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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

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

OPPOSITION TO MOTION TO DISMISS UNDER RULES 12(b)(1) AND 12(h)(3) FOR LACK OF SUBJECT MATTER JURISDICTION UNDER THE FALSE CLAIMS ACT'S PUBLIC DISCLOSURE BAR, 31 U.S.C. §3730(e)(4)(A)

Qui tam relator Law Project for Psychiatric Rights (PsychRights®) opposes the Defendants Motion To Dismiss Under Rules 12(b)(1) and 12(h)(3) For Lack Of Subject Matter Jurisdiction Under The False Claims Act's Public Disclosure Bar, 31 U.S.C. §3730(e)(4)(A), Dkt. No. 89 (Public Disclosure Bar Motion).

A. SUMMARY

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

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

> Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I).

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

The Public Disclosure Bar Motion, filed on April 5, 2010, relies on 31 U.S.C. §3730(e)(4), which was substantially amended thirteen days earlier by §10104(j)(2) of the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119. Thus, it is necessary to determine which version of the statute applies. As set forth below, while not without doubt, PsychRights believes the amended statute applies, but also that the public disclosure bar is not triggered under either version of the statute.

Incredibly, the Defendants assert the scope of 31 U.S.C. 3710(e)(4)(A), commonly known as "the public disclosure bar," is so broad that court decisions such as *Rost* and news media accounts of over-prescribing psychotropic drugs to children and youth through Medicaid constitute public disclosures that immunize from False Claims Act liability everyone who presents or causes the presentment of false claims to Medicaid for prescriptions drugs that are not for medically accepted indications.

The fundamental error made by the Defendants is that public disclosure of general information about the overprescribing of psychotropic drugs to children and youth, the great harm it causes, etc., does not constitutes public disclosure of the "allegations or transactions" upon which this action is "based" under the prior version of the statute, nor are they "substantially similar" to the allegations or transaction alleged in this action under the current version. Similarly, that court decisions, such as *Rost*, have held Medicaid can only pay for drugs that are for medically accepted indications do not immunize parties who present or cause the presentment of false claims for outpatient drugs to children and youth that are not for medically accepted indications. Nor can any alleged public disclosure trigger the public disclosure bar with respect to defendants not

directly identified in the alleged public disclosure or to claims that post-date such alleged public disclosure. In addition, the alleged public disclosures do not identify all of the essential elements of the transactions upon which this action is based as required under the prior version of §3730(e)(4)(A), nor are they substantially similar to the allegations to transactions as alleged herein, which is required for the public disclosure bar to be triggered under the current statute.

Specifically, the Public Disclosure Bar Motion asserts (1) correspondence between the Utah Attorney General's Office and the Federal Center for Medicare and Medicaid Services (CMS), (2) the "State of Alaska case,"*Law Project for Psychiatric Rights v. Alaska, et al*., (3) other court cases, such as *Rost*, and (4) articles in the press, trigger the public disclosure bar.[1] After discussing changes made in the 2010 amendments to §3730(e)(4) relevant to the Public Disclosure Bar Motion, and whether the current or former statute applies, PsychRights will discuss in turn each of the 4 alleged grounds for triggering the public disclosure bar under both the current and prior versions of §3730(e)(4)(A).

B. THE 2010 AMENDMENTS TO THE PUBLIC DISCLOSURE BAR

Prior to the recent amendment, 31 U.S.C. §3730(e)(4) provided:

> (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.
>
> (B) For purposes of this paragraph, "original source" means an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information.

[1] Dkt. No. 91, pp 13-15.

Section 10104(j)(2) of the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119, amended 31 U.S.C. §3730(e)(4), as follows:

> (2) Section 3730(e) of title 31, United States Code, is amended by striking paragraph (4) and inserting the following:
>
> > "(4)(A) THE COURT SHALL DISMISS AN ACTION OR CLAIM UNDER THIS SECTION, UNLESS OPPOSED BY THE GOVERNMENT, IF SUBSTANTIALLY THE SAME ALLEGATIONS OR TRANSACTIONS AS ALLEGED IN THE ACTION OR CLAIM WERE PUBLICLY DISCLOSED.--
> >
> > "(i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
> >
> > "(ii) in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
> >
> > "(iii) 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.
> >
> > (B) For purposes of this paragraph, "original source" means an individual who either (i) prior to a public disclosure under subsection (e)(4)(a), has voluntarily disclosed to the Government the information on which allegations or transactions in a claim are based, or (2) who has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section.

(1) The Public Disclosure Bar Is No Longer Jurisdictional

The current version provides that "the court shall dismiss an action. . .," rather than the prior version's "no court shall have jurisdiction over an action . . ." Thus, on the face of the amendment, the public disclosure bar is no longer jurisdictional.

(2) "Based Upon" Replaced with "Substantially the Same"

Under the prior version, the court did not have jurisdiction if the action was "based upon the public disclosure of allegations or transactions" through one of the "enumerated sources."[2] The current statute requires the court to dismiss the action "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed," through one of the amended enumerated sources. (emphasis added).

(3) The "Enumerated Sources" Have Been Substantially Trimmed Down

The enumerated sources have now clearly been restricted to federal sources, plus the news media, and with respect to the 1st enumerated categories, often referred to as "proceedings," only applies when the federal government or an agent is a party. The changes in the enumerated sources dramatically cuts down the categories of sources that can trigger the public disclosure bar, as interpreted by some of the courts. For example, some of the circuit courts including the Ninth Circuit,[3] interpreted the first category of sources (proceedings) to include state proceedings, while the current statute restricts the proceedings source not just to federal proceedings, but to those in which the federal government or its agent is a party. Similarly, some of the circuits, including the Ninth Circuit,[4] held that under the previous version of the statute, the second set of enumerated

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[2] *See, 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), holding that in order for the public disclosure bar to be triggered, there has to be public disclosure through one of the enumerated sources, those being "(1) in a 'criminal, civil, or administrative hearing,' (2) in a 'congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation,' or (3) in the 'news media.'" The formulation of the enumerated sources was substantially changed in the 2010 amendments to drastically reduce the types of public disclosures triggering the public disclosure bar, which will be discussed next, but the public disclosure bar can still only be triggered through one of the enumerated sources, as amended.

[3] *A-1 Ambulance Service v. California*, 202 F.3d 1238, 1244 (9th Cir. 2000)

[4] *U.S. ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 918 (9th Cir. 2006).

sources (reports), applied to state governmental sources, while others held the opposite,[5] which the Supreme Court just resolved in favor of state sources.[6]

C. THE 2010 AMENDMENTS PROBABLY APPLY TO THIS ACTION

On May 6, 2010, PsychRights filed its First Amended Complaint, Dkt. No. 107, primarily adding allegations identifying specific prescriptions constituting false claims to address the Defendants' motion to dismiss under the particularity requirement of Rule 9(b), Dkt. No. 83. In *Rockwell v. U.S.*, 549 U.S. 457, 474, 127 S.Ct. 1397, 1409 (2007), a False Claims Act case such as this, the Supreme Court held that "courts look to the amended complaint to determine jurisdiction." As most recently reiterated in *Desai v. Deutsche Bank Securities Ltd.*, 573 F.3d 931, 1262 (9th Cir. 2009), this is consistent with the long-standing, and oft-held principle that "'an amended pleading supersedes the original pleading,' which is 'treated thereafter as non-existent.'" *Ferdik v. Bonzelet*, 963 F.2d 1258, 1262 (9th Cir.1992). It was this principle to which the Supreme Court cited in *Rockwell*, which also indicated that an amended complaint can supply allegations the original complaint lacked, which will confer jurisdiction. *Id.*

In *Graham County*, decided March 30, 2010, just seven days after the president signed the legislation amending §3730(e)(4), at n. 1, the Supreme Court held the amendments did not apply to that case because Congress did not specifically make the amendment retroactive, saying that "would be necessary for its application to pending cases," citing to *Hughes Aircraft v. U.S. ex rel Schumer*, 520 U.S. 939, 117 S.Ct. 1871 (1997). In *U.S. v. Reynard*, 473 F.3d 1008, 1017, n.7 (9th Cir. 2007), the Ninth Circuit had occasion to discuss *Schumer* and held that it did not overrule the reliance analysis of

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[5] *United States ex rel. Dunleavy v. County of Del.*, 123 F.3d 734, 745 (3d Cir. 1997); *United States ex rel. Wilson v. Graham County Soil & Water Conservation Dist.*, 528 F.3d 292 (4th Cir. 2008). *See*, also *United States ex rel. Burns v. A.D. Roe Co.*, 186 F.3d 717, 725 (6th Cir. 1999).

[6] *Graham County Soil and Water Conservation District v. United States ex rel Wilson*, 559 U.S. __, 2010 WL 1189557, Dkt. No. 08-304, decided March 30, 2010.

the Supreme Court in *Landgraf v. USI Film Production*, 511 U.S. 244, 114 S.Ct. 1483 (1997); and *I.N.S v. St. Cyr*, 533 U.S. 289, 121 S.Ct. 2271 (2001).

In *Landgraf*, 511 U.S. at 270-271, 114 S. Ct. at 1499, the Supreme Court held:

> A statute does not operate "retrospectively" merely because it is applied in a case arising from conduct antedating the statute's enactment, or upsets expectations based in prior law. Rather, the court must ask whether the new provision attaches new legal consequences to events completed before its enactment.

(citation and footnote omitted). Similarly, in *St Cyr*, 533 U.S. at 321; 121 S.Ct. at 2290-91, the Supreme Court held:

> "The inquiry into whether a statute operates retroactively demands a commonsense, functional judgment about 'whether the new provision attaches new legal consequences to events completed before its enactment.'" A statute has retroactive effect when it "'takes away or impairs vested rights acquired under existing laws, or creates a new obligation, imposes a new duty, or attaches a new disability, in respect to transactions or considerations already past....'" As we have repeatedly counseled, the judgment whether a particular statute acts retroactively "should be informed and guided by 'familiar considerations of fair notice, reasonable reliance, and settled expectations.'"

(citations and footnote omitted).

In *Schumer*, it is respectfully suggested, the 1986 amendments to the public disclosure bar provisions of the False Claims Act were not made retroactive to Hughes' conduct because at the time of that conduct, Hughes providing the information to the government barred the claim. This is in stark contrast to the situation here where the claims were false when made. Therefore, it is respectfully suggested that the Ninth Circuit's reasoning in *Reynard* means the 2010 Amendments apply to this action under the First Amended Complaint.

A consideration that tends to confirm this is if the old version of §3730(e)(4)(A) applies to the First Amended Complaint because it acts retroactively, then for the next six

years, which is the statute of limitations under the False Claims Act,[7] different versions of the public disclosure bar will apply to the same fraudulent conduct depending on whether it occurred before or after March 23, 2010, and if the fraudulent course of conduct spans that date, different versions of the public disclosure bar will apply to different time periods. Again, the conduct would be just as much a violation of the False Claims Act both before and after March 23, 2010, the only question being whether under the prior version, one set of rules regarding public disclosures removes jurisdiction for conduct occurring before March 23, 2010, and after then, whether a different set of rules regarding public disclosure mandate dismissal.

To put this in the words of footnote 1 of *Graham*, the prior version of §3730(e)(4) only applies to pending actions, which does not include this action because the original complaint in this action was rendered "non-existent" with the filing of the First Amended Complaint. However, because this is not without doubt, PsychRights feels it is necessary to address the question of whether, to what extent, and to which defendants, the alleged public disclosures might bar this action under both versions of §3730(e)(4)(A).

D. THE PUBLIC DISCLOSURES ASSERTED BY DEFENDANTS DO NOT TRIGGER THE PUBLIC DISCLOSURE BAR UNDER EITHER VERSION OF 31 U.S.C. §3730(E)(4)(A)

As set forth above, the Public Disclosure Bar Motion asserts that

(1) correspondence between the Utah Attorney General's Office and CMS,

(2) the "State of Alaska case," *Law Project for Psychiatric Rights v. Alaska, et al.*,

(3) other court cases, and

(4) articles in the press,

trigger the public disclosure bar.[8] These will now be addressed in turn, under both the current and previous versions of §3730(e)(4)(A).

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[7] 31 U.S.C. §3731(b)(1).
[8] Dkt. No. 91, pp 13-15.

(1) The Letters From the Utah Attorney General's Office Do Not Trigger the Public Disclosure Bar

(a) State Sources Are Not One of the Enumerated Sources Under the Current Statute

As set forth above, 31 U.S.C. §3730(e)(4)(A)(ii), now restricts the second category of sources to federal sources. Thus, under the current statute, the letters from the Utah Attorney General's Office cannot invoke the public disclosure bar because they are a state source.[9]

(b) This Action is Not Based Upon, nor Substantially Similar to the Information in the Utah Correspondence

The correspondence between the Utah Attorney General's Office and the Center for Medicare and Medicaid Services (CMS) also cannot trigger the public disclosure bar under either the prior or current versions of §3730(e)(4)(A) because this action is neither based upon nor substantially similar to the information contained therein. First, the public disclosure bar only applies to defendants identified in the public disclosure. *United States ex rel. Alfatooni v Kitsap Physicians Services*, 163 F.3d 516, 523 (9th Cir. 1999) (public disclosure bar only applies to defendants identified in public disclosure). *U.S. ex rel. Foundation Aiding The Elderly v. Horizon West*, 265 F.3d 1011, n5 (9th Cir. 2001), reiterates this principle, and held at footnote 5 that 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

[9] Presumably, the Ninth Circuit will continue to hold under the current version of §3730(e)(4) that the alleged public disclosures must originate in one of the sources enumerated in the statute. *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).

was not specifically named or otherwise directly identified are insufficient to trigger the jurisdictional bar").

Defendants cite at footnote 37 to cases outside the Ninth Circuit for the proposition that public disclosure of widespread fraud immunizes all perpetrators from the *qui tam* provisions of the False Claims Act. The controlling Ninth Circuit case of *Foundation Aiding The Elderly*, at least as to the prior statute,[10] as set forth above, holds otherwise.

Alcan Electrical and Engineering, Inc., 197 F.3d 1014, 1018-19 (9th Cir. 1999), decided between *Alfatooni* and *Foundation Aiding The Elderly* does carve out an exception for "a narrow class of suspected wrongdoers," but again, in the later *Foundation Aiding The Elderly*, the Ninth Circuit held that general allegations of fraud against an industry do not trigger the public disclosure bar. Two of the three cases cited by Defendants acknowledge this restriction, *In re Pharmaceutical Industry Average Wholesale Price Litigtion*, 538 F. Supp.2d 367, 383 n.10 (N.D.N.Y. 2008) and *In re Natural Gas Royalties Qui Tam*, 562 F. 3d 1032, 1043 (10th Cir. 2009). Moreover, in *In re Pharmaceutical Industry*, it was only "unclear" whether the specific defendant was identified in the public disclosure because it was a subsidiary of one of the parties identified by the public disclosure. Even *U.S. v. Gear v. Emergency Med. Associates of Illinois, Inc.*, 436 F.32 726, 729 (7th Cir. 2006), requires that for such a general information to trigger the public disclosure bar, the defendants must be "directly identifiable from the public disclosures."

In any event, *Foundation Aiding The Elderly*, which is controlling as to the previous statute, and probably under the current statute, holds that general allegations of widespread fraud do not trigger the public disclosure bar.

[10] There is no reason to think this aspect of the Ninth Circuit's public disclosure bar jurisprudence would be different under the current version of §3730(e)(4)(A).

(c) The Utah Correspondence is Not an Investigation or Report Under Either Version of the Statute

It is also respectfully suggested the correspondence between the Utah Attorney General's Office and CMS does not constitute an administrative report, hearing, audit, or investigation within the meaning of the prior version of the statute, nor a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation under the current statute.

(2) *PsychRights v. Alaska, et al.*, Does Not Trigger the Public Disclosure Bar

The Defendants assert what they call "the State of Alaska case," more commonly known as *PsychRights v. Alaska*, attached as exhibits by the Defendants at Dkt. Nos. 91-7 and 91-8, triggers the public disclosure bar. PsychRights respectfully suggests this is erroneous.

(a) State Civil Cases No Longer Trigger the Public Disclosure Bar

First, under the current statute, the public disclosure bar cannot be triggered by *PsychRights v. Alaska* with respect to any defendant because it is not a federal case.

(b) Under The First Amended Complaint This Action is Not Based Upon or Substantially Similar to the Alleged Public Disclosure of Allegations or Transactions With Respect to Fifteen Defendants

The First Amended Complaint, Dkt. No. 107, identifies specific prescriptions constituting false claims for the following fifteen defendants.

- Tammy Sandoval[11]
- Fred Meyer Stores, Inc.[12]
- Safeway, Inc.[13]
- Wal-Mart Stores, Inc.[14]

[11] Amended Complaint, ¶s 187 & 188.
[12] Amended Complaint, ¶s 190 & 191.
[13] Amended Complaint, ¶s 192 & 193.
[14] Amended Complaint, ¶s 194 & 195.

- Alternatives Community Mental Health Services, D/B/A Denali Family Services[15]
- Fairbanks Psychiatric And Neurologic Clinic, PC[16]
- Frontline Hospital, LLC, D/B/A North Star Hospital[17]
- Osamu H. Matsutani, MD[18]
- Elizabeth Baisi, M.D.[19]
- Lina Judith Bautista, M.D.[20]
- Sheila Clark, M.D.[21]
- Ronald Martino, M.D.[22]
- Kerry Ozer, M.D.[23]
- William Hogan[24]
- William Streur[25]

Therefore, for these defendants, under the previous version of §3730(e)(4)A), this action is not "based upon" the allegations or transactions contained in *PsychRights v. Alaska*, and under the current version, they are not substantially similar to the allegations or transactions contained in *PsychRights v. Alaska*. Thus, at least with respect to these defendants, the public disclosure bar cannot be triggered by *PsychRights v. Alaska*.

(c) The Public Disclosure Bar is Not Triggered Under Either Version of the Statute for Any of the Defendants Not Identified In *PsychRights v. Alaska*

PsychRights v. Alaska, Dkt. No. 91-7, only names four defendants who are also defendants in this action, Hogan, Streur, Sandoval and McComb (Alaska State

[15] Amended Complaint, ¶s 201 & 202.
[16] Amended Complaint, ¶ 203.
[17] Amended Complaint, ¶ 204.
[18] Amended Complaint, ¶ 206.
[19] Amended Complaint, ¶ 207.
[20] Amended Complaint, ¶ 208.
[21] Amended Complaint, ¶ 209.
[22] Amended Complaint, ¶ 210.
[23] Amended Complaint, ¶ 211.
[24] Amended Complaint, ¶s 187-188, 190-195, 201-204, 206-211, as incorporated by ¶215.
[25] *Id.*

Officials). PsychRights respectfully suggests that under either version of the statute, *Alfatooni* and *Foundation Aiding The Elderly* apply with respect to the other defendants, rather than *Alcan* for a number of reasons.

The complaint in *PsychRights v. Alaska* does not identify mental health agencies or pharmacies even as general classes of suspected wrongdoers as required in *Alcan*, and neither licensed prescribers nor medical publishers is a "narrow class of suspected wrongdoers" sufficient to trigger the public disclosure bar. In *Alcan*, the Ninth Circuit found the public disclosure bar applied because "local electrical contractors who worked on federally funded projects over a four-year period" was a sufficiently narrow class of suspected wrongdoers. Here, the complaint in *PsychRights v. Alaska* didn't even identify mental health agencies or pharmacies as potential classes of suspected wrongdoers, and licensed prescribers and medical publishers are too large of classes of suspected wrongdoers for the *Alcan* exception to apply. PsychRights respectfully suggests that every medical information publisher, licensed prescriber of outpatient drugs, their employers and the pharmacies filling the prescriptions and presenting false claims for reimbursement are not the types of "narrow class of suspected wrongdoers" to which *Alcan* applies.

There is another consideration, to PsychRights' knowledge not yet addressed by the Ninth Circuit, which has recently been articulated by the First Circuit in *U.S. ex rel Duxbury v. Ortho-BioTech Products*, 579 F.3d 13, 27 (1st Cir. 2009):

> 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 government has pursued False Claims Act cases and achieved extremely large recoveries against drug companies for causing the presentment of claims to Medicaid for prescriptions of psychotropic drugs that are not for medically accepted indications, including Geodon and Seroquel for use in children and youth.[26] Claims presented or caused to be presented to Medicaid for psychotropic drugs prescribed to children and youth that are not for medically accepted indications by other parties, such as the defendants in this action, are just as much false claims as those caused by the drug companies, i.e., prescriptions presented to Medicaid that are not for a medically accepted indication. As the First Circuit noted in *Duxbury*, one of the purposes of the 1986 amendments was to encourage more private enforcement when the government failed to act. PsychRights respectfully suggests this Court should heed the First Circuit's caution against applying the public disclosure bar in a way that is not supported by the text of the statute against suits, such as this one, which constitute "productive private enforcement" in the face of government inaction, or even acquiescence.[27]

However, for the same reason as the Ninth Circuit in *Foundation Aiding The Elderly* found it unnecessary to decide whether the public disclosure at issue there was

[26] *See*, e.g., Dkt. No. 108-1, p.1; Dkt. No. 108-2 , pp. 8-9, 10, 31 & 100; and Dkt. No. 108-3, p. 6.

[27] That government officials acquiesce in the false claims does not immunize those who present or cause the presentment of false claims. *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1422 (9th Cir. 1996).

one of the "enumerated sources,"[28] it is unnecessary for this Court to decide whether all licensed prescribers in Alaska, their employers and pharmacies is such a "narrow class of suspected wrongdoers" that they don't have to be identified in the public disclosure. This also operates to preclude application of the public disclosure bar against the State of Alaska Officials.

(d) The Essential Elements of the Transactions Upon Which this Action is Based Were Not Publicly Disclosed Within the Meaning of the Previous Version of 31 U.S.C. §3730(e)(4)(A)

Under the previous version of §3730(e)(4)(A), all essential elements of the false claim transactions must have been publicly disclosed for the public disclosure bar to apply:

> In analyzing whether the transactions underlying a relator's complaint were publicly disclosed, however, we adopt the analysis first laid out by the District of Columbia Circuit in *Springfield Terminal*:
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> > [I]f X + Y = Z, Z represents the allegation of fraud and X and Y represent its essential elements. In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed.

Ex rel. Foundation Aiding The Elderly, 265 F.3d at 1015, citations omitted. *See*, also, *United States ex rel Haight v. Catholic Healthcare West*, 445 F.3d 1147, 1152 (9th Cir. 2006) ("essential elements" must be disclosed for public disclosure bar to apply); *A-1 Ambulance Service v. California*, 202 F.3d 1238, 1243 & 1245 (9th Cir. 2000) (for public disclosure bar to apply, "the material elements" must be included in the public disclosure).

As set forth above, "Medicaid can only pay for drugs that are used for a 'medically accepted indication,' meaning one that is either approved by the FDA or 'supported by citations' in one of three drug compendia, including DRUGDEX."[29] Thus, in order to

[28] 265 F.3d at 1015.
[29] *Rost*, 253 F.R.D. at 13-14.

know whether a prescription for an indication not approved by the FDA is a medically accepted indication and therefore covered under Medicaid, one must consult the identified compendia, including DRUGDEX. However, Thomson claims DRUGDEX is confidential. Dkt. No. 80-2, page 1.[30]

Paragraphs 166 and 167 of the First Amended Complaint identify the universe of medically accepted indications for use in children and youth for 48 psychotropic medications. Every other indication for which these medications might be prescribed to children and youth are not medically accepted indications. This information was not publicly disclosed prior to the filing of this action and is one of the "essential elements" upon which this action is based. Nowhere in *PsychRights v. Alaska* is this information disclosed, nor, for that matter, is it disclosed in any of the news media articles, the Utah correspondence, or "other court cases."

It does seem anomalous for the statute to use a non-public reference, but on the other hand, since all Medicaid participants are required to know and comply with its requirements,[31] the onus is on the party asserting a non-FDA approved indication is covered under Medicaid that such use is a medically accepted indication. In other words, before a Medicaid participant prescribes or presents a prescription for a psychotropic drug to a child or youth Medicaid beneficiary that is not for an indication approved by the FDA, such Medicaid participant is required to have determined that such a use is supported by one or more of the compendia.

The reality is that whether a particular non-FDA approved indication is "supported by" DRUGDEX is not publicly disclosed and was not publicly disclosed within the meaning of 31 U.S.C. §3730(e)(4)(A) until set forth, for a subset of the 48 drugs, in PsychRights' motion for preliminary injunction, Dkt. No. 78, and for all 48 drugs in the

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[30] In a telephone conversation following the e-mail exchange at Dkt. No. 80-2, local counsel for Thomson indicated he should have said "proprietary" rather than "confidential," but that doesn't change the analysis.

[31] *U.S. v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001).

First Amended Complaint herein, Dkt. No. 107.[32] Whether or not specific non-FDA approved indications for psychotropic drugs used in children and youth are medically accepted indications is an essential element of the false claims alleged in this action under the First Amended Complaint, and because this information was not publicly disclosed prior to the filing of this action, the public disclosure bar cannot apply to any claim or defendant in this case, including any of the State of Alaska Officials.

(e) The Public Disclosure Bar Cannot Apply to Post Public Disclosure Allegations or Transactions

Under *U.S. ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 920 (9th Cir. 2006), a public disclosure cannot trigger the public disclosure bar as to false claims that post date such public disclosure. The public disclosure bar thus cannot apply to any of the defendants, including the Alaska State Officials, with respect to false claims identified in the First Amended Complaint that were presented or caused to be presented after such public disclosure in late September 2008.[33]

(f) The Public Disclosure Bar Cannot Apply to Information Not Included in the Public Disclosure

It is also respectfully suggested that just as post-disclosure allegations cannot have been publicly disclosed at the time of the public disclosure, the non publicly disclosed nature of what is or is not a medically accepted indication for psychotropic drugs used in children and youth[34] means that the information in *PsychRights v. Alaska* cannot be substantially similar to the "allegations" contained in the First Amended Complaint.[35]

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[32] PsychRights began posting its chart of "Medically Accepted Indications for Pediatric Use of Psychotropic Medications," on its website on November 27, 2009, but this cannot trigger the public disclosure bar because (a) it post dates the filing of this action, and (b) is not one of the enumerated sources to which the public disclosure bar applies under either version of §3730(e)(4)(A).

[33] *See*, First Amended Complaint, paragraph 188 and paragraph 215, incorporating paragraph 188.

[34] First Amended Complaint, Dkt. No. 107, ¶s 166 & 167.

[35] *Ex rel. Foundation Aiding The Elderly*, 265 F.3d at 1015 makes the distinction between public disclosures regarding "allegations," which is triggered when the public disclosure

More specifically, the allegations concerning which are and are not medically accepted indications for psychotropic drug use in children and youth for the 48 drugs set forth in paragraphs 166 & 167 were not publicly disclosed in *PsychRights v. Alaska*, or for that matter, anywhere else to PsychRights' knowledge, before this action was filed.

(3) Other Court Cases, including *Parke-Davis* Do Not Immunize Parties from False Claims Act Liability

The defendants also argue that since court decisions such as *Rost* hold Medicaid is only allowed to pay for indications that are medically accepted indications, everyone who presents or causes the presentment of such false claims is immunized under the public disclosure bar. This cannot be so. None of these court cases identify the defendants here, nor do they describe any other elements of the Medicaid fraud at issue here. Ruling on a legal standard does not trigger the public disclosure bar as to all violations of that standard.

(4) The Articles in the News Media Do Not Trigger the Public Disclosure Bar

The Defendants also argue that general news media articles about the over-prescribing of psychotropic drugs to children and youth, including the great harm they cause and the prevalence of the practice in Medicaid recipients, are public disclosures triggering the public disclosure bar. PsychRights does not dispute these are public disclosures, but they are simply not public disclosures upon which this action is based or substantially similar to the allegations or transactions alleged in this action within the meaning of either version of 31 U.S.C. §3730(3)(4)(A), as set forth above. Virtually all

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is "substantially similar," to allegations upon which the action is based, citing to *United States ex rel. Lujan v. Hughes Aircraft Co.*, 162 F.3d 1027, 1033 (9th Cir.1998), and "transactions," which as set forth above, requires that all material or essential elements to have been publicly disclosed to trigger the public disclosure bar. In *Lujan*, the allegations were found to be substantially similar to the public disclosure because there was only a "meaningless distinction" between the claims and the public disclosure with the difference being "microscopically fine."

of the analysis above applies, with the controlling Ninth Circuit decisions that public disclosures of widespread fraud do not trigger the public disclosure bar perhaps being the most direct.

E. PSYCHRIGHTS ORIGINAL SOURCE STATUS IS NOT AT ISSUE

The Defendants also spend a considerable amount of space to the proposition that PsychRights is not an original source of the information under 31 U.S.C. §3730(e)(4)(B). Since none of the alleged public disclosures the Defendants assert trigger the public disclosure bar do so, PsychRights' status as an original source is irrelevant. In any event, PsychRights is not asserting original source status.

F. CONCLUSION

For the foregoing reasons, Defendants Motion To Dismiss Under Rules 12(b)(1) And 12(h)(3) For Lack Of Subject Matter Jurisdiction Under The False Claims Act's Public Disclosure Bar, 31 U.S.C. §3730(e)(4)(A), Dkt. No. 89, should be denied.

RESPECTFULLY SUBMITTED this 10th day of May, 2010.

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

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 10, 2010 a true and correct copy of this document was served electronically on all parties of record by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail.

/s/ James B. Gottstein
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