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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

REPLY TO OPPOSITION TO REFILED MOTION FOR PRELIMINARY INJUNCTION AGAINST DEFENDANTS HOGAN AND STREUR

I. SUMMARY

PsychRights' Refiled Motion for Preliminary Injunction Against Defendants Hogan and Streur, Dkt. No. 113 (Preliminary Injunction Motion), is grounded on Congress' restriction of coverage for outpatient drugs to those that are for a medically accepted indication.[1] The defendants, including Hogan and Streur against whom the injunction is sought, dispute that such restriction exists.[2]

[1] *See*, Dkt. No. 113, pp. 4-6. *See, also*, Dkt. No. 108.
[2] *See*, Dkt. Nos. 93 & 120.

The government has obtained multiple hundred million dollar judgments against drug companies,[3] and is currently proceeding against another,[4] for causing doctors to prescribe psychotropic drugs for use on children and youth Medicaid recipients that are not for medically accepted indications and are therefore false claims. If drug companies causing such prescriptions constitute false claims, the presentment of such prescriptions at the direction of defendants Hogan and Streur must also be false claims.

In their opposition to the Motion for Preliminary Injunction, Dkt. No. 130 (Opposition), Defendants Hogan and Streuer do not dispute that under their direction, the State of Alaska is presenting Medicaid federal financial participation (FFP) claims for prescriptions of psychotropic drugs to children and youth that are not for medically accepted indications. Dkt. No. 130 at note 3. Defendants Hogan and Streur also do not dispute PsychRights' listing of psychotropic drugs for which there are no medically accepted indications for use on children and youth under 18 years of age and the limited number of medically accepted indications for other specific drugs, Dkt. No. 113, pp 13-16. There are thus no disputed factual issues related to the Motion for Preliminary Injunction.

The defendants, including Hogan and Struer, note in their Rule 12(b)(6) motion reply, "Nowhere does federal Medicaid law forbid the State of Alaska from covering claims for which it does not or will not get federal financial participation."[5] This is precisely the point; if the State of Alaska wants to cover prescriptions for psychotropic drugs to children and youth that are not for a medically accepted indication and pay for them entirely with its own funds, those are not false claims. It is the presentment of the claims to the federal government, which makes them false.

Assuming the Department of Justice and PsychRights are correct that outpatient drug coverage under Medicaid is limited to medically accepted indications, the question

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[3] *See*, Dkt. Nos. 108, p. 7; 108-1, p.1; 108-3, p.6; 113, pp 5-6.
[4] Dkt. No. 108-2, pp. 8-9, at ¶s 26-30; p. 10, ¶37; p. 31 ¶97; p. 32, ¶100.
[5] Dkt. No. 120, footnote 4.

presented by the Motion for Preliminary Injunction is whether, under the standards applicable to preliminary injunctions, defendants Hogan and Streur should be allowed to continue to present false claims during the pendency of this action. PsychRights suggests not.

II. DEFENDANTS HOGAN AND STREUR CAN BE ENJOINED FROM CONTINUED VIOLATION OF FEDERAL LAW

In §I of their Opposition, Hogan and Streur, at page 3, argue that the injunction "would impermissibly reach beyond the parties in the case," by including within the scope of the injunction "agents, servants, employees and attorneys, and any persons who are in active concert or participation" with Hogan and Streur. At page 2, Hogan and Streur assert this Court has no jurisdiction to enter the injunction against these non-parties, citing to *In re Infant Formula Anti-trust Litigation, MDL 875 v. Abbot Laboratories*, 72 F.3d 842, 842-843 (11th Cir. 1995). Hogan and Streur are simply incorrect because under F.R.C.P. 65(d)(2) "agents, servants, employees and attorneys, and any persons who are in active concert or participation" are bound by an injunction even without being explicitly named. This was apparently not the situation in *In re Infant Formula*, with the plaintiff there seeking to enjoin non-parties in the first instance. The "agents . . . " language could be removed from the injunction and these parties would still be bound, but it seems better to include the language so that defendants Hogan's and Struer's employees, etc., not mistakenly believe they are not subject to the injunction.

At p. 4, Hogan and Struer also assert that they may not be sued under the False Claims Act because they are state officials acting in their official capacities, citing *Vermont Agency of Natural Resources v. Unites States ex rel Stevens*, 529 U.S. 765, 787-88 (2000), and *United States ex rel Stoner v. Santa Clara County Office of Education*, 502 F.3d 1116, 1122 (9th Cir. 2007). First, *Stoner*, 502 F.3d at 1123, after considering *Stevens*, specifically held that "official capacity" liability under the False Claims Act is an open question upon which it was not ruling. More importantly, *Stoner*, 502 F.3d at 1123-

24, specifically rejected defendants Hogan's and Struer's position that they can not be sued under the False Claims Act:

> The district court also held that Stoner failed to state an FCA claim against the individual defendants in their personal capacities because Stoner could not allege that the defendants' actions exceeded the scope of their official responsibilities. As explained below, this was an error. The plain language of the FCA subjects to liability "any person" who, among other things, knowingly submits a false claim or causes such a claim to be submitted to the United States. 31 U.S.C. § 3729. Although the FCA does not define the term "person," the Supreme Court has made clear that the term includes "natural persons." *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 125, 123 S.Ct. 1239, 155 L.Ed.2d 247 (2003); see also 1 U.S.C. § 1 (defining the term "person" for purposes of "determining the meaning of any Act of Congress" as including an individual). Therefore, state employees sued in their personal capacities are "persons" who may be subject to liability for submitting a false claim to the United States.

In the State of Alaska Officials'[6] reply regarding their 12(b)(6) motion to dismiss, Dkt. No. 117, pp. 2-3, they assert *Stoner* does not hold state officials are liable for actions "within the scope of their official responsibilities," but admit they are liable "for actions taken in the course of their official duties." The State Officials' position seems wrong on its face, because as set forth above, the Ninth Circuit held the district court was in error when it held that government officials could not be sued for actions that did not exceed the scope of their official responsibilities, but even under the State Officials' interpretation, defendants Hogan and Streur are liable for directing, or even allowing, their employees to present false claims.

III. THE REQUESTED PRELIMINARY INJUNCTION IS APPROPRIATE

In Section II of their Opposition, Hogan and Streur assert that the availability of a legal remedy, i.e., damages, precludes equitable relief arguing that because the State of Alaska is not a defendant, *California Pharmacists Ass'n v. Maxwell-Jolly*, 563 F.3d 847,

[6] The State of Alaska Officials include defendants Sandoval and McComb as well as Hogan and Struer.

852 (9th Cir. 2009), holding irreparable harm exists as a matter of law when a state is a defendant, does not apply. Hogan and Streur are not the State of Alaska, but official capacity liability is an open question in the Ninth Circuit under *Stoner*.

Most importantly, Hogan and Streur failed to address the point made by PsychRights at p. 10 of its Motion for Preliminary Injunction, Dkt. No. 113, that the continued violation of federal law constitutes irreparable harm as a matter of law.[7]

PsychRights respectfully suggests Hogan and Streur should not be allowed to continue to present, direct or authorize the presentment of false claims during the pendency of this action.

IV. PSYCHRIGHTS HAS MET ITS BURDEN OF ESTABLISHING THE REQUIREMENTS FOR A PRELIMINARY INJUNCTION

A. PsychRights is Likely to Succeed on the Merits

In asserting PsychRights is not likely to succeed on the merits, defendants Hogan and Streur incorporate by reference, four motions to dismiss, Dkt. Nos. 83, 89, 90 & 92. Except with respect to the fundamental issue of whether Medicaid is only allowed to reimburse for medically accepted indications, which is raised in Dkt. No. 92, and the State Officials' motion to dismiss on sovereign immunity grounds, Dkt. No. 90, incorporating these motions wholesale by reference does not seem particularly helpful because there are many issues involving the 30 other defendants that are not relevant to the instant motion. Of necessity PsychRights incorporates its oppositions to these four motions, to wit: Dkt. Nos. 108, 109, 110 & 111, but will also address specific points germane to the instant Motion for Preliminary Injunction.

[7] Hogan and Streur cite to *In re Schimmels*, 127 F.3d 875, 883 (9th Cir. 1997) in a way that suggests the court there was holding the False Claims Act does not allow injunctive relief. The point being addressed by the court in *Schimmels*, however, was that *relators* are suing on behalf of the federal government, which is the real party in interest.

(1) Medicaid Restricts Reimbursement for Outpatient Drugs to Medically Accepted Indications

In Dkt. No. 92, through its motion for dismissal under F.R.C.P. 12(b)(6), the defendants challenge the fundamental basis of this action, which is that Congress restricted reimbursement for prescriptions of outpatient drugs to those that are for a medically accepted indication (12(b)(6)Motion). PsychRights opposed the 12(b)(6) Motion at Dkt. No. 108, which is hereby incorporated by reference and the defendants replaied at Dkt. No. 125. Because of its centrality to the likelihood of success on the merits standard for issuing a preliminary injunction, PsychRights will address the key points.

In spite of the clear limitation Congress placed on reimbursements for outpatient drugs to those that are for a medically accepted indication,[8] the defendants argue such is not the case because (a) "prescribed drugs" is included in the definition of "medical assistance" in 42 U.S.C. §1396d(a)(12),[9] and (b) 42 U.S.C. §1396r-8(d)(1)(B)(i) allows states to exclude or otherwise limit coverage where the prescribed use is not for a medically accepted indication.[10]

With respect to the first argument, as set forth more fully in PsychRights' Opposition to the 12(b)(6) Motion at pp 2-5, the definition of "medical assistance" describes the universe of items that might be covered and much of the rest of the statute sets forth which or when elements of medical assistance Medicaid is authorized to reimburse.

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[8] For example, the court in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass 2008) held:

> 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).

[9] Dkt. No. 93, n. 19.

[10] Dkt. No. 93, §II.B., pp. 6-8.

With respect to the second argument, defendants' interpretation of the statute immediate falls apart when looking at the provision upon which they rely, §1396r-8(d)(1)(B)(i), which states:

> (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if--
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> > (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6) of this section);

This is circular because, "covered outpatient drug" is defined in 42 USC 1396R-8(k)(3) to "not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." In other words, this section allows the states to exclude or restrict coverage of a covered outpatient drug to a covered outpatient drug. There is thus simply no avoiding the conclusion that 42 U.S.C. §1396r-8(d)(1)(B)(i) is superfluous. Most importantly, it can not be used to override Congress' explicit limitation of Medicaid coverage for outpatient drugs to medically accepted indications.

As set forth more fully at 2-10 of PsychRights Opposition to the 12(b)(6) Motion, Dkt. No. 108, other provisions of the Medicaid statute clearly prohibit reimbursement of outpatient drug prescriptions that are not for a medically accepted indication. The Defendants argue "there is not a single statement to the effect that payment 'will not be made for any prescribed drug that is not a covered outpatient drug,'"[11] but this is simply not true. 42 U.S.C. §1396r-8(a)(1), begins the entire section titled, "Payment for covered outpatient drugs,"[12] with the restriction, "In order for payment to be available . . . for covered outpatient drugs . . ." and then at 42 U.S.C. §1396r-8(k)(3) provides, "The term

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[11] Dkt. No. 120, p. 4.

[12] Titles are an appropriate source from which to discern legislative intent. *United States v. Nader*, 542 F.3d 713, 717 (9th Cir. 2008). "Coverage" in the insurance context means "a. Inclusion in an insurance policy or protective plan. b. The extent of protection afforded by an insurance policy." *American Heritage Dictionary*, 4th Ed. *See*, also, *Black's Law Dictionary*. Congress using the term "covered outpatient drugs," in itself designates that this is what is being "covered," by Medicaid. That the title of 42 U.S.C. §1396r-8, is "Payment for covered outpatient drugs," also makes clear that "covered outpatient drugs," is what Medicaid "covers," or pays for.

'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication."

(2) The Public Disclosure Bar Does Not Preclude The Action Against Hogan and Streur

At page 7 of their Opposition, Hogan and Streur, incorporate the entirety of the defendants' Public Disclosure Bar Motion[13] and Reply[14] in support of their argument that the Public Disclosure Bar applies. However, the Public Disclosure Bar Motion, PsychRights' Opposition thereto,[15] and the defendants' Reply address how the Public Disclosure Bar does or does not apply to the different circumstances pertaining to the 32 defendants under the First Amended Complaint, Dkt. No. 107. PsychRights respectfully suggests a helpful way to look at this issue is to ask, "are there specific claims against defendants Hogan and Streur to which the Public Disclosure Bar can not apply?" If so, that the Public Disclosure Bar might apply to other claims is irrelevant for purposes of the instant Motion for Preliminary Injunction. Such is the case here.

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 Hogan and Streur with respect to false claims identified in the First Amended Complaint that were presented or caused to be presented by or under their direction after such public disclosure in late September 2008 when the amended complaint in *PsychRights v. Alaska* was filed.[16] Paragraph 188 of the First Amended Complaint here, Dkt. No. 107, pp. 44-46, identifies numerous such false claims which, as paragraph 215 states, defendants Hogan and Streur approved for presentment or presented to the government for FFP.

Similarly, the Public Disclosure Bar can not apply to the ongoing presentment to Medicaid for FFP reimbursement of prescriptions of psychotropic drugs used on children

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[13] Dkt. No. 91.
[14] Dkt. No. 119.
[15] Dkt. No. 111.
[16] *See,* Dkt. No. 91-7, p.8, paragraph 22, and page 54 (for the date).

and youth that are not for medically accepted indications, which defendants Hogan and Streur admit.[17] It is this ongoing presentment of such false claims that necessitates the granting of the requested preliminary injunction.

(3) PsychRights Has Satisfied Rule 9(b)'s Particularity Requirement With Respect to Defendants Hogan and Struer

At page 8 of their Opposition, Hogan and Streur incorporate wholesale the defendants' memorandum and reply pertaining to their Rule 9(b) motion to dismiss, Dkt. No. 83 (Particularity Motion). As with the Public Disclosure Bar Motion, the Particularity Motion covers a number of different scenarios with respect to the different status of various defendants, for some of whom specific false claims have not been identified. PsychRights believes the particularity requirement of F.R.C.P. 9(b) is satisfied with respect to the defendants for whom no specific claims are identified for the reasons stated in its Opposition to the Particularity Motion,[18] but that question does not pertain to Hogan and Struer. The First Amended Complaint identifies over 250 specific prescriptions to children and youth for psychotropic drugs that were not for a medically accepted indication that defendants Hogan and Streur caused to be presented or presented to Medicaid for FFP, which are therefore false.[19]

Many of these prescriptions are for drugs for which there are no medically accepted indications at all for use on children and youth,[20] to wit: Geodon used on AL,[21] Cymbalta used on MG,[22] Trazadone used on FH, and DG,[23] and Wellbutrin used on RT.[24] While the drugs in the other identified false claims do have limited medically

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[17] Dkt. No. 130, footnote 3.
[18] Dkt. No. 110, pp 3-11.
[19] Dkt. No. 107, paragraphs 187, 188, 191, 193, 195, 203 & 215.
[20] Dkt. No. 113-5 is the chart of medically accepted indications for use on children and youth of some 50 psychotropic drugs.
[21] *See*, Docket No. 107, paragraph 188.
[22] *See*, Dkt. No. 107, paragraphs 187, 202 & 206.
[23] *See*, Dkt. No. 107, paragraphs 192, 193, 203 used on FH and DG
[24] *See*, Dkt. No. 107, paragraph 191.

accepted indications, none of them were prescribed for a medically accepted indication. It is frankly difficult to see how the claims against Hogan and Streur can fail on particularity grounds when over 250 specific prescriptions caused to be presented or presented by Hogan and Streur that were not for medically accepted indications and therefore false have been identified. Hogan and Streur have essentially admitted that these prescriptions were not for medically accepted indications, but dispute that presentment of such prescriptions constitute false claims. That is the key question to be answered. Particularity, it is respectfully suggested, is not a genuine issue with respect to defendants Hogan and Streur.

As part of their particularity argument the defendants also assert at page 9 of both their Particularity Memorandum, Dkt. No. 84, and their lodged proposed reply, Dkt. No. 115-1, that the False Claims Act "requires a lie," citing primarily to *Wang v. FMC Corp.*, 975 F.2d 1412, 1420-21 (9th Cir. 1992), which, in turn, cites to *United States ex rel Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1421 (9th Cir. 1991). *Hagood* held:

> [W]hat constitutes the offense is not intent to deceive but knowing presentation of a claim that is either “fraudulent” or simply “false.” 31 U.S.C. § 3729(a)(1) and (2). The requisite intent is the knowing presentation of what is known to be false. That the relevant government officials know of the falsity is not in itself a defense.

In *Wang*, the allegation of false claim was based on math errors and the court held that did not constitute knowledge under the False Claims Act. Here the question is whether defendants Hogan and Streur are charged with knowledge of the legal requirements under Medicaid. To this latter question, under *U.S. v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001), defendants Hogan and Streur the answer is yes:

> "Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law...." *Heckler v. Cmty. Health Servs. of Crawford County, Inc.*, 467 U.S. 51, 63, 104 S.Ct. 2218, 81 L.Ed.2d 42 (1984). Participants in the Medicare program have a duty to familiarize themselves with the legal requirements for payment. *Id.* at 64, 104 S.Ct. 2218.

> The evidence established that Mackby was the managing director of the clinic. He was responsible for day-to-day operations, long-term planning, lease and build-out negotiations, personnel, and legal and ac-counting oversight. It was his obligation to be familiar with the legal requirements for obtaining reimbursement from Medicare for physical therapy services, and to ensure that the clinic was run in accordance with all laws. His claim that he did not know of the Medicare requirements does not shield him from liability.

Moreover, it is important to distinguish claims brought under 31 U.S.C. §1329(a)(1)(A), from those brought under §1329(a)(1)(B). §1329(a)(1)(A) makes a person liable if he or she "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," while §1329(a)(1)(B) makes the person liable if he or she, " knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" The latter classically involves a lie, while the former only requires knowing presentment or causing presentment of a false claim.

It also seems worth noting the Ninth Circuit in *Hagood*, 929 F.2d at 1421-22, also held:

> [E]stoppel will not lie against the United States “on the same terms as any other litigant.” *Heckler v. Community Health Services*, 467 U.S. 51, 60, 104 S.Ct. 2218, 2224, 81 L.Ed.2d 42 (1984). The defendant's “inability to retain money that it should never have received in the first place” is not the kind of detrimental reliance that justifies estoppel against the government. *Id.* at 61, 104 S.Ct. at 2225. Such is this case, if Hagood's allegations prove to be good. . . . Hagood claims that the Water Agency proceeded unscrupulously, indeed with knowledge of the falsity of its claim, with knowledgeable government officials abetting its behavior. Hagood's allegations constitute a cause of action.

Finally, it would be premature to dismiss the complaint on grounds the defendants do not meet the *scienter* requirement of the False Claims Act. *Hagood*, 929 F.2d at 1422.

B. Irreparable Harm Exists as a Matter of Law

Hogan and Streur do not address the point made by PsychRights in §B(2), p.10, of its Motion for Preliminary Injunction, Dkt. No. 113, that continued violation of federal law constitutes irreparable harm as a matter of law. This alone satisfies the irreparable harm requirement.

Hogan and Streur do assert at page 9 of their Opposition that PsychRights' point that irreparable harm is established as a matter of law because this Court can not issue a judgment for damages against a state under the Eleventh Amendment is irrelevant because the State of Alaska is not a defendant. Here, Hogan and Streur are attempting to have it both ways. Elsewhere, as discussed above, they assert the case should be dismissed against them because it is really against the State, while here they say the irreparable harm argument is irrelevant because the State is not a defendant. In any event, as set forth above, in *Stoner*, 502 F.3d at 1123, the Ninth Circuit left open the question of official capacity liability.

C. The Balance of Equities and Public Interest Are In Favor of Issuing the Injunction

At page 9 of their Opposition, Dkt. No. 130, Defendants Hogan and Streur do not dispute the authority cited by PsychRights at §B(3), pp 10-11, of its Motion for Preliminary Injunction, Dkt. No. 113, that the balance of equities and the public interest both favor issuance of the injunction as a matter of law where, as here, the injunction is to enjoin continuing violation of federal law. Instead, they argue that no public interest is served by enforcing Congress' prohibition against reimbursement for off-label prescriptions unless there is sufficient level of scientific support as cited in one or more of the compendia. They assert no public interest is served by depriving Medicaid recipients access to prescribed drugs that are available to patients with the means to pay for them. However, private patients with the means to pay have access to all sorts of medical assistance for which Medicaid does not pay. In fact, 42 U.S.C. §1396b(i) is a

long list of items Congress has decreed shall not be paid by Medicaid that patients with the means to pay can obtain.

V. CONCLUSION

For the foregoing reasons PsychRights' Motion for Preliminary Injunction, Dkt. No. 113, should be granted.

RESPECTFULLY SUBMITTED this 10th day of June, 2010.

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

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 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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