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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.)	
_____)	

**(Proposed) ORDER GRANTING
PRELIMINARY INJUNCTION**

Qui tam relator Law Project for Psychiatric Rights (PsychRights®) has moved 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) share¹ of outpatient prescriptions for psychotropic drugs to anyone under 18 (children and youth) that are not for a medically accepted indication. After hearing from PsychRights, Defendants Hogan and Streur, and all other parties wishing to be heard, for the reasons that follow, PsychRights' motion for preliminary injunction is **GRANTED**.

I. REASONS FOR ISSUANCE

1. Background

This is a case under the federal False Claims Act, 31 U.S.C. §3729, et seq., to 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 for an injunction prohibiting the defendants from presenting or causing the presentment of such claims to Medicaid. The parties which the motion seeks to enjoin are Defendants William Hogan and William Streur, their agents, servants, employees and attorneys, and any persons who are in active concert or participation with them. Defendant Hogan is the Commissioner of the Alaska Department of Health and Social Services (DHSS), and 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.

Through 42 USC § 1396r-8(k)(3); 42 USC § 1396r-8(k)(6), and 42 USC § 1396r-8(g)(1)(B)(i), Congress restricted payment for outpatient drugs by the federal government under Medicaid to those that are for "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 Formulary Service Drug Information, (ii) United States Pharmacopeia-Drug

¹ "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.

Information (or its successor publications), or (iii) DRUGDEX Information System (Compendia).

The State of Alaska, under the direction of Defendants Hogan and Streur, continues to approve or present claims for payment or reimbursement by Medicaid of the United States Government's federal financial participation (FFP) share of outpatient prescriptions for psychotropic drugs to children and youth that are not for a medically accepted indication, and thus not covered under the federal portion of the Medicaid program. This preliminary injunction prohibits this continued violation of federal law.

II. STANDARDS FOR PRELIMINARY INJUNCTIONS

In Order to prevail on its motion for a preliminary injunction, PsychRights must establish, (1) it is likely to succeed on the merits, (2) irreparable harm in the absence of preliminary relief, (3) the balance of equities tips in favor of such injunction, and (4) the injunction is in the public interest. *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).

III. DISCUSSION

2. Likelihood of Success on the Merits

PsychRights has demonstrated it is likely to succeed on the merits. 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 one or more of the three Compendia. *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass 2008); and *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d 39, 44,45 (D.Mass 2001).

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 & 705, the DUR

is required to include "prospective drug review" that confirms each prescription is properly reimbursable by Medicaid before such prescription is filled or delivered to a Medicaid recipient.

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).

Defendants Hogan and Streur are violating 42 USC § 1396r-8(k)(3); 42 USC § 1396r-8(k)(6), and 42 USC § 1396r-8(g)(1)(B)(i) by presenting or causing the presentment of claims to Medicaid for psychotropic drug prescriptions to children and youth that are not for a medically accepted indication. Defendants Hogan and Streur are also violating 42 USC § 1396r-8 (g)(1)(A), 42 CFR § 456.703 & 705, which require the State of Alaska to perform a prospective review to confirm eligibility before each prescription is filled or delivered to a recipient.

The court concludes PsychRights is likely to succeed on the merits.

3. Irreparable Harm

To the extent the State of Alaska is immune from an award of money damages for its presenting false claims to Medicaid, or causing the presentment of such false claims, irreparable harm is established as a matter of law. *California Pharmacists, supra.*, 563 at 852. However, under *Stoner v. Santa Clara County Office of Education*, 502 F.3d 1116, 1123 (9th Cir. 2007), the Ninth Circuit left open the possibility that the State of Alaska could be held liable under the False Claims Act. Because the Court finds that the continued violation of federal law constitutes irreparable harm, the Court does not decide at this time whether the State of Alaska is immune from an award of money damages under the False Claims Act through suing Defendants Hogan and Struer.

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); *Coalition for Economic Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997); and *Independent Living Center of Southern California, Inc., v Maxwell-Jolly*, 572 F.3d 644 (9th Cir. 2009), hold that enjoining a state statute constitutes irreparable harm as a matter of law. The Court concludes that if enjoining a state statute constitutes irreparable harm as a matter of law, the continued violation of a federal law also constitutes irreparable harm as a matter of law. Therefore, PsychRights has established irreparable harm if the preliminary injunction is not granted.

4. The Balance of Equities and Public Interest

Under *California Pharmacists, supra.*, 563 at 852-853, the balance of equities tips in favor of the plaintiff and a prospective preliminary injunction is in the public interest if, as here, the requested preliminary injunction is to enjoin continuing violation of federal law.

For these reasons, the Court finds the preliminary injunction should be granted.

IV. BOND

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

V. INJUNCTION

IT IS ORDERED that Defendants William Hogan and William Streur, their agents, servants, employees and attorneys, and any persons who are in active concert or participation with them (Enjoined Parties), are enjoined and prohibited 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 of outpatient prescriptions for psychotropic drugs to Medicaid recipients under 18 years of age that are not for a medically accepted indication.

IT IS FURTHER ORDERED, that subject to modification pursuant to the provisions set forth below, the Enjoined Parties, are prohibited from approving for

payment or reimbursement by Medicaid of the United States Government's federal financial participation (FFP) share of outpatient prescriptions for psychiatric drugs to anyone under 18 as follows:

1. The following drugs are prohibited entirely:

- a. Clozaril (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. All but the following indications are enjoined and prohibited for the following drugs:

Drug	Medically Accepted Indication	Notes
<u>Abilify</u> (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 or Mixed Episodes	10-17 years old for acute therapy
	Schizophrenia	13-17 years old
<u>Adderall</u> (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
<u>Anafranil</u> (clomipramine)		
	Obsessive-Compulsive Disorder	10 years and up
<u>Concerta</u> (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
<u>Depakote</u> (valproic acid)		
	Absence Seizure, Simple and Complex	10 years and older

Drug	Medically Accepted Indication	Notes
	and/or Complex Partial Epileptic Seizure	
<u>Dexedrine</u> (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
<u>Focalin</u> (dexmethylphenidate)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years and older
<u>Haldol</u> (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
	Schizophrenia	3 years old and up but ORAL formulations only
<u>Lamictal</u> (lamotrigine)		
	Epilepsy, Refractory	
<u>Lexapro</u> (escitalopram)		
	Major Depressive Disorder	12 years old and up
<u>Luvox</u> (fluvoxamine)		
	Obsessive-Compulsive Disorder	8 years old and up and immediate release formula only
<u>Mellaril</u> (thioridazine)		
	Schizophrenia, Refractory	
<u>Neurontin</u> (gabapentin)		
	Partial Seizure; Adjunct	3-12 years old
<u>Orap</u> (pimozide)		
	Gilles de la Tourette's syndrome	12 years and older
<u>Prozac</u> (fluoxetine)		
	Major Depressive Disorder	8 years old and up

Drug	Medically Accepted Indication	Notes
	Obsessive-Compulsive Disorder	7 years old and up
<u>Ritalin</u> (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
<u>Risperdal</u> (risperidone)		
	Autistic Disorder – Irritability	5 years old and up
	Bipolar I Disorder	10 years old and up
	Schizophrenia	13 years old and up (Orally)
<u>Seroquel</u> (quetiapine)		
	Manic episodes associated with bipolar disorder	10 years old to 17 years old
	Schizophrenia	13 years old to 17 years old
<u>Sinequan</u> (doxepin)		
	Alcoholism - Anxiety – Depression	12 years old and up
	Anxiety – Depression	12 years old and up
	Anxiety - Depression - Psychoneurotic personality disorder	12 years old and up
<u>Strattera</u> (atomoxetine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old and up
<u>Tegretol</u> (carbamazepine)		
	Epilepsy, Partial, Generalized, and Mixed types	
<u>Tofranil</u> (imipramine)		
	Nocturnal enuresis	6 years old and up
<u>Trileptal</u> (<i>oxcarbazepine</i>)		
	Partial Seizure, monotherapy	4 years old and up
	Partial seizure; Adjunct	2 years old and up
<u>Vyvanse</u> (lisdexamfetamine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old to 12 years old
<u>Zoloft</u> (sertraline)		

Drug	Medically Accepted Indication	Notes
	Obsessive-Compulsive Disorder	6 years old and up
Zyprexa (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

IT IS FURTHER ORDERED, that for psychotropic drugs not listed in paragraphs 1 or 2 above, the Enjoyed Parties are prohibited and enjoined from approving for payment or reimbursement by Medicaid of the United States Government's federal financial participation (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.

IT IS SO ORDERED,

This ____ day of _____, 2010.

By: _____
TIMOTHY M. BURGESS
UNITED STATES DISTRICT JUDGE