1	David B. Robbins (pro hac vice)
2	Renee M. Howard (<i>pro hac vice</i>) Bennett Bigelow & Leedom, P.S.
3	1700 Seventh Avenue, Suite 1900 Seattle, WA 98101
4	Telephone: 206-622-5511
5	Facsimile: 206-622-8986 Email: <u>drobbins@bbllaw.com</u>
6	Email: <u>rhoward@bbllaw.com</u>
7	Counsel for Defendants Providence Health & Services & Osamu Matsutani, M.D.
8	
9	Howard S. Trickey, Alaska Bar No. 7610138 Cheryl Mandala, Alaska Bar No. 0605019
10	Jermain, Dunnagan & Owens, P.C. 3000 A Street, Suite 300
11	Anchorage, AK 99503
12	Telephone: (907) 563-8844 Facsimile: (907) 563-7322
13	Counsel for Defendant
14	Anchorage Community Mental Health Services, Inc.
15	
16	IN THE UNITED STATES DISTRICT COURT DISTRICT OF ALASKA
17	UNITED STATES OF AMERICA,
18	Ex rel. Law Project for Psychiatric Rights, an NO. 3:09-cv-00080-TMB Alaskan non-profit Corporation,
19	Plaintiff,
20	Fiamum,
21	VS.
22	OSAMU H. MATSUTANI, MD, et al.,
23	Defendants.
24	
25	REPLY OF ALL DEFENDANTS IN SUPPORT OF
26	RULE 9(B) MOTION TO DISMISS
	REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB

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I. INTRODUCTION

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Plaintiff Law Project for Psychiatric Rights, Inc. ("PsychRights") responded to Defendants' Motion to Dismiss under Rule 9(b) by filing a brief and an Amended Complaint purporting to remedy the initial complaint's obvious defects. These responsive pleadings make abundantly clear why this case should be dismissed with prejudice for failing to plead fraud with particularity.

For more than half the Defendants, the Amended Complaint contains no additional allegations of fraud, leaving the allegations against those Defendants entirely generic and non-specific. With respect to the other Defendants, the Amended Complaint fails to correct the Rule 9(b) deficiencies, despite the newly-added information concerning certain drugs prescribed to six Medicaid beneficiaries. Accordingly, the Court should grant Defendants' Rule 9(b) motion to dismiss.

In order to understand the Amended Complaint's deficiencies and why they cannot be cured, the Court need only reflect on the nature of the allegedly fraudulent scheme described in the Amended Complaint. Like its predecessor pleading, the Amended Complaint is largely a generalized attack on the conduct of non-parties—*i.e.*, drug manufacturers' promotion of psychotropic medication for pediatric patients. Rather than directly challenge the drug manufacturers (who are named as defendants in other "off-label" promotion cases), PsychRights instead names a collection of largely unaffiliated mental health providers and pharmacies, certain state officials and a publisher. Without alleging a conspiracy, PsychRights generally asserts that all these parties somehow independently submitted, or caused to be submitted, claims to the Alaska Medicaid and CHIP programs that PsychRights contends were "false" by virtue of the drug manufacturers' illegal promotion practices. But PsychRights makes no allegations of "falsity," fraudulence or wrongdoing that relate to these

Defendants' conduct, and thus completely fails to satisfy Rule 9(b)'s requirement that it identify the <u>circumstances of fraud</u> with particularity.

The thrust of PsychRights's newly Amended Complaint, and the reason it does not state a False Claims Act ("FCA") violation as to any of the Defendants, is embodied in its own explanation of how claims for psychotropic medications submitted to the Medicaid program are "rendered false." According to PsychRights:

- "[A] drug manufacturer falsified studies or engaged in other, unlawful conduct to procure FDA approval or inclusion in a compendium." [Am. Compl. ¶ 173]
- "[A] drug manufacturer falsified studies or engaged in other unlawful, fraudulent conduct in the promotion of a drug that resulted in the prescription."

 [¶ 174]
- "Illegal off-label marketing [by a drug manufacturer] . . . results in the submission of impermissible claims for reimbursement" [¶ 175]

Thus, by PsychRights's own allegations, the alleged "falsity" of any identified claim is the result of the conduct of non-parties—drug manufacturers—and not the Defendants.

Nowhere does PsychRights allege facts demonstrating that any Defendant participated in illegal activities with drug manufacturers, or engaged in specific, independent fraudulent or inappropriate conduct that somehow rendered prescription drug claims "false."

The sum total of PsychRights's allegations of fraudulent conduct regarding the vast majority of the Defendants is that either:

(i) they wrote or filled prescriptions for psychotropic medications that were billed to Medicaid or CHIP where a federal statute (by PsychRights' reading)

¹ PsychRights's additional allegation that a claim could also be rendered "false" "if a physician submitted a claim for reimbursement for which he or she received a kickback in exchange for prescribing a particular drug" [¶ 176] is also unavailing, as PsychRights has not specifically identified a single kickback or other unlawful transaction between a drug manufacturer and any Defendant, in relation to a prescription drug or otherwise. REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS *Law Project for Psychiatric Rights v. Matsutani, et al.*, Case No. 3:09-cv-0080-TMB Page 3 of 30

allegedly prohibits federal financial participation in the payment of the claims under the circumstances prescribed; or

(ii) they wrote or filled prescriptions for psychotropic medications rendered "false" by some action of a drug manufacturer, such as falsification of studies that led to the drug's inclusion in an official compendium.

But PsychRights alleges no illegal, misleading or nefarious conduct of any of these Defendants demonstrating the circumstances under which each knowingly submitted or caused to be submitted claims for payment that PsychRights contends were false or fraudulent.

Further, PsychRights's theory of falsity itself is fundamentally impossible because the Alaska Medicaid and CHIP programs as administered, having been fully apprised of the nature of the claims, the drugs and the patients, considered the claims to be covered and paid for them.² Indeed, even the federal agency administering the Medicaid program, through its approval of the Alaska State Medicaid Plan, approves the reimbursement methodologies adopted by Alaska for this purpose.³ In short, there is no possibility of wrongdoing, fraud or falsity on the part of these Defendants because the Alaska Medicaid program knowingly

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² See State of Alaska Motion to Dismiss Claims, Dkt. 90 at 6 ("The [federal Medicaid] Act permits state Medicaid drug programs to cover FDA-approved psychotropic medication prescribed by physicians for indications that are not listed in the compendia, which Alaska's Medicaid drug program unambiguously does.") (emphasis added). See also Dkt. 93 at 9-11 (discussion of Alaska law covering off-label prescribed drugs without compendia support.)

³ The Medicaid program is administered by each state through a single Medicaid agency and the federal government participates by providing federal matching grants if certain statutory criteria are satisfied. 42 U.S.C. § 1396a(a)(5); 42 C.F.R. § 431.10. In order to qualify for federal financial participation in a given state's Medicaid program, the Secretary of Health and Human Services must approve the state's Medicaid Plan. *See generally* 42 U.S.C. § 1396a. By federal law, a state Medicaid Plan must describe the state's administration of the program, eligibility categories, coverage of services, reimbursement methodologies and other aspects of the program. Rules applicable to coverage and reimbursement methodologies for any given state's Medicaid program are promulgated by the states, consistent with federal guidelines. 42 U.S.C. § 1396a(a)(30); 42 C.F.R. Part 447.

covered the drugs identified in the Amended Complaint and knowingly paid for them. There was simply no reason for any Defendant to falsify or engage in subterfuge in order to get a claim paid, and thus no Defendant has any reason to engage in the type of fraudulent conduct that requires particularization under Rule 9(b). In short, no fraud on the part of these Defendants is or could be particularized because no fraud or falsity was required to have these claims paid (or would have been material to the government's decision to pay).

For the other Defendants—the State officials and the publisher Thomson Reuters ("Thomson")—the Amended Complaint also fails to particularize the "who, what and where" of any alleged fraud. The State officials are operating without any stated or apparent incentive to misinterpret federal law as the relator maintains, and no misconduct by Thomson is identified with particularity.

PsychRights attempts to salvage its fundamentally flawed and non-particularized theory of fraud by identifying a handful of drugs prescribed to a handful of Medicaid beneficiaries, and attributing some of these drugs to some of the Defendants. As discussed below, this additional information adds length to the pleading, but is patently insufficient to save the Amended Complaint from dismissal under Rule 9(b) and demonstrates that further amendment is futile.

II. The Amended Complaint Contains No Particularized Allegations of Fraud as to Any of the Defendants

A. Defendants with Only Generic Allegations of Fraud

The Amended Complaint does not even attempt to augment the allegations as to the following fifteen Defendants.

- 1. Anchorage Community Mental Health Services, Inc.
- 2. Bartlett Regional Hospital
- 3. Dr. Lucy Curtiss

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- 4. Dr. Ruth Dukoff
- 5. Juneau Youth Services
- 6. Dr. Jan Kiele
- 7. Dr. Heidi Lopez-Coonjohn

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1 2 3 4 5	 8. Dr. Claudia Phillips 9. Providence Health & Services 10. Dr. Irvin Rothrock 11. Dr. Robert Schults 12. Southcentral Foundation 13. Dr. Hugh Starks 14. Dr. Mark Stauffer 15. Peninsula Community Health Services
6	For each of these Defendants, PsychRights does nothing more than recite in boiler-plate
7	fashion the False Claims Act liability requirements. [¶¶183, 200, 205] Not a single claim,
8	action, or circumstance is identified linking these fifteen Defendants to the submission of any
9	allegedly false claims, or detailing what specific conduct each engaged in that could have
10	resulted in the submission of a false claim. ⁴ As such, PsychRights's pleading remains
11	deficient under Rule 9(b) and should be dismissed as to each of these Defendants.
12	In its Opposition, PsychRights admits that the Amended Complaint fails to identify
13	specific patients, prescriptions, or any other particularized information as to these fifteen
14	Defendants, and asserts that Rule 9(b) somehow does not require it to set forth particularized
15	allegations. ⁵ This assertion is groundless.
16	The cases PsychRights cites make clear the requirement that the Relator must provide
17	sufficiently specific allegations of fraud "to give defendants notice of the particular
18	misconduct which is alleged to constitute the fraud charged so that they can defend against the
19	charge and not just deny that they have done anything wrong." PsychRights contends that it
20	is sufficient for its Amended Complaint to identify medications it believes should not be
21	prescribed to pediatric patients, or should be prescribed only under certain circumstances, and
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23	⁴ The generic "prescriber" allegations at paragraphs 216–220 do not add any particularity, as

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⁴ The generic "prescriber" allegations at paragraphs 216–220 do not add any particularity, as they are asserted universally and with no supporting details of any Defendant's participation. *See also* discussion at Section B below.

⁵ Dkt. 110 at 3.

⁶ Bly-Magee v. California, 236 F.3d 1014, 1019 (9th Cir. 2001) (quoted at Dkt. 110, p. 4). REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB Page 6 of 30

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⁸ *Id*. 26

to further assert that each of the Defendants should know whether they have written any such prescriptions. This argument ignores the applicable legal framework and the purpose behind a requirement that FCA claims be pled with specificity.

PsychRights supports its argument with a quotation from *United States ex rel. Grubbs* v. Kanneganti, which it acknowledges was made "in a slightly different context." That "slightly different context" is a complaint that provided detailed, particularized allegations about each defendant's alleged submissions of false claims, described by the Fifth Circuit as follows:

In addition to the described scheme, the complaint avers at least one overt act of false billing for each doctor, each similar to this paragraph:

Dr. Desai billed Medicaid for psychotherapy services on January 8, 2004, CPT Code #90805, which constituted a false claim in that the medical records indicate that no psychotherapy was provided by Desai on that date.9

In response to a claim that these allegations did not satisfy Rule 9(b)'s heightened pleading requirements, the Fifth Circuit concluded that sufficiently specific information had been provided from which each defendant could admit or deny the allegations. The Court did not hold, as PsychRights suggests, that Rule 9(b)'s requirements could be satisfied by vaguely describing a "scheme," but providing no specified allegations of each defendant's participation in that scheme.

PsychRights's defense to the Rule 9(b) motion is that each Defendant must possess evidence of whether it ever prescribed various medications to unidentified pediatric patients (presumably who are also Medicaid or CHIP beneficiaries), as well as evidence of whether such medications were ever prescribed for so-called off-label, non-compendium uses, and

⁷ Dkt. 110 at 5-9.

⁹ United States ex rel. Grubbs v. Kanneganti, 565 F.3d 180, 184-185 (5th Cir. 2009). REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB Page 7 of 30

therefore PsychRights is absolved of responsibility to plead such claims with any specificity. 10 2 This argument turns Rule 9(b) on its head, and describes precisely the kind of fishing expedition and defamatory but fact-free fraud allegations the specificity requirement is intended to prevent. 11 5 Having failed to identify a single claim submitted by Anchorage Community Mental Health Services, Inc., Bartlett Regional Hospital, Juneau Youth Services, Providence Health & Services or Southcentral Foundation, or by Drs. Curtiss, Dukoff, Kiele, Lopez-Coonjohn, Phillips, Rothrock, Schults, Starks or Stauffer that was allegedly false, much less identifying any of the required circumstances of such claims that would provide a basis to allege fraud, 10 PsychRights's Complaint must be dismissed as to each of these Defendants. 11 В. **Defendants That Allegedly Caused False Claims Submissions** 12 For the following nine Defendants, the Amended Complaint identifies certain claims 13 information for a handful of Medicaid beneficiaries, and alleges that the Defendant caused the 14 submission of a false claim with respect to each of the identified claims: 15 1. Alternatives Community Mental Health Services d/b/a Denali Family Services Fairbanks Psychiatric and Neurologic Clinic, P.C. 2. 16 Frontline Hospital/Northstar Hospital 3. Dr. Elizabeth Baisi 17 4. Dr. Lina Judith Bautista 5. 18 Dr. Sheila Clark 6. Dr. Ronald Martino 7. 19 Dr. Osamu Matsutani 8. Dr. Kerry Ozer 9. 20 21 22 ¹⁰ Dkt. 110 at 10. 23 ¹¹ See Grubbs, 565 F.3d at 191 ("Rule 9(b) also prevents nuisance suits and the filing of baseless claims to gain access to a 'fishing expedition.'"); United States ex rel. Smith v. Yale 24 Univ., 415 F. Supp. 2d 58, 88 (D. Conn. 2006) (describing Rule 9(b)'s "purposes of, inter 25 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 26 reputations.").

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PsychRights mistakenly suggests that the identified claims conclusively cure any Rule 9(b) deficiencies—*i.e.*, that prescribing a drug for a non-compendium off-label use that was billed to Medicaid establishes some sort of "per se" FCA liability.¹²

PsychRights's position misconceives both the FCA and its Rule 9(b) pleading obligations. First, there is no such thing as a "per se false claim" and not surprisingly, PsychRights offers no legal support for such a patently incorrect assertion. As described in the opening memorandum, a false claim requires a lie, and even a violation of law or regulation in connection with a claim is not necessarily actionable under the FCA. Thus, simply identifying claims for drugs that allegedly were not covered by Medicaid or CHIP is insufficient to state an FCA violation.

More to the point, in order to satisfy Rule 9(b), "a party alleging fraud must 'set forth *more* than neutral facts necessary to identify the transaction." As the Eleventh Circuit noted in *Grubbs*, a case cited by PsychRights, mere claims information does not, *ipso facto*, provide the particulars of fraud: "Standing alone, raw bills—even with numbers, dates, and amounts—are not fraud without an underlying scheme to submit bills for unperformed or unnecessary work. It is the scheme in which particular circumstances constituting fraud may be found that make it highly likely the fraud was consummated through the presentment of false bills." 15

20 | 12 See Dkt. 110 at 2–3, 8.

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¹³ Dkt. 84 at 9-10.

¹⁴ Kearns v. Ford Motor Co., 567 F.3d 1120, 1124 (9th Cir. 2009) (quoting *In re GlenFed Sec. Litig.*, 42 F.3d 1541, 1548 (9th Cir. 1994)) (emphasis in original).

¹⁵ Grubbs, 565 F.3d at 190. See also United States ex rel. Stephens v. Tissue Sci. Labs., Inc., 664 F. Supp. 2d 1310, 1319 (N.D. Ga. 2009) ("While the Amended Complaint does provide product numbers for the pieces of Permacol sold, it still lacks "the content and manner in which [the false] statements misled the [surgeons]," which is required in order to satisfy Rule 9(b).") (quoting Brooks v. Blue Cross & Blue Shield, 116 F.3d 1364, 1380-81 (11th Cir. 1997)).

1	Here, even for those Defendants for whom the Amended Complaint now identifies an
2	allegedly offending prescription, PsychRights provides no allegation, much less specification,
3	as to how these Defendants "caused" the identified claims to be submitted nor is there any
4	specific allegation of wrongdoing, inaccuracy, falsification or fraud relative to these claims. 16
5	Instead, the allegations contain the following data, none of which concerns causing a
6	fraudulent claim to be submitted: (i) the initials of a person (and corresponding identification
7	number) who was allegedly prescribed medication that was "presented to Medicaid and/or
8	CHIP for reimbursement;" (ii) the name of a drug; (iii) a "date" (it is unknown if the date
9	provided refers to the date of the prescription, the date it was filled, the date it was submitted
10	for payment, the date it was paid, or some other date); and (iv) an "amount" (PsychRights does
11	not specify if the amount represents the amount billed to Medicaid or CHIP, the amount
12	Medicaid or CHIP paid for the drug, or some other amount).
13	For each drug, PsychRights also states whether, according to its own interpretation of
14	certain drug compendia, the drug has a "medically accepted indication for use in anyone under
15	18 years of age" [¶166] and, if so, what, by its reading, the compendia says are the medically-
16	accepted indications for such patients [¶167]. In addition, for the drug Risperdal and for the
17	entire category of anti-depressants called "SSRIs," PsychRights alleges that the manufacturers
18	of those drugs conducted unspecified "falsified studies," made unspecified "falsified
19	statements," or engaged in "other unlawful, fraudulent conduct" to obtain "FDA approval and
20	support in the Compendia for pediatric use" [¶¶ 218, 220]. It further alleges that the
21	"prescriber" Defendants—collectively—knew or should have known of the drug
22	manufacturers' alleged but unspecified misconduct. Id. Finally, PsychRights alleges, without
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24	16 It should be noted that these Defendants, presumably named for prescribing or supervising

the prescription of the drugs, are alleged to have engaged in an act—prescribing or supervising the prescription of the drugs, are alleged to have engaged in an act—prescribing a drug on an off-label basis—that is entirely legal. While drug manufacturer promotion of drugs for off-label purposes is arguably illegal under the federal Food, Drug & Cosmetic Act, that law does not purport to regulate prescriber discretion in this area.

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1	reference to any Defendant, patient, prescription, statement, alleged misdiagnosis or alleged
2	correct diagnosis, that "Prescribers make false statements misdiagnosing children and youth
3	for indications to justify prescribing drugs approved by the FDA or supported by one or more
4	of the Compendia." ¹⁷ [¶216]
5	These allegations do not provide any particulars of the alleged fraud for these nine
6	Defendants. As the Sixth Circuit aptly summarized, the details of fraud must at a minimum
7	provide:
8	(1) precisely what statements were made in what documents or oral
9	representations or what omissions were made, and (2) the time and place of each such statement and the person responsible for making (or in the case of
10	omissions, not making) same, and (3) the content of such statements and the
11	manner in which they misled the government, and (4) what the defendants obtained as a consequence of the fraud. 18
12	Even more fundamentally, the allegations must be factually plausible to survive the motion to
13	dismiss. 19 Here, there is no Rule 9(b) specificity as to the alleged falsity of the claims or the
14	causation of the submission of false claims. Nor is there the slightest hint of plausibility for
15	the underlying allegation of fraud, given that the Alaska Medicaid and CHIP programs as
16	approved by CMS expressly covered the drugs in question irrespective of whether they were
17	prescribed on an off-label basis.
18	To illustrate how the claims information falls short of Rule 9(b) requirements,
19	consider the allegations against Defendants Dr. Osamu Matsutani and Denali Family Services
20	("Denali"). PsychRights attributes the same universe of claims as having been "caused" by
21	17 The control of the
22	¹⁷ These generic "prescriber" allegations fail on their face to satisfy Rule 9(b) as they do not specify any Defendant's role in the alleged fraud. <i>See Lubin v. Sybedon Corp.</i> , 688 F. Supp.
23	1425, 1443 (S.D. Cal. 1988) ("indiscriminately grouping all of the individual defendants into [a] wrongdoing monolith" is prohibited by Rule 9(b)).
24	¹⁸ Sanderson v. HCA-The Healthcare Co., 447 F.3d 873, 877 (6 th Cir. 2006).
25	¹⁹ See Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555-57 (2007); Ashcroft v. Iqbal, 566
26	U.S, 129 S.Ct. 1937, 1950-51 (2009).
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1	both Denali and Dr. Matsutani—i.e., twenty-three Cymbalta and fifty-two Risperdal
2	prescriptions for patient "MG" with "dates" between January and December 2007 [¶¶202,
3	206]. Yet there is no allegation as to any relationship between these two Defendants (and
4	Defendants are unaware of any) that would explain how both could have caused the same
5	claims to be submitted or that describes the conduct in a manner to either join or differentiate
6	these two Defendants. ²¹ Thus, the failure to specify any fraud leaves the Defendants with the
7	task of sorting out and defending implausible allegations without responding to any identified
8	wrongdoing.
9	Moreover, merely listing a drug, a date of unknown reference, and an amount of
10	unknown reference for a given patient does not identify with particularity how the defendant
11	'caused" the alleged fraud or even what the alleged fraud is. For Dr. Matsutani and Denali:
12	There is no specific allegation of falsity, inaccuracy or subterfuge in the
13	prescriptions identified.
14	There is no allegation of who prescribed the identified drugs, as the same
15	universe of claims is attributed to each of them.
16	• There is no indication that "MG" was a nediatric natient (a necessary element

- There is no indication that "MG" was a pediatric patient (a necessary element of PsychRights' theory of fraud given its contentions at ¶¶166–67).
- There is no specification of the medical indication for which the drug Risperdal was prescribed in the fifty-two identified instances. Risperdal has some compendia-supported uses for pediatric patients [¶167]. Rather than identify the use for which the drug was actually prescribed for "MG," the

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²⁰ One claim is attributed solely to Dr. Matsutani, but the claim is nonsensical as PsychRights identifies its "date" as occurring over two months into the future (July 18, 2010) [¶206].

²¹ Similarly, PsychRights attributes the same universe of claims to Fairbanks Psychiatric and Neurologic Clinic, P.C. and Dr. Martino [¶¶203, 210], and the same universe of claims to North Star Hospital and Dr. Baisi [¶¶ 204, 207], but fails to differentiate between the Defendants as to their respective roles in allegedly causing the submission of a false claim.

- complaint merely concludes that all of the claims for "MG" "were not for a medically accepted indication" [¶¶202, 206]. 22
- There are no facts describing how or why Dr. Matsutani or Denali knew, or should have known, that "FDA approval and support in the Compendia for pediatric use of Risperdal was obtained through falsified statements or other unlawful, fraudulent conduct" [¶220].
- There is no allegation regarding "MG"'s diagnosis, or Dr. Matsutani's and Denali's participation in that diagnosis, that would add the requisite specificity to the generic "misdiagnosis" allegation asserted against all "prescribers" at ¶ 216.
- Medicaid law concerning federal financial participation in payment for off-label drugs, ²³ there are no facts pled demonstrating that Dr. Matsutani and Denali falsified any information or engaged in subterfuge or wrongdoing in writing these prescriptions for these patients. Nor is there an allegation that they knew, or should have known, that prescriptions for Cymbalta or Risperdal were not properly payable by the Alaska Medicaid or CHIP programs, given that the State of Alaska, which administers both programs, knowingly paid claims for such prescribed drugs for pediatric patients (demonstrated by the State officials' status as Defendants in this case, by their motion to dismiss the

²² For Defendants whose only identified prescriptions are for Risperdal, like Drs. Ozer and. Bautista, the Amended Complaint offers no clue as to whether these prescriptions were written for compendia-supported indications. Even by PsychRights's flawed theory, that failing is fatal to its obligation to specify fraud and comply with Rule 9(b).

²³ A detailed discussion of PsychRights's erroneous interpretation of federal Medicaid requirements is set forth in the Memorandum of Certain Defendants in Support of Their Motion to Dismiss under Rule 12(b)(6) [Dkt. 93].

1	case, ²⁴ and by PsychRights's recent filing of a preliminary injunction to halt
2	the State's continued reimbursement of these drugs). 25 Specification is
3	particularly needed where there is no apparent reason that anyone would
4	engage in wrongdoing or fraud relative to submission of the identified
5	claims. ²⁶
6	There is no identification of any legal or other authority that limits a
7	physician's ability to practice medicine by prescribing drugs for off-label uses,
8	likely because there is none. ²⁷ In other words, prescribing off-label is on its
9	face legal, appropriate and anticipated conduct, and PsychRights identifies no
10	factual basis to support that this lawful conduct became fraudulent activity by
11	these Defendants. ²⁸
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14	²⁴ Dkt. 90.
15	²⁵ Dkt. 113. In its Motion for Preliminary Injunction, PsychRights alleges: "The parties
16 17	[Hogan and Streuer] sought to be enjoined continue to present claims or cause claims to be presented to Medicaid for payment of prescriptions to children and youth for psychotropic drugs that are not for a medically accepted indication." [Dkt. 113 at 3, ¶2.]
18	²⁶ See United States ex rel. Rost v. Pfizer, Inc., 253 F.R.D. 11, *16 (D. Mass. 2008)
19	("Defendants have a compelling position that state approval of [off-label use] undermines the assertion of a 'false claim."").
20	²⁷ See United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 44 (D. Mass. 2001)
21	("[T]he FDA does not prevent doctors from prescribing the drug for uses that are different than those approved by the FDA. Allowing physicians to prescribe drugs for such 'off-label'
22	usage is an accepted and necessary corollary of the FDA's mission to regulate [pharmaceuticals] without directly interfering with the practice of medicine.") (internal
23	quotations omitted).
24	²⁸ See United States ex rel. Laucirica v. Stryker Corp., 1:09-CV-63, 2010 WL 1798321, *5
2526	(W.D. Mich. May 3, 2010) ("Nothing in Plaintiff's allegations make the inference of illegal intent and conduct any more plausible than the inference of legal intent and legal conduct.") (dismissing complaint under Rule 8(a) and 9(b)).

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There is no allegation of what any Defendant in this category "obtained as a consequence" of the alleged fraud.²⁹ This omission is particularly striking given that prescribers are not alleged to have benefitted financially from writing prescriptions, particularly where other medications were available to treat these patients.

In brief, PsychRights's allegations do not give rise to a claim for fraud that is facially plausible, 30 and do not specify circumstances demonstrating how Dr. Matsutani and Denali or the other Defendants in this category "caused" false claims to be submitted to Medicaid or CHIP. The same omissions of the particulars of fraud exist for all Defendants in this category, including the lack of information regarding the patient's diagnosis, the use for which the drug was prescribed, and facts suggesting that the particular defendant knew, or should have known, that the drug was not properly payable, particularly given the policy of the Alaska Medicaid and CHIP programs to cover and pay for these drugs.

Accordingly, the Amended Complaint should also be dismissed as to Defendants Denali, Fairbanks Psychiatric and Neurologic Clinic, P.C., Frontline Hospital/North Star Hospital, and Drs. Baisi, Bautista, Clark, Martino, Matsutani, and Ozer.

C. The Publisher Thomson

²⁹ Sanderson, 447 F.3d at 877.

PsychRights acknowledges that Thomson is in a "different category" than the other Defendants because "there is an additional link involved" in demonstrating that it allegedly

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³⁰ Twombly, 550 U.S. at 556-57; Iqbal, 129 S. Ct. at 1949. See also Iqbal, 129 S. Ct at 1950 (the determination of whether a complaint states a plausible claim is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense"). The allegations here are so bereft of plausible wrongdoing, given the State's decision to pay for these drugs, and the federal approval of the State's Medicaid Plan, that the complaint does not satisfy the *Iqbal* requirements under Rule 8(a), much less under Rule 9(b). See note 3, supra. Nevertheless, given that the allegations are made under the FCA, the more stringent requirements of Rule 9(b) apply. REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS

"caused false prescriptions to be presented to Medicaid." PsychRights offers not a shred of factual specification for its conclusory assertion that Thomson is causally "linked" to the presentation of false prescriptions through (a) its alleged provision of continuing medical education ("CME") programs paid for by pharmaceutical companies promoting off-label drug prescription and/or (b) allegedly false statements in its DRUGDEX compendium. First, with respect to CME programs that allegedly "exaggerat[ed]" the effectiveness

and "downplay[ed]" the harms of the off-label prescription of certain drugs, PsychRights has not alleged any facts that would allow Thomson to defend against this conclusory assertion. PsychRights does not specify: (a) the drugs allegedly promoted at these unidentified CME programs, (b) the off-label use or uses allegedly promoted, (c) the content of the CME programs, (d) the drug companies that allegedly sponsored them, and (e) when and where these CME programs occurred. Further, even if factual support for the allegation was forthcoming, PsychRights must also allege—which it does not and cannot—that Thomson engaged in such activity in order to cause the submission of false claims. 34

Similarly, PsychRights's conclusory allegation that Thomson made false statements in DRUGDEX is indisputably not pled with the specificity required by Rule 9(b). Again, there is no identification of any specific statements in DRUGDEX relating to any particular indications for any identified drugs that Plaintiff contends are false.³⁵ Moreover, not only

 $\frac{}{}_{31}$ Dkt. 110. at 10.

³² See Dkt. 110 at 10-11 (quoting FAC ¶¶ 196-199).

 $^{22 \}mid ^{33}$ Bly-Magee, 236 F.3d at 1018-19.

^{23 | 34} See Rost, 253 F.R.D. at 16-17 ("Merely alleging off-label marketing . . . is not sufficient, without more, to plead a false claims act violation. Plaintiff must allege that Defendant 'caused' the submission of a 'false claim' by a doctor.").

Notably, PsychRights itself relies on DRUGDEX ratings as its basis for asserting that various indications for psychotropic drugs are medically accepted. *See* Motion for Preliminary Injunction against Defendants Hogan and Streur, Dkt. 113, at 12 Particularly in REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS *Law Project for Psychiatric Rights v. Matsutani, et al.*, Case No. 3:09-cv-0080-TMB Page 16 of 30

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does PsychRights fail to identify specific DRUGDEX ratings or the studies underlying those ratings that it believes are false, it fails to allege—as it must—how Thomson knew they were false.³⁶

PsychRights's citation to case law from other circuits permitting an FCA claim to proceed where the allegations present "factual or statistical evidence to strengthen the inference of fraud beyond possibility" does not help its claim against Thomson. The cited cases—in stark contrast to the present allegations—all include specific factual evidence (detailed by actual insiders) that the courts could reasonably conclude supported an inference of fraud. While PsychRights believes it is enough to casually allege "Thomson was paid by

light of PsychRights's own adoption of DRUGDEX ratings, PsychRights's failure to identify those ratings—if any—it alleges are false further illustrates its claim against Thomson are meritless.

³⁶ Again, as detailed in Defendants' opening memorandum, it is not enough that the studies supporting DRUGDEX's ratings were scientifically incorrect to state an FCA claim. PsychRights must identify <u>facts</u> indicating Thomson knew the studies supporting its ratings to be "lies." Dkt. 84 at 9 (citing *Wang v. FMC Corp.*, 975 F.2d 1412, 1420-21); *see also Morton A Plus Benefits*, *Inc.*, 139 Fed. Appx. 980 (10th Cir. 2005) ("Falsity under the FCA 'does not mean scientifically untrue; it means a lie.").

³⁷ Dkt 110 at 11.

³⁸ See United States ex rel. Duxbury v. Ortho Biotech Products, L.P., 579 F.3d 13, 30-31 (1st Cir. 2009) (where complaint alleged, for example, with respect to a specified hospital, that defendant provided free as a kickback over \$5,000 of a specific drug that the hospital could then submit for reimbursement, court concluded that "although a close call," plaintiff alleged the "who what, where, and when of the allegedly false of fraudulent representations" and also sufficiently alleged facts "with respect to the medical providers he identifies that support his claim that OBP *intended* to cause the submission of false claims") (emphasis in original); Grubbs 565 F.3d at 191-92 ("The Complaint sets out the particular workings of a scheme that was communicated directly to the relator by those perpetrating the fraud. [Plaintiff] describes in detail, including the date, place and participants, the dinner meeting at which two doctors in his section attempted to bring him into the fold of their on-going fraudulent plot. He alleges his first hand experience of the scheme unfolding as it related to him . . . Also alleged are specific dates that each doctor falsely claims to have provided services to patients and often the type of medical service or its Current Procedural terminology code that would have been used in the bill."); Rost, 253 F.R.D. at 13 (plaintiff physician employed by defendant pharmaceutical company alleged specific, illegal off-label marketing tactics of a specific drug REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB Page 17 of 30

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³⁹ Dkt. 110. at 11.

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drug companies to promote the off-label prescribing that caused the false claims," Rule 9(b) exists precisely to prevent such generalized allegations of allegedly fraudulent schemes asserted without factual support. Accordingly, the Amended Complaint should be dismissed as to Defendant Thomson.

D. **Defendants That Allegedly Directly Submitted False Claims**

1. Pharmacy Defendants

For pharmacy Defendants Fred Meyer, Safeway, and Wal-Mart, the Amended Complaint identifies a limited number of prescription drug claims that each allegedly presented to Medicaid or CHIP for payment. 40 As with the claims attributed to the nine Defendants alleged to have "caused" false claims described in Section B above, PsychRights makes the generalized allegation that none of the claims were for a medically-accepted indication [¶¶ 190–195], and suggests that by adding the claims information to the Amended Complaint, it meets its obligations under Rule 9(b). These allegations do not, however, add any particulars of fraud for at least the following reasons:

- There is no allegation of falsity, inaccuracy or subterfuge in these Defendants' submissions to the Alaska Medicaid and CHIP programs, likely because the State of Alaska, by rule and policy, paid for these claims.
- There is no allegation that the Medicaid beneficiaries in question ("AL" and "RT" for Fred Meyer; "FH" and "DG" for Safeway; "AL" and "SM" for Wal-Mart) were under 18 years old.

for use with children and alleged that tactics were employed to cause the submission of false claims by doctors).

⁴⁰ For example, the Amended Complaint attributes only four claims to Wal-Mart, only one of which was written by a named Defendant. REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB Page 18 of 30

- There is no allegation of the indications for which the drugs were prescribed (for many drugs listed, PsychRights alleges there are some medically-indicated uses for pediatric patients), 41 other than the bald allegation that none of the drugs were prescribed for a medically-accepted indication according to PsychRights's interpretation of certain drug compendia.
- Assuming a drug was prescribed for a non-indicated use, there is no allegation
 that Fred Meyer, Safeway, and Wal-Mart knew or should have known the use
 for which the non-indicated drug was prescribed.
- There are no facts pled suggesting Fred Meyer, Safeway, and Wal-Mart knew or should have known that any claims submitted were the result of prescribers' purportedly wrongful behaviors, such as "misdiagnosing" [¶216] or prescribing drugs that were improperly studied or unlawfully promoted by drug companies [¶¶217, 219].
- Even accepting as true PsychRights' incorrect interpretation of federal Medicaid law, there are no facts pled suggesting that Fred Meyer, Safeway, and Wal-Mart knew or should have known that the identified drugs were not properly payable. Indeed, as noted above, Alaska Medicaid and CHIP has historically paid, and continues to pay, for them under the circumstances identified in PsychRights's Amended Complaint.

Accordingly, the Amended Complaint should be dismissed as to Defendants Safeway, Fred Meyer and Wal-Mart.

⁴¹ Indeed, both medications that Wal-Mart is alleged to have dispensed, Seroquel and Zoloft, have compendia-supported indications for pediatric patients. Seroquel is FDA approved for bipolar disorder and schizophrenia, and Zoloft is FDA approved for obsessive-compulsive disorder and is compendia-supported for generalized anxiety disorder and depression. REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS *Law Project for Psychiatric Rights v. Matsutani, et al.*, Case No. 3:09-cv-0080-TMB Page 19 of 30

2. State Defendants

The allegations against the individual representatives of various state agencies (the "State Defendants") also remain deficient under Rule 9(b). First, the roles of each State Defendant are so vaguely defined and unconnected to the claims identified in the Amended Complaint that they are incomprehensible. For example, the Amended Complaint singles out State Defendant Tammy Sandoval (Director of the Office of Children's Services) [¶12] as a party that caused the submission of false claims, and associates with her 160 claims for two individuals ("MG" and "AL"). Yet there is no specification whatsoever as to Sandoval's role in either the generation or processing of these claims, nor are there facts pled that differentiate her role from that of the other State Defendants, William Hogan (Commissioner of DHSS) [¶11], Steve McComb (Director of Division of Juvenile Justice) [¶13], and William Streur (Directory of the Division of Health Care Services within DHSS). 42 Moreover, there is no explanation as to why PsychRights associates 160 of the 280 total identified claims with any given State Defendant, given its allegations that all 280 claims were submitted to the Medicaid or CHIP programs.

Finally, PsychRights fails to plead any facts regarding the State Defendants that allege the circumstances under which they engaged in fraudulent conduct.⁴³ At most, PsychRights identifies its disagreement regarding an interpretation of federal Medicaid law, as it is

⁴² PsychRights' brief, at footnotes 14 and 15, attempts to extend the claims expressly associated with Sandoval to Defendants Hogan and Streur, without pleading additional facts as to the latter Defendants' roles in the generation or processing of these claims [Dkt. 110 at 3-4]. This is a particularly glaring omission where the Amended Complaint states that some State Defendants caused the submission of false claims (Sandoval and McComb), and other State Defendants (Hogan and Streur) authorized their reimbursement [¶¶ 11–14].

⁴³ 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 asserted that the defendant "concealed the fraudulent submission of false claims . . . to avoid repayment of funds to the United States" and that the defendant conspired to "defraud the United States by obtaining payment of fraudulent claims.").

undisputed that the Alaska Medicaid and CHIP programs have paid for and continue to pay
for the drugs in question in this litigation. ⁴⁴ Actions taken based on a good faith interpretation
of an ambiguous federal statute do not, axiomatically, amount to false claims submissions. ⁴⁵
Moreover, it is not specified as to why representatives of the State, which bears much of the
cost of the Medicaid and CHIP programs, would drive up its own expenses by engaging in
false, fraudulent or otherwise wrongful conduct relative to the federal government, which
only partially pays for the programs. Certainly, any aspect of the conduct that is alleged to be
improper is unspecified and unexplained in the Amended Complaint.
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In any event, PsychRights fails to identify any claims submitted by the State Defendants that were themselves "false." While there may be some legal theory under which a state health care benefits program could be liable for authorizing the payment of claims (even against its economic self-interest) that are not payable under a federal statute, the FCA is not such an enforcement vehicle. 46 For example, the Amended Complaint contains no specification of any "false or fraudulent claim" that the State Defendants "presented" (or "cause[d] to be presented") for payment. 31 U.S.C. § 3729(a)(1)(A) (emphasis added). The vague allegation that Defendants Hogan and Streur "authorize[ed] false claims for

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⁴⁴ See Dkt. 93 (Memorandum of Certain Defendants in Support of Motion to Dismiss Pursuant to Rule 12(b)(6)) & Dkt. 113 (PsychRights' Motion for Preliminary Injunctions against State Defendants to enjoin their reimbursement of certain Medicaid prescription drugs).

²⁰ 21

⁴⁵ See, e.g., United States v. Southland Mgmt. Corp., 326 F.3d 669, 684 (5th Cir. 2003) (en banc) (Jones, J. concurring) ("Where there are legitimate grounds for disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim."); *United States ex rel*. Hagood v. Sonoma Water Agency, 81 F.3d 1465, 1477–78 (9th Cir. 1996).

⁴⁶ A state health care benefits program itself is not subject to liability under the FCA. Vermont Agency for Nat. Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000) (states and state agencies are not "persons" within the meaning of the FCA and thus not amenable to suit). Naming individual State officials acting in their official capacities appears to be a ploy

reimbursement by the Government of the United States Government's [sic] federal financial participation share" [Am. Compl. ¶ 213] does not satisfy Rule 9(b)'s requirement that a false claim be identified with particularity. The Amended Complaint does not specify any "claim" submitted by a State Defendant to the federal government for "federal financial participation share," nor does it identify any statement on such a claim that was allegedly false or fraudulent.

PsychRights likewise fails to identify any "false record or statement material to a false or fraudulent claim" that the State Defendants allegedly submitted to obtain federal financial participation in connection with the identified medications, 31 U.S.C. § 3729(a)(1)(B), nor does it allege that the State Defendants were engaged in a conspiracy to violate the FCA. *Id.* § 3739(a)(1)(C). In sum, the Amended Complaint is plainly deficient as to the State Defendants, and must be dismissed as to these Defendants as well.

III. Dismissal of the Amended Complaint With Prejudice Is Appropriate

After being fully apprised of the original complaint's Rule 9(b) deficiencies, PsychRights filed an Amended Complaint on May 6, 2010 which appears to represent its best efforts to cure the failings identified in the original. While the amended pleading adds limited claims information for a few Medicaid beneficiaries, it still contains no particularized allegations whatsoever as to fifteen of the Defendants. Further, the limited claims information provided for the remaining Defendants does not remedy the basic Rule 9(b) defect, which is the absence of any specific and particularized <u>circumstances of fraud</u>.

PsychRights's fundamental problem is that even if it did have more specific claims information, such as more Medicaid claims, copies of actual prescriptions, or actual claims that pharmacies submitted for payment to Medicaid or CHIP, these details would not constitute the particulars of fraud, as the Amended Complaint does not identity any facts

demonstrating that the underlying conduct of any Defendant was improper. For example, no facts are pled (nor could any such facts be pled) demonstrating how perfectly legal conduct, such as off-label prescribing, or the State Defendants paying for drugs that are reimbursable under the State's own regulations, constitutes fraud.

Having failed to identify the circumstances of fraud with particularity after notice of the deficiencies and an opportunity to amend, it appears that PsychRights has alleged all of the facts in its possession, and thus further amendment would be futile. Accordingly, the Court should dismiss its Amended Complaint with prejudice.

IV. CONCLUSION

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PsychRights maintains that the only purpose of Rule 9(b) is to enable the Defendants to sufficiently understand the fraud so they can respond to the complaint and not simply deny that they have done anything wrong.⁴⁹ That is but one of several purposes identified by the Ninth Circuit, which include

(1) . . . provid[ing] defendants with adequate notice to allow them to defend the charge and deter plaintiffs from the filing of complaints as a pretext for the

⁴⁷ 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 Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1015 (11th Cir. 2005) (with prejudice dismissal under Rule 9(b) appropriate where the most recently amended complaint contained the same deficiencies as the previous complaint).

⁴⁸ PsychRights is not permitted to avoid dismissal of its case and cure the pleading deficiencies through discovery. As noted above, PsychRights's response states that the 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." [Dkt. 110 at 10] To the extent that this statement is a prelude to a discovery request, discovery cannot precede compliance with Rule 9(b). *See United States ex rel. Russell v. Epic Healthcare Mgmt. Group*, 193 F.3d 304, 308 (5th Cir. 1999) (in the absence of reliable allegations that particulars of fraudulent claims exist, a qui tam plaintiff is not entitled to receive a "ticket to the discovery process" in order to meet Rule 9(b)'s particularity requirement).

⁴⁹ Dkt. 110 at 4.

1	discovery of unknown wrongs; (2) protect[ing] those whose reputation
2	would be harmed as a result of being subject to fraud charges; and (3) 'prohibit[ing] plaintiff[s] from unilaterally imposing upon the court, the
3	parties and society enormous social and economic costs absent some factual basis. ⁵⁰
4	Ending the litigation now by granting this motion to dismiss would serve all the
5	salutary purposes of Rule 9(b), particularly given that PsychRights has demonstrated its
6	inability to make a plausible accusation of fraud. Thus, the Court should dismiss the
7	Amended Complaint with prejudice as to all Defendants.
8	Respectfully submitted this 18th day of June, 2010.
9	
10	BENNETT, BIGELOW, LEEDOM, P.S.
11	Attorneys for Providence Health & Services and Osamu Matsutani, M.D.
12	By: /s/David B. Robbins
13	David B. Robbins, pro hac vice
14	Renee M. Howard, <i>pro hac vice</i> 1700 Seventh Avenue, Suite 1900
15	Seattle, WA 98101 Telephone: (206)622-5511
16	Facsimile: (206)622-8986 drobbins@bbllaw.com
17	rhoward@bbllaw.com
18	
19	JERMAIN, DUNNAGAN & OWENS, P.C. Attorneys for Anchorage Community
20	Mental Health Services, Inc.
21	By: /s/Howard S. Trickey (consented)
22	Howard S. Trickey Alaska Bar No. 7610138
23	Cheryl Mandala
24	Alaska Bar No. 0605019 3000 A Street, Suite 300
25	Anchorage, AK 99503 Telephone: (907) 563-8844
26	

⁵⁰ *Kearns*, 567 F.3d at 1125 (internal quotations and citations omitted). REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS *Law Project for Psychiatric Rights v. Matsutani, et al.*, Case No. 3:09-cv-0080-TMB Page 24 of 30

1	Facsimile: (907) 563-7322
2	htrickey@jdolaw.com cmandala@jdolaw.com
3	
4	GRUENSTEIN & HICKEY Attorneys for Providence Health & Services and
5	Osamu Matsutani, M.D.
6	By: /s/Daniel W. Hickey (consented)
7	Daniel W. Hickey Alaska Bar No. 7206026
	Resolution Plaza
8	1029 W. 3rd Avenue, Suite 510 Anchorage, AK 99501
9	Telephone: (907) 258-4338
10	Fax: (907) 258-4350
10	Email: <u>ghlaw3@gci.net</u>
11	DANIEL S. SULLIVAN ATTORNEY
12	GENERAL STATE OF ALASKA
	Attorneys for Defendants William Hogan,
13	William Streur, Tammy Sandoval and Stephen
14	McComb
15	By: /s/R. Scott Taylor (consented)
16	R. Scott Taylor Alaska Bar No. 8507110
17	Senior Assistant Attorney General
	1031 W. Fourth Avenue, Suite 200 Anchorage, AK 99501
18	Telephone: (907) 375-7775
19	Fax: (907) 279-8644
20	Email: Scott.Taylor@alaska.gov
21	
22	
23	
24	
25	
26	

REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB Page 25 of 30

1 2	LAW OFFICE OF VANCE A. SANDERS, LLC Attorneys for Defendant Juneau Youth Services, Inc.
3 4	By: /s/Vance A. Sanders (consented)
5	Vance A. Sanders Alaska Bar No. 8611131
6	P.O. Box 240090 Douglas, Alaska 99284
7	Telephone: (907) 586-1648
8	Fax: (907) 586-1649 Email: <u>vsanders@gci.net</u>
9	CLAPP, PETERSON, VAN FLEIN
10	TIEMESSEN & THORSNESS, LLC Attorneys for Defendants Ronald A. Martino,
11	MD, Irvin Rothrock, MD, and Fairbanks
12	Psychiatric and Neurological Clinic
13	By: <u>/s/John J. Tiemessen (consented)</u> John J. Tiemessen
14	Alaska Bar No. 9111105
15	411 Fourth Avenue, Suite 300 Fairbanks, Alaska 99701
16	Telephone: (907) 479-7776 Fax: (907) 479-7966
17	Email: jjt@cplawak.com
18	CLAPP, PETERSON, VAN FLEIN
19	TIEMESSEN & THORSNESS, LLC Attorneys for Defendants Elizabeth Baisi, MD,
20	Ruth Dukoff, MD, Lina Judith Bautista, MD, Jan Kiele, MD, and Frontline Hospitals, a Limited
21	Liability Company
22	By: /s/Linda J. Johnson (consented)
23	Linda J. Johnson Alaska Bar No. 8911070
24	711 H Street, Suite 620 Anchorage, Alaska 99501
25	Telephone: (907) 272-9272
26	Fax: (907) 272-9586 Email: <u>ljj@cplawak.com</u>
-	

REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB Page 26 of 30

1 2	SEDOR, WENDLANDT, EVANS & FILIPPI, LLC
3	Attorneys for Defendants Kerry Ozer, MD and Claudia Phillips, MD
4	By: /s/Allen Frank Clendaniel (consented)
5	Allen Frank Clendaniel Alaska Bar No. 0411084
6	500 L Street, Suite 500 Anchorage, Alaska 99501
7	Telephone: (907) 677-3600 Fax: (907) 677-3605
8	Email: <u>clendaniel@alaskalaw.pro</u>
9	DORSEY & WHITNEY, LLP
10	Attorneys for Defendants Southcentral Foundation, Safeway, Inc. and Fred Meyer
11	Stores, Inc.
12	By: /s/Robert C. Bundy (consented) Robert C. Bundy
13	Alaska Bar No. 7206021
14	1031 W. 4th Avenue, Suite 600 Anchorage, Alaska 99501
15	Telephone: (907) 257-7853 Fax: (907) 276-4152
16	Email: <u>bundy.robert@dorsey.com</u>
17	BROWN, WALLER & GIBBS, PC
18	Attorneys for Defendants Sheila Clark, MD and Lucy Curtiss, M.D
19	By: /s/Keith Brown (consented)
20	Keith Brown Alaska Bar No. 6903003
21	Sanford M. Gibbs Alaska Bar No. 6903013
22	821 N Street, Suite 202
23	Anchorage, Alaska 99501 Telephone: (907) 276-2050
24	Fax: (907) 276-2051 Email: <u>akwrangler@aol.com</u>
25	
26	

REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB Page 27 of 30

1	SONOSKY, CHAMBERS, SACHSE,
2	MILLER & MUNSON, LLP Attorneys for Defendants Heidi F.
3	Lopez-Coonjohn, MD, Robert D. Schults, MD,
4	Mark H. Stauffer, MD, and City and Borough of Juneau, Alaska (Bartlett Regional Hospital)
	Julieau, Alaska (Bartiett Regional Hospitai)
5	By: /s/Richard D. Monkman (consented)
6	Richard D. Monkman Alaska Bar No. 8011101
7	302 Gold Street, Suite 201
8	Juneau, Alaska 99801 Telephone: (907) 586-5880
	Fax: (907) 586-5883
9	Email: dick@sonoskyjuneau.com
10	LANE POWELL, LLC
11	Attorneys for Defendant Alternative Community
12	Mental Health d/b/a Denali Family Services
13	By: /s/Matthew W. Claman (consented)
	Matthew W. Claman Alaska Bar No. 8809164
14	301 W. Northern Lights Blvd., Suite 301
15	Anchorage, Alaska 99503-2648 Telephone: (907) 277-3311
16	Fax: (907) 276-2631
17	Email: <u>clamanm@lanepowell.com</u>
18	STOEL RIVES LLP
	Attorneys for Defendant Thomson Reuters
19	(Healthcare) Inc.
20	By: <u>/s/James E. Torgerson (consented)</u>
21	James E. Torgerson Alaska Bar No. 8509120
22	510 L Street, Suite 500
23	Anchorage, Alaska 99501-1959 Telephone: (907) 277-1900
	Fax: (907) 277-1900
24	Email: jetorgerson@stoel.com
25	
26	

1 2 3	SATTERLEE STEPHENS BURKE & BURKE LLP Attorneys for Defendant Thomson Reuters (Healthcare) Inc.
4	By: /s/James F. Rittinger (consented)
5	James F. Rittinger, pro hac vice Thomas J. Cahill, pro hac vice
6	230 Park Avenue, Suite 1130 New York, NY 10169
7	Telephone: (212) 818-9200 Fax: (212) 818-9606
9	Email: <u>tcahill@ssbb.com</u> Email: <u>jrittinger@ssbb.com</u>
10	JONES DAY
11	Attorneys for Defendant Wal-Mart Stores, Inc.
12	By: /s/Eric P. Berlin (consented)
13	Eric P. Berlin, <i>pro hac vice</i> 77 West Wacker, Suite 3500
14	Chicago, Illinois 60601 Telephone: (312) 269-4117
15	Fax: (312) 782-8585
16	Email: epberlin@jonesday.com
17	DELANEY WILES, INC.
18	Attorneys for Defendant Peninsula Community Health
	Services of Alaska, Inc.
19	By: /s/ Howard A. Lazar (consented)
20	Howard A. Lazar Alaska Bar No. 8604013
21	1007 West Third Avenue, Suite 400
22	Anchorage, Alaska 99501 Telephone: 907-279-3581
23	Fax: 907-277-1331
24	Email: hal@delaneywiles.com
25	
26	

1	Certificate of Service
2	I certify that on this 25th day of May 2010, I caused a true and correct copy this Reply of all Defendants in Support of Rule 9(b) Motion to Dismiss served on all parties of record by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not by ECF, by first class regular mail as follows:
3	
4	
5	Assistant U.S. Attorney United States Attorney's Office 222 West 7 th Avenue, #9 Anchorage, AK 99513-5071 Commercial Litigation Branch Ben Franklin Station
6	
7	
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9	
10	/ <u>s/ David B. Robbins</u> {0310.00019/M0147158.DOC; 1}
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	REPLY OF ALL DEFENDANTS IN SUPPORT OF RULE 9(B) MOTION TO DISMISS Law Project for Psychiatric Rights v. Matsutani, et al., Case No. 3:09-cv-0080-TMB Page 30 of 30