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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,	)	Case No. 3:09-cv-0080-TMB
v.	)	
OSAMU H. MATSUTANI, MD., et al.,	)	
Defendants.	)	

MEMORANDUM OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS

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I. INTRODUCTION

The Law Project for Psychiatric Rights ("PsychRights") has filed a *qui tam* lawsuit under the Federal False Claims Act ("FCA")[1] accusing numerous members of the Alaskan mental healthcare community of "defrauding" the Alaska Medicaid program and the Children's Health Insurance Program ("CHIP") by submitting or causing to be submitted claims for reimbursement for psychiatric medications prescribed to minors in need. The complaint, which reads more like a polemic against the pharmaceutical industry than a fraud case against Alaskan healthcare providers, does almost nothing to illuminate what PsychRights believes the Defendants have done to warrant being sued under the FCA. Because the complaint contains no particularized allegations of fraud against the Defendants as required by Federal Rule of Civil Procedure 9(b), and because PsychRights cannot cure the deficiencies in its complaint, the Court should dismiss the complaint with prejudice.

II. CASE OVERVIEW

A. Procedural History

PsychRights filed this lawsuit in April 2009, naming as defendants an array of Alaska hospitals, psychiatrists, community mental health centers, state officials, national

[1] The FCA permits private persons (known as "relators") to file a *qui tam* action against, and recover damages on behalf of the United States from, any person who: (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government. 31 U.S.C. § 3729(a)(1)-(2).

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pharmacy retailers, and a pharmaceutical data publisher (collectively, "Defendants"). [Para. 7, 10-41] PsychRights is an Alaska non-profit public interest law firm whose stated "mission" is "to mount a strategic litigation campaign in the United States against psychiatric drugging and electroshocking people against their will." [Para. 9]

After this case was filed under seal in accordance with the FCA's requirements, the Attorney General – without contacting any of the Defendants – rapidly declined to intervene in the matter.[2] On January 22, 2010, the case was unsealed and was served on at least some of the Defendants shortly thereafter.

B. The Defendants

The thirty-two Defendants represent the spectrum of the mental healthcare delivery system in Alaska: fourteen individual physicians, numerous community outpatient behavioral health clinics and youth centers, residential treatment facilities and hospitals, Alaska's largest hospital and healthcare system, three major retailers providing pharmacy services, an international data publishing company, and a few Alaska state officials. [Para. 10–41] Improbably, PsychRight's core allegation is that this diverse and voluminous (but almost entirely unrelated) group of Defendants contemporaneously defrauded the Medicaid and CHIP programs. As discussed below, PsychRights's accusation is made without alleging any specific facts regarding the circumstances of the alleged fraud or any individual Defendant's actual participation in the scheme.

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[2] *See* 31 U.S.C. § 3730(b)(4).

C. The Complaint

A significant portion of the 209-paragraph complaint details what PsychRights contends is a vast conspiracy by unidentified members of the pharmaceutical manufacturing industry— a group noticeably absent from the long list of defendants[3]—to (i) obtain unjustified FDA approval for unidentified psychiatric medications, (ii) improperly influence unidentified prescribers in unspecified ways to prescribe these drugs to, or misdiagnose, unidentified patients, and (iii) encourage the use of such medicines for unspecified non-approved ("off-label") purposes. [Para. 40-84] The complaint also alleges that psychiatric medications are not sufficiently studied in children, should not be used in children, and are over-used in children. [Para. 85 - 163]

The complaint contains no specific allegations that any Defendant engaged in these activities, nor any explanation as to why the "facts" alleged are relevant to an FCA claim against any of the Defendants. More important for this motion, the complaint also does not identify specifically any claims submitted, or caused to be submitted, by any of the Defendants, despite its central allegation that the Defendants violated the FCA by submitting, or causing to be submitted, false claims for non-reimbursable, off-label psychiatric drugs. Indeed, the complaint is entirely devoid of specification as to the time, place, or manner of any alleged fraud or false claim submission by or on behalf of any of the Defendants.

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[3] Their absence is all the more striking given that the allegations of fraud directly attack, though largely do not identify, those companies. *See* Complaint, Para. 178-180, 199 (alleging that improper manufacturer activities "render false" the claims for reimbursement for prescriptions of the manufacturers' drugs).

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The Defendants themselves are not mentioned or referenced at all in the vast majority of allegations. [Para. 1-6, 8-9, 42-172, 174-187, 203-204] In the few instances where a Defendant is mentioned (for most, just twice), the Defendant's participation in the alleged fraud is stated only in the most conclusory and formulaic of fashions, with rote recitals of the FCA's statutory elements.[4]

As one emblematic example, Defendant Anchorage Community Mental Health Services, Inc. ("ACMHS"), a community mental health center, is alleged to have "submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth." [Para. 9] Later, the complaint contains a conclusory allegation that ACMHS has caused such claims to be submitted for reimbursement of prescriptions which "are not for an indication that is approved by the FDA or supported by one or more of the Compendia." [Para. 196] That is the sum total of the allegations against ACMHS. The complaint includes no particularized facts or details explaining the basis for this allegation. Specifically, the complaint fails to identify any patient(s) treated by ACMHS, the prescribed drug(s) used to treat the patient(s), the allegedly off-label use or "indication" for which these drug(s) were supposedly prescribed, or any details whatsoever as to the persons involved, when the claims were submitted, or what about the claims was false or inaccurate. In short, the complaint contains none of the "who, what, when, where and

[4] One Defendant, Dr. Curtiss, is not even alleged to have participated in any of the alleged fraudulent activity. She is described in Paragraph 32, but not mentioned again in the Complaint or included among the defined "Prescribers" in Counts 6 and 7. [Para. 197–199]

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how" of the ACMHS's allegedly "fraudulent" activity, as required by Rule 9(b). The allegations relative to the remaining Defendants are equally lacking in detail, generally grouping the unrelated Defendants together and alleging that they submitted, caused or authorized the submission of uncovered or false claims.[5]

D. The False Claims Act

The FCA[6] was enacted in 1863 to address widespread fraud during the Civil War.[7] The purpose was pecuniary—to "protect the funds and property of the Government from fraudulent claims."[8] The FCA "prohibits persons from knowingly presenting a false or fraudulent claim for payment or approval by the federal government."[9] However, it is

[5] Somewhat different, though not material, allegations are made regarding Defendants the Complaint identifies as "Prescribers" and the publisher Thomson Reuters. The thirteen individual "Prescribers" are lumped together and their conduct is generally described in the same formulaic manner as the other Defendants [Para. 197]. Then they are collectively accused of having made unspecified false statements under unspecified circumstances for unidentified pediatric patients to justify prescribing unidentified drugs [Para. 198], and prescribing SSRI anti-depressants and Risperdal under unspecified circumstances to unidentified patients for unidentified indications, allegedly knowing that the FDA approval or Compendia listings for the drugs were falsely procured by unnamed manufacturers. [Para. 200, 202] Thomson Reuters is alleged to have conducted unspecified seminars sponsored by unidentified drug manufacturers that made unidentified false statements that promoted unidentified off-label uses of unidentified drugs [Para. 193], and otherwise made unidentified false statements concerning the indications for the unspecified drugs in its DrugDex publication. [Para. 194–195]. There are no factual allegations that Thomson Reuters made any statement that it knew to be false about any drug.

[6] 31 U.S.C. §§ 3729-33.

[7] *R.S. Rainwater, et al. v. United States*, 356 U.S. 590, 592 (1958).

[8] *Id.*

[9] *Pfingston v. Ronan Eng'g Co.*, 284 F.3d 999, 1002-03 (9th Cir. 2002).

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not an "all-purpose anti-fraud statute."[10] Congress enacted the FCA to incentivize whistle-blowers with inside information to protect the financial interests of the United States, not to afford plaintiffs an opportunity to pursue a "less pecuniary and more expansive social agenda."[11]

PsychRights's social agenda is the very point of this litigation. The complaint states that the mission of PsychRights "is to mount a strategic litigation campaign in the United States against psychiatric drugging and electroshocking people against their will," and that "PyschRights has made a priority the massive, mostly ineffective, and extremely harmful over-drugging of children and youth with psychiatric drugs." [Para. 9] Further, the Complaint takes express issue not with the barely-mentioned conduct of the Defendants, but with the statutory and regulatory framework governing testing, labeling, marketing, and prescribing drugs for children in the United States, i.e., the "[m]ainstream health practice [which] endorses a 'medical model' of mental illness that supports medicating children and youth with little or no evidence of the drugs' safety or efficacy." [Para. 46-66, 85]

The Complaint is, in sum, not a vindication of the pecuniary rights of the United States, but a vehicle for PsychRights's attack on the mainstream practice of medicine and the statutory and regulatory framework that governs it. A federal district court recently dismissed just such a case, involving an attack on the use of animals in medical research.

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10 *Allison Engine Co., Inc. v. United States ex rel. Sanders*, 553 U.S. 662, 128 S.Ct. 2123, 2130 (2008).

11 *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 464-65 (S.D.N.Y. 2002).

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The court held that "[t]he purpose of the False Claims Act is to remedy fraud against the government, not to provide a vehicle for relators to pursue their own agenda."[12] Likewise here, the Court should dismiss this complaint with prejudice.

III. ARGUMENT

A. FCA Allegations Must Satisfy Rule 9(b)'s Heightened Pleading Requirements.

Rule 9(b) requires a plaintiff alleging fraud to: "1) specify the statements that the plaintiff contends were fraudulent; 2) identify the speaker; 3) state where and when the statements were made; and 4) explain why the statements were fraudulent."[13] In other words, as the Ninth Circuit has explained, "[a]verments of fraud must be accompanied by 'the who, what, when, where, and how' of the misconduct charged."[14] Thus, "mere conclusory allegations of fraud are insufficient."[15] Beyond pleading facts of time, place, and nature of the alleged fraud, a plaintiff must also explain "what is false or misleading about a statement and why it is false."[16]

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12 *United States ex rel. Haight v. Catholic Healthcare West, et al.*, 2008 WL 607150, at *1 (D. Ariz. Feb. 29, 2008).

13 *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004).

14 *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003) (citing *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997)). *See also United States ex rel. Hopper v. Solvay Pharm.*, 588 F.3d 1318, 1325-28 (11th Cir. 2009) (dismissing case involving off-label drug promotion where relator failed to plead the particulars of who, what, where, when and why of any given claim); *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.") (internal quotation marks and citations omitted).

15 *Moore v. Kayport Package Exp., Inc.*, 885 F.2d 531, 540 (9th Cir. 1989).

16 *In re Glenfed, Inc. Sec. Litig.*, 42 F.3d 1541, 1547-48 (9th Cir. 1994).

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It is settled that Rule 9(b) applies to FCA allegations.[17] Critically, the Ninth Circuit has held that knowing falsity under the FCA "does not mean 'scientifically untrue'; it means 'a lie.'"[18] Thus, a plaintiff asserting an FCA claim must set forth the alleged details supporting its allegations of such deceitful conduct with the particularity required by Rule 9(b).[19]

In an FCA case, the relator must also specify why the false statement is material to the payment decision of the government.[20] A violation of laws or regulations alone does

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17 *See United States ex rel. Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001).

18 *Wang v. FMC Corp.*, 975 F.2d 1412, 1420-21 (9th Cir. 1992) (relator's surviving claims were properly dismissed as "[t]he [FCA] is concerned with ferreting out 'wrongdoing,' not scientific errors . . . . What is false as a matter of science is not, by that very fact, wrong as a matter of morals. The Act would not put either Ptolemy or Copernicus on trial.").

19 *See, e.g., Morton v. A Plus Benefits, Inc.*, No. 04-4148, 2005 WL 1672221, at *3 (10th Cir. July 19, 2005) (affirming dismissal of complaint because relators failed to allege a false or fraudulent claim, which "is a common requirement of all three subsections of § 3729(a)," the court explained that "[a]t a minimum the FCA requires proof of an objective falsehood . . . . Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false") (internal citations and quotations omitted); *Haas v. Gutierrez*, No. 07 CV 3623(GBD), 2008 WL 2566634 at *4 (S.D.N.Y. June 26, 2008) (dismissing complaint with prejudice for failure to state a claim, court held that purported errors based on scientific judgments or flawed reasoning are not false for purposes of the FCA.); *U.S. ex rel. Prevenslik v. University of Washington*, No. Civ.A. MJG-02-80, 2003 WL 23573424 at *4 (D. Md. June 20, 2003)(granting defendants' joint motion to dismiss with prejudice)("Even assuming that Relator is correct and Defendants are incorrect in their respective theories concerning bubble temperature, courts have held that such 'scientific errors' are not proper subjects of FCA suits."); *U.S. v. Caci Int'l Inc.*, No. 96 CIV. 7827(RWS), 1997 WL 473549 at *12 (S.D.N.Y Aug. 18, 1997)(granting defendants' motions to dismiss for failure to state a claim under the FCA because complaint alleged "extreme incompetence rather than falsity").

20 *United States v. Bourseau*, 531 F.3d 1159, 1170-71 (9th Cir. 2008).

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not create a cause of action under the FCA, and so simply alleging that a provider has submitted claims that violate legal or regulatory prohibitions (*i.e.*, are not covered by public payment programs) is insufficient.[21]

The Ninth Circuit has held that, in order to satisfy 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."[22] Other courts have likewise described the heightened pleading requirements applicable to FCA actions. For example, in an often cited opinion, the First Circuit stated:

> [A] relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However . . . we believe that some of

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[21] *Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996); *see also United States ex rel. Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) ("a claim for reimbursement made to the government is not legally false simply because the particular service furnished failed to comply with the mandates of a statute, regulation or contractual term"); *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002), *cert. denied*, 537 U.S. 11.5 (2003) (dismissing complaint under Rule 9(b) because, among other reasons, the FCA does not create liability for mere violations of government regulations).

[22] *Neubronner v. Milken*, 6 F.3d 666, 672 (9th Cir. 1993) (emphasis added).

this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).[23]

The *sine qua non* of FCA liability is the presentation of a claim that is false.[24] As such, courts have consistently held that a complaint alleging FCA violations must, at the very least, identify the false claims actually submitted to the government.[25] As a federal district court recently explained, "a relator cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted."[26] As discussed below, PsychRight's complaint—while detailed as to its poor opinion of the pharmaceutical industry—does not identity a single claim submitted by any Defendant that was allegedly

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[23] *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232-33 (1st Cir. 2004) (internal citations and quotations omitted) (emphasis added).

[24] *Clausen*, 290 F.3d at 1310; *see also id. at* 1311–12 ("[I]f Rule 9(b) is to be adhered to, some indicia of reliability must be given to support the allegation of *an actual false claim* for payment being made to the Government.") (emphasis in original).

[25] *See United States ex rel. Aflatooni v. Kitsap Physicians Serv.*, 314 F.3d 995, 997 (9th Cir. 2002) ("It seems to be a fairly obvious notion that a False Claims suit ought to require a false claim."). *See also Hopper v. Solvay Pharm.*, 588 F.3d at 1326 (failure to identify the allegedly off-label prescription drug claims by date, time and amount); *United States ex rel. Garst v. Lockheed-Martin Corp.*, 328 F.3d 374, 376 (7th Cir. 2003), *cert. denied*, 540 U.S. 968 (2003), *and reh'g denied*, 540 U.S. 1097 (2003) (affirming dismissal under 9(b) where the complaint failed to identify a false statement made to obtain payment); *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 564 (6th Cir. 2003) ("The failure to identify specific parties, contracts, or fraudulent acts requires dismissal."); *United States ex rel. Butler v. Magellan Health Serv., Inc.*, 101 F. Supp. 2d 1365, 1369 (M.D. Fla. 2000) ("Plaintiff does plead a fraudulent scheme of conduct which may well be prohibited by law. However, Plaintiff pleads no specific occurrences of a false claim. . . . [T]he absence of specific allegations of fraudulent false claims is determinative.").

[26] *United States ex rel. Polansky v. Pfizer, Inc*, 2009 WL 1456582, at *5 (E.D.N.Y. May 22, 2009) (citing *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 731 (1st Cir. 2007)). *See also United States ex rel. Sikkenga v. Regence Bluecross of Utah*, 472 F.3d 702, 727 (10th Cir. 2006); *Karvelas*, 360 F.3d at 232; *Clausen*, 290 F.3d at 1311.

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false, much less any of the required circumstances of such claims that would provide a basis to allege fraud.

B. PsychRight's Vague, Conclusory Claims Fail To Satisfy Rule 9(b)'s Heightened Pleading Requirements.

1. The Complaint Fails To Differentiate Among Defendants.

To satisfy Rule 9(b), a complaint alleging fraud must differentiate among the defendants, identifying each defendant's specific role in the alleged fraud.[27] PsychRights's 46-page complaint, however, pays almost no attention to the actual conduct of any Defendant. Again, ACMHS, as an example, is mentioned in exactly two paragraphs. In Paragraph 22, ACMHS is identified as a non-profit corporation doing business in Alaska. As with each of the thirty-one other defendants, the paragraph then makes the rote assertion that ACMHS "submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth." [*Id*.] ACMHS is not mentioned again until paragraph 196, where PsychRights—in a single sentence—lumps together its claim against ACMHS and eight other unrelated defendants by merely parroting the language of the FCA. [*Id*. at 196]

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[27] *See United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 192 (5th Cir. 2009) (complaint failed to allege hospital-physician conspiracy to submit false claims as there was no specification as to hospital's actions, intent or vicarious liability); *United States ex rel. Grynberg v. Alaska Pipeline Co.*, 1997 U.S. Dist. LEXIS 5221, at * 13 (D.D.C. March 27, 1997) (relator had "fir[ed] out more than ten accusations at seventy defendants, hoping that some accusations stick on some defendants").

Nowhere in the remaining 208 paragraphs, however, does PsychRights provide a single detail of the "who, what, when and where" of these alleged activities for ACMHS – or, likewise, for any other Defendant. Instead, PsychRights "indiscriminately group[s] all of the individual defendants into [a] wrongdoing monolith," a practice clearly prohibited by Rule 9(b).[28]

2. The Undifferentiated Allegations Lack Particulars of the Alleged Fraud.

In addition to failing to distinguish among the Defendants, PsychRights has not identified any particularized details supporting its claims against any Defendant, much less all of the Defendants. As noted above, the sum total of PsychRights's allegations against each Defendant is generally found in two paragraphs in PsychRights's complaint, in which PsychRights summarily concludes that the Defendants knowingly submitted or caused to be submitted claims to Medicaid and/or CHIP for drugs prescribed to minors for an off-label use. Such broad, conclusory allegations are precisely the sort of unsubstantiated statements that courts routinely dismiss as insufficient under Rule 9(b).[29]

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[28] *Lubin v. Sybedon Corp.*, 688 F. Supp. 1425, 1443 (S.D. Cal. 1988).

[29] *See, e.g.*, *Bly-Magee*, 236 F.3d at 1018-19 (upholding dismissal of relator's FCA complaint under Rule 9(b) where relator broadly alleged that defendant "concealed the fraudulent submission of false claims . . . to avoid repayment of funds to the United States" and conspired to "defraud the United States by obtaining payment of fraudulent claims"); *Lee*, 245 F.3d at 1051 (affirming dismissal of relator's FCA complaint under Rule 9(b) where relator conclusorily alleged that the defendant "knowingly . . . changed control numbers [on various tests] to wrongfully represent that the laboratory results fell within an acceptable standard of care" absent any supporting factual details); *Karvelas*, 360 F.3d at 232 (upholding dismissal of relator's FCA complaint under Rule 9(b) because relator failed to allege his FCA claim with sufficient particularity).

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Indeed, FCA complaints with far greater levels of detail have been held to be insufficiently particular under the pleading requirements of Rule 9(b). In *United States ex. rel. Lee v. SmithKline Beecham*, the Ninth Circuit upheld the Rule 9(b) dismissal of a complaint alleging improper Medicare billing of faulty lab tests, even though Lee's complaint alleged the following details:

> Lee alleged that when test results for control samples fell outside the acceptable standard of error, SmithKline falsified the results and made no attempt to investigate the source of the error, fix the problem, or retest the affected patient specimens. Lee alleged that because SmithKline billed Medicare for these allegedly worthless tests and falsely certified the payment requests that it sent to the government, SmithKline had violated the FCA.[30]

Despite these details, because "Lee did not specify the types of tests implicated in the alleged fraud, identify the SmithKline employees who performed the tests, or provide the dates, times, or places the tests were conducted," his complaint was properly dismissed under Rule 9(b).[31]

Similarly, other off-label marketing FCA cases—which, unlike this case, usually name the drug manufacturers themselves as defendants—have been dismissed under Rule 9(b) for similar insufficiencies in their fraud allegations. For example, in *U.S. ex rel. West v. Ortho-McNeil Pharmaceuticals*,[32] the district court dismissed a complaint

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30 *United States ex rel Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1050 (9th Cir. 2001).

31 *Id*. (emphasis added).

32 *U.S. ex rel. West v. Ortho-McNeil Pharmaceuticals*, 2007 WL 2091185 (N.D. Ill. July 20, 2007).

alleging that improper off-label marketing practices caused the submission of false claims but did not identify any facts supporting the general alleged scheme:

> With respect to the sales representatives' allegedly false statements to doctors, West does not identify which sales representatives made the statements, when they made them, to which doctors they made them or how they communicated them. Nor does West identify which executives at Ortho-McNeil told sales representatives to make these false statements. At best, West describes the general subject of the alleged misrepresentations, and the general category of individuals who made them. Such generalized allegations are insufficient….[33]

Here, of course, PsychRights alleges far less than the relators in *Lee* and *West*. Indeed, it has not asserted a single fact particularized to any Defendant regarding the "who, what, when and where" of their respective supposed fraud. Instead, it relies entirely on conclusory allegations with no factual support or specification whatsoever.[34] As a matter of law, the complaint "is not specific enough to give [the Defendants] notice of the particular misconduct which is alleged to constitute the fraud charged so that [each] can defend against the charge and not just deny that [it has] done anything wrong."[35]

Rule 9(b)'s heightened pleadings requirements serve an important purpose. The relator must set forth allegations which are "specific enough to give defendants notice of

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[33] *Id*. (emphasis added). *See also United States ex rel. Poteet v. Lenke*, 604 F. Supp. 2d 313, 324 (D. Mass. 2009) (complaint lacked linkage between general allegations of kickbacks to promote off-label use and specification of the filing of false claims with the government).

[34] Even the chart reproduced as paragraph 203 provides no details of the alleged fraud perpetrated by any Defendant. For example, the Medicaid claims tallied in the chart are not alleged to be connected to the Defendants, nor is there any specification of off-label use or the ages of the patients for whom the medications were prescribed.

[35] *Lee*, 245 F.3d at 1050 (*quoting Neubronner*, 6 F.3d at 671).

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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."[36] Because PsychRights has failed to satisfy this threshold requirement, the complaint must be dismissed.

C. Rule 9(b) Pleading Requirement Must be Satisfied Before Discovery.

An FCA relator is not entitled to conduct discovery in order to cure Rule 9(b) deficiencies. As the Ninth Circuit explained:

> Rule 9(b) serves not only to give notice to defendants of the specific fraudulent conduct against which they must defend, but also "to deter the filing of complaints as a pretext for the discovery of unknown wrongs, to protect [defendants] from the harm that comes from being subject to fraud charges, and to prohibit plaintiffs from unilaterally imposing upon the court, the parties and society enormous social and economic costs absent some factual basis."[37]

Allowing discovery prior to satisfying Rule 9(b) would allow plaintiffs to "set off on a long and expensive discovery process in the hope of uncovering some sort of wrongdoing."[38] Thus, "in the absence of reliable allegations indicating that particulars of fraudulent claims exist . . . [plaintiffs are] not entitled to receive a 'ticket to the discovery process' in order to meet Rule 9(b)'s particularity requirement."[39]

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36 *Neubronner*, 6 F.3d at 672.

37 *Bly-Magee*, 236 F.3d at 1018 (quoting *In re Stac Elec. Sec. Litig.*, 89 F.3d 1399, 1405 (9th Cir. 1996)).

38 *Decker v. Massey-Ferguson, Ltd.*, 681 F.2d 111, 116 (2d Cir. 1982).

39 *United States ex rel. Lusby v. Rolls-Royce Corp.*, 2007 U.S. Dist. LEXIS 94144 at *21 (S.D. Ind. 2007) (quoting *United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 308 (5th Cir. 1999); *see also United States. ex rel. Stinson, Lyons & Bustamante, P.A., v. Blue Cross Blue Shield of Ga.*, 755 F. Supp. 1040, 1051 (S.D. Ga. 1990) (staying discovery in FCA case pending compliance with Rule 9(b)).

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PsychRights has already announced that it intends to use discovery to attempt to obtain the information that it so clearly lacks under Rule 9(b) standards. In its February 22, 2010, Rule 26(f) conference memorandum, it stated:

> PsychRights contemplates the three main subjects of discovery by PsychRights will pertain to (a) damages, which will primarily involve discovery of the claims presented or caused to be presented to Medicaid for reimbursement of psychiatric drug prescriptions to children and youth by the defendants that were not for medically accepted indications, (b) participation in the fraudulent scheme including (i) contacts and contracts with drug companies and their representatives, (ii) compensation from drug companies, such as, without limiting its generality, for giving presentations, (iii) continuing medical education programs, who paid for them, participants, and the content of such programs, and (c) discovery that may be necessary to address prospective motions to dismiss.[40]

Of course, PsychRights would not need to conduct such discovery if it could comply with Rule 9(b)'s threshold pleading requirement, which it cannot. Courts consistently reject such discovery attempts as "fishing expeditions" that thwart Rule 9(b)'s "purposes of, *inter alia*, preventing conclusory allegations of fraud from serving as a basis for strike suits and fishing expeditions, and protecting defendants from groundless charges that may damage their reputations."[41]

D. The Complaint Should Be Dismissed With Prejudice Because Amendment Is Futile.

False Claims Act dismissals under Rule 9(b) are legion,[42] and this complaint is plainly far worse than most that are dismissed. PsychRights has merely compiled

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40 Exhibit A, p. 16.

41 *United States ex rel. Smith v. Yale Univ.*, 415 F. Supp. 2d 58,, 88 (D. Conn. 2006).

42 *See generally* John Boese, Civil False Claims and Qui Tam Actions 3rd Ed. § 5.04[B] (Vol. 2, Aspen 2010-1 suppl.) (listing hundreds of examples of FCA cases dismissed on Rule 9(b) grounds).

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publicly-available data, the names of mental health providers and pharmacy retailers, and certain excerpts from the False Claims Act into a 209-paragraph complaint.[43]

The manifest lack of any claim information or any particularized allegations regarding the individual Defendants is not surprising, though, given that PsychRights is a public interest law firm rather than an insider or whistleblower with actual information about any of the Defendants and their connection to the submission of claims to the government. Given this reality, and the representations PsychRights has already made to the Defendants in its Rule 26(f) submission[44] and to the government regarding its limited knowledge of Defendants' operations,[45] it is clear that PsychRights has no additional

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[43] The vagueness of the complaint and the fact that it derives much or perhaps all of its allegations from publicly-available information makes it extremely difficult for the Court to satisfy itself that it even has subject matter jurisdiction under the FCA's "public disclosure" bar, which provides:

> No court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.

31 U.S.C. § 3730(b)(4)(A). The Defendants, however, anticipate challenging the Court's subject matter jurisdiction.

[44] *See* note 38, *supra*.

[45] Depending on the Court's determination regarding the status of certain court documents that are currently under seal, Defendants may provide the Court with additional information in their Reply brief in support of their argument that amendment would be futile. Regardless, the Court has access to such memoranda and representations without the quotation of them here. [Dkt. 3-2]

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facts to support its fraud claim. Therefore, amendment of the complaint would be futile.[46]

IV. CONCLUSION

At most, the complaint states plaintiff's counsel's grievance with the pharmaceutical industry for alleged improper marketing practices. It does not, though, state a claim against any of the named Defendants. Because the complaint manifestly lacks the required degree of specificity under Rule 9(b), and PsychRights cannot cure that deficiency, the Court should dismiss the complaint with prejudice.

Dated in Anchorage, Alaska this 30th day of March, 2010.

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[46] Fed. R. Civ. P. 15(a); *Eminence Capital v. Aspeon, Inc.*, 316 F.3d 1048, 1052 (9th Cir. 2003) (leave to amend should be granted unless complaint cannot be saved by amendment). *See also United States ex rel Gale v. Raytheon Co.*, 2009 WL 3378976 (S.D. Cal. Oct. 19, 2009) (FCA complaint dismissed with prejudice based upon futility of amendment under Rule 9(b)); *United States ex rel. Phipps v. Comprehensive Comm. Dev. Corp.*, 152 F. Supp. 2d 443, 455 (S.D.N.Y. 2001) (dismissing with prejudice in part because relator "has not proffered any evidence to suggest that she could even cure the Rule 9(b) deficiencies in her complaint").

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CERTIFICATE OF SERVICE
I hereby certify that on March 30, 2010, a true and correct copy of the Memorandum of All Defendants in Support of Rule 9(b) Motion to Dismiss was served electronically on all parties of record.

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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

PSYCHRIGHTS' RULE 26(f) CONFERENCE MEMORANDUM

Table of Contents

A. CLAIMS

(1) Reimbursement Under Medicaid Is Restricted to Medically Accepted Indications

The fundamental basis for False Claims Act liability under the Complaint is Congress limited Medicaid reimbursement for outpatient prescriptions to those that are for a "medically accepted indication." A claim made to Medicaid which is not for a medically accepted indication is therefore a false claim *per se*.

This was recognized in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass 2008) where the Court held:

> 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). . . . Further, each prospective Medicaid provider must agree that he will comply with all Medicaid requirements

Similarly, in *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d 39, 44,45 (D.Mass 2001), the Court held:

> Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program. Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." Id. § 1396r-8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. Id. § 1396r-8(k)(6). See also id. § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

(footnote omitted)

PsychRights has developed a chart of medically accepted indications for common psychiatric drugs prescribed to children and youth and invites the parties to correct any mistakes that might be contained in it. Because DRUGDEX is universally acknowledged as the most expansive of the compendia, the Medically Accepted Indications Chart is based on DRUGDEX. PsychRights has both the 2009 and 2010 versions of the American Hospital Formulary Service (AHFS) compendium, which confirms this conclusion.[1]

There can no doubt be an argument around the edges about whether certain indications are "supported" in a compendium. For example, the Medically Accepted Indications Chart takes the position that only DRUGDEX Strength of Recommendation Classes I & IIa constitute support. It can be theoretically argued that at least some of Class IIb ("The given test, or treatment may be useful, and is indicated in some, but not most, cases") indications might be considered "supported," but in order to do so, one must demonstrate in which minority of cases such a use is indicated. A review of the DRUGDEX monographs for the included drugs do not appear, as a general matter, to provide any basis for making such a determination. Thus, it is hard to see how IIb Strength of Recommendations can be considered support for the drugs in question.

The Government's Statement of Interest in *Rost* has a discussion of when a citation in a compendia constitutes "support," which is incorporated into ¶167 of the Complaint:

[1] PsychRights believes after inquiry that the United States Pharmacopeia-Drug Information (or its successor publications), is no longer being published.

> Whether a particular use is supported by a compendium depends on a variety of factors, including the type of drug and indication at issue, the compendium's assessment of the drug's efficacy in treating the indication, the content of the compendium citation, and the scope and outcome of the studies as described in the compendium

However, even in the unlikely event all of the IIb recommendations were accepted by the 9th Circuit as "support," an extremely high percentage of the prescriptions for psychotropic drugs used on children and youth and presented or caused to be presented by the defendants in this action to Medicaid during the relevant period are fraudulent.

(2) Knowledge

Under the False Claims Act, in order for liability to be established, the defendant must have "knowingly," presented or caused the presentation of false claims. Knowingly, is broadly defined to include (i) actual knowledge; (ii) deliberate ignorance of the truth or falsity; or (iii) reckless disregard of the truth or falsity, and no proof of intent to defraud is required. 31 U.S.C. §3729(b)(1)(a).

U.S. v. Mackby, 261 F.3d 821, 828 (9th Cir. 2001) made clear that all Medicaid, participants are required to know its requirements and thus have the requisite knowledge for liability purposes:

> "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 requirements does not shield him from liability. By failing to inform himself of those requirements, particularly when twenty percent of Asher Clinic's patients were Medicare beneficiaries, 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.

(3) Public Disclosure Bar

Currently, the non-public transactions forming the basis of the complaint are contained in paragraph 203 of the Complaint, which were obtained through an Alaska Freedom of Information Act request. Under *United States v. Catholic Healthcare West*, 445 F.3d 1147, 1156 (9th Cir. 2006), this is not a disqualifying public disclosure:

> We hold that whether a document obtained via FOIA request should invoke the jurisdictional bar should be determined by reference to the nature of that document itself. If the document obtained via FOIA request is a public disclosure of a "criminal, civil, or administrative hearing, ... a congressional, administrative, or [General] Accounting Office report, hearing, audit, or investigation, or [is] from the news media," then the jurisdictional bar is applicable. If, as was the case here, the document obtained via FOIA does not itself qualify as an enumerated source, its disclosure in response to the FOIA request does not make it so.

In fact, no state FOIA response is a disqualifying public disclosure under *Catholic Healthcare*.

(4) Particularity

Complaints under the False Claims Act must meet the particularity requirement of F.R.C.P. 9(b). *Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir. 2001). The requirement is described as follows in *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997):

> We hold that the complaint meets the particularity requirement of Rule 9(b). Overall, the complaint " 'identifies the circumstances of the alleged fraud so that defendants can prepare an adequate answer.' "

U.S. ex rel. Lee v. SmithKline Beecham, Inc., 245 F.3d 1048, 1051-52 (9th Cir. 2001):

> Rule 9(b) may not require Lee to allege, in detail, all facts supporting each and every instance of false testing over a multi-year period. See *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997) (Where complaint asserting claims of improper revenue recognition identified (i) some of the specific customers defrauded, (ii) the type of conduct at issue, (iii) the general time frame in which the conduct occurred, and (iv) why the conduct was fraudulent, it was "not fatal to the complaint that it [did] not describe in detail a single specific transaction ... by customer, amount, and precise method.").

The Government's Statement of Interest in *Rost* also discusses the particularity requirement:

> [T]he identification of specific false claims is not an absolute prerequisite to satisfying the particularity requirement of Rule 9(b) in FCA cases. So long as the complaint as a whole is sufficiently particular to strengthen the inference of fraud beyond possibility, a court may conclude, as this one has in other cases, that Rule 9(b) is satisfied.

The Complaint in this case more than meets the particularity requirement under F.R.C.P. 9(b). Most particularly, the Complaint alleges that the defendants presented or caused to be presented claims to Medicaid that were not for medically accepted indications and identifies thousands of such prescriptions in Alaska alone. The Complaint also describes the broader fraudulent scheme in which the specific defendants were participants, whether wittingly so or not.

These allegations are certainly sufficient to allow the defendants to prepare an adequate answer. Either they did or did not present or cause to be presented claims to

Medicaid for prescriptions during the relevant period (since April 27, 2003) that were not for "medically accepted indications." It is very simple. All of the defendants did, although the liability of Thomson Reuters (HealthCare) derives from a more indirect causing of the false claims of a similar nature to that which resulted in (a) Eli Lilly paying $1.4 Billion in criminal and civil fines for promoting Zyprexa's use on children and youth, among others, and (b) Pfizer paying $2.3 Billion for promoting a number of drugs for uses that were not for medically accepted indications, including Geodon for use on children and youth for which there is no medically accepted indication.

PsychRights is also prepared to identify specific prescriptions that constitute false claims in an amended complaint.[2]

(5) Damages

Under 31 U.S.C. §3729(a) each defendant is liable to the United States Government for a civil penalty of not less than $5,500 and not more than $11,000, plus 3 times the amount of damages which the Government sustains for each prescription to a child or youth that is not for a medically accepted indication that such defendant presented or caused to be presented to Medicaid.

(a) Psychiatrist Defendants

The following is a calculation of the damages due for one psychiatrist defendant's prescriptions to one patient:

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[2] In *Bly-Magee*, 236 F.3d at 1019, the 9th Circuit noted, "We consistently have held that leave to amend should be granted unless the district court "determines that the pleading could not possibly be cured by the allegation of other facts."

Date	Drug	Amount	Pharmacy
10/26/2004	Trazadone	$ 11.01	Safeway
11/9/2004	Abilify	$ 335.70	Safeway
11/19/2004	Zoloft	$ 163.49	Safeway
12/3/2004	Trazadone	$ 11.01	Safeway
12/6/2004	Zoloft	$ 163.49	Safeway
12/27/2004	Abilify	$ 171.65	Safeway
12/28/2004	Trazadone	$ 11.01	Safeway
1/11/2005	Zoloft	$ 171.38	Safeway
1/19/2005	Abilify	$ 335.00	Safeway
1/25/2005	Trazadone	$ 14.43	Safeway
2/9/2005	Zoloft	$ 179.56	Safeway
2/15/2005	Abilify	$ 335.70	Safeway
2/24/2005	Trileptal	$ 132.29	Safeway
2/26/2005	Trazadone	$ 14.43	Safeway
3/7/2005	Zoloft	$ 179.56	Safeway
3/17/2005	Abilify	$ 335.70	Safeway
3/24/2005	Trileptal	$ 194.65	Safeway
4/7/2005	Trazadone	$ 14.43	Safeway
4/18/2005	Abilify	$ 335.70	Safeway
4/23/2005	Trileptal	$ 198.99	Safeway
5/10/2005	Trazadone	$ 14.43	Safeway
5/10/2005	Zoloft	$ 179.56	Safeway
5/16/2005	Abilify	$ 335.70	Safeway
5/21/2005	Trileptal	$ 210.55	Safeway
6/8/2005	Trazadone	$ 12.56	Prescription Ctr.
6/8/2005	Zoloft	$ 181.11	Prescription Ctr.
6/20/2005	Abilify	$ 335.70	Safeway
7/5/2005	Trileptal	$ 210.55	Safeway
7/18/2005	Zoloft	$ 179.56	Safeway
7/26/2005	Abilify	$ 335.70	Safeway
8/9/2005	Zoloft	$ 179.56	Safeway
8/19/2005	Trileptal	$ 210.55	Safeway
8/20/2005	Trazadone	$ 14.43	Safeway
8/31/2005	Abilify	$ 350.45	Safeway
9/19/2005	Trazadone	$ 11.01	Safeway
9/19/2005	Trileptal	$ 210.55	Safeway
9/19/2005	Zoloft	$ 179.56	Safeway
9/29/2005	Abilify	$ 350.45	Safeway

10/19/2005	Trazadone	$	11.01	Safeway
10/19/2005	Trileptal	$	210.55	Safeway
10/19/2005	Zoloft	$	179.56	Safeway
10/22/2005	Abilify	$	350.45	Safeway
Total Cost of Prescriptions		**$**	**7,562.73**	
Trebled Cost of Prescriptions		**$**	**22,688.19**	
No. of Rx times $5,500		$	231,000.00	
No. of Rx times $11,000		$	462,000.00	
Total Minimum FCA Damages		**$**	**253,688.19**	
Total Maximum FCA Damages		**$**	**484,688.19**	

Every psychiatrist defendant has had at least dozens of such patients during the relevant period, most hundreds, and some perhaps thousands. This particular patient/customer was given these prescriptions that were not for a medically accepted indication for just a year, while many patients/customers have such prescriptions for many years. The statute of limitations for this action is April 27, 2003, so at this point there is such liability for almost seven years.

(b) Provider Defendants

The same type of calculation would apply to each patient/client of the provider defendants.

(c) Pharmacy Defendants

The above type of calculation would also apply to pharmacies for every customer throughout the United States, except that in the above particular calculation, because two of the prescriptions were filled by a pharmacy other than Safeway, Safeway's total liability for the false claims it submitted for this one customer would be reduced by the damages attributable to those two prescriptions. The pharmacy defendants have at least tens of thousands of such customers nation-wide during the relevant period, more likely

hundreds of thousands, or even a million or more. Or estimated another way, each of the pharmacy defendants, with the possible exception of Fred Meyer, has no doubt presented over one million false claims for reimbursement by Medicaid for prescriptions to children and youth that were not for medically accepted indications. Using the one million false claims figure, the minimum total liability is $5.5 Billion, plus triple the cost of the prescriptions.

(d) Defendants Administering State Programs Presenting or Causing the Presentment of False Claims (Sandoval & McComb)

The same type of calculation would be involved with respect to children and youth participating in programs that are under Ms. Sandoval's and Mr. McComb's purview, which presented or caused to be presented claims for reimbursement by Medicaid of prescriptions for psychotropic drugs to children and youth that are not for medically accepted indications.[3]

(e) Defendants Approving the Presentment of False Claims (Hogan & Streur)

While the same type of calculation also applies to all claims defendants Hogan & Steuer presented or authorized to be presented to Medicaid for reimbursement, a rough order of magnitude of which can be estimated from just two classes of drugs from the State of Alaska Freedom of Information Act response as follows.

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[3] It might be noted here that since September of 2008, defendants Sandoval and McComb, as well as Hogan and Streur, have actual knowledge that such claims they were causing were false because they are defendants in *PsychRights v. Alaska*, Case No. 3AN 08-10115CI, Third Judicial District, State of Alaska, now on appeal, and ¶ 22 of the Amended complaint in that action is specifically about the Medicaid reimbursement limitation to medically accepted indications.

Dates	Anti-Convulsants Claims per Month	Anti-Convulsants Amount Per Month	2nd Generation Neuroleptics Claims per Month	2nd Generation Neuroleptics Amount Per Month
12/1/2004 to 2/28/05	1,393	$ 122,224	1,532	$ 277,746
1/1/2005 to 3/31/2005	1,402	$ 123,963	1,490	$ 285,762
5/1/2005 to 7/31/2005	1,436	$ 136,939	1,705	$ 319,725
2/1/2006 to 4/30/2006	1,240	$ 118,954	1,492	$ 272,717
3/1/2006 to 5/31/2006	1,260	$ 120,047	1,552	$ 281,919
4/1/2006 to 6/30/2006	1,210	$ 114,838	1,521	$ 272,009
5/1/2006 to 7/31/2006	1,225	$ 116,052	1,534	$ 277,940
8/1/2006 to 10/31/2006	1,252	$ 121,346	1,648	$ 284,966
11/1/2006 to 1/31/2007	1,298	$ 121,519	1,800	$ 289,540
1/1/2007 to 3/31/2007	1,259	$ 121,925	1,735	$ 288,238
4/1/2007 to 6/30/2007	1,270	$ 139,718	1,730	$ 312,815
Average	1,295	$ 123,411	1,613	$ 287,580

The State of Alaska represented to PsychRights that it had destroyed the other reports within the time frame of PsychRights' Alaska FOIA request; however there is no doubt the same pattern and rough magnitude exists for time periods before, within, and after those set forth in the above table for the relevant time period.

There is no medically accepted indications for use on children and youth for the listed anti-convulsants misbranded as "mood stabilizers," with the possible exception of short term use of valproate (Depakote) in combination with aripiprazole (Abilify) during acute phases of manic or mixed episodes of youth (10 years and older) diagnosed with Bipolar I Disorder,[4] and all but a trivial percentage of prescriptions to children and youth

[4] There appears to be an inconsistency between there being no FDA approved indication for pediatric use of valproate and its approval of Abilify as adjunctive therapy to valproate for acute manic or mixed episodes of people diagnosed with Bipolar I Disorder.

and presented to Medicaid for reimbursement of second generation neuroleptics are false, so the damages calculation for these *per se* false claims is as follows:

84 Months of Claims at $5,500 per claim	$	1,343,496,000
84 Months of Claims at $11,000 per claim	$	2,686,992,000
Treble Damages for 84 Months of Anti-Convulsants	$	31,099,572
Treble Damages for 84 Months of Neuroleptics	$	72,470,160
Total Minimum FCA Damages	**$**	**1,447,065,732**
Total Maximum FCA Damages	**$**	**2,790,561,732**

(f) THOMSON Reuters (Healthcare)

As mentioned above, THOMSON Reuters (HealthCare)'s liability derives from a more indirect causing of the false claims of the same nature which resulted in (a) Eli Lilly paying $1.4 Billion in criminal and civil fines for promoting the use of Zyprexa on children and youth, and (b) Pfizer paying $2.3 Billion for promoting a number of drugs for uses that were not for medically accepted indications, including Geodon for use on children and youth for which there is no medically accepted indication. Thus, the damage calculation for THOMSON Reuters (Healthcare) depends on how many of the false claims submitted nation-wide to Medicaid for prescriptions of psychotropic drugs to children and youth that were not for a medically accepted indication since April 27, 2003 were caused by its continuing medical education programs and false statements in DRUGDEX.

B. SETTLEMENT

The liability figures set forth above are, of course, staggering, but they are not out of line with the Eli Lilly and Pfizer settlements. Because PsychRights' objective in this litigation is to stop the harm to children and youth caused by the prescribing of

psychotropic drugs for non-medically accepted indications presented to Medicaid for reimbursement, as contrasted with obtaining the maximum monetary recovery possible, the defendants in this case have an opportunity to settle on better terms than might otherwise be obtained. At the same time, because this is an action on behalf of the Government to recover for the Medicaid Fraud perpetrated by the defendants by presenting or causing the presentment of claims for prescriptions of psychotropic drugs to children and youth that are not for medically accepted indications, the monetary recovery must be, in PsychRights' view, both reasonable and "meaningful." What is reasonable and meaningful will depend on the status of each defendant.

The key question for each defendant, is whether PsychRights is correct that Congress limited reimbursement for outpatient drugs under Medicaid to medically accepted indications. If so, and there is not really any doubt about it, is such defendant going to deliberately, and one might say defiantly, incur minimum liability in excess of $5,500 for each such prescription going forward? For those defendants for whom the decision is not, then an agreement to that effect can be entered into along with an agreement on the penalty amount under the False Claims Act.

Another thing to consider is that should PsychRights fail to prevail on various technicalities, such as whether the psychiatrist and provider defendants had the requisite level of knowledge, that PsychRights could bring a new action(s) based on false claims that were caused after such dismissal. Such amount must be both reasonable and

meaningful, keeping in mind that while the Government has no veto power, its views will be obtained before the Court will accept such a settlement.[5]

(1) Psychiatrist & Provider Defendants

It is apparent that should PsychRights prevail, all of the psychiatrist and provider defendants will be wiped out financially.

With respect to the psychiatrist defendants, what PsychRights considers a reasonable and meaningful amount will depend on the psychiatrist's culpability, net worth, and the extent to which such psychiatrist submitted false claims.

With respect to the provider defendants, for settlement purposes, PsychRights recognizes that some of them operate on a very thin working capital cushion, which will be taken into account.

With respect to both the psychiatrist and provider defendants, earlier settlers will tend to receive more favorable settlement terms than later settlers.

(2) Pharmacy Defendants and THOMSON Reuters (HealthCare)

In the 9th Circuit, under *U.S. ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715 (9th Cir. 1994), unlike in the 5th Circuit[6] and the 6th Circuit,[7] since the Government has declined intervention, it has no veto power over settlements. Particularly for the national and regional pharmacy defendants, this provides an especially good opportunity to cap their total federal liability nation-wide on more favorable terms than might otherwise be obtained for their presenting false claims to Medicaid for reimbursement of prescriptions

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[5] *See*, Docket No. 16, ¶7.
[6] *Searcy v. Philips Electronics North America Corp.*, 117 F.3d 154 (5th Cir. 1997).
[7] *U.S. v. Health Possibilities, P.S.C.*, 207 F.3d 335 (6th Cir. 2000).

of psychiatric drugs to children and youth that were not for medically accepted indications. The same is true for the false claims caused to be presented by THOMSON Reuters (Healthcare). In light of the Government's declination to intervene and PsychRights' settlement standard of reasonable and "meaningful," it seems likely that any settlement worked out between PsychRights and any defendant(s) would pass Government muster. Any such settlement must, of course, include agreeing not to present or cause the presentment of claims to Medicaid for reimbursement of prescriptions to children and youth that are not for medically accepted indications going forward.

(3) State Employee Defendants

One suspects the state employee defendants will be surprised and dismayed to learn that while the State of Alaska may be immune from False Claims Act liability under the 11th Amendment, it is clear they are personally liable.[8] To the extent the State of Alaska is indemnifying these defendants for their personal liability, maximum recovery will be sought with continuing executions against these defendants' assets contemplated. Otherwise, much the same considerations as with respect to the psychiatrist defendants will apply.

[8] *Stoner v. Santa Clara County Office of Educ.*, 502 F.3d 1116, 1122, 1123 & 1124 (9th Cir. 2007).

C. DISCOVERY PLAN

(1) What changes should be made in the timing, form, or requirement for disclosures under Rule 26(a), including a statement of when initial disclosures were made or will be made;

(a) Time for Initial Disclosures

The time for initial disclosures in F.R.C.P. 26(a)(1)(C) is acceptable to PsychRights.

(b) Indemnity Agreements

PsychRights proposes the disclosures under F.R.C.P. 26(a)(1)(A)(iv) should be expanded to include any kind of indemnity agreement, whether an insurance agreement or not.

(2) Subjects On Which Discovery May Be Needed, When Discovery Should Be Completed, And Whether Discovery Should Be Conducted In Phases Or Be Limited To Or Focused On Particular Issues;

Without limiting its right to conduct discovery as to other subjects, PsychRights contemplates the three main subjects of discovery by PsychRights will pertain to (a) damages, which will primarily involve discovery of the claims presented or caused to be presented to Medicaid for reimbursement of psychiatric drug prescriptions to children and youth by the defendants that were not for medically accepted indications, (b) participation in the fraudulent scheme including (i) contacts and contracts with drug companies and their representatives, (ii) compensation from drug companies, such as, without limiting its generality, for giving presentations, (iii) continuing medical education programs, who paid for them, participants, and the content of such programs, and (c) discovery that may be necessary to address prospective motions to dismiss.

(3) Any Issues About Disclosure Or Discovery Of Electronically Stored Information, Including The Form Or Forms In Which It Should Be Produced.

PsychRights proposes that all discovery be produced in electronic format as follows. Hard copy documents, provided in Acrobat format, which has been processed with reasonably up-to-date optical character recognition software. Data be produced in SQL database format compatible with standard Windows operating system SQL database software tools, with all fields defined, any applicable lookup tables provided, and all other information required to process, understand and interpret the data provided.

It is anticipated some of the databases will be quite large and to the extent any file won't fit on a standard DVD, PsychRights proposes that unless some other mechanism is feasible, and subject to agreement by the producing party and PsychRights to some other mechanism, that the producing party notify PsychRights of the size of the production and PsychRights provide a hard drive large enough to accommodate the production.

(4) Issues About Claims Of Privilege Or Of Protection As Trial-Preparation Materials.

It seems any such claims can be raised as they come up if they do so.

(5) What Changes Should Be Made In The Limitations On Discovery Imposed Under The Rules Or By Local Rule, And What Other Limitations Should Be Imposed

It should be made clear that the limitations on discovery imposed on Plaintiff under the F.R.C.P. or local rules, apply separately to each defendant. Otherwise, PsychRights believes the limitations contained in the F.R.C.P. or local rules are fine, subject to agreement by the affected parties or application to the Court to vary them.

The defendants should coordinate their discovery requests to eliminate duplication.

(6) Other Orders That The Court Should Issue Under Rule 26(c) Or Under Rule 16(b) And (c).

The form of Qualified HIPAA Protective Order proposed by PsychRights, or as otherwise agreed to, should be entered pursuant to Rule 26(c).

It seems to PsychRights the Court should conduct a scheduling conference for purposes of entering the Scheduling Order under F.R.C.P. 16(b).

Most importantly, it seems to PsychRights it would be beneficial to the Court, and the orderly management of the case, to enter an order under F.R.C.P. 16(b)(3)(vi) setting a schedule for filing pre-Answer motions, opposition(s) and other potential responses, such as amending the complaint, and replies.

A potential schedule could be:

- March 15, 2010--motions to dismiss and/or answers due.
- April 15, 2010--opposition(s) and amended complaint, or 30 days after the last motion to dismiss is filed, which ever is later.
- April 30, 2010-replies to opposition(s) to motions to dismiss due, or 15 days after the opposition(s) to the motions to dismiss is filed.

However, we might want to push this out a bit because not all of the defendants have been served and it appears the names of two corporate entities need to be changed and the correct entities served.

PsychRights can deal with multiple motions essentially making the same arguments, but it might be useful to the Court for there to be some consolidation of motions by different classes of defendants in order to reduce such duplication.

D. Other Scheduling and Planning Conference Report Items

(1) Expected Contested Issues of Fact and Law at Trial

PsychRights expects this case will be decided on summary judgment, with the possible exception of issue of how many false claims for psychotropic drugs prescribed to children and youth that were not for a medically accepted indication were caused by THOMSON Reuters (HealthCare).

(2) Alternative Dispute Resolution

PsychRights supports an "Early Neutral Evaluation" to the extent any defendants might elect to participate.

(3) Trial

If we try the case and all defendants are still in, PsychRights estimates it will take two days for each defendant to present its affirmative case, inclusive of 5 days of general testimony. In other words, approximately 60 trial days. To the extent that defendants settle, figure on the 5 days of general testimony, plus 2 days for each defendant, except THOMSON Reuters (HealthCare), which might take five days for PsychRights to put on its affirmative case.

We might consider suggesting the trial be broken up by defendant classes and defendants, so that the jury would separately consider the liability of each defendant.

This would be like bifurcating liability and damages, except that it would be by defendant.

More fundamentally, maybe we should suggest that trial length estimate be deferred until it may be estimated with more accuracy.

DATED: February 22, 2010.

Law Project for Psychiatric Rights

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