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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

UNITED STATES OF AMERICA)	
<i>Ex rel.</i> Law Project for Psychiatric)	CIVIL ACTION NO.
Rights, an Alaskan non-profit)	<u>3:09-CV-00080-TMB</u>
corporation,)	
)	FILED UNDER SEAL
Plaintiff,)	
)	
vs.)	FALSE CLAIMS ACT
)	MEDICAID FRAUD
OSAMU H. MATSUTANI, MD, <i>et al.</i> ,)	
)	DEMAND FOR JURY TRIAL
Defendants.)	
_____)	

**MOTION TO UNSEAL COMPLAINT (IF NECESSARY) AND
SERVE ON DEFENDANTS**

Qui tam relator Law Project for Psychiatric Rights (PsychRights®) hereby moves
to:

- (1) unseal the Complaint in this matter pursuant to 31 U.S.C. §3730(b)(3), if
necessary, and
- (2) serve the Complaint on defendants pursuant to 31 U.S.C. §3730(b)(2) .

I. SUMMARY

The "False Claims Act" or "Act" was enacted during the Civil War in an effort to "combat rampant fraud in Civil War defense contracts."¹ The Act empowers private persons, on behalf of the federal Government,² to sue persons who knowingly have presented the Government with false or fraudulent claims³ and to share in any proceeds ultimately recovered as a result of such suits.⁴

The False Claims Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty between \$5,500 and \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government.⁵ The Act defines "knowingly" to include acts committed with "actual knowledge," as well as acts committed "in deliberate ignorance" or in "reckless disregard" of their truth or falsity.⁶

The Act requires that the complaint be filed under seal for 60 days, with a copy provided the Government in order to allow the Government time to conduct its own investigation and to determine whether to intervene and take over the action.⁷ The Government may seek to extend the time the Complaint remains sealed by filing a motion showing good cause before the expiration of the 60 day period.⁸ The Complaint shall not be served on the defendant(s) unless so ordered by the court.⁹

The time within which the Government may move for an extension of the 60 day sealing period has passed without any such motion. The literal interpretation of the Act is the Complaint is no longer sealed as a result. However, PsychRights has found no case

¹ S. Rep. No. 99-345, at 8 (1986), reprinted in 1986 U.S.C.C.A.N. 5266, 5273.

² 31 U.S.C. § 3730(b).

³ 31 U.S.C. § 3729(a)(1).

⁴ 31 U.S.C. § 3730(c) & (d).

⁵ 31 U.S.C. §3729(a).

⁶ 31 U.S.C. §3729(b).

⁷ 31 U.S.C. § 3730(b).

⁸ 31 U.S.C. § 3730(b)(3) & (4).

⁹ 31 U.S.C. § 3730(b)(2).

on this issue. In fact, PsychRights has not found any case in which the Government has failed to file its election of whether to intervene and take over the case or move for an extension within the required 60 days. Therefore, PsychRights has filed this motion to clarify that the Complaint is unsealed or, if necessary that the Complaint be unsealed.

PsychRights is also moving the Court to so order the Complaint being served on the defendants. Unlike whether the Court must act before the Complaint is unsealed, the Act is clear that the Complaint shall not be served on the defendant(s) until so ordered by the Court.¹⁰

The gravamen of the Complaint is thousands of false or fraudulent claims for reimbursement of psychiatric drug prescriptions to children and youth by Medicaid have been,

1. caused to be submitted by defendant Thomson Reuters (Healthcare),
2. caused to be submitted by the psychiatrist defendants and their employers,
3. submitted by the pharmacy defendants, and
4. approved for payment by State of Alaska employee defendants.

More specifically, the claims are false or fraudulent because they violate the coverage restriction under Medicaid for outpatient drugs to those prescribed for a "medically accepted indication," defined as indications approved by the Food and Drug Administration (FDA), or supported by one or more of the following Compendia:

- (i) American Hospital Formulary Service Drug Information,
- (ii) United States Pharmacopeia-Drug Information (or its successor publications), or
- (iii) DRUGDEX Information System,

(Covered Outpatient Drugs).¹¹

¹⁰ 31 U.S.C. § 3730(b)(2).

¹¹ 42 U.S.C. §1396r-(8)(k)(3), 42 U.S.C. §1396r-(8)(k6), and 42 U.S.C. §1396r-(g)(1)(B)(i).

II. UNSEALING THE COMPLAINT

A. The Complaint Is Now Unsealed By Operation of Law Or Is To Be Automatically Unsealed.

31 U.S.C. § 3730(b)(2)-(4) provide:

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall--

- (A) proceed with the action, in which case the action shall be conducted by the Government; or
- (B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

A copy of the complaint and written disclosure of substantially all material evidence and information (Written Disclosure) was served April 27, 2009, on the Government by (i) personal delivery to the United States Attorney for the District of Alaska, and (2) by mail on the Attorney General.¹²

60 days has now passed and under the literal provisions of 31 U.S.C. § 3730(b)(2)-(4), PsychRights respectfully suggests the Complaint is now unsealed as a matter of law. Alternatively, PsychRights respectfully suggests all that is required is the ministerial-like

¹² Exhibit 1.

step of this Court confirming the Complaint is unsealed. §§(b)(2) states the Government has 60 days to elect to intervene, §§(b)(3) allows a motion to extend for good cause if filed within the 60 days, and §§(b)(4) requires the Government to proceed with the case or notify the Court that it declines to take over the case before the expiration of the 60 days.

The one thing that gives PsychRights pause about whether the Complaint is now unsealed by operation of law, is §§(b)(2) provides the Complaint shall not be served on the defendant(s) until the court so orders. While this doesn't technically conflict with the Complaint now being unsealed as a matter of law, it seems anomalous that the Complaint is unsealed without an order of the Court, but the Complaint not be served until so ordered by the Court. What does seem clear, however, is the 60 day time period is mandatory, the Government has waived its right to intervene or move to extend the sealing period, the Complaint either is or should be unsealed and should be served on the defendants without delay. While PsychRights has found no cases directly on point, the Legislative History of the False Claims Act and decisions on related issues confirm PsychRights' straightforward interpretation of the False Claims Act.

Congress' 1986 enactment of the Secrecy Provisions was the result of a compromise between Congress's desire for the expeditious processing of *qui tam* cases and concerns expressed by the United States Department of Justice (DOJ) that the filing of a *qui tam* suit by a private party might "tip off" investigation targets when the government's criminal inquiry was still at a sensitive stage.¹³ The DOJ stated that *qui tam* civil suit "might overlap with allegations already under criminal investigation."¹⁴ The Senate Report evidences the express intent of Congress that, "[t]he government should not, in any way, be allowed to unnecessarily delay lifting of the seal from the civil

¹³ 1986 U.S.C.C.A.N. at 5288-89.

¹⁴ *Id.* at 5289 (emphasis added).

complaint or processing of the *qui tam* action."¹⁵ The Senate Report further explained that under the proposed amendments, the *qui tam* plaintiff was to act "as a check that the government does not neglect evidence, cause unduly [sic] delay, or drop the false claims case without legitimate reason."¹⁶

Significantly, Congress intended to allow "good cause" extensions of the 60 day deadline only in the most extraordinary cases such as a pending criminal prosecution, stating in the Senate report:

... The Committee feels that with the vast majority of cases, 60 days is an adequate amount of time to allow Government coordination, review and decision. Consequently, "good cause" would not be established merely upon a showing that the Government was overburdened and had not had a chance to address the complaint. While a pending criminal investigation of the allegations contained in the *qui tam* complaint will often establish "good cause" for staying the civil action, the Committee does not intend that criminal investigations be considered an automatic bar to proceeding with a civil fraud suit.¹⁷

Perhaps the most analogous case PsychRights has found is *United States ex rel McCoy v. California Medical Review, Inc.*,¹⁸ in which the Government had timely intervened but desired to keep the case sealed (and stayed) pending completion of possible criminal proceedings. The District Court for the Northern District of California soundly rejected the Government's motion as not authorized under the False Claims Act:

Section 3730(b)(3) allows the Government to move the court for "extensions of the time during which the complaint remains under seal under paragraph (2) [section 3730(b)(2)]." The section provides no authority, however, for extending the seal once the Government has intervened. The legislative history of section (b)(3) also indicates that

¹⁵ S. Rep. No. 99-345, 99th Cong., 2d Sess. at 25, reprinted in 1986 U.S. Code Cong. & Admin. News at 5290.

¹⁶ *Id.* at 5290-91.

¹⁷ S.Rep. 345, 99th Cong., 2d Sess 24-25 (1986), reprinted in 1986 USCCAN 5266, 5289-90.

¹⁸ 715 F. Supp. 967 (ND Cal. 1989).

once the Government has elected whether to intervene under paragraph (2), unsealing of the complaint is virtually automatic:¹⁹

In PsychRights' view, by failing to timely move for an extension of time to decide whether to intervene, the Government has waived the right to move for an extension and, using the *ex rel McCoy* formulation, the decision of "whether to intervene" was necessarily made in the negative by failing to move for an extension of time. Thus, while in *ex rel McCoy* unsealing was "virtually" automatic upon timely intervention by the Government, PsychRights respectfully suggests unsealing is totally automatic when, as here, the Government fails to move to extend the sealing within the 60 day limit.

In *United States by Dep't. of Defense and Pantagen Technologies International v. CACI International*,²⁰ citing to *ex rel McCoy*, the District Court for the Southern District of New York, noted:

("Congress' objectives in amending the Act [were] principally to expand the role of *qui tam* plaintiffs and to keep pressure on the United States to prosecute the cases") In the context of requesting extensions, Congress stated, "[t]he Government should not, in any way, be allowed to unnecessarily delay lifting of the seal from the civil complaint or processing of the *qui tam* litigation."

Certainly, the Government should not be allowed to "unnecessarily delay lifting of the seal" by flouting the 60 day time limit imposed by Congress as it has done here.

B. The Government Has Flouted the 60 Day Time Limit

In preparing to file this action, PsychRights became aware that False Claim Act *qui tam* cases, usually with the agreement of the *qui tam* relators, are often kept under seal far longer than the 60 days, stretching to years on average. Thus, in its very first communication with the Government, to wit, its Written Disclosure, PsychRights notified the Government it was concerned about extending the sealing period:²¹

Because of the great harm inflicted on America's children and youth through these false claims, PsychRights believes the Complaint should be

¹⁹ *Id* at 968-969, footnote omitted, emphasis added

²⁰ 885 F.Supp 80, 82 (SDNY 1995), citations omitted.

²¹ Exhibit 1, page 9.

unsealed as soon as possible. No significant investigation is needed. With the possible exception of Thomson Reuters (Healthcare)'s role in the scheme to defraud Medicaid, it should be easy for the Government to confirm the facts. The real question is, now that PsychRights has brought to the Government's attention that the psychiatrists, their employers, pharmacies, and state employees, are liable for these false claims, whether it has the political will or ability to act against these defendants to stop the fraud. It should be possible to decide that within 60 days.

Two days later, PsychRights asked the US Attorney's Office that it be informed when someone had been assigned to this matter with whom it could communicate and was told, "Of course. You should understand that it may take some time to get this case initially reviewed and assigned."²² Not having heard back a month later, on June 2, 2009, PsychRights wrote the local US Attorney's Office:

Has anyone been assigned to the qui tam case we filed April 27th? There is less than a month left in the 60 day investigation period and as I suggested in my letter, because of the importance of this becoming public, we will not necessarily be agreeing to an extension keeping the complaint sealed. I would note that Senate Report 99-345, 25, states with respect to the 60-day sealing period:

The Committee feels that with the vast majority of cases, 60 days is an adequate amount of time to allow Government coordination, review and decision. Consequently, 'good cause' would not be established merely upon a showing that the Government was overburdened and had not had a chance to address the complaint.²³

The attorney assigned to the case called that day, and there was complete disagreement as to how continued sealing would be resolved.²⁴

The conclusion PsychRights reaches is the Government believes it may ignore the 60 day period mandated by Congress with impunity. PsychRights respectfully suggests this Court should not countenance such an approach and allow the Government to

²² Exhibit 2.

²³ Exhibit 3.

²⁴ Declaration of James B. Gottstein filed contemporaneously herewith.

"unnecessarily delay lifting of the seal from the civil complaint or processing of the qui tam litigation"²⁵ by ignoring the 60 day time limit mandated by Congress.

C. It Appears Unlikely the Government Will Decide to Intervene.

Subsequent to its Written Disclosure, PsychRights learned the false or fraudulent nature of claims for prescriptions that are not for a medically accepted indication, had been brought to the Government's attention in October of 2007, and the Government declined to stop the fraud.²⁶ More particularly, on October 22, 2007, David Stallard, State of Utah Assistant Attorney General, after reciting essentially the same analysis regarding Covered Outpatient Drugs set forth in the Summary above specifically asked the Centers for Medicare and Medicaid Services (CMS), which administers Medicaid for the Government:

ISSUE #1: Does CMS interpret federal law to restrict [Federal Financial Participation (FFP)] for state Medicaid programs to uses of otherwise "covered outpatient drugs" that are either FDA-approved or supported in the specified compendia?

ISSUE #2: If the answer to question #1 is yes, has the federal government delegated to the states any authority to approve exceptions, i.e., to expand FFP-eligible Medicaid prescription drug coverage? (e.g., May a state grant its Drug Utilization Review Board the authority to approve FFP-eligible Medicaid reimbursement for off-label indications not supported in the specified compendia?)²⁷

CMS responded on December 6, 2007, that

Section 1927 of the Social Security Act (the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations.²⁸

²⁵ *Pantagen, supra*, 885 F.Supp at 82, citing to *ex rel McCoy*, citing to the Legislative History.

²⁶ *See*, Exhibits 4-7.

²⁷ Exhibit 4.

²⁸ Exhibit 5.

CMS then went on to suggest that Congress' explicit prohibition for reimbursement of off-label drugs not "supported" by one or more of the Compendia was not mandatory with discretion left up to the states.²⁹

Incredulous, the Utah Assistant Attorney General wrote back on December 17, 2007:

With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal Financial Participation) does not include "a drug or biological used for a medical indication which is not a medically accepted indication."

This federal statute defining the term "covered outpatient drug" clearly delineates that Medicaid drugs are covered only so long as they are used for "medically accepted indications." Congress apparently intended that Medicaid not be so restrictive as to prohibit all off-label use, but that it not be so expansive as to cover experimental uses not yet medically accepted. The criterion Congress chose for permissible off-label use was that the particular use be "supported" in at least one of the specified compendia [(k)(6)].

Frankly, I do not see how CMS can ignore this unambiguous statutory definition of "covered outpatient drug."

I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.³⁰

By letter dated January 30, 2008, CMS wrote back, stating "I wish to confirm that our previous response to you is correct."³¹

This motion is not the place to litigate the false or fraudulent nature of the claims, and the foregoing is set forth herein not for that purpose, but instead to show it is unlikely the Government will pursue these particular false or fraudulent claims. This is another

²⁹ *Id.*

³⁰ Exhibit 6.

³¹ Exhibit 7.

reason why the Court should not allow the Government to "unnecessarily delay lifting of the seal from the civil complaint or processing of the qui tam litigation"³² by ignoring the 60 day time limit mandated by Congress.

As the Court said in *ex rel McCoy*

Congress clearly intended to bestow upon relators in proceedings under the Act substantial power to force the prosecution of cases.³³

CMS has adopted a tortured interpretation of the Social Security Act that Congress intended to allow Medicaid to pay for all off-label prescriptions, including the incredibly harmful practice of prescribing the most powerful psychiatric drugs to children and youth involved in the false or fraudulent claims here. This issue should proceed to determination without delay caused by continued sealing of the Complaint.

D. The Defendants Are Seriously Prejudiced by Continued Sealing

Another extremely serious problem caused by continued sealing is the defendants remain unaware that they have been charged with false or fraudulent claims and continue submitting or causing the submission of false or fraudulent claims. They should be notified of this lawsuit without delay so they can stop their participation in the false or fraudulent claims at issue here if they so choose. As set forth in PsychRights' Written Disclosure, it appears that something on the order of 1,600 false or fraudulent claims totaling almost \$290,000 per month are being paid in Alaska relating to what is known as the second generation neuroleptics and 1,300 false or fraudulent claims, totaling about \$58,000 per month for what are known as SSRI antidepressants.³⁴ Using the lowest per false or fraudulent claim penalty of \$5,500 and the treble damages specified in 31 U.S.C. §3729(a),³⁵ just under \$17 million in penalties and damages are accruing each month.

³² *Pantagen, supra*, 885 F.Supp at 82, citing to *ex rel McCoy*, citing to the Legislative History.

³³ 750 F.Supp. at 970.

³⁴ Exhibit 1.

³⁵ The statute provides a penalty of between \$5,000 and \$10,000 per false or fraudulent claim but this has been increased to between \$5,500 and \$11,000 by regulation.

While not all of these are the result of the activities of the specific named defendants, certainly a large number are because the defendants were identified based on PsychRights' knowledge of which of the potential defendants were likely to be the largest transgressors. It can also be noted here it is not just the named defendants who are prejudiced by continued sealing, but all of the other potential defendants, both in and outside the State of Alaska, who are submitting or causing this type of false or fraudulent claims to be submitted to the Government.

III. SERVICE OF COMPLAINT

31 U.S.C. §3730(b)(2) prohibits the Complaint from being served on a defendant until it is so ordered by the Court. Whether or not the Complaint is currently unsealed by operation of law or the Court must take some step to unseal it in implementing Congress' mandate, service of the Complaint still requires authorization by the Court. PsychRights respectfully suggests the Court should do this now.

IV. CONCLUSION

For the foregoing reasons, PsychRights respectfully suggests this Court should issue an Order that the Complaint is unsealed and be served on defendants. A proposed order to do so has been lodged contemporaneously herewith.

DATED: June 28, 2009.

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

By: _____
James B. Gottstein, Esq.

Certificate of Service

The undersigned hereby certifies that a copy hereof has been mailed this date to:

Eric Holder, U.S. Attorney General
Attn: Evan Zoldan
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

Dated: June 28, 2009.

James B. Gottstein, Esq.