No. 10-35887

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LAW PROJECT FOR PSYCHIATRIC RIGHTS, ex rel. United States of America;
DANIEL I. GRIFFIN, ex rel. United States of America,
Plaintiffs-Appellants
v.
OSAMU H. MATSUTANI, MD; *et al.*,
Defendants-Appellees.

ON APPEAL FROM THE U.S. DISTRICT COURT
FOR THE DISTRICT OF ALASKA,
THE HONORABLE TIMOTHY M. BURGESS PRESIDING
AK U.S. DISTRICT COURT CASE Nos. 3:09-cv-80-TMB & 3:09-cv-246-TMB

APPELLANTS' REPLY BRIEF

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III. SUMMARY

The Opening and Answering Briefs present the central issue on appeal quite squarely: is the Public Disclosure Bar triggered by public disclosure of industry-wide fraud? Plaintiffs-Appellants (PsychRights/Griffin) rely on this Court's decision in *U.S. ex rel. Foundation Aiding The Elderly v. Horizon West*, 265 F.3d 1011, n5 (9th Cir. 2001), *amended* at 275 F.3d 1189, that it does not:

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

The Defendants-Appellees (Matsutani *et al*) assert that the facts here are different, arguing in this case, public disclosure of industry-wide fraud does trigger the Public Disclosure Bar, including immunizing ongoing fraud from *qui tam* liability. Of course the facts here are different, just as they are different in every case, but *Foundation Aiding The Elderly* is applicable and thus Matsutani *et al's* position is contrary to directly controlling authority of this Court.

Apparently concerned this Court would not overrule *Foundation Aiding the Elderly*, and uphold the District Court's dismissal of this case on the grounds granted -- that public disclosure of industry wide fraud triggers the Public

Disclosure Bar -- they requested the District Court's decision be upheld on the alternative grounds that (a) Congress did not limit Medicaid reimbursement for prescriptions of outpatient drugs to those that are for a "medically accepted indication," or (b) the Amended Complaint does not meet the particularity requirement of Civil Rule 9(b). Neither of these contentions are well taken. When the Medicaid statute is parsed, Matsutani *et al's* argument that Congress did not limit Medicaid coverage to those for a medically accepted indication is the same as arguing that Congress did not limit coverage of outpatient drugs to covered outpatient drugs. This is nonsensical. With respect to Civil Rule 9(b), PsychRights/Griffin identified specific prescriptions constituting false claims for about half of the defendants and for the rest, identify the circumstances of the alleged fraud with sufficient particularity so that the defendants can prepare an adequate answer.

IV. PUBLIC DISCLOSURE OF INDUSTRY-WIDE FRAUD DOES NOT TRIGGER THE PUBLIC DISCLOSURE BAR

A. The Government Must Be "Put on the Trail" of Specific Defendants Or a Narrow Class of Wrongdoers To Trigger the Public Disclosure Bar

Matsutani *et al's* assertion at § X.A.3.a. of their Brief that the Public Disclosure Bar is triggered whenever the Government is "put on the trail of the alleged fraud," is misplaced because the government has to be put on the trail of

the specific defendants[1] (or a narrow class of wrongdoers)[2] to trigger the Public Disclosure Bar.

The 1st Circuit recently noted in *United States ex rel Duxbury v. Ortho Biotech Products*, 579 F.3d 13, 27 (1st Cir. 2009) that courts should not expand upon the statutory text because:

> Although we have recognized that a "public disclosure" regime has the benefit, one lacking in a "government notice" regime, of providing "public pressure" on the government to act, there also may arise situations when even that is not enough, and the government would benefit from suits brought by relators with substantial information of government fraud even though the outlines of the fraud are in the public domain.

(citation omitted).

That is precisely the situation here. The Government is pursuing drug company perpetrators at Step 1 of the Fraudulent Scheme depicted below, but not the perpetrators at Steps 2 and 3.

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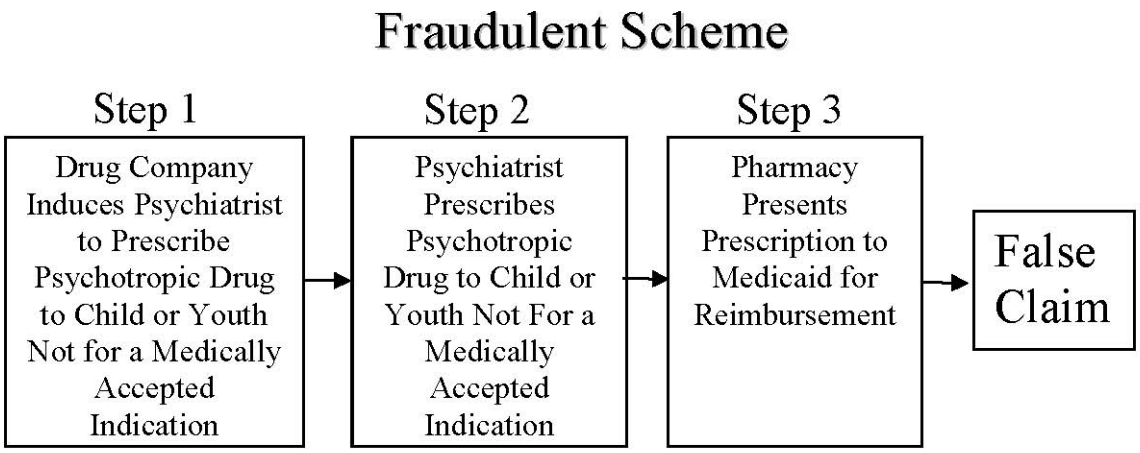
[1] *Foundation Aiding the Elderly*, n5.

[2] *United States ex rel Harshman v.Alcan Electrical and Engineering, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999).



PsychRights/Griffin agree the Government knows about the broad outline of the fraud and could bring suits at Steps 2 and 3. The question presented by this appeal is whether the Public Disclosure Bar prevents private *qui tam* enforcement against particular defendants even though the broad outlines of the fraud are in the public domain.

> As this Court said in *Seal 1 v. Seal A*, 255 F.3d 1154, 1160 (9th Cir. 2001):
>
> "[t]he 1986 amendments also reflected Congress's recognition that the government simply lacks the resources to prosecute all viable claims, even when it knows of fraudulent conduct."

(citation omitted).[3]

[3]In the United States' *Baltazar Amicus* Brief for which judicial notice has been requested, the government noted, "Were government reports and media accounts of such acts sufficient to invoke the public disclosure bar, the bar would apply in practically every healthcare fraud case." App. Dkt. 20-2, p. 15.

B. The Public Disclosure Bar Was Not Triggered Under the *Springfield Terminal* Test.

Matsutani *et al* assert at 29-30, that the *Springfield Terminal* test[4] means the Public Disclosure Bar applies. This is erroneous because under this Court's jurisprudence the identity of the defendants[5] (or a "narrow class of suspected wrongdoers")[6] is one of the essential elements under the *Springfield Terminal* test which must be publicly disclosed to trigger the Public Disclosure Bar, as is the date of the false claim.[7]

C. The Recent 7th Circuit Decision in *Baltazar* Is In Accord with PsychRights/Griffin's Position

In PsychRights/Griffin's Opening Brief, they asked this Court to take judicial notice of the Government's *Amicus* Brief in the then pending appeal, *United States ex rel. Baltazar v. Warden*, Case No. 09-2167.[8] On February 18, 2011, the Seventh Circuit issued its opinion in *United States ex rel Baltazar v. Warden*, __ F.3d __, 2011 WL 559393 (7th Cir. 2011), essentially adopting the Government's position, which is the same as PsychRights/Griffin's.

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[4] *United States ex rel Springfield Terminal Ry. Co. v. Quinn*, 14 F.3d 645, 653 (.D.C. Cir. 1994).

[5] *Foundation Aiding the Elderly*, n.5.

[6] *Ex rel Harshman*, 197 F.3d at 1019.

[7] *U.S. ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 920 (9th Cir. 2006).

[8] App-DktEntry. No. 20, opposed at App-Dkt. No. 24.

Matsutani *et al* attempt to minimize the *Baltazar* decision, but it represents a thorough repudiation of Matsutani *et al's* position. In *Baltazar* there had been numerous public disclosures of wide-spread industry-wide fraud by chiropractors. For example, one report (the "2005 Report") concluded that 57% of chiropractors' claims were for services not covered by the Medicare program. *Baltazar* at *1. The Seventh Circuit pointed out:

> As far as we can tell, no court of appeals supports the view that a report documenting widespread false claims, but not attributing them to anyone in particular, blocks qui tam litigation against every member of the entire industry.

The Seventh Circuit then went on to say the closest is its own decision in *United States ex rel. Gear v. Emergency Medical Associates of Illinois, Inc.*, 436 F.3d 726 (7th Cir.2006), which is heavily relied upon here by Matsutani *et al*. The Seventh Circuit explained that *Gear* is inapposite because the Government had begun to audit all 125 of the nation's medical schools and their associated hospitals. *Baltazar* at *3. Gear's case was parasitic because the Government was already pursuing the matter and it "did not add one jot to the agency's fund of information." *Id* at *4.

The Supreme Court recently said in *Graham County Soil and Water Conservation Dist. v. U.S. ex rel. Wilson*, __ U.S. __, 130 S.Ct. 1396, 1406 (2010), the "quintessential" parasitic suit is the one where the *relator* copies the allegations

in a criminal indictment." *See*, also *United States ex rel Zaretsky v. Johnson Controls*, 457 F.3d 1009, n5 (9th Cir. 2006).

Here, the Government is focusing its attention in enforcing Congress' Medicaid coverage restriction for outpatient drugs to those for a medically accepted indication against the drug companies, and not bringing cases against prescribers causing, and pharmacies presenting, the exact same sort of false claim. There can thus be nothing parasitic about PsychRights/Griffin's action.

The Seventh Circuit also held in *Baltazar*, at *2, that where not every member of an identified class is known to be presenting the same type of false claims, "it takes a provider-by-provider investigation to locate the wrongdoers" and it takes specific information about a particular provider committing a particular fraud to trigger the Public Disclosure Bar. Here, PsychRights/Griffin has identified both particular providers, and as to about half of the defendants, particular false claims.

For example, paragraph 206 of the First Amended Complaint, Exc. 141-143, alleges that Osamu Matsutani, MD, caused the following false claims for prescriptions to MG, Claim Recipient Id No. 0600223318, that were not for a medically accepted indication:

Amount	Date	Drug
$ 54.18	7/9/2007	Cymbalta

	Amount	Date	Drug
$	36.38	7/30/2007	Cymbalta
$	36.38	7/18/2010	Cymbalta
$	36.38	8/6/2007	Cymbalta
$	41.33	10/9/2007	Cymbalta
$	137.83	12/17/2007	Cymbalta
$	39.42	9/4/2007	Cymbalta
$	40.83	9/24/2007	Cymbalta
$	41.33	12/4/2007	Cymbalta
$	41.33	11/6/2007	Cymbalta
$	41.33	11/27/2007	Cymbalta
$	39.42	8/28/2007	Cymbalta
$	39.42	8/22/2007	Cymbalta
$	39.42	8/16/2007	Cymbalta
$	41.33	11/20/2007	Cymbalta
$	41.33	12/11/2007	Cymbalta
$	41.33	11/12/2007	Cymbalta
$	39.42	9/10/2007	Cymbalta
$	40.83	9/17/2007	Cymbalta
$	41.33	10/29/2007	Cymbalta
$	41.33	10/22/2007	Cymbalta
$	51.41	8/8/2007	Cymbalta
$	41.33	10/15/2007	Cymbalta
$	48.09	10/9/2007	Risperdal
$	45.76	7/30/2007	Risperdal
$	45.76	7/16/2007	Risperdal
$	48.09	8/20/2007	Risperdal
$	48.09	9/4/2007	Risperdal
$	45.76	6/11/2007	Risperdal
$	45.76	5/14/2007	Risperdal
$	64.58	1/24/2007	Risperdal
$	45.26	2/26/2007	Risperdal
$	48.09	9/10/2007	Risperdal
$	45.26	3/25/2007	Risperdal
$	45.76	7/2/2007	Risperdal
$	45.26	3/4/2007	Risperdal
$	45.76	8/13/2007	Risperdal

	Amount	Date	Drug
$	48.09	9/24/2007	Risperdal
$	45.76	6/18/2007	Risperdal
$	45.26	3/18/2007	Risperdal
$	45.76	6/4/2007	Risperdal
$	45.76	5/27/2007	Risperdal
$	48.09	8/27/2007	Risperdal
$	48.09	9/17/2007	Risperdal
$	45.76	7/9/2007	Risperdal
$	45.76	5/21/2007	Risperdal
$	45.26	3/11/2007	Risperdal
$	45.26	2/2/2007	Risperdal
$	45.26	2/8/2007	Risperdal
$	45.26	2/14/2007	Risperdal
$	45.26	2/20/2007	Risperdal
$	45.76	8/6/2007	Risperdal
$	45.76	4/29/2007	Risperdal
$	45.76	5/6/2007	Risperdal
$	45.76	4/2/2007	Risperdal
$	45.76	4/9/2007	Risperdal
$	45.76	4/16/2007	Risperdal
$	45.76	4/22/2007	Risperdal
$	66.41	3/18/2007	Risperdal
$	66.41	3/25/2007	Risperdal
$	66.41	2/26/2007	Risperdal
$	66.40	2/20/2007	Risperdal
$	66.41	2/14/2007	Risperdal
$	66.91	5/14/2007	Risperdal
$	66.91	4/9/2007	Risperdal
$	66.91	4/16/2007	Risperdal
$	66.91	4/22/2007	Risperdal
$	66.91	4/29/2007	Risperdal
$	66.91	5/6/2007	Risperdal
$	97.81	1/24/2007	Risperdal
$	66.41	3/4/2007	Risperdal
$	66.91	4/2/2007	Risperdal
$	66.41	3/11/2007	Risperdal

	Amount	Date	Drug
$	66.41	2/2/2007	Risperdal
$	66.41	2/8/2007	Risperdal

This is precisely the type of non-public information that turns general allegations of industry-wide fraud into a False Claims Act case against a specific defendant.

D. The Public Disclosure Bar Does Not Immunize Ongoing Medicaid Fraud From *Qui Tam* Liability

At § X.A.3.b., Matsutani *et al* assert the Public Disclosure Bar immunizes ongoing fraud from *qui tam* liability, arguing the clear holding to the contrary by this Court in *U.S. ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 920 (9th Cir. 2006), is inapplicable, citing to this Court's earlier decision in *United States ex rel. Lujan v. Hughes Aircraft Co.*, 162 F.3d 1027 (9th Cir. 1998).[9] It seems to PsychRights/Griffin that *Bly-Magee* is controlling. Even if it is not, this issue only applies to defendants-appellees Hogan, Streur, Sandoval, McComb and Thomson, because they are the only defendants-appellees identified in any of the public

[9] At § X.B.3.c. of their Answering Brief, Matsutani *et al* assert Plaintiffs-Appellants are incorrect when they state the effect of the District Court's decision is to "somehow immunize" defendants because the government can still bring such suits. PsychRights/Griffin never suggested the government could not still bring such suits. The point is the decision immunizes all past, present and future participants in the fraudulent scheme from "*qui tam*" liability, i.e., *relators* suing on behalf of the government. *See*, Opening Brief at 3 & 14. PsychRights could have been more clear where the point is mentioned at other places in the brief.

disclosures. To hold public disclosure of general industry-wide fraud immunizes all future false claims from *qui tam* liability would be a breath-taking expansion of the Public Disclosure Bar and contrary to Congress' intent in the 1986 Amendments to encourage private enforcement through the *qui tam* mechanism.

Matsutani *et al.* also cite to *United States ex rel. Rosales v. San Francisco Housing Auth*, 173 F. Supp. 2d 987, 996-997 (N.D.Cal 2001), for the proposition that the Public Disclosure Bar applies to ongoing fraud. This Court, of course, is not bound to follow this district court decision, but more importantly, *Rosales* relied upon *Lujan*, which seems to have been superseded by *Bly-Magee.*

Matsutani *et al.* assert it is absurd to allow *relators* to file new complaints raising claims for new false claims. PsychRights/Griffin suggest it is not absurd for defrauders to be held accountable for *qui tam* liability when they persist in making false claims even after they have been sued. PsychRights/Griffin suggest it would be curious indeed for the Public Disclosure Bar to be interpreted as immunizing continuing fraud from *qui tam* liability.

V. THE COURT SHOULD NOT AFFIRM ON THE ALTERNATIVE GROUNDS REQUESTED BY APPELLEES

Matsutani *et al* also ask this Court to affirm the dismissal on two alternative grounds not addressed by the District Court. An appellate court may properly decline to reach issues not addressed by the court below in order to obtain both a

fully developed record and the benefit of the district court's treatment of the issue. *Corder v. Gates*, 947 F.2d 374, 383 (9th Cir. 1991). Substantively, Matsutani *et al* are wrong. Matsutani *et al's* argument in their Rule 12(b)(6) motion boils down to the assertion that Congress did not limit Medicaid coverage of outpatient drugs to "covered outpatient drugs," which is illogical and wrong.[10] Matsutani *et al's* particularity argument is erroneous because for half of the defendants specific prescriptions constituting false claims have been identified and for the other half, the Amended Complaint identifies the circumstances of the alleged fraud so that defendants can prepare an adequate answer.

A. Matsutani et al's Rule 12(b)(6) Analysis Is Erroneous

(1) Congress Limited Coverage of Outpatient Drugs Under Medicaid to Those that Are For a Medically Accepted Indication

§ X.B.2. of Matsutani *et al.'s* Brief asks this Court to affirm the dismissal on the grounds that Congress did not limit Medicaid coverage to uses that are for a "medically accepted indication." In its Statement of Interest in *United States of*

[10] At pages 58-59 of their Brief, Matsutani *et al* assert that because Medicaid regulations defines "prescription drugs," it covers all such drugs. Frankly, this is nonsense. Congress carved out from the universe of prescription drugs those it would cover under Medicaid, defining them as "covered outpatient drugs," which "does not include a drug . . . used for a medical indication which is not a medically accepted indication," 42 U.S.C. § 1396r-8(k)(2)-(3). Thus, Matsutani *et al* are arguing Congress did not limit Medicaid coverage of outpatient drugs to covered outpatient drugs.

America ex rel Polansky v. Pfizer, Inc., EDNY, Case No. 1:04-cv-0074-ERK-ALC (U.S. Statement of Interest) of which judicial notice has been sought,[11] citing to 42 U.S.C. § 1396r-8(k)(2), (3) and (6), the United States Government walks through the statutory provisions that a "covered outpatient drug . . does not include a drug . . . used for a medical indication which is not a medically accepted indication."[12]

Under 42 U.S.C. § 1396r-8(k)(6), the term "medically accepted indication" means any use which is approved by the Food and Drug Administration (FDA), or the use of which is supported by one or more citations included or approved for inclusion in any of the three compendia set forth at 42 U.S.C. § 1396r-8(g)(1)(B)(i). In other words, covered outpatient drugs only includes an unapproved ("off-label") use if it is "supported" by one of the specified compendia.

Polansky involves the drug Lipitor and thus the United States said with respect to it:

> Prescription claims for Lipitor would be "false" if they were prescribed for unapproved uses that were not supported by a citation in one of the statutorily-identified compendia.[13]

This is precisely the type of *per se* false claim PsychRights/Griffin is asserting; if a claim for reimbursement is made to Medicaid for an outpatient psychotropic drug

[11] App. Dkt. Entry 37-1.

[12] App. Dkt. Entry 37-2, pp. 3-4.

[13] App. Dkt. 37-2, pp 7-8.

prescription to a child or youth that is not for a medically accepted indication, it is not covered under Medicaid, and therefore a false claim.

The United States explained why Congress prohibited coverage of drugs that were not for a medically accepted indication:

> It . . . would undermine the gatekeeping role of the federal government in protecting public health as well as the public fisc in ensuring that, based on the information available at the time, only indications that have been FDA-approved or are sufficiently supported by scientific literature as safe and effective are reimbursed.[14]

Whether or not judicial notice is taken of the U.S. Statement of Interest in *Polansky*, this analysis is correct and is PsychRights/Griffin's position.

§ X.B.2. of Matsutani *et al.'s* Brief also raises issues that are not related to Matsutani *et al's* assertion that Congress did not limit coverage of outpatient drugs to "covered outpatient drugs."

(2) <u>An Intentional Lie is Not Required</u>

At page 61, Matsutani *et al.* assert PsychRights/Griffin's claims are based on certified statements being false, citing to Exc. 118-123, and then assert "for a certified statement to be 'false' under the Act, it must be an intentional, palpable lie. Innocent mistakes . . . differences in interpretation are not false certifications under

[14] *Id*., at p. 8. Matsutani *et al*., point out that doctors are free to prescribe drugs for any use, which is true, but it is also true that if they prescribe a drug to a Medicaid recipient that is not for a medically accepted indication, they are causing a false claim.

the Act," citing to *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th cir. 1996), citing *United States ex rel Hagood v. Sonoma Cnty. Water Agency*, 929 F.2d 1416, 1478 (9th Cir. 1991).

First, Matsutani *et al* fail to mention *U.S. ex rel. Plumbers and Steamfitters Local Union No. 38 v. C.W. Roen Const. Co.*, 183 F.3d 1088, 1093 (9th Cir. 1999), in which this Court specifically held otherwise, saying, "some of our cases may contain extraneous comments that might be read out of context to suggest that the FCA requires an intentional lie to trigger liability."

Second, PsychRights/Griffin are not asserting Matsutani *et al* made false certifications. Exc. 118-123 does not allege false certification. For example, paragraph 163 of the Amended Complaint, Exc. 119, simply states, "Every Medicaid provider must agree to comply with all Medicaid requirements." This is directed at the False Claims Act's *scienter* requirement, 31 U.S.C. § 3729(a). Under this Court's decision in *United States v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001), "Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment" and failure to do so satisfied the *scienter* requirement. The same is true of Medicaid providers and Paragraph 163 of the Amended Complaint reinforces this by alleging that every Medicaid provider defendant has even signed an agreement to that effect.

The balance of Exc. 118-123 connect the dots regarding prescriptions to children and youth Medicaid recipients for psychotropic drugs that are not for a medically accepted indication being false claims. They do not allege false certification.

As the United States said in its Statement of Interest in *Polansky*:

> When a claim is false because it is for a non-reimbursable item (e.g., an off-label indication that is not otherwise covered by federal health programs), an analysis under a "certification theory" is simply inapposite. See Def. Br. at 19 (discussing false certification theory of liability). Whether the provider "certified" on the claim for payment that the prescribed usage was on-label or otherwise reimbursable is irrelevant. Rather, the core question for "falsity" under the FCA is whether the government received a bill from a healthcare provider for an item or service that was not legally reimbursable. This is an objective question and is not, as defendant argues, a "subjective interpretation of defendant's legal duties" that preclude a finding of falsity.[15]

Again, PsychRights/Griffin have asked this Court to take judicial notice of the U.S. Statement of Interest in *Polansky*,[16] but even if it does not, it is a correct statement of the law and PsychRights/Griffin take the same position.

Alternatively, PsychRights/Griffin respectfully suggest should actual knowledge be required in spite of *Mackby*, it is a factual issue not proper for summary dismissal under Civil Rule 12(b)(6).

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[15] App. Dkt.Entry. 37-2, pp 5-6.

[16] App. Dkt. Entry 37-1

(3) That Government Officials Are Allowing the False Claims Does Not Protect Matsutani *et al*

Matsutani *et al* also assert at footnote 75 of their Brief that because Alaska and federal officials are allowing the claims to be reimbursed they cannot be charged with causing or presenting false claims. This is incorrect:

> Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law

Heckler v. Community Health Services, 467 U.S. 51, 63, 104 S.Ct. 2218, 2225 (1984). Citing to *Heckler*, in *Hagood*, 929 F. 2d at 1422, this Court held that United States government officials' approval of a contract based on an erroneous interpretation of law did not defeat a False Claims Act cause of action, and reversed the district court's dismissal under Rule 12(b)(6).

B. The Amended Complaint Complies With Civil Rule 9(b)

Matsutani *et al*, at § X.B.2 of their Brief also urge this Court to affirm the dismissal on the ground that the Amended Complaint does not comply with Civil Rule 9(b)'s particularity requirement. The First Amended Complaint identifies particular false claims for about half of the defendants-appellees, such as those caused by Dr. Matsutani set forth above. PsychRights/Griffin know of no decision

holding this is insufficient to satisfy Rule 9(b)'s particularity requirement. This leaves particularity questions only as to defendants who caused false claims to be presented for whom no specific offending prescriptions were identified.[17]

PsychRights/Griffin have not found any opinion where this Court has ruled on the issue of whether specific offending prescriptions have to be pled in False Claims Act Medicaid fraud cases concerning non-covered prescriptions, but it has spoken on Rule 9(b)'s pleading requirement under the False Claims Act:

> 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."

Bly-Magee, 236 F.3d at 1019.

Here, the Amended Complaint alleges the defendants for whom specific false claims have not been identified caused false claims for prescriptions to children and youth that are not for a medically accepted indication. These defendants know whether that is true or not and can deny the allegations if they are not true. However, they know the allegations are true and in fact, have essentially admitted they are continuing to cause such false claims.

[17] Specific false claims have been identified for all of the defendants-appellees who presented false claims, Walmart, Safeway, Fred Meyer, Hogan and Struer.

Thomson/Reuters HealthCare (Thomson) is in a somewhat different category because they caused false claims by being paid by pharmaceutical companies to induce doctors to prescribe psychotropic drugs to children and youth that are not for medically accepted indications. Paragraphs 196-198 of the Amended Complaint, Exc. 135-136. Whereas the linkage to the presentment of a false claim is direct when a doctor prescribes the drug to a Medicaid recipient, *i.e.* step 2 of the Fraudulent Scheme depicted above, Thomson is participating in the Fraudulent Scheme at Step 1, where the linkage is not so direct.

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) addresses Civil Rule 9(b)'s particularity requirement at Step 1 of the Fraudulent Scheme:

> 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*, 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.").

The United States Government agrees this is the correct standard in its Statement of Interest in *Polanski*. App. Dkt. No. 37-2, p11. The Amended Complaint meets this standard, even as to Thomson. However, should it be determined more particularity is required, PsychRights should be allowed to amend its complaint to provide it.

VI. CONCLUSION

For the foregoing reasons, Plaintiffs-Appellants, *relators* Griffin and PsychRights urge this Court to (1) REVERSE the District Court's holding that 31 U.S.C. § 3730(e)(4)(A) applies to disclosures of industry-wide fraud, and (2) hold 31 U.S.C. § 3730(e)(4)(A) does not divest the District Court of jurisdiction to hear the *Griffin* and *Matsutani* Actions.

RESPECTFULLY SUBMITTED this 29th day of March, 2011.

Law Project for Psychiatric Rights, an Alaska non-profit corporation and Daniel I. Griffin, Plaintiffs-Appellants

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VII. STATEMENT WITH RESPECT TO ORAL ARGUMENT

Plaintiffs/Appellants (PsychRights/Griffin) believe oral argument is not needed because the dispositive issues in this case have been authoritatively decided by this Court. In *U.S. ex rel. Foundation Aiding The Elderly v. Horizon West*, 265 F.3d 1011, n5 (9th Cir. 2001) this Court held public disclosure of industry-wide fraud does not trigger the Public Disclosure Bar.[18] In *U.S. ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 920 (9th Cir. 2006), this Court held the Public Disclosure Bar does not apply to false claims caused or presented after the date of the public disclosure.

If the Court does not agree these cases authoritatively decide the Public Disclosure Bar issues against the Defendants/Appellees (Matsutani *et al*), it seems oral argument should be held on those issues.

In addition, should this Court entertain Matsutani *et al.'s* request that this Court affirm the dismissal on the alternative grounds that Congress did not limit Medicaid coverage of outpatient drugs to covered outpatient drugs, or that the Amended Complaint in this matter does not satisfy the particularity requirement of

[18] Unless a narrow class of wrongdoers is identified in the public disclosure. *United States ex rel Harshman v.Alcan Electrical and Engineering, Inc*., 197 F.3d 1014, 1019 (9th Cir. 1999).

Civil Rule 9(b), PsychRights/Griffin believe oral argument should be held because there is so little briefing on these issues.

VIII. CERTIFICATE OF COMPLIANCE

1. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(b)(ii) because it contains 4462 words, including the 49 words in the Fraudulent Scheme graphic, but excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(b)(iii).

2. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface, Times New Roman, 14 point font, using Microsoft Word 2007.

/s/ James B. Gottstein
JAMES B. GOTTSTEIN

IX. ADDENDUM

42 U.S.C. § 1396r-8(g)(1)(B)(i)

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(IV) Repealed. Pub.L. 108-173, Title I, § 101(e)(9)(B), Dec. 8, 2003, 117 Stat. 2152.

42 U.S.C. § 1396r-8(k)(2)

(2) Covered outpatient drug

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means--

(A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355 or 357] or which is approved under section 505(j) of such Act [21 U.S.C.A. § 355(j)];

(ii) (I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning

of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug; and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C.A. § 331, 332(a), or 334(a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C.A. § 352(f) or 355(a)]; or

(iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which--

(i) may only be dispensed upon prescription,

(ii) is licensed under section 262 of this title, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 356].

42 U.S.C. § 1396r-8(k)(3)

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians' services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

42 U.S.C. § 1396r-8(k)(6)

(6) Medically accepted indication

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

X. CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the Appellants' Reply Brief with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system on March 29, 2011. Participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system. I further certify that some of the participants in the case are not registered CM/ECF users. On March 29, 2011, I mailed the Appellants' Reply Brief by First-Class Mail, postage prepaid to the following non-CM/ECF participants:

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