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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 REPLY
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)**

DEFENDANT SAFEWAY, INC.'S REPLY IN SUPPORT OF MOTION TO DISMISS
*U.S. EX REL LAW PROJECT V. MATSUTANI, ET AL., AND U.S. EX REL DANIEL I. GRIFFIN V. RONALD A.
MARTINO, ET AL.*; Case Nos. 3:09-cv-0080-TMB and 3:09-cv-00246-RRB (Consolidated)

I. INTRODUCTION

Relator's assertion, as set forth in his brief in opposition, that Safeway submitted a false or fraudulent claim to Medicaid in violation of the False Claims Act ("FCA") is based on his erroneous assumption that all claims submitted to the Alaska Medicaid program for a prescription drug's off-label use that is not supported by one of three "compendia" specified in the Medicaid rebate law are *per se* false because, according to Relator, federal Medicaid law prohibits states from covering such non-compendium uses. That position cannot be squared with the rebate law itself or the fact that the Federal Centers for Medicare and Medicaid Services ("CMS"), the agency responsible for administering the federal Medicaid program, has approved the Alaska State Medicaid Plan which *unambiguously* provides for reimbursement of all prescribed medications, with or without compendia support, with few exceptions not relevant here.

Moreover, Relator's position is wholly inconsistent with the FCA, which is intended to reward relators with previously undisclosed information and to punish defendants for knowingly submitting false or fraudulent claims that cause the federal government to overpay. This case, however, does not involve previously undisclosed information, and punitive treble damages and civil penalties based on (at best for Relator) an ambiguous statutory provision—which has been construed in Safeway's favor by CMS and the State of Alaska—are inappropriate. Indeed, Relator's mistaken belief pushes application of the FCA in this case far beyond any previous interpretation of that statute.

For these reasons, as well as those set forth below, in Safeway’s opening brief, and in the briefs filed in support of all defendants’ motions to dismiss filed in the consolidated case,¹ United States ex rel. Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB, Safeway respectfully requests that the Court dismiss Relator’s complaint against Safeway with prejudice.

II. ARGUMENT

A. Relator’s Complaint Should Be Dismissed Under Rule 12(b)(1) Because It Is Barred Under 31 U.S.C. § 3730(e)(4)(A)’s Public Disclosure Bar.

Relator’s complaint is based upon information disclosed in public documents and Relator has neither alleged nor argued that he is an “original source” of the information alleged in the Complaint. Most of the identified public disclosures discussed a systemic issue that would apply to all Medicaid providers, although at least one public disclosure—PsychRights’ complaint—did identify Safeway. Relator merely claims that he was one of the many Medicaid recipients who received such a prescription—information readily available to the government.

Moreover, Relator does not dispute that the identified public documents disclosed the theory of liability that Relator pursues in this case. Instead, Relator responds that his complaint names particular defendants and Medicaid claims that were not included in those previous

¹ The memoranda of law filed in support of the motions to dismiss filed in United States ex rel. Law Project for Psychiatric Rights v. Matsutani, Case No. 3:09-cv-0080-TMB, are as follows: Mem. in Supp. of Mot. to Dismiss under Rules 12(b)(1) and 12(h)(3) for Lack of Subject Matter Jurisdiction (Docket 91) and Reply (Docket 119); Mem. in Supp. of Mot. to Dismiss under Rule 12(b)(6) (Docket 93) and Reply (Docket 120); and Mem. in Supp. of Mot. to Dismiss under Rule 9(b) (Docket 84) and Reply (Docket 116). The arguments set forth in those briefs are hereby incorporated by reference in support of Safeway’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).

disclosures.² However, the public disclosure bar does not require identification of each of the named defendants or the precise claims at issue;³ it requires only that the allegations be based upon and substantially the same as the allegations contained in the prior, public disclosures, as is the case here.⁴

Moreover, Relator offers no response to Safeway's assertion that he is not an "original source" of the information contained in his complaint.⁵ As a result, Relator's complaint should be dismissed with prejudice under Federal Rule of Civil Procedure 12(b)(1).

B. The First-to-File Rule Bars Relator's Complaint.

The first-to-file bar applies for similar reasons. Relator, represented by PsychRights' counsel, does not dispute that Safeway was named as a defendant in the previously filed federal action, with which this case was consolidated, that the prior action alleged that Safeway violated the FCA by submitting claims to Medicaid for psychotropic drugs prescribed to minors for off-label, "non-compendium approved" uses (the "Matsutani" action), or that the Matsutani action was "pending" within the meaning of 31 U.S.C. § 3730(b)(5) when this case was filed. Nevertheless, Relator argues that the instant complaint is not a "related action" sufficient to trigger the first-to-file Rule because "the specific offending prescriptions" identified in the

² Relator cannot dispute that the PsychRights case, with which his case was consolidated, named Safeway as a defendant. Safeway addresses this point in the next section.

³ See Reply in Supp. of Mot. to Dismiss Under Rules 12(b)(1) and 12(h)(3) for Lack of Subj. Matter Jsd. Under the False Claims Act's Pub. Discl. Bar, 31 U.S.C. § 3730(E)(4)(A) (Case No. 3:09-cv-0080-TMB) (Docket 119) at 9-13.

⁴ *Id.*; see also Mem. in Supp. of Mot. to Dismiss under Rules 12(b)(1) and 12(h)(3) for Lack of Subject Matter Jurisdiction (Case No. 3:09-cv-0080-TMB) (Docket 91) at 10-15.

⁵ *Id.*

instant complaint were not identified in the Matsutani case until after the filing of Relator's complaint.⁶ Once again, however, Relator misstates and misconstrues the appropriate standard.

Contrary to Relator's assertion, the standard is not whether the "specific offending prescriptions" were identified in the prior suit, but whether the "same type of wrongdoing" was alleged in that prior action."⁷ In fact, the Ninth Circuit Court of Appeals has specifically rejected the position asserted by Relator here—that a "related action" must be based on "identical" facts—in favor of a "material facts" test.⁸ Under the "material facts" test, "an 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."⁹ Under this standard, Relator's complaint and the Matsutani action are surely "related actions;" both indisputably involve the "same type of wrongdoing" in that they both allege that Safeway submitted false claims to Medicaid for reimbursement of psychotropic drugs prescribed to minors for off-label, non-compendium uses. Indeed, the two cases were consolidated without opposition from Relator, for precisely that reason.¹⁰

Finally, the cases cited by Relator are inapposite. Both the First Circuit Court of Appeals and the United States District Court for the Eastern District of Massachusetts agree with the Ninth Circuit that Section 3730(b)(5) bars a subsequent suit involving the same material facts underlying a fraudulent scheme. In United States ex rel. Duxbury v. Ortho Biotech Products,

⁶ See Griffin Opp. at 21-22 (Docket 151).

⁷ See United States ex rel. Lujan v. Hughes Aircraft Co., 243 F.3d 1181, 1188 (9th Cir. 2001).

⁸ *Id.*

⁹ United States ex rel. Apollo Group, Inc., 2009 WL 3756623, *3, Case No. 08-cv-1399-JM (S.D. Cal. Nov. 6, 2009) (citation and quotation omitted).

¹⁰ See, Mem. in Supp. of Motion for Consolidation, U.S. ex rel. Griffin v. Martino, et al., Case No. 3:09-cv-0246-RRB (Docket 16).

L.P., the First Circuit Court of Appeals held only that the first-to-file rule did not bar a subsequent complaint where the original complaint alleged only “one method of off-label promotion,” and the later complaint “alleged six different promotion methods.”¹¹ The First Circuit concluded that the later complaint was the first to allege a widespread off-label promotion scheme, and thus did not trigger the first-to-file rule. Similarly, in United States ex rel. Westmoreland v. Amgen, Inc., the court concluded that the first-to-file rule did not apply because the later complaint was the first to plead a “widespread promotion scheme of encouraging and teaching providers to bill for overfill” and the “first to allege a new methodology of inducing providers with free samples in the form of overfill.”¹²

Here, unlike in Duxbury and Westmoreland, Relator’s complaint does not allege any new methods, theories, or schemes that were not included in the Matsutani complaint. Rather, it raised precisely the same allegedly widespread off-label reimbursement scheme identified in the earlier complaint, but narrowed the allegations to a single plaintiff. Tellingly, Relator’s counsel essentially conceded the breadth of the scheme alleged in the Matsutani complaint because he amended that complaint to identify the “specific offending prescriptions” (that is, the scheme alleged in the original Matsutani complaint already encompassed those “specific offending prescriptions”). In short, the Matsutani complaint is a “related action” and thus bars Relator’s complaint under the first-to-file Rule.

¹¹ United States ex rel. Westmoreland v. Amgen, Inc., 2010 WL 1634315, *4 (citing United States ex rel. Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13, 33 (1st Cir. 2009)).

¹² *Id.*

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

In his opposition, Relator ignores that both CMS and the Alaska Medicaid program have rejected his interpretations of the SSA. Relator also ignores the Act’s legislative history and other provisions of the Act; and he misconstrues language in published federal cases.

1. Relator ignores the Alaska and federal regulatory scheme.

Relator completely ignores the fact that CMS, the agency responsible for the administration of the federal Medicaid program, has approved the Alaska State Medicaid Plan which *unambiguously* provides for reimbursement of all prescribed medication, with or without compendia support for off-label prescribed uses, except for a short list of drugs, none of which is a psychotropic drug at issue in this action.¹³ Moreover, CMS has *expressly* approved the submission of the types of claims Relator challenges in this action.¹⁴ CMS’s interpretation of the SSA to permit Medicaid payment for off-label, non-compendia supported prescriptions and CMS’s express approval of Alaska doing so are fatal to Relator’s claim for at least three reasons.

a) The federal agency to which deference should be given in this matter—CMS—interprets the SSA the same as defendants and the State of Alaska. Relator acknowledges that in order for his complaint to stand, the court must agree with his conclusion that the SSA does not allow for Medicaid coverage of drugs prescribed for off-label uses not supported by the compendia.¹⁵ Yet for Relator to succeed, this court must conclude that CMS—the agency with responsibility to administer the federal Medicare and Medicaid programs, was wrong when it approved the Alaska State Medicaid Plan and when it specifically declined to adopt Relator’s

¹³ See Mem. in Supp. of Mot. to Dismiss under Rule 12(b)(6) (Docket 93) at 8-9.

¹⁴ See Mem. in Supp. of Mot. to Dismiss under Rule 12(b)(1) and 12(h)(3) (Docket 91) at 4 n.6.

¹⁵ See Opp. to Mot. to Dismiss (Docket 151) at 4, 12.

reading of the SSA when urged to do so by the Utah Attorney General.¹⁶ The court would also have to conclude the State of Alaska officials who drafted and submitted the Alaska State Medicaid Plan are wrong. CMS—and the State—have carefully considered the argument advanced by Relator and have rejected it.¹⁷ This court should do likewise.

b) Relator can point to nothing indicating that, despite CMS’s and the State’s interpretation of the SSA that allows for payment of the claims at issue here, the State Medicaid would have refused to pay, and the CMS would have refused to reimburse, the claims at issue in this case. Obviously, both CMS and the State have been aware of the reading Relator gives the SSA for some time¹⁸ and have not changed their claims-paying practices. It follows that nothing said, or impliedly certified¹⁹, by Safeway would have affected the government’s decision to pay out money.

The FCA, however, requires a material statement; that is, a statement that causes the government to make a payment it otherwise would not have.²⁰ Because the claims would have

¹⁶ See Memorandum in Support of Motion to Dismiss under Rules 12(b)(1) and 12(h)(3) (Docket 91) at 4 n.6.

¹⁷ *Id.*

¹⁸ See Mem. in Supp. of Mot. to Dismiss under Rule 12(b)(1) and 12(h)(3) (Docket 91) pp. 6-9.

¹⁹ The Ninth Circuit has recently recognized that a person may violate the FCA under the theory of “implied false certifications.” Ebeid v. Lungwitz, ___ F.3d ___; 2010 WL 3092637 (9th Cir., Aug. 9, 2010). That theory recognizes that claims for payment submitted to the government represent an implied certification of continuing adherence to the requirements for participation in the relevant government program. *Id.*, 2010 WL 3092637, at *4. However, an FCA false certification claim must still contain the four essential elements: 1) a false statement or fraudulent course of conduct; 2) made with scienter; 3) that was material, causing 4) the government to pay out money. *Id.* at *6 (citing Hentrow v. University of Phoenix, 461 F.3d 1166, 1174 (9th Cir. 2006)).

²⁰ Hentrow, 461 F.3d at 1172 (“[T]false statement must be material to the government’s decision to pay out moneys to the claimant.”); Mikes v. Straus, 247 F.2d 687, 697 (2d Cir. 2001) (“[I]t would be anomalous to find liability when the alleged noncompliance would not have influenced the government’s decision to pay.”).

been paid regardless of Relator's interpretation of the SSA, Relator has failed to identify an actionable statement under the FCA, and his complaint should be dismissed.

c) The FCA, with its treble damages and civil fines, is a punitive statute and cannot apply when a relator can point only to his own interpretation of a statutory provision that has been expressly rejected by the very agency responsible for interpreting that provision. At best for his case, Relator has established only that the relevant SSA provisions are open to more than one interpretation. Relator maintains that his interpretation of the SSA is right, and that the CMS and the State of Alaska are wrong. He believes that, if he is right, then Safeway should have known his interpretation would prevail over CMS's and the State's and this misreading should subject Safeway to the severe penalties of the FCA.

His very claim belies the FCA's application to this case. The FCA is a punitive statute providing for penalties so severe they are subject to analysis under the Excessive Fines Clause of the Eighth Amendment.²¹ To apply the FCA to a case like this would make business with the government a trek through a minefield. No one can predict when an agency might have its interpretation of the law challenged. Indeed, to apply the FCA when the government specifically authorizes payment by regulation contravenes the FCA's purpose and is manifestly unfair.

Relator's use of the FCA in this case is rather like trying to shove a round peg into a square hold. It is apparent from Relator's counsel's rhetoric in this²² and the PsychRights case²³,

²¹ United States v. Mackby, 261 F.3d 821, 831 (9th Cir. 2001) (Treble damages under the FCA, in combination with the civil penalty provisions are essentially punitive in nature and subject to Excessive Fines Clause analysis.).

²² *See* Opp. to Mot. to Dismiss (Docket 151) at 11 ("doctors are unduly swayed by drug company swag and other means of persuasion.").

²³ *See, e.g.*, Amended Complaint (Docket 107) at 5.

and from his prior suit against the State²⁴, Relator's counsel is simply trying to stop doctors from prescribing drugs he objects to. While courts have permitted plaintiff's some elasticity in applying the FCA, Relator here attempts to stretch the FCA far beyond the breaking point.

2. Relator ignores or misinterprets other, critical provisions of the SSA.

Relator persists in the fundamental error of relying on an interpretation of the SSA that would render parts of the Act superfluous, contrary to accepted rules of statutory interpretation. Relator asserts that one section of the Medicaid rebate law entirely describes and limits the "prescribed drugs" benefit and that the states may cover as "prescribed drugs" only those drugs that are "covered outpatient drugs" as defined in the rebate law. Relator simply shrugs when told that his statutory interpretation renders other provisions superfluous.

Under the SSA, "prescribed drugs" and "covered outpatient drugs" are distinct terms, and no provision equates them. Indeed, the definition of "covered outpatient drugs" in the rebate law makes it clear that "covered outpatient drugs" are merely a subset of the prescribed drugs that states may cover under their Medicaid program:

Subject to the exception in paragraph (3), the term "covered outpatient drug" means—

(A) *of those drugs which are treated as prescribed drugs* for the purposes of Section 1396(d)(a)(2) of this title, a drug which...²⁵

²⁴ See, Mem. in Support of Mot. to Dismiss Under Rules 12(b)(1) and 12(h)(3) (Docket 91) at 6-7.

²⁵ 42 U.S.C. § 1396r-8 (k)(2) (emphasis added).

This definition alone is fatal to Relator's claim.²⁶ Consistent with section (k)(2), another provision of the rebate law, § 1396r-8 (d)(1)(B), also recognizes that the states may cover prescribed medication for off-label, non-compensated uses:

A state *may* exclude or otherwise restrict coverage of a covered outpatient drug if—1) the prescribed use is not for a medically excepted indication (as defined in subsection (k)(6) of this section.²⁷

By allowing states to exclude coverage for drugs prescribed for non-compensated supported uses, the statute obviously contemplates that they will also have discretion to cover drugs covered prescribed for such uses.

Relator's contrary interpretation is based solely on its argument that the rebate statute's definition of "covered outpatient drug" in subsection 1396r-8 (k)(3)—"a drug or biological use for a medical indication which is not a medically accepted indication"²⁸—renders the provisions in subsections (k)(2) and (d)(1)(B) superfluous. In asking the court to disregard these two provisions of the SSA, Relator's argument violates the canons of statutory construction which require that statutes must be interpreted to give effect to all provisions.²⁹

3. Relator ignores the clear legislative intent of the Medicaid rebate law.

Relator claims:

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 compendium.³⁰

²⁶ See Reply in Supp. of Mot. to Dismiss under Rule 12(b)(6) (Docket 120) at 3-4.

²⁷ 42 U.S.C. § 1396r-8 (d)(1)(B) (emphasis added).

²⁸ 42 U.S.C. § 1396r-8 (k)(3).

²⁹ See, e.g., Connecticut National Bank v. Germain, 503 U.S. 249, 253-254 (1992) (noting canon of construction that statutes must be interpreted to give effect to all provisions) (citing Wood v. United States, 16 Pet. 342, 363 (1842)).

³⁰ See Opposition to Motion to Dismiss (Docket 151) at 11.

Relator provides no support for that assertion, and it is directly contrary to the Medicaid rebate law's clear legislative intent.

The rebate law was expressly intended to ensure that the poor and disabled Americans who rely on Medicaid would have the same access as wealthier Americans to the medications prescribed by their physicians. Congress acted to *expand* state Medicaid drug coverage not restrict it.³¹

Relator's interpretation would stand this legislative purpose on its head. Unlike wealthy or insured patients, Medicaid recipients would be unable to obtain medications their physicians deem necessary in their exercise of their professional judgment. It cannot be over-emphasized that Relator's argument applies not just to drugs prescribed for the psychotropic pediatric uses he finds so offensive; it extends to all off-label, non-compensated prescription of drugs, including those prescribed for cancer, orthopedic indications and many other conditions. Relator's reading of the drug rebate statute would place the Congress of the United States directly between physician and patient, a position Congress expressly eschewed.³²

4. Relator misconstrues the language in *Rost*.

Relator misconstrues quotes from the Rost decision.³³ The quoted language appears in the "Facts" section of the opinion, which the Rost court noted "are taken from the Amended

³¹ See Reply in Supp. of Mot. to Dismiss under Rule 12(b)(6) (Docket 120) at 6-8.

³² "The [Medicaid Rebate] bill would not require therapeutic substitution or in any other way alter in any way the current relationships between Medicaid beneficiaries and their physicians or their pharmacists." H. Rep. No. 881, 101st Cong., 2d Sess. at 98, reprinted in U.S. Congress and Administrative News at 2110 (Reply in Supp. of Mot. to Dismiss under Rule 12(b)(6) (Docket 120), Ex. 1).

³³ Opposition to Motion to Dismiss (Docket 151) at 8.

Complaint and treated as undisputed for purposes of this motion.”³⁴ Moreover, the drug at issue in Rost, a human growth hormone, was listed in the DRUGDEX Compendium. The parties’ dispute was whether this listing, and statements in the compendium that the use was “possibly effective,” required states to cover the use.³⁵

Rost is also factually distinct from the present case. In Rost, the defendant pharmaceutical manufacturer pleaded guilty to the expressly prohibited marketing of human growth hormone—which the FDA approved for three pediatric uses— to an adult population for non-FDA uses such as anti-aging and body mechanics, and to the expressly prohibited offering of “kickbacks” in connection with its distribution of the drug. There simply is no holding in Rost supporting Relator’s contentions.

D. Relator Has Failed to Satisfy the Heightened Pleading Requirements Under Rule 9(b).

Contrary to his assertion, Relator has failed to satisfy the heightened pleading requirements under Rule 9(b), requiring dismissal of his complaint against Safeway. Relator’s belief that he has alleged fraud with the requisite particularity is based on his incorrect assumption that the submission of claims to Medicaid for certain “drug combinations,” for which there is “no medically accepted indication,” constitute *per se* false claims. For the reasons discussed above, there is no such thing as a *per se* false claim and Relator’s identification of claims for certain “drug combinations” that were allegedly not covered by Medicaid is insufficient to state a False Claims Act violation.

³⁴ Docket 151 at 8.

³⁵ Rost, 253, F.R.D. at 12-13 (citing Rost’s Am. Compl., ¶¶ 42, 43).

Nor does Safeway's alleged knowledge of the medical indication for which certain individual drugs were prescribed rise to the level of scienter required under the False Claims Act. Simply put, Safeway cannot be "charged with knowledge as a matter of law" simply because it allegedly knew that a particular medication was prescribed for an off-label, non-compendium use; a claim that is allegedly not payable under the Medicaid scheme does not make the submission of that claim "false."³⁶ In short, Relator has not alleged—as he is required to do—any facts indicating that Safeway mislead, lied, or otherwise engaged in illegal or nefarious conduct related to any of the claims he identified.³⁷

Importantly, Relator relies solely on these baseless "*per se*" theories of liability in support of his assertion that Safeway *knowingly* submitted *false* claims to Medicaid for reimbursement. Relator has not identified any additional facts regarding Safeway's knowledge or the falsity of any claim that would support granting leave to amend in this case. Safeway simply filed claims as expressly allowed by the State's Medicaid Plan. Relator has alleged nothing more, as he must in order to state a claim. Nor, for that matter, has Relator alleged any facts sufficient to show that the prescriptions he identifies were for non-compendium, off-label indications. For these reasons, Relator's complaint should be dismissed under Rule 9(b).

III. CONCLUSION

For the foregoing reasons, Safeway respectfully requests that the Court dismiss Relator's complaint with prejudice against Safeway.

³⁶ See Safeway Mem. of Law in Supp. of Mot. to Dismiss at 14-15.

³⁷ *Id.*

CERTIFICATE OF SERVICE

On the 30th day of August, 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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