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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

UNITED STATES OF AMERICA *Ex rel.* Law Project for Psychiatric Rights, an Alaskan non-profit corporation, Plaintiff, vs. OSAMU H. MATSUTANI, MD, *et al*., Defendants.	Case No. 3:09-CV-00080-TMB
UNITED STATES OF AMERICA, ex rel Daniel I. Griffin, Plaintiff, v.s 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-00246-TMB (CONSOLIDATED)

OPPOSITION TO MOTIONS TO DISMISS GRIFFIN COMPLAINT BY DEFENDANTS SAFEWAY, MARTINO and FAMILY CENTERED SERVICES

Qui tam relator Daniel I. Griffin (Daniel) opposes:

(1) Defendant Safeway, Inc.'s 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), Dkt. No. 142, which was joined by Defendant Family Centered Services of Alaska (FCSA) at Dkt. No. 146 and Defendant Ronald A. Martino (Martino) at Dkt. No. 149 (Safeway Motion to Dismiss),

and

(2) Defendant FCSA's Motion to Dismiss Relator Griffin's Claims Pursuant to 31 U.S.C. §3730(b)(5), Dkt. No. 144 (FCSA Motion to Dismiss).

I. OVERVIEW

As succinctly stated by the court in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass. 2008):

> Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I).

Daniel, while in foster care and a Medicaid recipient, was prescribed psychotropic drugs that were not for a medically accepted indication by Defendant Martino.[1] Physicians employed by Defendant FCSA, on other occasions, prescribed psychotropic drugs to Daniel that were not for medically accepted indications.[2] All but two of these

[1] ¶ 19 of the Complaint in *ex rel Griffin*, 3:09-cv-246-TMB, Dkt. No. 1.
[2] ¶ 20 of the Complaint in *ex rel Griffin*, 3:09-cv-246-TMB, Dkt. No. 1.

prescriptions were presented to Medicaid for payment by Defendant Safeway.[3] They are false claims.

Thus, Daniel filed his Complaint on behalf of the federal government in Case No. 3:09-cv-246-TMB,[4] under the federal False Claims Act, 31 U.S.C. §3729, *et seq*. (FCA), to:

(a) recover for false claims presented to and paid by Medicaid for outpatient psychiatric drugs prescribed to children and youth that were not for a "medically accepted indication;" and

(b) order the defendants to cease and desist from presenting or causing the presentment of such false claims.

All of the defendants in both of the consolidated cases dispute the holding in *Rost* that Medicaid can only pay for drugs used for a medically accepted indication.[5] However, 42 USC 1396R-8(k)(3) provides in pertinent part, "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." Since the term "covered outpatient drug" is specifically defined to exclude drugs that are not used for a "medically accepted indication," the defendants position is that Congress did not limit coverage of outpatient drugs to "covered outpatient drugs." This position is untenable.

The defendants also assert (i) the action is barred under 31 U.S.C. § 3730(e)(4), commonly known as the Public Disclosure Bar,[6] and (ii) should be dismissed under Rule 9(b), asserting that identifying specific prescriptions constituting false claims is not

[3] ¶s19 - 21 of the Complaint in 3:09-cv-246-TMB, Dkt. No. 1.
[4] This case has been consolidated into 3:09-0080-TMB. Dkt. No. 140.
[5] Dkt. No. 92 (12(b)(6) Motion), joined by FCSA at Dkt. No. 145, and the Safeway Motion, Dkt. No. 141, joined by FCSA at Dkt. No.146 and Martino at Dkt. No. 149.
[6] Dkt. No. 89 (Public Disclosure Bar Motion), joined by FCSA at Dkt. No. 145, and the Safeway Motion, Dkt. No. 141, joined by FCSA at Dkt. No.146 and Martino at Dkt. No. 149

particular enough.[7] In addition to the Safeway Motion raising these same issues raised by the defendants in *Matsutani,* it and the FCSA Motion assert the *ex rel Griffin* Complaint is barred under 31 U.S.C. §3730(b)(5), commonly known as the "First to File Rule."

Were the defendants right that *Rost* is incorrect in holding "Medicaid can only pay for drugs that are used for a 'medically accepted indication,' " both of the complaints in the consolidated cases would be dismissed with prejudice. However, the defendants' assertion that coverage for outpatient drugs under Medicaid is not limited to "covered outpatient drugs" is untenable. This will be briefly addressed below and was more fully addressed at Dkt. No. 108.

The Public Disclosure Bar cannot be triggered for the *ex rel Griffin* defendants because the public disclosure cited to by the *ex rel Griffin* defendants did not identify them and the narrow exception to the rule that only public disclosures that identify the defendant trigger the Public Disclosure Bar is inapplicable.

The only new issue in the motions to dismiss by Safeway and FCSA in 3:09-cv-00246-TMB, to which this opposition is in response, is under the First to File Rule, which provides, "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." Since FCSA was not named as a defendant in the earlier action, the First to File Rule does not operate to bar the *ex rel Griffin* Complaint. While Safeway and Martin were named in the *Matsutani* case, 3:09-cv-0080-TMB, the *ex rel Griffin* Complaint includes specific offending prescriptions so it is not based on the same underlying facts of the *Matsutani* action as it existed at the time.

These four issues, (1) whether coverage for outpatient drugs is limited to "covered outpatient drugs," (2) whether the public disclosure bar has been triggered, (3) whether the *ex rel Griffin* Complaint is sufficiently particular, and (4) whether the First to File Rule applies, will be addressed in turn. Before addressing these issues however, because

[7] Dkt No. 84 (Particularity Motion), joined by FCSA at Dkt. No. 145, and the Safeway Motion, Dkt. No. 141, joined by FCSA at Dkt. No.146 and Martino at Dkt. No. 149.

the Safeway Memorandum in support of the Safeway Motion (Safeway Memo),[8] at various points, also raises *scienter* or knowledge, *scienter* will be discussed first.

II. ANALYSIS

(A) The Defendants Are Charged with Knowledge or *Scienter* as a Matter of Law

Under the False Claims Act, 31 U.S.C. §3729(b)(1):

> (1) the terms "knowing" and "knowingly" --
>
> (A) mean that a person, with respect to information--
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> (i) has actual knowledge of the information;
>
> (ii) acts in deliberate ignorance of the truth or falsity of the information; or
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> (iii) acts in reckless disregard of the truth or falsity of the information; and
>
> (B) require no proof of specific intent to defraud;

Because of the "deliberate ignorance" and "reckless disregard" basis for satisfying the False Claims Act's *scienter* requirement, and because they agree to comply with Medicaid's legal requirements, all Medicaid providers, including all of the defendants here, are presumed to have knowledge of Medicaid's legal requirements:

> "Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law...." *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63, 104 S.Ct. 2218, 81 L.Ed.2d 42 (1984). Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment. *Id*. at 64, 104 S.Ct. 2218.
>
> The evidence established that Mackby was the managing director of the clinic. He was responsible for day-to-day operations, long-term planning, lease and build-out negotiations, personnel, and legal and accounting oversight. It was his obligation to be familiar with the legal requirements for obtaining reimbursement from Medicare for physical therapy services, and to ensure that the clinic was run in accordance with all laws. His claim that he did not know of the Medicare

[8] Dkt No. 142.

> requirements does not shield him from liability. By failing to inform himself of those requirements . . . he acted in reckless disregard or in deliberate ignorance of those requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question.

U.S. v. Mackby, 261 F.3d 821, 828 (9th Cir. 2001).

However, in another context, it has been held that a good faith interpretation of regulations can negate the *scienter* element. *U.S. v. Bourseau*, 531 F.3d 1159 (9th Cir. 2008). It is unclear whether or not the good faith interpretation defense can even apply in this case. If it does, though, whether good faith exists is a factual issue that must be developed through discovery and testimony, and is not subject to proper disposition at this stage of the litigation. *U.S. ex rel Oliver v. The Parsons Company*, 195 F.3d 457, 463, 464 (9th Cir. 1999) discusses the interplay between the issue of whether a claim is false and whether the *scienter* requirement has been met as follows:

> [I]t is Parsons' compliance with these regulations, as interpreted by this court, that determines whether its accounting practices resulted in the submission of a "false claim" under the Act.
>
> . . .
>
> A contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or "reasonable" but because the good faith nature of his or her action forecloses the possibility that the *scienter* requirement is met

The court then went on to hold that factual issue precluded the grant of summary judgment. 195 F.3d at 465.

That the State of Alaska may have promulgated regulations in contravention of Congress' limitation of Medicaid coverage of outpatient drugs to those that are for a medically accepted indication is not a defense. Citing to *Heckler*, in *U.S. ex rel Hagood v. Sonoma County Water Agency*, 929 F. 2d 1416, 1422 (9th Cir 1991), in a False Claims Act case such as this, the Ninth Circuit held that United States government officials' approval of a contract based on an erroneous interpretation of law did not defeat a False Claims Act cause of action, and reversed the district court's dismissal under Rule 12(b)(6).

Safeway also asserts that because it did not attempt to mislead when it submitted the false claims it is not liable.[9] This, however, is not a defense. 31 U.S.C. §3729(b)(1)(B) specifically provides proof of specific intent to defraud is not required. As the Ninth Circuit held most recently in *Bourseau*, 531 F.3d at 1166:

> The FCA defines "knowing" and "knowingly" to mean that, with respect to information, a person: "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). "[N]o proof of specific intent to defraud is required." Id. " 'The requisite intent is the knowing presentation of what is known to be false,' as opposed to innocent mistake or mere negligence. '

Putting all of this together in the context of this case, there is a presumption that when the defendants caused or presented claims for psychiatric drugs used on children and youth that were not for a medically accepted indication, they knew such claims were false, thus satisfying the *scienter* requirement. In order to negate this presumption, the other defendants must come forward with evidence that they relied on a good faith interpretation *before* submitting the false claims. Daniel will be entitled to discovery on this issue if such evidence is presented. Reliance on the State of Alaska's improper allowance of false claims does not negate the existence of knowledge under *Mackby*.

(B) This Action Should Not be Dismissed

(1) The Defendants' Position that Coverage for Outpatient Drugs is Not Limited to "Covered Outpatient Drugs" is Untenable

Whether or not Congress limited coverage[10] for outpatient drugs to "covered outpatient drugs" was extensively briefed in connection with all of the defendants' Rule

[9] Dkt. No. 142, pp 14.

[10] "Coverage" in the insurance context means "a. Inclusion in an insurance policy or protective plan. b. The extent of protection afforded by an insurance policy." *American Heritage Dictionary*, 4th Ed. *See*, also, *Black's Law Dictionary*. Congress using the term "covered outpatient drugs," in itself designates that this is what is being "covered," by Medicaid. That the title of 42 U.S.C. §1396r-8, is "Payment for covered outpatient drugs," also makes clear that "covered outpatient drugs," is what Medicaid "covers," or

12(b)(6) Motion, Dkt. No. 92, which was incorporated in the Safeway Motion under consideration here, Dkt. No. 142, p. 9. Daniel similarly incorporates PsychRights' arguments at Dkt. Nos. 108, 113, pp. 4-6, and 132, pp. 2, 6-8. The defendants' position that Congress did not limit coverage for outpatient drugs to "covered outpatient drugs," is untenable.

42 USC 1396R-8(k)(3) provides in pertinent part, "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." 42 USC 1396R-8(k)(6) provides:

> The term "medically accepted indication" means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 USC § 1396R-8(g)(1)(B)(i), in turn, designates the compendia as

> (I) American Hospital Formulary Service Drug Information;
> (II) United States Pharmacopeia-Drug Information (or its successor publications); and
> (III) the DRUGDEX Information System.

(Compendia).

In sum, Medicaid is only permitted by Congress to reimburse the states for expenditures on outpatient drugs for "medically accepted indications," defined as indications approved by the FDA or "supported by" a citation in any of the three Compendia.

This is exactly what the Court in *Rost* has held, as set forth above. It is also the government's official position in other False Claims Act cases. In September of 2009, the Department of Justice issued a news release announcing a $2.3 Billion settlement with Pfizer, stating, "[Pfizer] caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered

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pays for. *United States v. Nader*, 542 F.3d 713, 717 (9th Cir. 2008) ("Titles are also an appropriate source from which to discern legislative intent.").

by those programs."[11] Similarly, the Government's February 13, 2009, Complaint in Intervention in *U.S. ex rel Gobble v. Forest Laboratories*, Case No. 03-cv-10395-NMG, District of Massachusetts, states that prescriptions presented to Medicaid that are not for medically accepted indications are false claims.[12] To the same effect is the settlement agreement in *U.S. ex rel Wetta v. AstraZeneca Pharmaceuticals*, Case No. 04-cv-3479-BMS, Eastern District of Pennsylvania.[13]

At page 9 of the Safeway Memo, Dkt. No. 142, Safeway, Martino and FCSA assert, "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." However, the prescriptions identified in the Complaint were submitted for federal financial participation and thus false claims. Page 11 of the Safeway Memo, Dkt. No. 142, makes the dubious assertion "there can be no FCA liability for submitting a Medicaid claim that state law does allow," citing to *United States ex rel Quinn v. Omnicare*, 382 F.3d 432, 441 (3d Cir. 2004). However, Safeway's interpretation of *Quinn* has been soundly rejected in the unreported case of *U.S. ex rel Monahan v. Robert Wood Johnson University Hosp.* 2009 WL 1288962, n.1 (D.N.J. 2009). In *Quinn* the question was whether it was a false claim when medication was returned, no credit was issued for Medicaid's 50% federal share and then rebilled when it was sold again. In *Monahan*, the Court held that was inapposite to the situation where Congress had explicitly required that there be a correlation between costs and charges. Similarly, where, as here, Congress has limited Medicaid coverage of outpatient drugs to "covered outpatient drugs," the Alaska regulations that allow it are invalid to the extent federal reimbursement is sought or obtained.

The Safeway Memo, Dkt. No. 142, at various points, seriously misstates the basis of the false claims here by equating "off-label" prescriptions for "indications that are not

[11] Dkt. No. 108-1, p.1.
[12] Dkt. No. 108-2, pp. 8-9, at ¶s 26-30; p. 10, ¶37; p. 31 ¶97; p. 32, ¶100.
[13] Dkt. No. 108-3, p.6.

for a medically accepted indication."[14] Daniel is asserting no such thing. What Congress decreed was Medicaid could only pay for off-label prescriptions if supported by one or more of the Compendia. If there is no such scientific support for the use, Congress prohibits Medicaid from paying for such use. Thus, the statement at the end of footnote 25 of the Safeway Memo stating, "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" misses the point. Some off-label prescribing has scientific support, some does not, and when it does not, can be especially dangerous. Doctors should not be prescribing drugs without such scientific support for its use. The First Amended Complaint in *Matsutani*, Dkt. No. 107, describes such lack of efficacy and harm at ¶s 85, 88-93, 111, 113-116, 118-128, 134, 135-137, 139-145, 148, 151-152, 154-155[15] with respect to psychotropic drugs administered to children and youth. In many cases, contrary to the assertions in the Safeway Memo, the drugs in question have failed to establish safety or efficacy for children and youth in studies that have been conducted--it is not just that there have been no studies.

For example, the FDA has noted 12 of the 15 pediatric antidepressant trials failed, rejecting the applications of six manufacturers seeking approval to sell their antidepressants to children.[16] In fact, reviewers writing in the British Medical Journal

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[14] *E.g.*, Footnote 25, p. 11.

[15] An "annotated" version of the original complaint in the *Matsutani* case, 3:09-cv-0080-TMB, Dkt. No. 1, is available on the Internet at http://psychrights.org/States/Alaska/Matsutani/AnnotatedComplaint.htm. This "Annotated Complaint," includes hyperlinks to the sources cited in most cases. There is some numbering difference between the original complaint, Dkt. No. 1, and the First Amended Complaint, Dkt No. 107.

[16] Thomas P. Laughren, M.D., "Background Comments for February 2, 2004 Meeting of Psychopharmacological Drugs Advisory Committee (PDAC) and Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee (Peds AC)," Food and Drug Administration Center for Drug Evaluation and Research, January 5, 2004, which is available on the Internet at http://www.fda.gov/ohrms/dockets/ac/04/briefing/2004-4065b1-04-Tab02-Laughren-Jan5.pdf.

made the same point. "Recommending (SSRIs) as a treatment option" for children, "let alone as first line treatment, would be inappropriate."[17]

In the final analysis, recognizing that doctors are unduly swayed by drug company swag and other means of persuasion, Congress determined that Medicaid would only be allowed to pay for off-label uses that are supported by citations in one or more of the Compendia. This is a completely sensible approach. Most importantly, it is the law and the basis for this action.

The Safeway Memo also repeats the assertion made by the defendants in the *Matsutani* Case in support of the Rule 12(b)6) Motion, Dkt. No. 92, that because 42 U.S.C. § 1396r-8(d)(1)(B)(i), provides a state may exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication that *implies* Medicaid is not otherwise restricted. This has some appeal to it if considered in isolation from the rest of the statute, but ends up being untenable when considering the rest of the statute.[18]

Defendants' interpretation of the statute immediate falls apart when looking at the provision upon which they rely, §1396r-8(d)(1)(B)(i), which states:

> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--
>
> > (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

This is circular because, "covered outpatient drug" is defined in 42 USC 1396R-8(k)(3) to "not include any . . . drug . . . used for a medical indication which is not a medically accepted indication."

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[17] Jon N Jureidini, *et al.*, "Efficacy and safety of antidepressants for children and adolescents," *British Medical Journal*, Vol 328:879-883 (2004), available on the Internet at http://psychrights.org/research/Digest/AntiDepressants/bmj2004efficacyandsafety.pdf.

[18] Daniel incorporates PsychRights' arguments on this issue. Dkt. Nos. 108, 113, pp. 4-6, and 132, pp. 2, 6-8.

Thus, substituting the definition of "medically accepted indication" the statutory provision relied upon by the Defendants states,

> A State may exclude or otherwise restrict coverage of a covered outpatient drug to a covered outpatient drug.

or, substituting the definition of "covered outpatient drug:"

> A State may exclude or otherwise restrict coverage of drugs prescribed for a medically accepted indication to drugs prescribed for a medically accepted indication.

There is thus simply no avoiding the conclusion that 42 U.S.C. §1396r-8(d)(1)(B)(i) is superfluous. Most importantly, it cannot be used to override Congress' explicit limitation of Medicaid coverage for outpatient drugs to medically accepted indications.

The issue of whether Congress limited Medicaid coverage for outpatient drugs to "covered outpatient drugs," under 42 USC §1396R-8(k)(3), 42 USC §1396R-8(k)(6) and 42 USC § §1396R-8(g)(1)(B)(i), is the lynchpin of both of the consolidated cases. If Daniel, PsychRights and the Department of Justice are all wrong in stating the tautology that Congress limited Medicaid coverage for outpatient drugs to "covered outpatient drugs," all of the claims in both cases disappear.

At Dkt. No. 102, defendants Matsutani, Curtiss, Clark and Providence ask the Court to decline to answer this fundamental question until after it has decided particularity under Rule 9(b). Presumably, this is because they hope to escape liability on this technicality and then continue to claim lack of knowledge that they are causing the presentment of false claims for prescriptions of psychotropic drugs to children and youth Medicaid recipients that are not for a medically accepted indication. As set forth above and at Dkt. No. 132, pp 10-11, under *Mackby*, 261 F.3d at 828, the defendants should all be charged with knowledge as a matter of law. However, if the Court find the defendants lacked knowledge or *scienter* at the time the complaint was unsealed, when would the defendants be charged with *scienter*? Would they be charged with *scienter* upon the unsealing of the complaint? When this Court issues a decision? The defendants,

including Safeway, Martino and FCSA, untenably assert Congress did not restrict Medicaid coverage for outpatient drugs to "covered outpatient drugs." Does their taking that untenable position obviate *Mackby*? It seems not, but to the extent that it does, Daniel respectfully suggests this Court should lay to rest the question of whether Congress restricted Medicaid coverage for outpatient drugs to "covered outpatient drugs" so that the defendants can no longer claim they relied on a good faith interpretation of the law.

Daniel respectfully suggests Matsutani, Curtiss, Clark and Providence have it backwards. Daniel believes this fundamental issue of whether Congress restricted Medicaid coverage of outpatient drugs to "covered outpatient drugs," is the first thing this Court should decide.

(2) The Public Disclosure Bar Does Not Apply

Safeway, and through their joinders, Martino and FCSA, adopt by reference the arguments made in support of the Public Disclosure Bar Motion by the defendants in the *Matsutani* case. Daniel similarly adopts by reference PsychRights' opposition to the Public Disclosure Bar Motion, Dkt. No. 111. However, the Public Disclosure Bar Motion involves circumstances where the analysis varies depending on the specific circumstances of the defendant(s). With respect to the defendants in the *ex rel Griffin* Complaint in 3:09-cv-00246-TMB, which is at issue here, the Public Disclosure Bar cannot apply because they were not identified in the alleged public disclosure. *United States ex rel. Alfatooni v Kitsap Physicians Services*, 163 F.3d 516, 523 (9th Cir. 1999) (public disclosure bar only applies to defendants identified in public disclosure).

U.S. ex rel. Foundation Aiding The Elderly v. Horizon West, 265 F.3d 1011, n5 (9th Cir. 2001), reiterates this principle, and held at footnote 5 that allegations of general or widespread fraud do not trigger the public disclosure bar:[19]

[19] *Alcan Electrical and Engineering, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999), decided between *Alfatooni* and *Foundation Aiding The Elderly* does carve out an exception for "a narrow class of suspected wrongdoers," but again, in the later

> Appellees also point to general allegations of fraud that were directed at the nursing home industry in general. But, as pointed out by Appellants, none of these "disclosures" related to Horizon West or specifically to any of its facilities. Therefore, they do not trigger the jurisdictional bar. See *Cooper v. Blue Cross & Blue Shield of Fla., Inc*., 19 F.3d 562, 566 (11th Cir. 1994) ("The allegations of widespread ... fraud made in sources in which BCBSF was not specifically named or otherwise directly identified are insufficient to trigger the jurisdictional bar").

Simply put, the Public Disclosure Bar cannot apply to the defendants in this case, *ex rel Griffin*, because they were not identified in the alleged public disclosure.[20]

(3) The *ex rel Griffin* Complaint Satisfies Rule 9(b)

(a) The Complaint Sufficiently Pleads Particularity

The Safeway Memo also asserts the *ex rel Griffin* Complaint fails to plead with sufficient particularity as required under Rule 9(b).[21]

Safeway first quotes the following from *U.S. ex rel Grubbs v Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) in support of its assertion Daniel did not plead with sufficient particularity:

> Standing alone, raw bills-even with numbers, dates, and amounts-are not fraud without an underlying scheme to submit the 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.

This quote is taken out of context by Safeway in a way that conveys the Court's decision in a very misleading way.

In *Grubbs*, the question to which that quote was directed was whether specific false claims had to be identified in order to satisfy the particularity requirement of Rule 9(b). In that case, the *relator* alleged that other physicians and the hospital billed Medicaid and Medicare for services that were not provided and the *relator* had not

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Foundation Aiding The Elderly, the Ninth Circuit held that general allegations of fraud against an industry do not trigger the public disclosure bar.

[20] Daniel does not claim "original source" status.

[21] Dkt. No. 142, pp. 11-15.

identified specific false claims. In holding the allegations in the complaint nonetheless satisfied particularity, the court said:

> Appellees retort that because presentment is the conduct that gives rise to § 3729(a)(1) liability, Rule 9(b) demands that it is the contents of the presented bill itself that must be pled with particular detail and not inferred from the circumstances. We must disagree with the sweep of that assertion. Stating "with particularity the circumstances constituting fraud" does not necessarily and always mean stating the contents of a bill. The particular circumstances constituting the fraudulent presentment are often harbored in the scheme. A hand in the cookie jar does not itself amount to fraud separate from the fib that the treat has been earned when in fact the chores remain undone. Standing alone, raw bills-even with numbers, dates, and amounts-are not fraud without an underlying scheme to submit the 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.
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> In sum, the "time, place, contents, and identity" standard is not a straitjacket for Rule 9(b). Rather, the rule is context specific and flexible and must remain so to achieve the remedial purpose of the False Claim Act. We reach for a workable construction of Rule 9(b) with complaints under the False Claims Act; that is, one that effectuates Rule 9(b) without stymieing legitimate efforts to expose fraud. We hold that to plead with particularity the circumstances constituting fraud for a False Claims Act § 3729(a)(1) claim, a relator's complaint, if it cannot allege the details of an actually submitted false claim, may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.

Id. Here, in contrast to *Grubbs*, Daniel has pled 42 specific false claims, including date, drug and amount that Defendant Martino caused to be submitted,[22] 10 that Defendant FCSA caused to be presented,[23] and 50 that Safeway presented.[24]

[22] *Ex rel Griffin* Complaint, ¶ 19.
[23] *Ex rel Griffin* Complaint, ¶ 20.
[24] *Ex rel Griffin* Complaint, ¶s 19 - 21.

The *Grubbs* court went on to hold:[25]

> Defendants either have or do not have evidence that the alleged phony services were actually provided; they either have or do not have evidence that recorded, but unprovided or unnecessary, services did not result in bills to the Government. Discovery can be pointed and efficient, with a summary judgment following on the heels of the complaint if billing records discredit the complaint's particularized allegations.

Here, Daniel has identified 52 specific false claims and it seems it would be useful to go through a few of them specifically.

From October, 2004 through mid-February, 2005, Dr. Martino prescribed Zoloft, Abilify, Trazadone, concurrently,[26] in what is known as "polypharmacy."[27] Such polypharmacy, by itself, constitutes false claims because there is no medically accepted indication for such a drug combination used on children and youth. Abilify used as adjunctive therapy with lithium or valproate (Depakote/Depakene) for acute manic or mixed episodes of Bipolar 1 Disorder, is one of the very few situations where concurrent use of more than one psychotropic drug at the same time is a medically accepted indication for use on children and youth.[28] However, again, there is no medically accepted indication for the concurrent use of Zoloft, Abilify and Trazadone on children and youth, so all of these are *per se* false claims.

Taking these drugs separately, the only medically accepted indication for the use of Zoloft in children and youth is Obsessive Compulsive Disorder,[29] which was not why it was used on Daniel. Daniel has not heretofore identified for what indications these prescriptions were issued, but he can in an amended complaint, should the court order it is required. However, it is not required because defendant Martino knows or has records of what indication the Zoloft was prescribed for. Dr. Martino either prescribed it for

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[25] 565 F.3d at 191.
[26] *Ex rel Griffin* Complaint, ¶ 19.
[27] *See*, *ex rel Matsutani* First Amended Complaint, Dkt. No. 107, ¶87.
[28] Dkt. No. 113-5, p.1.
[29] Dkt. No. 113-5, p.6.

Obsessive-Compulsive Disorder or he did not. He can deny the allegation that it was not for a medically accepted indication if it was prescribed for Obsessive-Compulsive Disorder. Similarly, FCSA knows the diagnosis for the other psychiatrists it employed to prescribe these drugs for non-medically accepted indications to Daniel. Also, as more fully set forth at Dkt. No. 113, pp 6-9, the Medicaid regulations require that the indication (called diagnosis in the regulations) accompany electronically submitted Medicaid Claims. This is why Safeway knows what the indication is.

The only medically accepted indications for the use of Abilify on children and youth are Bipolar I Disorder, manic or mixed episodes, and Schizophrenia.[30] Neither of these were the indication for which the Abilify was prescribed. The situation for Trazadone (Desyrel) is even more stark because there is no medically accepted indication whatsoever for the use of it in children and youth.[31] Thus, Safeway did not need to know for what indication it was prescribed. It doesn't matter because there is no medically accepted indication at all for the use of Trazadone in children and youth. The same is true of the Trileptal[32] that was prescribed to Daniel from February 24, 2005 through October 19, 2005, by Dr. Martino. [33]

In *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997), the Court held that where a complaint "identifies the circumstances of the alleged fraud so that defendants can prepare an adequate answer" it meets the particularity requirement of Rule 9(b). In *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001), the Ninth Circuit held the following was required in a False Claims Act complaint:

> 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."

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[30] Dkt. No. 113-5, p.1.
[31] Dkt. No. 113-5, p.2.
[32] Dkt. No. 113.-5, p.6.
[33] *Ex rel Griffin* Complaint, ¶ 19.

In *U.S. ex rel Lee v. SmithKline Beecham*, 245 F.3d 1048, 1051-52 (9th Cir. 2001), the Ninth Circuit reiterated Rule 9(b) only requires the complaint to be specific enough to give defendants enough notice to defend against the charge and not just deny they have done anything wrong.

Daniel respectfully suggests the real dispute is over whether Congress limited Medicaid's coverage of outpatient drugs to "covered outpatient drugs," not that he has failed to identify false claims with sufficient particularity.

(b) Daniel Will Move to Amend The Complaint if It is Determined More Particularity is Required

At page 15 of the Safeway Memo, Dkt. No. 142, Safeway asserts the following as grounds for dismissing for lack of particularity:

(i) Relator makes no allegation regarding to which agency Safeway allegedly submitted the claims;

(ii) Relator makes no allegation regarding his mental health diagnoses;

(iii) Relator does not allege the indications for which the drugs were prescribed;

(iv) Relator does not allege the specific off-label use for which the medication(s) at issue was prescribed;

(v) 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 nonindicated drug was prescribed;

(vi) 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;

(vii) 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.

With respect to, (i), Daniel can amend his complaint if that is deemed necessary. It doesn't seem it should be necessary, however.

(ii)-(iv) are really the same thing and Daniel can amend the complaint to include it if necessary. For the reasons set forth above, however, Daniel does not believe that is necessary.

With respect to (v), Safeway is incorrect. ¶ 25 of the Complaint contains such an allegation. Moreover, as set forth above, the electronic Medicaid claim system through which Safeway submits claims is required to include the diagnosis (indication). Finally, as set forth above, some of the drugs at issue have no medically accepted indication for use in children and youth.

With respect to (vi) Daniel could, if necessary add into his complaint, the same extensive allegations regarding the overall scheme that has resulted in doctors prescribing psychotropic drugs for use in children and youth that are not for a medically accepted indication. However, this should not be necessary, because as set forth above, Safeway is charged with knowledge of Medicaid's legal requirements under *Mackby*.

Similarly, with respect to (vii), under *Mackby*, Safeway is charged with knowledge of Medicaid's legal requirements.

(c) Submission of a Claim to Alaska's Medicaid Office Not Allowed by Medicaid Constitutes a Violation of the False Claims Act

Without any citation to any authority for the proposition, Safeway argues that because it submitted the claims to the State of Alaska it cannot have violated the False Claims Act.[34] This seems to be erroneous on its face because Medicaid is a joint federal/state program, administered by the states, with the federal government paying 50% of the cost in most cases. Presentation of claims to the state Medicaid program is thus a presentation to the federal government. Even if not, Safeway caused the submission of the false claims and is liable therefor. The Complaint can be amended to include that allegation if the Court determines it is necessary.

[34] Dkt. No. 142, p. 13-14.

(4) The First To File Rule Does Not Bar the *Ex Rel Griffin* Complaint

The only new issue raised by the Safeway Motion,[35] which is also the subject of the FCSA Motion[36] is under 31 U.S.C. §3730(b)(5), providing "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," commonly known as the First to File Rule.

Under *Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1189 (9th Cir. 2001), in order for the First to File Rule to bar a subsequent action, the subsequent complaint must allege the "same material elements." Under *Campbell v. Redding Med. Ctr.*, 421 F.3d 817, 825 (9th Cir. 2005), the First to File Rule does not apply if the pending action was subsequently determined to have been jurisdictionally deficient, such as through the Public Disclosure Bar.

In *U.S., ex rel., Pfeifer v. Ela Medical, Inc.*, 2010 WL 1380167 (D.Colo. 2010), the District Court for the District of Colorado recently held:

> In determining whether the first-to-file bar acts to foreclose a subsequent qui tam action, courts are to look at the facts as they existed at the time the subsequent action was brought. Id. (citing *Smith v. Sperling*, 354 U.S. 91, 93 n. 1 (1957)). Changes in the prior action after the date that the subsequent action was brought--including amendments, new or different claims, and settlement of the matter--are not relevant to whether the subsequent action is a "related action based on the facts underlying the pending action." *Grynberg*, 390 F.3d at 1279 n. 2.
>
> The identity of the defendant is a material element of a fraud claim and consequently, the first-to-file bar does not prevent subsequent qui tam suits alleging the same material elements of fraud against different defendants. *CO2 Appeals*, 566 F.3d at 962. Rather, in order for a subsequent qui tam claim to be barred under the first-to-file bar, it must be asserted against the same defendants as was the prior claim. *Id*.

[35] Dkt. No. 141.
[36] Dkt. No. 143.

(Footnote omitted).

With respect to whether the First to File Rule applies to a different, unrelated, defendant, the cited *CO2 Appeals*,[37] held:

> The identity of a defendant constitutes a material element of a fraud claim, which, under our "same material elements" standard, brings it under the statutory definition of "facts" upon which the action is based

Finally, *U.S. ex rel. Westmoreland v. Amgen, Inc.*, --- F.Supp.2d ----, 2010 WL 1634315, p. 4 (D.Mass. 2010) held:

> There, the original complaint and a later complaint contained "significant similarities," both alleging that the pharmaceutical company promoted an off-label dosing regimen to increase Medicare payments, causing false claims to be filed. *Duxbury*, 579 F.3d at 33. The First Circuit, however, explained that the complaints "differ in one crucial respect," as the later complaint "contained a number of allegations that discuss, in significant detail, OBP's promotion of the 'off-label' use" and alleged six different promotion methods. *Id.* Because the original complaint alleged only one method of off-label promotion, the court held that the original complaint "fail[ed] to allege the 'essential facts' of the 'off-label' promotion scheme contained in the [later complaint].

Westmoreland and *Duxbury* also held that the First to File Rule is inapplicable to a different defendant.

Here, *Matsutani* was filed on April 27, 2009, and *ex rel Griffin* was filed on December 14, 2009. The *ex rel Griffin* Complaint included the 52 specific prescriptions constituting false claims set forth above, while the original *Matsutani* Complaint did not identify any specific prescriptions constituting false claims. The First Amended Complaint in the *Matsutani* Case,[38] filed May 6, 2010, added the same 52 specific prescriptions constituting false claims in response to the motion by the defendants in *Matsutani* to dismiss under Rule 9(b).[39]

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[37] 566 F.3d 956 (10th Cir. 2009).
[38] Dkt. No. 107.
[39] Dkt. No. 83.

Applying the above rules to these facts, neither complaint is barred by the First to File Rule. FCSA is not a defendant in *Matsutani* and therefore the First to File Rule cannot apply. With respect to Safeway and Martino, while they are also defendants in *Matsutani*, the *ex rel Griffin* Complaint, added the material element of the specific offending prescriptions, precluding application of the First to File Rule.[40]

III. CONCLUSION

For the foregoing reasons, Safeway's Motion to Dismiss, Dkt. No. 141 and FCSA's Motion to Dismiss, Dkt. No. 143, should be denied.

RESPECTFULLY SUBMITTED this 16th day of August 2010.

Law Project for Psychiatric Rights, an Alaskan non-profit corporation, attorney for Daniel Griffin

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[40] If this court were to dismiss Safeway and Martino from *ex rel Griffin* because of the First to File Rule, and assuming the identification of the specific false claims in *ex rel Griffin* satisfies Rule 9(b), logic demands that none of the defendants, with the possible exception of Thomson Reuters (Healthcare), can properly be dismissed in *Matsutani* under Rule 9(b).

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on August 16, 2010, a true and correct copy of this document was served electronically on all parties of record by 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.

/s/ James B. Gottstein
JAMES B. GOTTSTEIN