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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	)	Case No. 3:09-CV-00080-TMB
Rights, an Alaskan non-profit	)	
corporation,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	
	)	
OSAMU H. MATSUTANI, MD, <i>et al.</i> ,	)	
	)	
Defendants.	)	
_____	)	

**MOTION FOR PRELIMINARY INJUNCTION AGAINST  
DEFENDANTS HOGAN AND STREUR**

*Qui tam* relator Law Project for Psychiatric Rights (PsychRights®) moves for a preliminary injunction prohibiting defendants William Hogan and William Streur, their agents, servants, employees and attorneys, and any persons who are in active concert or participation with them, from presenting claims or causing claims to be presented to Medicaid for reimbursement or payment of the United States Government's federal

financial participation (FFP) share<sup>1</sup> of outpatient prescriptions for psychotropic drugs to recipients under the age of 18 (children and youth) that are not for a medically accepted indication.

## I. BACKGROUND

This is a case under the federal False Claims Act, 31 U.S.C. §3729, *et seq.*, to:

- (a) recover for false claims presented to and paid by Medicaid for outpatient psychiatric drugs prescribed to children and youth that were not for a "medically accepted indication;" and
- (b) order the defendants to cease and desist from presenting or causing the presentment of such false claims.

This motion seeks to enjoin Defendants William Hogan and William Streur, their agents, servants, employees and attorneys, and any persons who are in active concert or participation with them from presenting claims or causing claims to be presented to Medicaid for outpatient prescriptions for psychotropic drugs to children and youth that are not covered under that program. Defendant Hogan is the Commissioner of the Alaska Department of Health and Social Services (DHSS), and Defendant William Streur is the Director of the Division of Health Care Services (HCS) within DHSS. Defendant Streur is in charge of the administration of the Medicaid program by the State of Alaska under the direction and supervision of Defendant Hogan. In other words, Defendants Hogan and Streur are in charge of the administration of the Medicaid program by the State of Alaska.

Congress restricted reimbursement for outpatient drugs by the federal government under Medicaid to those that are "medically accepted indications," defined as indications approved by the Food and Drug Administration (FDA), or the use of which is supported by one or more citations included or approved for inclusion in (i) American Hospital

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<sup>1</sup> "FFP" stands for "Federal Financial Participation," which means "the Federal Government's share of a State's expenditures under the Medicaid program." 42 CFR §400.203.

Formulary Service Drug Information, (ii) United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System (Covered Outpatient Drugs). 42 USC § 1396r-8(k)(3); 42 USC § 1396r-8(k)(6); 42 USC § 1396r-8(g)(1)(B)(i).

The parties sought to be enjoined continue to present claims or cause claims to be presented to Medicaid for payment of prescriptions to children and youth for psychiatric drugs that are not for a medically accepted indication. This motion thus seeks to preliminarily enjoin such continuing violation of federal law.

## **II. STANDARDS FOR PRELIMINARY INJUNCTIONS**

In *California Pharmacists Ass'n v. Maxwell-Jolly*, 563 F.3d 847, 849 (9th Cir. 2009), citing to *Winter v. Natural Res. Def. Council, Inc.*, --- U.S. ----, 129 S.Ct. 365, 376, 172 L.Ed.2d 249 (2008), the 9th Circuit, recently had occasion to state the standard for obtaining a preliminary injunction:

Plaintiffs seeking a preliminary injunction in a case in which the public interest is involved must establish that they are likely to succeed on the merits, that they are likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that an injunction is in the public interest. .

These factors will be discussed in turn.

## **III. THE STANDARDS FOR ISSUANCE OF A PRELIMINARY INJUNCTION ARE MET HERE**

### **A. PsychRights is Likely to Succeed on the Merits**

#### **(1) Medicaid Coverage for Outpatient Drugs is Limited to "Medically Accepted Indications**

42 USC 1396R-8(k)(3) provides in pertinent part, "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication." 42 USC 1396R-8(k)(6) provides:

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

42 USC § 1396R-8(g)(1)(B)(i), in turn, designates the compendia as

- (I) American Hospital Formulary Service Drug Information;
- (II) United States Pharmacopeia-Drug Information (or its successor publications); and
- (III) the DRUGDEX Information System.

(Compendia).

In sum, Medicaid is only permitted by Congress to reimburse the states for expenditures on outpatient drugs for "medically accepted indications," defined as indications approved by the FDA or "supported" by a citation in any of the three Compendia. This was recognized in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass 2008) where the Court 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).

Similarly, in *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d 39, 44,45 (D.Mass 2001), the Court held:

Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program. Reimbursement under Medicaid is, in most circumstances, available only for “covered outpatient drugs.” 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are “used for a medical indication which is not a medically accepted indication.” *Id.* §1396r-8(k)(3). A medically accepted indication, in turn, includes a use “which is approved under the Federal Food Drug and Cosmetic Act” or which is included in specified drug compendia. *Id.* § 1396r-8(k)(6). See also *id.* § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, unless a particular off-label use for a drug is included in one of the

identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

(footnote omitted)

The Department of Justice concurs as shown by its news release announcing the \$2.3 Billion settlement with Pfizer, in which it stated, "[Pfizer] caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs." Exhibit A.

**(2) Defendants Hogan and Streur Are Personally Liable for Presenting or Causing False Claims to be Presented to Medicaid.**

Under *Stoner v. Santa Clara County Office of Education*, 502 F.3d 1116, 1124-5 (9th Cir. 2007), Defendants Hogan and Steur are personally liable for presenting or causing the presentment of false claims to Medicaid:

The district court also held that Stoner failed to state an FCA [False Claims Act] 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." . . . 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. . . .

To state a claim against Wilcox, Fimiani, and Wong in their personal capacities, Stoner need show only that the individual employees "knowingly present[ed], or cause[d] to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval."

(citations omitted).

**(3) Defendants Hogan and Streur Are Flouting Medicaid Requirements By Presenting or Causing the Presentment of Claims for Prescriptions of Psychotropic Drugs to Children and Youth That Are Not For A Medically Accepted Indication**

In *ex rel Rost*, 253 F.R.D. at 14 the district court noted, "Each prospective Medicaid provider must agree that he will comply with all Medicaid requirements." States must similarly agree to abide by Medicaid requirements as a condition of participation. Attached hereto as Exhibit B is a copy of the State of Alaska's agreement to comply with all Medicaid requirements.

Among these requirements, under 42 USC §1396r-8 (g)(1)(A), the State of Alaska is required to have a drug use review program (DUR) "designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud."

Under 42 CFR §456.703, the DUR is required to include "prospective drug review." 42 CFR §456.705 in turn provides in pertinent part:

**42 CFR §456.705 Prospective drug review.**

(a) General. Except as provided in Sec. Sec. 456.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient . . . . The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements . . . . The pharmacies, in turn, must provide this information to their pharmacists.

In other words, through this prospective drug review, before each prescription is filled, the state Medicaid agency is required to review it to determine if it is eligible for reimbursement by Medicaid.

42 CFR §456.722 allows for this prospective review of prescriptions to occur through a computerized system:

**42 CFR §456.722 Electronic claims management system.**

(a) Point-of-sale system. Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is,

immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. . . . If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) Functional requirements. The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. . . .

(2) Claims data capture, including the following: . . .

(iii) Minimum data set (as defined in Part 11 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

Included in the data set of Part 11 of the State Medicaid Manual<sup>2</sup> are:

\*6. Recipient's Date of Birth:

The date of birth of the recipient. . .

\*61. Principal Diagnosis Code:

a. The diagnosis code for the principal condition requiring medical attention. . . .

62. Other Diagnosis Code:

a. The diagnosis code of any condition other than the principal condition which requires supplementary medical treatment. . . .

88. Drug Code:

Codes identifying particular drugs; e.g., National Drug Code, drug tables.

89. Diagnosis Code:

A table of codes identifying medical conditions; i.e., ICD-9-CM.

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<sup>2</sup> Exhibit C, downloaded from [http://www.cms.hhs.gov/manuals/downloads/P45\\_11.zip](http://www.cms.hhs.gov/manuals/downloads/P45_11.zip) on March 17, 2010.

90. Drug Name:  
The generally accepted nomenclature for a particular drug.
91. Drug Classification:  
The therapeutic group in to which a drug is categorized.
92. Minimum Days Supply of Drugs:  
The minimum units of a drug prescription eligible for payment.
93. Maximum Days Supply of Drug:  
The maximum units of a drug prescription eligible for a particular drug. . . .
95. Diagnosis Name:  
The generally accepted nomenclature for a diagnosis. Name is required only if not encoded by provider. (See Data Element No. 61.)

These statutory and regulatory provisions require the State of Alaska to screen prescriptions for compliance with the requirement that it not seek federal Medicaid payment for outpatient prescriptions to children and youth for psychotropic drugs that are not for a medically accepted indication.

To summarize: 42 USC §1396r-8 (g)(1)(A) requires a DUR program, 42 CFR §456.703 requires the DUR program to include prospective drug review, and 42 CFR §456.705 requires such prospective review to verify eligibility before the prescription is filled. Under 42 CFR §456.722, the State's electronic claims management system is required to collect the minimum data specified in Part 11 of the State Medicaid Manual, relevant elements of which are set forth above. These elements can determine whether psychotropic drugs prescribed to children and youth are or are not for a medically accepted indication.

Under Defendants Hogan's and Steur's administration of Alaska's Medicaid program, these requirements are being flouted.

#### **(4) Injunctive Relief is Available Against Defendants Hogan and Steur**

Injunctive relief to enjoin a state official from violating a federal statute is proper and not barred by the 11th Amendment to the United States Constitution. *Armstrong v. Wilson*, 124 F.3d 1019 (9th Cir. 1997); *Independent Living Center of Southern*

*California, Inc., v Maxwell-Jolly*, 572 F.3d 644 (9th Cir. 2009). Where a district court has the power to issue a permanent injunction, it also has authority to issue preliminary injunctions. *F.T.C. v. H. N. Singer, Inc.*, 668 F.2d 1107, 1111 (9th Cir. 1982).

**B. The Plaintiff Will Suffer Irreparable Harm Without the Preliminary Injunction**

**(1) To the Extent the 11th Amendment Prohibits a Monetary Judgment Against the State of Alaska for its Medicaid Fraud, Irreparable Harm is Established as a Matter of Law.**

In *California Pharmacists, supra.*, 563 at 852, the 9th Circuit held that to the extent the 11th Amendment prevents a federal court from awarding a damages remedy against a state, irreparable harm is established as a matter of law:

Because the economic injury doctrine rests only on ordinary equity principles precluding injunctive relief where a remedy at law is adequate, it does not apply where, as here, the Hospital Plaintiffs can obtain no remedy in damages against the state because of the Eleventh Amendment.

(citation and footnote omitted).

In *Stoner*, as set forth above, the Ninth Circuit held that state employees are personally liable under the False Claims Act for Medicaid violations while acting within the scope of their official duties. However, it specifically held open the question of whether the 11th Amendment prevented the district court from awarding money damages against a state under the False Claims Act through its employees:

With respect to the official capacity claims, the district court held that the individually named defendants could not be sued for damages in their official capacities because such a suit would, in effect, be against the state. . . . The parties do not challenge this ruling and we express no opinion on the merits of the district court's conclusion.

572 F.3d at 1123 (citation omitted).

*California Pharmacists* does not mention *Stoner*, and the two cases are certainly distinguishable, especially in that *California Pharmacists* is not a False Claims Act case

while *Stoner* is, but it can be read to suggest that even under the False Claims Act, the 11th Amendment bars a federal court from awarding monetary damages against a state.

If Defendants Hogan and Streur, who are being represented by the Alaska Department of Law as to both their individual and official capacities,<sup>3</sup> concede that the State of Alaska is subject to monetary damages by virtue of Defendants Hogan and Streur having been sued in their official capacities as well as individually, then irreparable harm will not have been established on the grounds that the 11th Amendment bars this Court from awarding monetary damages against the State of Alaska through Defendants Hogan and Streur. However, if the State of Alaska, through Defendants Hogan and Streur, does not concede the State is subject to monetary damages, and this Court concludes the State of Alaska is immune, under *California Pharmacists*, irreparable harm has been established as a matter of law.

As will be discussed in the next section, however, even if the Court concludes the State of Alaska through Defendants Hogan and Streur is subject to monetary damages in this case and therefore irreparable harm has not been established for that reason, irreparable harm is established as a matter of law because the continuing violation of a federal statute constitutes irreparable harm as a matter of law.

**(2) The Continuing Violation of a Federal Statute is Irreparable Harm as a Matter of Law.**

In *New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351, 98 S.Ct. 359, 363, 54 L.Ed.2d 439 (1977) (Rehnquist, J., in chambers), the U.S. Supreme Court held, "any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." In *Coalition for Economic Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997), citing *New Vehicle*, the Ninth Circuit held, "it is clear that a state suffers irreparable injury whenever an enactment of its people or their representatives is enjoined." In *Independent Living*

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<sup>3</sup> See, Docket Nos. 52 & 55.

*Center, supra.*, 572 F.3d at 658, the Ninth Circuit clarified, that while that may be true, enforcing federal law pre-empts such irreparable harm suffered by a state, stating:

As the cited authority suggests, a state may suffer an abstract form of harm whenever one of its acts is enjoined. To the extent that is true, however, it is not dispositive of the balance of harms analysis. If it were, then the rule requiring “balance” of “competing claims of injury,” *Winter*, 129 S.Ct. at 376, would be eviscerated. Federal courts instead have the power to enjoin state actions, in part, because those actions sometimes offend federal law provisions, which, like state statutes, are themselves “enactment [s] of its people or their representatives,”

PsychRights respectfully suggests the Ninth Circuit has thus implicitly held that allowing continuing violation of federal law constitutes irreparable harm as a matter of law.

**C. The Balance of Equities Tips in Favor of the Plaintiff and the Injunction is in the Public Interest as a Matter of Law**

Under *California Pharmacists, supra.*, 563 at 852-853, as a matter of law, the balance of equities tips in favor of the plaintiff and a prospective preliminary injunction is in the public interest if the requested preliminary injunction is to enjoin continuing violation of federal law (“it is clear that it would not be equitable or in the public's interest to allow the state to continue to violate the requirements of federal law”). Thus, these two factors are satisfied as a matter of law. Where, as here, the violation of law is clear, the court must not allow it to continue.

**IV. SCOPE OF THE REQUESTED PRELIMINARY INJUNCTION**

Whether a prescription for a psychotropic drug to a child or youth that is not for an FDA approved indication is nonetheless covered under Medicaid because it is a medically accepted indication, the American Hospital Formulary Service and DRUGDEX compendia citations must be consulted to be if such use is “supported.”<sup>4</sup>

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<sup>4</sup> It is PsychRights' understanding, after inquiry, that United States Pharmacopeia-Drug Information (or its successor publications), the other compendium specified in 42 U.S.C. 1396r-8(g)(1)(B)(i), is no longer being published.

Attached hereto as Exhibit D are the most recent citations in the American Hospital Formulary Service compendium, and Exhibit E the most recent citations in DRUGDEX<sup>5</sup> available to PsychRights,<sup>6</sup> for specific prescription psychotropic drugs often prescribed to children and youth. These establish the following with respect to medically accepted indications prescribed to children and youth for the specific psychotropic drugs:

1. The following psychotropic drugs have no medically accepted indication for anyone under 18 years of age and should be prohibited entirely:

- a. Clorazil (clozapine)
- b. Cymbalta (duloxetine)
- c. Desyrel (trazadone)
- d. Effexor (venlafaxine)
- e. Geodon (ziprasidone)
- f. Invega (paliperidone)
- g. Paxil (paroxetine)
- h. Symbyax (fluoxetine hydrochloride/olanzapine)

2. The only medically accepted indications for anyone under 18 years of age are as set forth below for the following psychotropic drugs and all other indications should be prohibited:

<b>Drug</b>	<b>Medically Accepted Indication</b>	<b>Notes</b>
<b><u>Abilify</u></b> (Aripiprazole)		
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	10 yrs old and up
	Bipolar I Disorder, monotherapy, Manic	10-17 years old for acute therapy

<sup>5</sup> Exhibit F is a copy of the DRUGDEX Recommendation, Evidence and Efficacy Ratings.

<sup>6</sup> PsychRights has requested Defendant Thomson Reuters (Healthcare), the publisher of DRUGDEX, for the most recent citations in DRUGDEX and to keep them current so that any additions to medically accepted indications may be reflected in the requested preliminary injunction. *See*, Exhibit G.

<b>Drug</b>	<b>Medically Accepted Indication</b>	<b>Notes</b>
	or Mixed Episodes	
	Schizophrenia	13-17 years old
<b>Adderall</b> (amphetamine/dextroamphetamine )		
	Attention Deficit Hyperactivity Disorder (ADHD)	3 years old and up for immediate-release and 6 years old and up for extended-release
	Narcolepsy	6 years old and up for immediate release
<b>Anafranil</b> (clomipramine)		
	Obsessive-Compulsive Disorder	10 years and up
<b>Concerta</b> (methylphenidate)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old to 12 years old
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old and up for ConcertaR
<b>Depakote</b> (valproic acid)		
	Absence Seizure, Simple and Complex and/or Complex Partial Epileptic Seizure	10 years and older
<b>Dexedrine</b> (dextroamphetamine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release))
	Narcolepsy	6 years old and up
<b>Focalin</b> (dexmethylphenidate)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years and older
<b>Haldol</b> (haloperidol)		
	Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy	3 years old and up
	Problematic Behavior in Children (Severe), With failure to respond to non-antipsychotic medication or psychotherapy	3 years old and up
	Psychotic Disorder	3 years old and up but ORAL formulations only

<b>Drug</b>	<b>Medically Accepted Indication</b>	<b>Notes</b>
	Schizophrenia	3 years old and up but ORAL formulations only
<b><u>Lamictal</u></b> (lamotrigine)		
	Epilepsy, Refractory	
<b><u>Lexapro</u></b> (escitalopram)		
	Major Depressive Disorder	12 years old and up
<b><u>Luvox</u></b> (fluvoxamine)		
	Obsessive-Compulsive Disorder	8 years old and up and immediate release formula only
<b><u>Mellaril</u></b> (thioridazine)		
	Schizophrenia, Refractory	
<b><u>Neurontin</u></b> (gabapentin)		
	Partial Seizure; Adjunct	3-12 years old
<b><u>Orap</u></b> (pimozide)		
	Gilles de la Tourette's syndrome	12 years and older
<b><u>Prozac</u></b> (fluoxetine)		
	Major Depressive Disorder	8 years old and up
	Obsessive-Compulsive Disorder	7 years old and up
<b><u>Ritalin</u></b> (methylphenidate)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years to 12 years old (extended release)
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old and up (immediate release)
	Narcolepsy	6 years and up, and Ritalin(R) -SR only
<b><u>Risperdal</u></b> (risperidone)		
	Autistic Disorder – Irritability	5 years old and up
	Bipolar I Disorder	10 years old and up
	Schizophrenia	13 years old and up (Orally)
<b><u>Seroquel</u></b> (quetiapine)		
	Manic episodes associated with bipolar disorder	10 years old to 17 years old
	Schizophrenia	13 years old to 17 years old
<b><u>Sinequan</u></b> (doxepin)		
	Alcoholism - Anxiety – Depression	12 years old and up

<b>Drug</b>	<b>Medically Accepted Indication</b>	<b>Notes</b>
	Anxiety – Depression	12 years old and up
	Anxiety - Depression - Psychoneurotic personality disorder	12 years old and up
<b><u>Strattera</u></b> (atomoxetine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old and up
<b><u>Tegretol</u></b> (carbamazepine)		
	Epilepsy, Partial, Generalized, and Mixed types	
<b><u>Tofranil</u></b> (imipramine)		
	Nocturnal enuresis	6 years old and up
<b><u>Trileptal</u></b> ( <i>oxcarbazepine</i> )		
	Partial Seizure, monotherapy	4 years old and up
	Partial seizure; Adjunct	2 years old and up
<b><u>Vyvanse</u></b> (lisdexamfetamine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old to 12 years old
<b><u>Zoloft</u></b> (sertraline)		
	Obsessive-Compulsive Disorder	6 years old and up
<b><u>Zyprexa</u></b> (olanzapine)		
	Schizophrenia	13 years old to 17 years old
	manic or mixed episodes associated with bipolar I disorder	13 years old to 17 years old

For psychotropic drugs not listed, PsychRights respectfully suggests the parties sought to be enjoined should be prohibited from approving for payment or reimbursement by Medicaid of the United States Government's FFP share of outpatient prescriptions for psychiatric drugs to anyone under 18 unless (a) it is for an indication approved by the FDA, or (b) upon application to the Court with notice to the other parties to determine whether such use is for a medically accepted indication.

**V. BOND**

Under F.R.C.P. 65(c) the United States is not required to give security. Since the United States is the real party in interest in this action, *Stoner, supra*, 502 F.3d at 1126, no security is required.

**VI. CONCLUSION**

For the foregoing reasons PsychRights' motion for a preliminary injunction should be granted.

RESPECTFULLY SUBMITTED this 24th day of March, 2010.

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

By: /s/ James B. Gottstein  
JAMES B. GOTTSTEIN  
ABA #7811100

Attorney for *relator*, Law Project for Psychiatric Rights

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on March 24 2010, a true and correct copy of this document and accompanying proposed order 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  
JAMES B. GOTTSTEIN, ABA  
#7811100  
Law Project for Psychiatric Rights