Circuit has noted, mere claims of information do not provide the particulars of fraud: "Standing alone, raw bills—even with numbers, dates, and amounts—are not fraud without an underlying scheme to submit bills for unperformed or unnecessary work. It is the scheme in which particular circumstances constituting fraud may be found that make it highly likely the fraud was consummated through the presentment of false bills."[43]

In this case, Relator fails to allege anything more than "neutral facts necessary to identify the transaction," and thus fails to allege sufficient particularized facts or details supporting the allegation that Safeway has submitted false or fraudulent claims to the federal government. Tellingly, Relator alleges only that Safeway submitted claims to "Medicaid." But as Relator is aware, Medicaid providers do not submit claims to the federal government at all; rather, they

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40 See Neubronner, 6 F.3d at 672; see also Vess v. Ciba-Geigy Corp. U.S.A., 317 F.3d 1097, 1006 (9th Cir. 2003) ("Averments of fraud must be accompanied by the who, what, when, where, and how of the misconduct charged.") (quotations omitted); United States ex rel. Thompson v. Columbia/HCA Healthcare Corp., 125 F.3d 899, 903 (5th Cir. 1997) ("Rule 9(b) requires that a plaintiff set forth the who, what, when, where and how of the alleged fraud.").

41 See Moore v. Kayport Package Express, Inc., 885 F.2d 531, 540 (9th Cir. 1989) ("[M]ere conclusory allegations of fraud are insufficient."); see also Bly-Magee, 236 F.3d at 1018-19 (upholding dismissal of complaint because plaintiff's "broad allegations [of fraud] included no particularized supporting detail."); Lee, 245 F.3d at 1051-52 (upholding dismissal of complaint that included broad claims of fraud without factual supporting details).

42 Kearns v. Ford Motor Co., 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting In re GlenFed Sec. Litig., 42 F.3d 1541, 1548 (9th Cir. 1994)) (emphasis in original).

43 Grubbs, 565 F.3d at 190.

submit them to the State. It is the State Medicaid agency, in this case, the Alaska Division of Health Care Services, which may seek reimbursement from the federal government pursuant to a State Medicaid Plan approved by CMS, an agency of the federal government.[44] Relator has failed to allege a single fact that would implicate Safeway in any attempt to mislead the State or cause it to pass on a false claim.

In fact, Relator identifies only the following data, none of which establishes that Safeway submitted a false claim for reimbursement: (1) a "date" (Relator does not state if the date provided refers to the date of the prescription, the date it was filled, the date it was submitted for payment, the date it was paid, or some other date); (2) the name of a drug; (3) a dollar "amount" (Relator does not state if the amount refers to the amount billed to the Alaska Medicaid, the amount that Alaska Medicaid paid for the drug, or some other amount); and, (4) the name of a "pharmacy."[45]

Most importantly, Relator fails to allege any facts that Safeway *knowingly* submitted a *false* claim to the *federal* government.[46] Relator has not alleged any facts indicting that Safeway mislead, lied, or otherwise engaged in illegal or nefarious conduct related to any of the claims he identifies. He simply alleges that Safeway submitted certain claims for reimbursement to "Medicaid" (by which he must mean the Alaska Medicaid program; he certainly does not state otherwise) that he claims could not be reimbursed by the federal government under the Social Security Act. Relator apparently assumes that submitting a claim to Medicaid for a drug prescribed for an off-label, non-compendium use amounts to "per se" liability under the FCA. Yet, for the reasons stated above, that position has no support in the law. In short, Relator has failed to allege any falsehood, inaccuracy or subterfuge in Safeway's submissions to Medicaid—

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44 See, p. 8-9, infra.

45 Compl., ¶¶ 19-20.

46 31 U.S.C. § 3729(b).

"the *sine qua non* of a False Claims Act violation."[47]

In addition to this fatal shortcoming, merely listing a drug, a date of unknown reference, and an amount of unknown reference for a given patient does not identify any particulars of fraud for at least the following additional reasons:

- Relator makes no allegation regarding to which agency Safeway allegedly submitted the claims;
- Relator makes no allegation regarding his mental health diagnoses;
- Relator does not allege the indications for which the drugs were prescribed;
- Relator does not allege the specific off-label use for which the medication(s) at issue was prescribed;
- Assuming that a drug was prescribed for a non-indicated use, Relator does not allege that Safeway knew or should have known the use for which the non-indicated drug was prescribed;
- There are no facts pled suggesting Safeway knew or should have known that any claims submitted were the result of a prescriber's purportedly wrongful behaviors, such as prescribing drugs that were improperly studied or unlawfully promoted by drug companies;
- Even accepting as true Relator's incorrect interpretation of the Social Security Act, Relator alleges no facts suggesting that Safeway knew or should have known that the State Medicaid Plan was contrary to that interpretation of the Social Security Act.

In short, absent these particularized allegations of fraud, Relator cannot survive a Rule 9(b) motion to dismiss.

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47 United States ex rel. Rost v. Pfizer, Inc., 253 F.R.D. 11, 15 (D. Mass. 2008); see also United States v. Kitsap Physicians Serv., 314 F.3d 995, 1002 (9th Cir. 2002) ("The False Claims Act**,** then, focuses on the submission of a claim, and does not concern itself with whether or to what extent there exists a menacing underlying scheme."); United States ex rel. Hopper v. Anton, 91 F.3d. 1261, 1265-66 (9th Cir. 1996) (stating that the FCA requires a false claim and explaining that "[t]his does not mean that other types of violations of regulations, or contracts, or conditions set for the receipt of moneys, or of other federal laws and regulations are not remediable; it merely means that such are not remediable under the FCA or the citizen's suit provisions contained therein").

IV. CONCLUSION

For the reasons discussed above, the Court should dismiss Relator's complaint with prejudice for lack of subject matter jurisdiction under Rule 12(b)(1), or, in the alternative under 31 U.S.C. § 3730(b)(5) based on Relator's violation of the first-to-file rule. In addition, the Court should dismiss Relator's complaint with prejudice for failure to state a claim upon which relief can be granted under Rule 12(b)(6), and for failure to plead fraud with particularity under Rule 9(b).

DATED this 27th day of July, 2010, at Anchorage, Alaska.

DORSEY & WHITNEY LLP

By: /s/ Robert C. Bundy

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CERTIFICATE OF SERVICE

On the 27th day of July, 2010, a true and correct copy of the foregoing was sent via electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail to the following:

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