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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

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

OPPOSITION TO MOTION OF ALL DEFENDANTS TO DISMISS COMPLAINT PURSUANT TO RULE 9(b)

Qui tam relator Law Project for Psychiatric Rights (PsychRights®) opposes the Motion of All Defendants to Dismiss Complaint Pursuant to Rule 9(b), Dkt. No. 83 (Particularity Motion).

I. THE FIRST AMENDED COMPLAINT IDENTIFIES SPECIFIC FALSE CLAIMS FOR SOME, BUT NOT ALL DEFENDANTS

The gravamen of this action is that presenting or causing the presentment of claims to Medicaid for prescriptions of psychotropic drugs to children and youth that are

not for "medically accepted indications" constitute violations of the False Claims Act, 31 U.S.C. §3729 *et seq*.

> 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).

US ex rel Rost v. Pfizer, 253 F.R.D. 11, 13-14 (D. Mass. 2008).

The entire thrust of Defendants Particularity Motion is that PsychRights did not identify any specific false claims, i.e., specific prescriptions to children and youth for psychotropic drugs that are not for a medically accepted indication presented to and paid by Medicaid. PsychRights has since filed it First Amended Complaint, Dkt. No. 107, which identifies specific prescriptions constituting such false claims for the following defendants.

- Tammy Sandoval[1]
- Fred Meyer Stores, Inc.[2]
- Safeway, Inc.[3]
- Wal-Mart Stores, Inc.[4]
- Alternatives Community Mental Health Services, D/B/A Denali Family Services[5]
- Fairbanks Psychiatric And Neurologic Clinic, PC[6]
- Frontline Hospital, LLC, D/B/A North Star Hospital[7]
- Osamu H. Matsutani, MD[8]
- Elizabeth Baisi, M.D.[9]
- Lina Judith Bautista, M.D.[10]
- Sheila Clark, M.D.[11]

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[1] Amended Complaint, ¶s 187 & 188.
[2] Amended Complaint, ¶s 190 & 191.
[3] Amended Complaint, ¶s 192 & 193.
[4] Amended Complaint, ¶s 194 & 195.
[5] Amended Complaint, ¶s 201 & 202.
[6] Amended Complaint, ¶ 203.
[7] Amended Complaint, ¶ 204.
[8] Amended Complaint, ¶ 206.
[9] Amended Complaint, ¶ 207.
[10] Amended Complaint, ¶ 208.
[11] Amended Complaint, ¶ 209.

- Ronald Martino, M.D.[12]
- Kerry Ozer, M.D.[13]
- William Hogan[14]
- William Streur[15]

The Defendants' Particularity Motion, thus fails with respect to the above defendants.

The remaining question is whether the First Amended Complaint also meets the particularity requirement of Rule 9(b) for the other defendants. For the reasons that follow, PsychRights respectfully suggests it does.

II. THE COMPLAINT SATISFIES THE PARTICULARITY REQUIREMENT OF RULE 9(b) FOR THOSE DEFENDANTS FOR WHOM NO SPECIFIC PRESCRIPTIONS ARE IDENTIFIED

A. Rule 9(b) Particularity Standards

There are five defendants who directly presented false claims, the three pharmacy defendants, Safeway, Walmart and Fred Meyer, and the two State of Alaska officials defendants who administrator Alaska's Medicaid program, Hogan, and Streur. The First Amended Complaint identifies particular false claims for all of these defendants,[16] leaving particularity questions only as to defendants who caused false claims to be presented for whom no specific offending prescriptions are identified.

PsychRights has not found a Ninth Circuit opinion directly addressing the issue of the differing Rule 9(b) standards between those who present and those who cause the presentment of false claims, but the recent First Circuit case of *U.S. ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13, 29, (1st Cir. 2009) does:

> In applying Rule 9(b), the district court held that the rule "requires relators to 'provide details that identify particular false claims for payment that were submitted to the government.' " *Duxbury*, 551 F.Supp.2d at 114 (quoting *Rost*, 507 F.3d at 731) (emphasis added). This was error. In *Rost*,

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[12] Amended Complaint, ¶ 210.
[13] Amended Complaint, ¶ 211.
[14] Amended Complaint, ¶s 187-188, 190-195, 201-204, 206-211.
[15] *Id*.
[16] Specific offending prescriptions are also identified for ten of the other defendants.

> we noted a distinction between a qui tam action alleging that the defendant made false claims to the government, and a qui tam action in which the defendant induced third parties to file false claims with the government. 507 F.3d at 732 (noting that latter action is "in a different category" than former). In the latter context, we held that a relator could satisfy Rule 9(b) by providing "factual or statistical evidence to strengthen the inference of fraud beyond possibility" without necessarily providing details as to each false claim. *Rost*, 507 F.3d at 733; see also *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009) (holding that FCA claims under Rule 9(b) "may nevertheless survive by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted.").

Footnote omitted.

While the Ninth Circuit has not ruled on the precise issue of whether specific offending prescriptions have to be pled in False Claims Act Medicaid fraud cases, it has spoken generally on Rule 9(b)'s pleading requirement, including under the False Claims Act. In *Cooper v. Pickett*, 137 F.3d 616, 627 (9th Cir. 1997), the Court held that where a complaint "identifies the circumstances of the alleged fraud so that defendants can prepare an adequate answer" it meets the particularity requirement of Rule 9(b). In *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001), the Ninth Circuit held the following was required in a False Claims Act complaint:

> To comply with Rule 9(b), allegations of fraud must be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong."

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

B. Application of Rule 9(b) to Those Defendants For Whom the First Amended Complaint Does Not Identify Offending Prescriptions

Turning to the application of the above standard to the defendants for whom offending prescriptions have not been identified, the First Amended Complaint first

alleges ways in which drug companies have engaged in a course of conduct to induce the psychiatrist defendants to prescribe psychotropic drugs to children and youth that are not for medically accepted indications.[17]

Paragraph 166 of the First Amended Complaint then alleges the following psychotropic drugs have no medically accepted indication for use in anyone under 18 years of age:

a. Ambien (zolipidem)
b. Buspar (buspirone)
c. Celexa (citalopram)
d. Clozaril (clozapine)
e. Cymbalta (duloxetine)
f. Desyrel (trazadone)
g. Effexor (venlafaxine)
h. Geodon (ziprasidone)
i. Invega (paliperidone)
j. Limbitrol (chlordiazepoxide/amitriptyline)
k. Lunesta (eszopiclone)
l. Paxil (paroxetine)
m. Pristiq (desvenlafaxine)
n. Sonata (zaleplon)
o. Symbyax (fluoxetine hydrochloride/olanzapine)
p. Wellbutrin (bupropion)

Paragraph 167 of the First Amended Complaint alleges the following psychotropic drugs have only the following medically accepted indications for use in anyone under 18 years of age.

a. Abilify (Aripiprazole)
    (i) Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes; 10 yrs old and up
    (ii) Bipolar I Disorder, monotherapy, Manic or Mixed Episodes; 10-17 years old for acute therapy
    (iii) Schizophrenia; 13-17 years old

b. Adderall (amphetamine/dextroamphetamine)
    (i) Attention Deficit Hyperactivity Disorder (ADHD); 3 years old and up for immediate-release and 6 years old and up for extended-release
    (ii) Narcolepsy; 6 years old and up for immediate release] drug)

[17] *See*, ¶s 67-84 of the First Amended Complaint, Dkt. No. 107.

c. Anafranil (clomipramine)
   (i) Obsessive-Compulsive Disorder; 10 years and up

d. Ativan (lorazepam)
   (i) Anxiety; oral only, 12 years and older
   (ii) Chemotherapy-induced nausea and vomiting; Prophylaxis
   (iii) Insomnia, due to anxiety or situational stress
   (iv) Seizure
   (v) Status epilepticus

e. Concerta (methylphenidate)
   (i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old to 12 years old
   (ii) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old and up re ConcertaR

f. Dalmane (flurazepam)
   (i) Insomnia; 15 years and older

g. Depakote (valproic acid)
   (i) Absence Seizure, Simple and Complex and/or Complex Partial Epileptic Seizure; 10 years and older
   (ii) Complex Partial Epileptic Seizure; 10 years and older
   (iii) Seizure, Multiple sezure types; Adjunct; 10 years and older

h. Dexedrine (dextroamphetamine)
   (i) Attention Deficit Hyperactivity Disorder (ADHD); 3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release))
   (ii) Narcolepsy; 6 years old and up

i. Focalin (dexmethylphenidate)
   (i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years and older

j. Haldol (haloperidol)
   (i) Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy; 3 years old and up
   (ii) Problematic Behavior in Children (Severe), With failure to respond to non-antipsychotic medication or psychotherapy; 3 years old and up
   (iii) Psychotic Disorder; 3 years old and up but ORAL formulations only
   (iv) Schizophrenia; 3 years old and up but ORAL formulations only

k. Klonopin (clonazepam)
   (i) Seizure; up to 10 years or up to 30 kg

l. Lamictal (lamotrigine)
   (i) Convulsions in the newborn, Intractable

(ii) Epilepsy, Refractory
(iii) Lennox-Gastaut syndrome; Adjunct; yes (2 years and older)
(iv) Partial seizure, Adjunct or monotherapy; 13 years and older, extended-release only; 2 years and older, chewable dispersible
(v) Tonic-clonic seizure, Primary generalized; Adjunct; 2 years and older

m. Lexapro (escitalopram)
(i) Major Depressive Disorder; 12 years old and up

n. Luvox (fluvoxamine)
(i) Obsessive-Compulsive Disorder; 8 years old and up and immediate release formula only

o. Mellaril (thioridazine)
(i) Schizophrenia, Refractory

p. Moban (molindone) - antipsychotic, Dihydroindolone
(i) Schizophrenia; 12 years and older

q. Neurontin (gabapentin) anticonvulsant
(i) Partial seizure; Adjunct; 3-12 years old

r. Orap (pimozide)
(i) Gilles de la Tourette's syndrome; 12 years and older

s. Prozac (fluoxetine)
(i) Major Depressive Disorder; 8 years old and up
(ii) Obsessive-Compulsive Disorder; 7 years old and up

t. Ritalin (methylphenidate)
(i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years to 12 years old (extended release)
(ii) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old and up (immediate release)
(iii) Narcolepsy; 6 years and up, and Ritalin(R) -SR only

u. Risperdal (risperidone)
(i) Autistic Disorder, Irritability; 5 years old and up
(ii) Bipolar I Disorder; 10 years old and up
(iii) Schizophrenia; 13 years old and up (Orally)

v. Seroquel (quetiapine)
(i) Bipolar disorder, maintenance; 10-17 regular release only (12/4/09)
(ii) Manic bipolar I disorder; 10-17 regular release only (12/4/09)
(iii) Schizophrenia; 13-17, regular release only (12/4/09)

w. Sinequan (doxepin)
(i) Alcoholism - Anxiety - Depression; 12 years old and up
(ii) Anxiety - Depression; 12 years old and up

(iii) Anxiety - Depression - Psychoneurotic personality disorder; 12 years old and up

x. Strattera (atomoxetine)
   (i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old and up

y. Tegretol (carbamazepine)
   (i) Epilepsy, Partial, Generalized, and Mixed types

z. Tofranil (imipramine)
   (i) Nocturnal enuresis; 6 years old and up

aa. Topamax (topiramate)
   (i) Lennox-Gastaut syndrome, Adjunct; 2 years and older
   (ii) Partial seizure, Initial monotherapy; 10 years and older
   (iii) Partial seizure; Adjunct, 10 years and older
   (iv) Tonic-clonic seizure, Primary generalized; Adjunct, 2 to 16 years old
   (v) Tonic-clonic seizure, Primary generalized (initial monotherapy), 10 years and older

bb. Tranxene (clorazepate)
   (i) Partial seizure; Adjunct, 9 years and older

cc. Trileptal (oxcarbazepine)
   (i) Partial Seizure, monotherapy 4 years old and up
   (ii) Partial seizure; Adjunct, 2 years old and up

dd. Vyvanse (lisdexamfetamine)
   (i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old to 12 years

ee. Zoloft (sertraline)
   (i) Obsessive-Compulsive Disorder; 6 years old and up

ff. Zyprexa (olanzapine)
   (i) Bipolar 1, Disorder, Acute Mixed or Manic Episodes, 13-17, oral only (12/4/09)
   (ii) Schizophrenia 13-17, oral only (12/4/09).

Any prescription to a child or youth on Medicaid for a drug listed in ¶166 of the First Amended Complaint, or any prescription for a drug listed in ¶167 of the First Amended Complaint for an indication other than those listed for such drug, is a *per se* false claim.[18]

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[18] In addition, ¶168 alleges that except for an extremely limited number of psychotropic drugs, such as Abilify in combination with Lithium or valproate for manic or mixed

Finally, the First Amended Complaint alleges at ¶183 that each of the defendants presented or caused the presentment of one or more of the following Medicaid claims for reimbursement of pediatric psychotropic medications to Alaskan children and youth that were not for a medically accepted indication:

Dates	Anti-depressants	Anti-Convulsants	2nd Generation Neuroleptics
12/1/2004 to 2/28/05	4,389	4,179	4,596
1/1/2005 to 3/31/2005	4,446	4,205	4,471
5/1/2005 to 7/31/2005	4,155	4,309	5,114
2/1/2006 to 4/30/2006	3,656	3,719	4,476
3/1/2006 to 5/31/2006	3,823	3,781	4,655
4/1/2006 to 6/30/2006	3,755	3,629	4,563
5/1/2006 to 7/31/2006	3,645	3,675	4,602
8/1/2006 to 10/31/2006	3,570	3,756	4,944
11/1/2006 to 1/31/2007	3,585	3,895	5,399
1/1/2007 to 3/31/2007	3,589	3,776	5,205
4/1/2007 to 6/30/2007	3,476	3,809	5,191

Taken together, these allegations satisfy the *Duxbury* and *ex rel Grubb* formulation by alleging particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that false claims were actually submitted.

In a slightly different context, the Fifth Circuit had another observation in *ex rel Grubbs* PsychRights hopes is helpful to the Court:

> Defendants either have or do not have evidence that the alleged phony services were actually provided; they either have or do not have evidence that recorded, but unprovided or unnecessary, services did not result in bills to the Government. Discovery can be pointed and efficient, with a summary

episodes of Bipolar I disorder, polypharmacy, i.e., prescribing multiple psychotropic drugs at the same time, is not for a medically accepted indication. Such prescriptions are also *per se* false claims.

> judgment following on the heels of the complaint if billing records discredit the complaint's particularized allegations.[19]

Here, the psychiatrist defendants for whom offending prescriptions have not been identified, either have or do not have evidence that they did or did not prescribe a psychotropic drug to a Medicaid beneficiary under the age of 18 that was not for a medically accepted indication. Similarly, all of the mental health provider defendants for whom offending prescriptions have not been identified, either have or do not have evidence that none of their Medicaid clients under the age of 18 were prescribed a psychotropic drug not for a medically accepted indication. Similarly, defendant McComb either has or does not have evidence that no prescription of a psychotropic drug to a Medicaid beneficiary under the age of 18 in the custody of the Division of Juvenile Justice that was not for a medically accepted indication was presented to Medicaid. It is respectfully suggested, as in *ex rel Grubbs*, the First Amended Complaint satisfies Rule 9(b) with respect to these defendants.

Thomson is in a different category because there is an additional link involved as to whether its false statements exaggerating the positives, and minimizing or failing to state the negatives, in promoting the off-label use of psychotropic drugs in children and youth, caused false prescriptions to be presented to Medicaid.

It is respectfully suggested the First Amended Complaint satisfies Rule 9(b)'s particularity requirement with respect to Thomson as well. Paragraphs 196 - 199 of the First Amended Complaint allege:

> 196. One of Thomson's scientific and health-care division's biggest operations during at least part of the applicable period was or is running continuing medical education seminars paid by pharmaceutical companies which promote off-label prescribing of such drug companies' drugs under patent through making false statements exaggerating their effectiveness and downplaying their harms.
>
> 197. Thomson, through DRUGDEX, makes false statements in supporting the prescription of psychotropic drugs to children and youth for indications not approved by the FDA.

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[19] 565 F.3d at 191.

> 198. Thomson's false statements in favor of the prescription of psychotropic drugs to children and youth through continuing medication seminars and DRUGDEX for indications not approved by the FDA were made knowing they would be used to support claims being paid or approved by Medicaid and/or CHIP, and Thomson is liable under the False Claims Act therefor.
>
> 199. As a result of the false statements made by Thomson through its continuing medical education programs and/or in DRUGDEX, millions of false Medicaid claims for reimbursement of pediatric psychotropic medications have been made.

These allegations combined with the allegation at paragraph 183 of the First Amended Complaint satisfy Rule 9(b).

In sum, PsychRights has alleged Thomson was paid by pharmaceutical companies to give continuing medical education programs designed to cause the off-label prescribing of psychotropic drugs to children and youth and the presentation of false claims thereby, and alleged a large number of offending prescriptions. Under the *Duxbury* and *ex rel Grubbs* formulation these are allegations of particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted. Or to use another part of the *Duxbury* formulation, these allegations present "factual or statistical evidence to strengthen the inference of fraud beyond possibility." In fact, it is way beyond possibility. It strains credulity that none of the tens of thousands of false claims identified in ¶183 of the First Amended Complaint were not caused by Thomson's false statements.

This is essentially the same sort of claim the First Circuit allowed to proceed in *Rost*, except that in *Rost* it was a drug company alleged to have promoted the off-label prescribing that caused the false claims, whereas here it is alleged Thomson was paid by drug companies to promote the off-label prescribing that caused the false claims.

III. SHOULD THIS COURT GRANT THE MOTION AS TO ANY DEFENDANTS, PSYCHRIGHTS SHOULD BE ALLOWED TO FURTHER AMEND THE COMPLAINT

If this Court decides the First Amended Complaint fails to satisfy Rule 9(b), it will presumably state in which way it fails to do so. PsychRights should be allowed to further amend its complaint to address such deficiencies. Therefore, PsychRights respectfully suggests any dismissal should be without prejudice to file a further amended complaint. Defendants admit at page 19 such amendment should be allowed unless futile. Here, such an amendment would be far from futile.

IV. PSYCHRIGHTS' NON-MONETARY MOTIVATION IS NEITHER DISQUALIFYING, NOR RELEVANT TO THE RULE 9(b) MOTION TO DISMISS

Finally, the Defendants cite to dicta in *U.S. ex rel. Alcohol Foundation v. Kalmanovitz Charitable Foundation*, 186 F.Supp. 2d 458, 464-65 (S.D.N.Y. 2002), and the unpublished decision in *U.S. ex rel. Haight v. Catholic Healthcare West, et al.*, 2008 WL 607150 at *1 (D. Ariz. Feb. 29, 2008), for the proposition that the False Claims Act was not enacted to further social purposes.

In *Kalmanovitz*, the district court dismissed the action because the complaint "does not specify what or whose particular false or fraudulent claims deriving from Defendants were submitted to the Government for payment or approval."[20] In essence, the ruling was that a beneficial social agenda does not relieve a *relator* from complying with Rule 9(b) in False Claims Act cases.[21] In *Haight*, the district court refused to hold the *relator's* social agenda against the *relators*:

> [W]e cannot say that the promotion of plaintiffs' social agenda was paramount over asserting their non-frivolous claims that, if successful, could have earned them a sizable award.[22]

[20] 186. F. Supp at 464.
[21] *See*, 186 F. Supp at 464, n.5.
[22] 2008 WL 607150 at *2.

Moreover, in the earlier appeal of the *Haight* case, *United States ex rel. Haight v. Catholic Healthcare W.*, 445 F.3d 1147 (9th Cir. 2006), the Ninth Circuit reversed the district court's dismissal of Haight's claims under the "public disclosure bar," contained in 31 U.S.C. §3730(e)(4)(A).[23] There, the *relators'* social agenda was no impediment to proceeding under the False Claims Act. The Ninth Circuit addressed the issues based on the text of the False Claims Act.

PsychRights respectfully suggests the Defendants' Rule 9(b) Motion to Dismiss should be based on Rule 9(b)'s requirements, not Defendants' disagreement with PsychRights' desire to protect children and youth from the massive amount of harm the Defendants are causing by participating in the pervasive psychiatric drugging through Medicaid of poor children and youth for indications not approved by the FDA, nor supported by scientific evidence as set forth in the Compendia.

V. CONCLUSION

For the foregoing reasons, the Defendants' Rule 9(b) Motion to Dismiss should be denied.

RESPECTFULLY SUBMITTED this 8th day of May, 2010.

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

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[23] Defendants have also filed a motion to dismiss under this provision at Dkt. No. 89, which will be opposed separately by PsychRights.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 8, 2010, a true and correct copy of this document was served electronically on all parties of record by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail.

/s/ James B. Gottstein
JAMES B. GOTTSTEIN