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' OPENING BRIEF

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I. CORPORATE DISCLOSURE STATEMENT

One of the plaintiffs-appellants, the Law Project for Psychiatric Rights, Inc., is an Alaska non-profit corporation. No one, including no corporation, owns any stock in PsychRights.

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IV. JURISDICTIONAL STATEMENT

Basis for District Court Jurisdiction

The District Court had subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and the False Claims Act, 31 U.S.C. §§ 3729, 3730 and 3732.

Basis for Court of Appeals Jurisdiction

Appellate jurisdiction is conferred in this case by 28 U.S.C. §1291. Plaintiffs-Appellants, the Law Project for Psychiatric Rights (PsychRights®) and Daniel Griffin (Griffin), collectively the "*Relators*," filed their Notice of Appeal on September 30, 2010, following entry of a final judgment disposing of all claims against all parties on September 30, 2010 by the District Court. The Notice of Appeal is proper pursuant to 28 U.S.C. § 1294 in that the United States District Court for the District of Alaska, is within the confines of the Ninth Circuit.

V. STATEMENT OF ISSUE PRESENTED FOR REVIEW

The Court below erred in concluding *Relators'* complaints were based upon the public disclosure of allegations or transactions within the meaning 31 U.S.C. § 3730(e)(4)(A) and dismissing the Complaints.

VI. STATEMENT OF THE CASE

A. Nature of the Case

This appeal involves two consolidated *qui tam* cases under 31 U.S.C. § 3729, *et seq.* (False Claims Act), to recover damages and civil penalties against

various defendants-appellees (Defendants) for causing and presenting claims to Medicaid for prescriptions of psychotropic drugs used on children and youth that are not for a "medically accepted indication," and therefore not covered (legally reimbursable) under Medicaid. The False Claims Act authorizes private parties to sue on behalf of the United States Government to recover for such false claims and share in the recovery, if any. 31. U.S.C. § 3730(b)-(d).

The District Court dismissed both cases on the grounds that public disclosure of industry-wide fraud triggers what is commonly referred to as the "Public Disclosure Bar" under 31 U.S.C. § 3730(e)(4)(A).[1] This is contrary to controlling precedent of this Court, *U.S. ex rel. Foundation Aiding The Elderly v. Horizon West*, 265 F.3d 1011, n5 (9th Cir. 2001), which explicitly held allegations of general or widespread fraud do not trigger the public disclosure bar. Under other 9th Circuit precedent, the Public Disclosure Bar is not triggered unless the public disclosure identifies the specific defendants[2] or "a narrow class of suspected

[1] Exc. 1, 21-22.

[2] *United States ex rel. Aflatooni v Kitsap Physicians Services*, 163 F.3d 516, 523 (9th Cir. 1999).

wrongdoers,"[3] and cannot be triggered with respect to false claims presented after the public disclosure.[4]

This 9th Circuit jurisprudence precludes the dismissal ordered by the District Court below. Thus, this case presents the question of whether this Court will overrule its existing precedent and uphold the District Court, and in so doing immunize from *qui tam* liability under the False Claims Act, all members of an industry for committing fraud against the Government for future as well as past false claims when there has been public disclosure of industry-wide fraud.

B. Course of Proceedings

PsychRights filed its Complaint in Case No. 3:09-cv-00080-TMB, against defendant-appellee Osamu Matsutani and others (*Matsutani* Action),[5] on April 27,

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[3] *United States ex rel Harshman v. Alcan Electrical and Engineering, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999).

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

[5] The defendants-appellees of the *Matsutani* Action, after a couple of corrections, Dkt. Nos. 99 & 100, are: Osamu H. Matsutani, MD; William Hogan, individually and as Commissioner of the Department of Health and Social Services; Tammy Sandoval, individually and as Director of the Alaska Office of Children's Services; Steve McComb, individually and as Director of the Alaska Division of Juvenile Justice; William Streur, individually and as Director of The Alaska Division of Health Care Services; Juneau Youth Services, Inc., an Alaska non-profit Corporation; Providence Health & Services, an Alaska non-profit Corporation; Elizabeth Baisi, MD; Ruth Dukoff, MD; Kerry Ozer, MD; Claudia Phillips, MD; SouthCentral Foundation, an Alaska non-profit Corporation; Sheila Clark, MD; Lina Judith Bautista, MD; Heidi F. Lopez-Coonjohn, MD; Robert D. Schults, MD;
----------(footnote continued)

2009, for violating the False Claims Act by causing or presenting false claims to the United States Medicaid program for reimbursement of prescriptions of psychotropic drugs prescribed to children and youth for indications that are not medically accepted indications and therefore not covered (reimbursable) under Medicaid. Dkt. No. 1.[6]

Griffin filed his Complaint in Case No. 3:09-cv-00246-TMB, against Dr. Martino, Family Centered Services, Inc., and Safeway[7] on December 14, 2009, for violating the False Claims Act by causing or presenting false claims to the Medicaid program for reimbursement of prescriptions for psychotropic drugs prescribed to Griffin and other children and youth for indications that are not medically accepted indications and therefore not covered under Medicaid (*Griffin* Action). Exc. 290-299.

(Continued footnote)----------
Mark H. Stauffer, MD; Ronald A. Martino, MD; Irvin Rothrock, MD; Jan Kiele, MD; Alternatives Community Mental Health Services, d/b/a Denali Family Services; Anchorage Community Mental Health Services, an Alaska non-profit Corporation; Lucy Curtiss, MD; Fairbanks Psychiatric and Neurologic Clinic, PC; Peninsula Community Health Services Of Alaska, Inc.; Bartlett Regional Hospital, an Agency of The City And Borough Of Juneau; Thomson Reuters (Healthcare) Inc.; Wal-Mart Stores, Inc., Safeway, Inc.; Fred Meyer Stores, Inc.; Frontline Hospital, LLC, d/b/a North Star Hospital.

[6] Unless otherwise indicated, all references to documents by "Dkt. No." are to the *Matsutani* Action, 3:09-cv-80-TMB.

[7] Dr. Martino and Safeway are also defendants in the *Matsutani* Action.

Both complaints were filed under seal pursuant to 31 U.S.C. § 3730(b)(2). On December 31, 2009 the United States declined to intervene in the *Matsutani* Action, Dkt. No 14 and it was unsealed January 25, 2010, Dkt. No. 16.

On April 5, 2010, the *Matsutani* Defendants-Appellees moved to dismiss for lack of jurisdiction under 31 U.S.C. § 3730(e)(4)(A), commonly known as the "Public Disclosure Bar," Dkt. No. 89, which was opposed at Dkt. No. 111.

On April 26, 2010, the United States declined to intervene in the *Griffin* Action, Dkt. No. 9 in 3:09-cv-246-TMB, and it was unsealed May 17, 2010. Dkt. No. 10 in 3:09-cv-246-TMB.

On May 6, 2010, PsychRights filed an Amended Complaint in the *Matsutani* Action, Exc. 87-151.

On July 14, 2010, upon motion by the defendant-appellee Martino in the *Griffin* Action, Dkt. No. 15 in 3:09-cv-246-TMB, which was not opposed by Mr. Griffin, Dkt. No. 18 in 3:09-cv-246-TMB, the *Matsutani* Action and the *Griffin* Action were consolidated, Dkt. No. 23 in 3:09-cv-246-TMB, and all further consolidated pleadings ordered filed in the *Matsutani* Action docket, Dkt. Nos. 23 & 25 in 3:09-cv-246-TMB.

On July 27, 2010, at Dkt. No. 141, *Griffin* Action defendant-appellee Safeway filed a motion to dismiss under 31. U.S.C. § 3730(e)(4)(A) and other

grounds. This motion was joined by defendant-appellee Family Centered Services of Alaska (FCSA) at Dkt. No.146 and defendant-appellee Martino at Dkt. No. 149, and opposed at Dkt. No. 151.

On September 24, 2010, the District Court granted the motions to dismiss under the Public Disclosure Bar in both actions, Exc. 4-28, which was made final September 30, 2010, when the District Court issued a final judgment. Exc. 3. The Notice of Appeal was filed the same day. Exc. 29-30.

On October 14, 2010, certain of the defendants filed a motion for attorney's fees, at Dkt. No., 173, supported by separate affidavits at Dkt. Nos. 175-182, 184 and 186. This was opposed at Dkt. No. 196. The District Court denied the motion for attorney's fees on December 7, 2010. Exc. 1.

C. <u>Disposition Below</u>

The September 24, 2010 Order, Exc. 4-28, and the September 30, 2010, Final Judgment, Exc. 3, dismissed both the *Matustani* and *Griffin* complaints with prejudice on the grounds that public disclosure of industry-wide fraud invoked the Public Disclosure Bar, 31 U.S.C. § 3730(e)(4)(A).

The December 7, 2010, Order, Exc. 1, denied the motion for attorney's fees against PsychRights on the grounds there was "no consensus as to whether industry-wide allegations of fraud are sufficient to invoke the Public Disclosure Bar," and the "*Relators'* argument that their allegations were not disclosed

because the prior disclosures did not name specific defendants was not wholly without merit." Exc. 1.

VII. STATEMENT OF FACTS

A. The Fraudulent Scheme

Coverage for outpatient drugs under Medicaid is restricted to those prescribed for "medically accepted indications," which means indications approved by the Food and Drug Administration (FDA) or "supported" by at least one of three specified drug references, known as the "Compendia."[8] In other words, Congress did not completely prohibit coverage of "off-label" prescriptions, which are prescriptions not for FDA approved indications, but limited off-label coverage to those that have sufficient scientific support as documented in the Compendia.

Through various means, pharmaceutical companies have induced doctors, including the doctor defendants-appellees here, to prescribe psychotropic drugs to children and youth Medicaid recipients that are not for medically accepted indications, including:[9]

> 77. Drug companies pay sales representatives to make false statements to prescribers to induce them to prescribe particular psychotropic drugs to children and youth for uses not approved by the FDA.

[8] Exc. 118-119, ¶158 of First Amended Complaint.

[9] Exc. 91, 100-105, ¶s 5, 51-57, 59- 84 of the Amended Complaint.

78. Drug companies give or gave gifts to prescribers to induce them to prescribe particular psychotropic drugs to children and youth for uses not approved by the FDA.

83. Less than one minute spent by sales representatives with doctors results in a 16 percent change in such doctors' prescribing in favor of the drug companies' drug(s).

84. After three minutes with a sales representative there is a 52 percent change in such doctors' prescribing in favor of the drug companies' drug(s).

These means have been successful in spite of the well-documented lack of effectiveness and harm caused by such prescriptions, including:[10]

85. Mainstream mental health practice endorses a "medical model" of mental illness that supports medicating children and youth with little or no evidence of the drugs' safety or efficacy.

88. Most psychotropic medication classes lack scientific evidence of their efficacy or safety in children and youth.

89. No studies have established the safety and efficacy of polypharmacy [multiple psychotropic drugs at the same time] in children and youth.

90. Almost all psychiatric drugs have been shown to cause brain damage in the form of abnormal cell growth, cell death and other detrimental effects, which is especially harmful for growing and developing children and youth.

91. Psychotropic drugs given to children and youth cause drug-induced adverse effects and behavioral changes, including apathy, agitation, aggression, mania, suicidal ideation and psychosis, known as "behavioral toxicity."

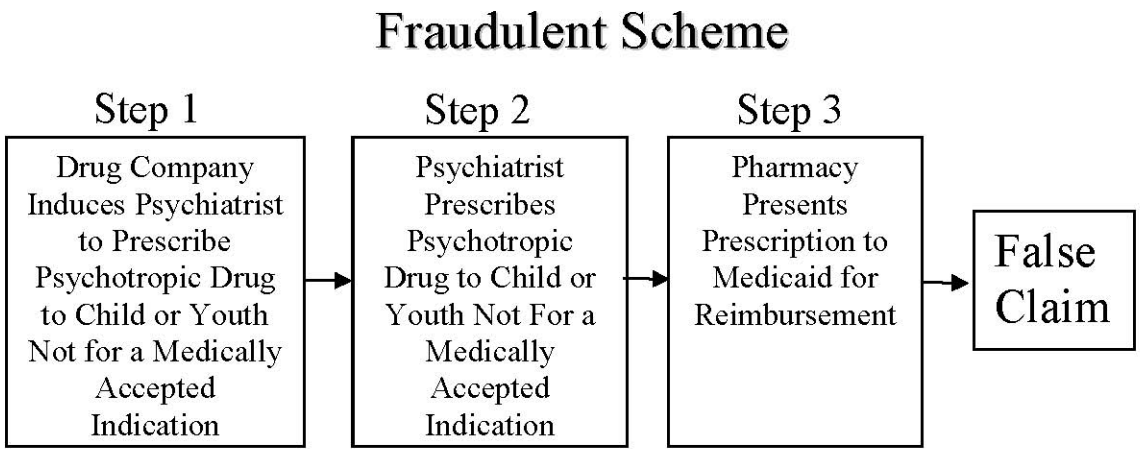
[10] Exc. 105-118, ¶s 84-155 of the Amended Complaint.

92. Psychotropic drugs given to children and youth suppress learning and cognition and produce cognitive neurotoxicity, interfering with the basic mental development of the child, which adverse effects often do not go away after the drugs are withdrawn.

93. No studies show that giving psychotropic drugs to children and youth increases learning or academic performance in the long term.

After doctors prescribe such drugs they are taken to pharmacies, including the pharmacy Defendants here, which then fill the prescriptions and present false claims to Medicaid for payment.[11]

The broad outline of this fraudulent scheme can be depicted as follows:



The Government is currently devoting its enforcement resources to address Step 1.[12] These enforcement efforts have not stopped the practice of child psychiatrists

[11] Exc. 92, 132-135, ¶s 7(c), 189-195 of the Amended Complaint.

[12] *See*, e.g. Exc. 31-45, 61-86.

prescribing drugs to children and youth that are not for a medically accepted indication and thus causing false claims.[13]

Other categories of participants in this fraudulent scheme who are defendants-appellees here are (1) mental health agencies which employed the psychiatrist Defendants to write the prescriptions constituting false claims,[14] (2) two state of Alaska officials responsible for authorizing payment of such false claims,[15] (3) two other state officials who run programs that cause such false claims,[16] and (4) a medical publisher who caused such false claims by promoting off-label use of psychotropic drugs on children and youth not for a medically accepted indication in continuing medical education programs and one of the Compendia, known as DRUGDEX®.[17]

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[13] Exc. 278.

[14] Amended Complaint, ¶7(b), Exc. 92; Amended Complaint ¶s200-204, Exc. 136-141.

[15] Amended Complaint ¶7(d), Exc. 92; Amended Complaint ¶11, Exc. 93; Amended Complaint ¶14, Exc. 94; Amended Complaint, ¶s 212- 215, Exc. 146-147.

[16] Amended Complaint ¶s 12 & 13, Exc. p. 93-94; Amended Complaint ¶s 185-188, Exc. 127-132.

[17] Amended Complaint ¶7(e), Exc. 92, Amended Complaint ¶38, Exc. 98; Amended Complaint ¶196-199, Exc. 135-136.

B. The Alleged Public Disclosures

(1) News Media

In the last few years there have been some alarms raised in the media about the inappropriate prescribing of these dangerous, ineffective drugs to children and youth.[18] None of these identify any of the Defendants. Neither do they identify the Congressional restriction of Medicaid to medically accepted indications, although some do generally question whether some of it may constitute Medicaid fraud.[19] There was also a Wall Street Journal article about how the expansive listings of indications in DRUGDEX, published by Thomson, increases Medicaid payments.[20] With the exception of Thomson in the Wall Street Journal article, none of the Defendants were identified in any of these news media reports.

(2) CCHR White Paper

A private advocacy group, known as the Citizens Commission for Human Rights (CCHR) issued a "white paper" about the problem in Florida,[21] including

[18] Exc. 152-159, 161, 186-196.

[19] *Id.*

[20] Exc. 285-289.

[21] Exc. 162-185.

that drugs not prescribed for medically accepted indications may constitute Medicaid Fraud.[22] None of the Defendants were identified.

(3) The State Case

Detailing the extreme harm caused by the practice of prescribing psychotropic drugs to children and youth, the Amended Complaint in, *Law Project for Psychiatric Rights v. State of Alaska, et al.*, Case No. 3AN-08-10115CI, Superior Court, Third Judicial District, State of Alaska (State Case) sought an injunction against the State of Alaska and a declaratory judgment that Alaskan children and youth have the right not to be administered psychotropic drugs unless and until,

(i) evidence-based psychosocial interventions have been exhausted,
(ii) rationally anticipated benefits of psychotropic drug treatment outweigh the risks,
(iii) the person or entity authorizing administration of the drug(s) is fully informed of the risks and potential benefits, and
(iv) close monitoring of, and appropriate means of responding to, treatment emergent effects are in place.[23]

Paragraph 22 of the Amended Complaint in the State Case recites Medicaid's restriction on coverage to medically accepted indications.[24] This complaint was twice further amended regarding coverage under Medicaid being restricted to

[22] Exc. 172-173.

[23] Exc. 207.

[24] Exc. 212.

medically accepted indications.[25] Four of the Defendants, Hogan, Struer, Sandoval, and McComb were identified in the State Case.

(4) Utah Attorney General Office/CMS Correspondence

In late 2007-early 2008, there was an exchange of correspondence between the Utah Attorney General's Office and the Centers for Medicare and Medicaid Services (CMS) regarding whether Congress restricted coverage for outpatient drugs under Medicaid to those that were for a medically accepted indication.[26] None of the Defendants were identified.

(5) PsychRights Web Pages

Two PsychRights web pages refer to and describe the Fraudulent Scheme and publish a "Model *Qui Tam* Complaint" for use around the country.[27]

(6) CMS Compendia Clarification

On May 4, 2006, CMS issued a document to State Medicaid Directors, titled "Compendia Clarification," which "reiterated" the definition of "medically accepted indication" as meaning "any use for a covered outpatient drug which is approved by the

[25] Exc. 197-204;

[26] Exc. 55-60.

[27] Exc. 278-280, 282-284.

Food and Drug Administration, or a use which is supported by one [of the Compendia]."[28]

VIII. SUMMARY OF ARGUMENT

Contrary to controlling precedent of this Court, the District Court dismissed both actions on the grounds that public disclosure of industry wide-fraud triggers the Public Disclosure Bar under 31 U.S.C. § 3730(e)(4)(A). This effectively immunizes from *qui tam* liability under the False Claims Act all past, present and future participants in the Fraudulent Scheme described above.

United States ex rel. Aflatooni v Kitsap Physicians Services, 163 F.3d 516, 523 (9th Cir. 1999), holds the Public Disclosure Bar is not triggered unless the qualifying public disclosure identifies the specific defendants. The subsequent case of *United States ex rel Harshman v. Alcan Electrical and Engineering, Inc.*, 197 F.3d 1014, 1018-19 (9th Cir. 1999), carves out an exception if "a narrow class of suspected wrongdoers" has been identified. Subsequent to these two decisions, *U.S. ex rel. Foundation Aiding The Elderly v. Horizon West*, 265 F.3d 1011, n5 (9th Cir. 2001), explicitly held allegations of general or widespread fraud do not trigger the Public Disclosure Bar. Finally, *U.S. ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 920 (9th Cir. 2006), holds the Public Disclosure Bar does not apply to

[28] Exc. 281.

false claims presented after the public disclosure. This controlling precedent precludes the dismissals below.

Dismissal of the psychiatrist, mental health agency, and pharmacy defendants is precluded because they were not identified in any of the cited public disclosures, nor were they members of a narrow class of wrongdoers identified in any of the disclosures. Dismissal of the State of Alaska officials and Thomson was not proper because the Public Disclosure Bar does not apply to false claims presented after the public disclosures.

IX. ARGUMENT

A. Reviewability and Standard of Review

The issue on review was raised at Dkt. No. 89, and opposed at Dkt. No. 111. This Court reviews the District Court's findings of fact relevant to its determination of subject matter jurisdiction for clear error. Whether a particular disclosure triggers the jurisdictional bar of 31 U.S.C. § 3730(e)(4)(A), however, is a mixed question of law and fact that this Court reviews de novo. *Foundation Aiding The Elderly*, 265 F.3d at 1013.

B. The Public Disclosure Bar Does Not Immunize All Participants In A Fraudulent Scheme When There Has Been Public Disclosure of Industry-Wide Fraud

(1) The False Claims Act and the Public Disclosure Bar

> "The [False Claims Act] was enacted during the Civil War with the purpose of forfending widespread fraud by government contractors who were submitting inflated invoices and shipping faulty goods to the government." *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265-66 (9th Cir.1996). To encourage insiders to disclose fraud and thereby bolster enforcement, the FCA contains a *qui tam* provision that permits private persons (known as "relators") to bring civil actions on behalf of the United States and claim a portion of any award. See 31 U.S.C. § 3730(b), (d) (2008)

Ebeid ex rel. U.S. v. Lungwitz, 616 F.3d 993, 995 (9th Cir. 2010).

Under 31. U.S.C. § 3730(b)(2) & (4) such *qui tam* complaints are filed under seal for a limited time to allow the government time to investigate and decide whether to intervene and take over the case. If, as here, the government declines to intervene, under the Public Disclosure Bar, 31 U.S.C. § 3730(e)(4)(A), as it existed prior to 2010 amendments, the District Court lacks jurisdiction if the "allegations or transactions" of the complaint are "based upon the public disclosure" in certain "enumerated sources." [29]

[29] *U.S. ex rel Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1199 (9th Cir. 2009), citing to *A-1 Ambulance Service v. California*, 202 F.3d 1238, 1243 (9th Cir. 2000).

(2) Controlling 9th Circuit Precedent is Contrary to the Dismissal Ordered by the District Court Here

The District Court dismissed these actions based upon public disclosure of industry-wide fraud:

> The Relators . . . urge this Court to reject or distinguish cases suggesting that industrywide allegations of fraud are sufficient to invoke the Public Disclosure Bar. Indeed, there is no consensus on that broad proposition. A fair reading of all of these cases, however, supports the proposition that where the information in the prior disclosure is sufficient for the Government to initiate an investigation against the defendants, the Public Disclosure Bar applies. [30]

That public disclosure of industry-wide fraud was the basis for the dismissal was reiterated in the District Court's denial of attorney's fees against PsychRights:

> As the Court noted in its Order granting Defendants' motion to dismiss, there is "no consensus" as to whether "industry-wide allegations of fraud are sufficient to invoke the Public Disclosure Bar."[31]

While there may be no consensus as between the other circuits, it is settled law in this Circuit that the Public Disclosure Bar cannot be triggered by disclosure of general, widespread industry-wide fraud. In arriving at its contrary conclusion the District Court mostly cited out of Circuit decisions.[32]

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[30] Exc. 21-22, footnotes deleted.

[31] Exc. 1.

[32] Exc. 21-22, n. 120.

U.S. ex rel. Foundation Aiding The Elderly v. Horizon West, 265 F.3d 1011, n5 (9th Cir. 2001), explicitly held allegations of general or widespread fraud do not trigger the Public Disclosure Bar:

> 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 District Court cited to this specific footnote, characterizing it as holding:

> [T]he relevant question when examining the level of detail in prior disclosures is whether those disclosures "would give the government sufficient information to initiate an investigation" against the defendants.

However, that part of footnote 5 rejected application of the Public Disclosure Bar because the specific defendant was not identified ("we do not believe that this report would give the government sufficient information to initiate an investigation against this facility") (emphasis added).

Previously, in *United States ex rel. Aflatooni v Kitsap Physicians Services*, 163 F.3d 516, 523 (9th Cir. 1999), this Court held:

> The public disclosure bar cannot be applied to the PAKC Defendants unless the evidence supports the district court's finding that the allegations against those particular defendants were disclosed in the news media.

(emphasis added). Ten months after *Aflatooni*, in *United States ex rel Harshman v.Alcan Electrical and Engineering, Inc.*, 197 F.3d 1014, 1019 (9th Cir. 1999), this Court carved out a very limited exception if the public disclosure identifies "a narrow class of suspected wrongdoers."

Finally, in 2006, *U.S. ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 920 (9th Cir. 2006), held the Public Disclosure Bar cannot be triggered by false claims occurring after the public disclosure:

> Bly-Magee alleges in her complaint, however, that the false claims continued through the 1999-2000 fiscal year, which ended June 30, 2000. We conclude, therefore, that on the present record the district court appears to have had jurisdiction over allegations in the complaint of false claims occurring after June 30, 1999, because they were not publicly disclosed.
>
> We accordingly reverse the dismissal of those portions of the complaint alleging the making of false claims after June 30, 1999.

Thus, this Court's jurisprudence is the Public Disclosure Bar cannot be triggered unless the public disclosure identifies the specific defendants, or "a narrow class of suspected wrongdoers," and cannot be triggered with respect to acts occurring after the public disclosure. That this jurisprudence means allegations of industry-wide fraud do not trigger the Public Disclosure Bar was explicitly held by this Court in *Foundation Aiding The Elderly*. It is accordingly suggested the District Court's holding to the contrary should be reversed.

C. The Court Should Decline to Extend the Public Disclosure Bar to Immunize All Past, Present and Future Participants in a Fraudulent Scheme Where There Has Been a Public Disclosure of Industry-Wide Fraud

With the exception of the State of Alaska officials and Thomson, none of the cited public disclosures identify any of the Defendants. With the exception of the State Case and the two PsychRights web pages, none of the putative public disclosures even involve Alaska. With respect to the State of Alaska officials, PsychRights relied on the holding in *Bly-Magee* that the Public Disclosure Bar cannot apply to false claims that post date the public disclosure and the same principle applies to Thomson.[33] The District Court distinguished the *Bly-Magee* case saying, "Here, unlike *Bly-Magee*, the public disclosures allege a continuing course of conduct which are not limited to specific time periods."[34] The effect of the District Court's ruling is to immunize all past, present, and future participants in the Fraudulent Scheme. As set forth above, this is contrary to this Court's jurisprudence. Griffin and PsychRights urge this Court to not so dramatically limit the application of the False Claims Act.

[33] Dkt. No. 111, p. 17

[34] Exc. 25.

The text of 31 U.S.C. § 3730(e)(4)(A) does not support the District Court's construction. As the First Circuit in *U.S. ex rel Duxbury v. Ortho-BioTech Products*, 579 F.3d 13, 27 (1st Cir. 2009), cautioned:

> Both the D.C. Circuit and the Sixth Circuit have focused on the concern with "parasitic" suits, concluding that any such suit brought after a "public disclosure" was necessarily "parasitic." As noted above, we question that conclusion. But we also note that the 1986 amendments equally sought to end a regime that resulted in the "under-enforcement" of the FCA, one that rested too much on government notice to prevent fraud. As we have noted, Congress "amended the statute to 'encourage more private enforcement suits.'" 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. . . .
>
> [J]ust as we eschewed reading an exclusion in *Rost* that did not have textual support and resulted in discouraging "productive private enforcement," we similarly decline to do so here.

(citations omitted).

The District Court cited *U.S. ex rel. Poteet v. Bahler Medical, Inc.*, 619 F.3d 104 (1st Cir 2010) as undercutting *Duxbury* when it said the Public Disclosure Bar "is designed to preclude parasitic qui tam actions."[35] However, *Poteet* does not cite to *Duxbury* and there is no indication it repudiates *Duxbury's* conclusion that the

[35] Exc. 14.

Public Disclosure Bar should not be read so broadly as to discourage "productive private enforcement" where there is no textual support in the statute.

Because plaintiffs-appellants are *qui tam relators*, this action is brought on behalf of the United States, which is the real party in interest.[36] Thus, even where, as here, the United States declines to intervene and the case proceeds *qui tam*, the United States has an interest in the outcome. Because the United States was so alarmed the Seventh Circuit might affirm a district court decision similar to the one here, it filed an *amicus* brief in *United States ex rel. Baltazar v. Warden*, Case No. 09-2167 (U.S. *Baltazar* Brief). Griffin and PsychRights have requested this Court take judicial notice of the U.S. *Baltazar* Brief, because it seems the Court should be aware of the United States' view as to the application of the Public Disclosure Bar to allegations of industry-wide fraud:[37]

The U.S. *Baltazar* Brief notes that the federal government cannot possibly pursue all instances of industry-wide fraud where there are a large number of

[36] *Cedars-Sinai Medical Center v. Shalala*, 125 F.3d 765, 768 (9th Cir. 1997); *U.S. ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, n.8 (9th Cir. 1996); *U.S. ex rel. Killingsworth v. Northrop Corp.*, 25 F.3d 715, 720 (9th Cir. 1994).

[37] DktEntry 20-1, here. A copy of the U.S. *Amicus* Brief is at DktEntry 20-2 here.

members of the industry.[38] In *Seal 1 v. Seal A*, 255 F.3d 1154, 1160 (2001), this Court reiterated,

> "[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).

The U.S. *Baltazar* Brief also includes the following regarding the application of the Public Disclosure Bar where, as here, there have been public disclosures of industry-wide fraud:

> The district court relied on various government and media reports to conclude that Baltazar's allegations were precluded by the public disclosure bar. None of the reports identified any particular actors who had committed fraud against the United States, or the specific methods by which such fraud had been achieved. The district court nevertheless held Baltazar's suit to be barred by these disclosures, reasoning that for such purposes it was "sufficient that the public disclosures contain information regarding industry-wide abuses that mimic closely the plaintiff's alleged fraud."
>
> That analysis is incorrect. . . . [T]he public disclosure bar applies only "'when the critical elements exposing the transaction as fraudulent are placed in the public domain.'" . . . <u>The identity of a fraud's perpetrator</u> and the method used to achieve the fraud are <u>among the most fundamental elements of an allegation under the False Claims Act</u>. . . .
>
> The disclosures likewise fail to identify fraudulent acts with specificity. . . .
>
> Descriptions of fraudulent conduct at this level of generality do not

[38] U.S. *Baltazar* Brief, p. 14, DktEntry:20-2 here, p19.

> provide the "critical elements" of a False Claims Act suit. 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. . . .
>
> [R]egardless of whether a disclosure concerns the practices of an individual or an industry, a disclosure of "allegations or transactions" must put the government on notice of both the mechanics of an alleged fraud and the perpetrators of the fraud.[39]

(emphasis added, citations omitted).

Griffin and PsychRights urge this Court not drastically undercut the effectiveness of the False Claims Act and heed the government's caution in the U.S. *Baltazar* Brief that it would bar "practically every healthcare fraud case."[40] This was not Congress's intent in enacting the Public Disclosure Bar.

D. The Public Disclosure Bar Does Not Otherwise Divest the District Court of Jurisdiction

The District Court analyzed the alleged qualifying public disclosures in four categories (1) The Utah/CMS Correspondence, (2) the State Case, (3) prior cases involving Medicaid fraud allegations based on off-label prescriptions, and (4) various media reports.[41] For the reasons that follow, none of these trigger the Public Disclosure Bar here.

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[39] U.S. *Baltazar* Brief, pp12-15, DktEntry:20-2 here, pp.18-20

[40] U.S. *Baltazar* Brief, p. 15, DktEntry:20-2 here, p.20.

[41] Exc. 17.

(1) The Utah/CMS Correspondence

In addition to the Utah/CMS Correspondence,[42] at best, only disclosing industry-wide fraud, it cannot trigger the Public Disclosure Bar in this case because it is not one of the "enumerated sources" of 31 U.S.C. § 3730(e)(4)(A).[43] The District Court cited *Seal 1*,[44] for the proposition that it is an "investigation," within the meaning of 31 U.S.C. § 3730(e)(4)(A), because "the term 'investigation' is extremely broad, encompassing "any kind of government investigation - civil, criminal, administrative or any other kind." However, *Seal 1* nowhere suggests that simple correspondence from an agency constitutes an investigation.[45]

(2) The State Case

The State Case does identify four of the Defendants, Hogan, Streur, Sandoval, and McComb, all of whom are State of Alaska officials. Hogan and Streur administered Alaska's Medicaid program and are therefore responsible for

[42] Exc. 55-60.

[43] In addition, as discussed above, under *Bly-Magee*, the Public Disclosure Bar cannot apply to false claims presented after a public disclosure. This point applies to all of the disclosures relied upon by the defendants and District Court below, but will only be discussed specifically in connection with the State Case and Thomson.

[44] Exc. 17, n. 96.

[45] There is also a serious question about the legitimacy of the CMS responses. See, Dkt. No. 160-1, §II, pp 4-7.

having the false claims paid by Medicaid.[46] Sandoval and McComb ran programs that cause false claims for prescriptions of psychotropic drugs to children and youth that are not for medically accepted indications.[47] The Public Disclosure Bar does not apply to these defendants because under *Bly-Magee*, the Public Disclosure Bar cannot apply to false claims presented subsequent to the disclosure.

With respect to all of the other Defendants, the Public Disclosure Bar does not apply because under *Harshman*, in light of *Aflatooni*, they are not among "a narrow class of suspected wrongdoers" identified by the State Case. In *Aflatooni*, this Court rejected application of the Public Disclosure Bar because the two groups were distinct.[48] In *Harshman*, this Court held the Public Disclosure Bar applied because it was a relatively small group of defendants who were all of the same class, to wit, electrical contractors who conspired with the Alaska Chapter of the International Brotherhood of Electrical Workers, Local 1547, to defraud the government on federally funded projects in Alaska over a four-year period.[49] Here, with the exception of the State of Alaska official defendants, none of the defendants are in the same class. In addition, the number of potential defendants in

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[46] Amended Complaint ¶s11 & 15, Exc. 93 & 94.

[47] Amended Complaint ¶s 12 & 13, Exc. 93-94.

[48] *Harshman*, 197 F.3d at 1018,citing to *Aflatooni*.

[49] 197 F.3d at 1016 & 1019.

all of the potential classes involved in the Scheme to Defraud is too large for *Harshman* to apply.

(3) Prior Court Cases

The Defendants also asserted the Public Disclosure Bar applied because "Previous cases have also included allegations that allegedly false claims for off-label, non-compendium drug prescriptions have been paid by Medicaid."[50] The District Court cited this as a public disclosure that "unsupported uses may not be reimbursable through Medicaid under the law," triggering the Public Disclosure Bar.[51] Perhaps this is the best example of the District Court's breathtaking expansion of the Public Disclosure Bar far beyond the text of 31 U.S.C. § 3730(e)(4)(A) and Congressional intent. The idea that cases enforcing Congress's limitation of reimbursement under Medicaid to medically accepted indications triggers the Public Disclosure Bar immunizing all other parties committing similar fraud is unfathomable.

Since the District Court held *Bly-Magee* was inapplicable because these public disclosures "allege a continuing course of conduct which are not limited to

[50] Dkt. No. 91-8.

[51] Exc. 23. *See*, also, Exc. 10.

specific time periods,"[52] the effect is to preclude private *qui tam* enforcement actions for all future false claims as well as those already having occurred. This sweeping immunization of all such fraudulent conduct is an invitation to continued massive fraud and is not supported by the text or Congress's intent in 31 U.S.C. § 3730(e)(4)(A).

(4) Media Reports

There is no doubt disclosures in the news media can trigger the Public Disclosure Bar, but the question is whether the action is based upon allegations or transactions included in such news media reports. As discussed above, the controlling law in this Circuit is disclosures of industry-wide fraud do not trigger the Public Disclosure Bar. Most of the news media cited by the defendants and District Court at best disclose industry-wide fraud in other states.

News media relied upon by the District Court include articles in Texas,[53] Illinois,[54] and New York;[55] a BusinessWeek article that doesn't even discuss off-label prescribing;[56] a Salon.Org web page that generally discusses overmedicating

[52] Exc. 25.

[53] Exc. 152-158.

[54] Exc. 186.

[55] Exc. 161.

[56] Exc. 188.

kids;[57] an article about an upcoming Congressional hearing,[58] and a "White Paper" about Florida from a non-profit, that is not one of the "enumerated sources" and thus does not qualify as a public disclosure.[59]

The only news media disclosure that identifies any of the Defendants is a Wall Street Journal article, which identifies Thomson.[60] However, again, this disclosure cannot trigger the Public Disclosure Bar as to false claims presented subsequent to the article. Moreover, the Amended Complaint in the *Matsutani* Action adds critical elements not disclosed in the Wall Street Journal article.[61]

X. CONCLUSION

For the foregoing reasons, Plaintiffs-Appellants, *relators* Griffin and PsychRights, on behalf of the United States Government, urge this Court to (1) REVERSE the District Court's holding that 31 U.S.C. § 3730(e)(4)(A) applies to

[57] Exc. 191. It is also unclear whether such a web page is one of the enumerated sources.

[58] Exc. 159.

[59] Exc. 162-183. The District Court did not cite PsychRights' web pages, Exc. 278-280, 282-284, as public disclosures, perhaps because they are not one of the "enumerated sources," or because they post-date the *Matsutani* and *Griffin* complaints.

[60] Exc. 285-289.

[61] Amended Complaint ¶s 196-199, Exc. 135-136.

disclosures of industry-wide fraud, and (2) that 31 U.S.C. § 3730(e)(4)(A) does not divest the District Court of jurisdiction to hear the *Griffin* and *Matsutani* Actions.

XI. STATEMENT OF RELATED CASES

Griffin and PsychRights know of no related case pending in this Court.

RESPECTFULLY SUBMITTED as of the 10th day of January, 2011.

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

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XII. CERTIFICATE OF COMPLIANCE

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.

XIII. ADDENDUM

31 U.S.C. 3730(e)(4)(A) the "Public Disclosure Bar"

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