PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth

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The Insane Psychiatric Drugging of America's Children and Youth

- Millions of Children Involved
- Very harmful with no proven benefit
- Most harmful drugs and multiple drugs (polypharmacy).
- Children and Youth in State Custody Particularly vulnerable.

Medicaid Fraud:
Non Medically Accepted Indication

- Medicaid reimbursement prohibited for outpatient drug prescriptions except for "medically accepted indications," which means indications approved by the Food and Drug Administration (FDA) or "supported" by a citation in at least one of the following compendia:
  - American Hospital Formulary Service Drug Information,
  - United States Pharmacopeia-Drug Information (or its successor publications), or
  - DRUGDEX Information System.

 42 USC§ 1396R-8(k)(3); 42 USC §1396R-8(k)(6); 42 USC §1396R-8(g)(1)(B)(i)

False Claims Act

- Civil War Era Statute to Address Rampant Fraud Against Government
- Amended in 1986 and just last year
- Allows citizens to bring suit on behalf of the government and share in recovery if any.
- Called "Relators" (for the King)

 31 U.S.C §3729, et seq.

False Claims Act:
Liability

- It is a False Claim to:
  - **(A)** knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval
  - **(B)** knowingly make, use, or cause to be made or used, a false record or statement material to a false or fraudulent claim

(to the Federal Government)

 31 USC §3729(a)(1)

False Claims Act:
Knowingly Defined As:

- **(i)** Actual knowledge;
- **(ii)** Deliberate ignorance of the truth or falsity; or
- **(iii)** Reckless disregard of the truth or falsity

No proof of intent to defraud required

 31 USC §3729(b)(1)(a)

False Claims Act:
Pfizer/Geodon Settlement

- Multiple Drugs/Relators
- $2.3 Billion in Criminal Fine and *Qui Tam* Recovery
- $1.3 Billion Criminal Fine & Forfeiture
- US and States split $1 Billion civil recovery
- *Qui Tam Relators* split $102 million
  - Stefan Kruszewski, MD, $29 million *relator* share for Geodon
- Promotion of Geodon for use in children for non-medically accepted indications.

False Claims Act:
Zyprexa Settlement

- $1.4 Billion Combined *Qui Tam* & Criminal Penalties
- $800 million *Qui Tam* Recovery
- *Qui Tam Relators* split $79 million
- According to NY Times, the release of the Zyprexa Papers caused investigation to "gain momentum"

These $Billion Settlements Against Drug Manufacturers Not Stopping Massive, Inappropriate Psychiatric Drugging of Children & Youth

- Cost of doing business.
- Have established practice by psychiatrists and other prescribers
- The Government is continuing to pay the false claims
- Caps Liability

False Claims Act:
Model Complaint

- Drafted for former foster youth, but anyone with non-public information (i.e., specific prescriptions) can bring.
- Cases percolating in a number of states.

False Claims Act:
Model Complaint Defendants

- Prescribers:
  - Cause the Medicaid claims to be submitted
  - Know or should know the prescriptions are not for medically accepted indications
- Employers liable for same reason
- Pharmacies:
  - Make the false claims
  - Know or should know not for medically accepted conditions

False Claims Act:
US ex rel PsychRights v. Matsutani, et al.
Additional Defendants

- State Employees (personally)
  - Medicaid personnel approving claims
  - Program personnel submitting or causing false claims to be submitted
- Continuing Medical Education Provider
  - False information causing false claims

Examples of Drugs With No Pediatric Medically Accepted Indications (*per se* Medicaid Fraud)

- Symbyax (Zyprexa & Prozac together)
- Cymbalta
- Geodon
- Paxil
- Invega
- Trazadone

Other Pediatric non-Medically Accepted Indications (*per se* Medicaid Fraud)

- Virtually All Polypharmacy?
- Otherwise, *see* Medically Accepted Indication Chart (DRUGDEX as a practical matter)
  - For example, Oppositional Defiant Disorder is not a medically accepted indication for any neuroleptic, but seen it prescribed
- Estimate well over half are false claims.

Medically Accepted Indication: What Does Support Mean?

- "Whether a particular use is supported by a compendium depends on a variety of factors, including the type of drug and indication at issue, the compendium's assessment of the drug's efficacy in treating the indication, the content of the compendium citation, and the scope and outcome of the studies as described in the compendium."

US Statement of Interest in *Rost v. Pfizer*, USDC Mass. 1:03-cv-11084-PBS

False Claims Act:
Penalties

- $5,500 to $11,000 per false claim, plus treble damages.
  - Each offending prescription is a false claim

31 USC §3729(a)

False Claims Act:
(Relator Recovery)

- If Government intervenes and takes over case, *Relator* receives 15% to 25%.
- If Government doesn't intervene, Relator receives 25% to 30%.

31 USC §3730(d)

False Claims Act:
Filed Under Seal (in Secret)

- Complaint filed under seal to allow Government time to investigate and decide whether to intervene and take over case.
  - Serve the Department of Justice with a copy of the complaint and written disclosure of substantially all material evidence and information.
  - Seal can be extended for "good cause."
  - Average is 13 months.
  - Zyprexa: 5 years; Geodon 2 years

31 USC §3730(b)

False Claims Act:
Prosecution of Case

- If government intervenes and takes over case, *Relator* can still participate unless found to interfere with or unduly delay the Government's prosecution of the case, or be repetitious, irrelevant, or harassing
- If government does not intervene, *Relator* gets to proceed.
- Government can settle or dismiss, but subject to court supervision with *Relator* input.

31 USC §3730(c)

False Claims Act:
Non-Public Rule

- "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. "

31 USC §3730(e)(4)(A)

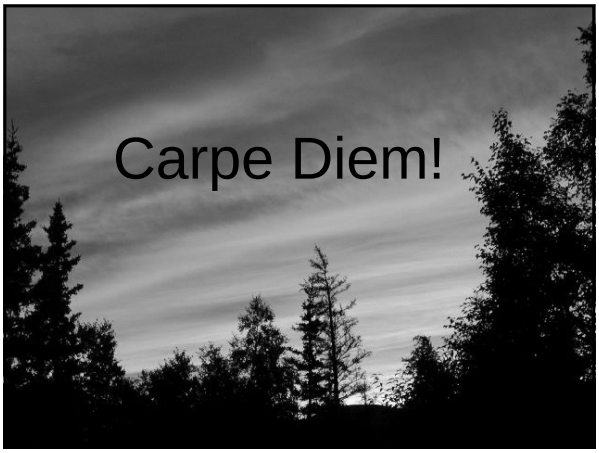
False Claims Act:
(First to File Rule)

- "In no event may a person bring an action . . . which is based upon allegations or transactions which are the subject of a civil suit or an administrative civil money penalty proceeding in which the Government is already a party."

31 USC §3730(e)(3)

False Claims Act:
Miscellaneous

- Attorney required.
- Six Year Statute of Limitations



Medically Accepted Indications for Pediatric Use of Psychotropic Medications
by
The Law Project for Psychiatric Rights (PsychRights

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Key:	White Background: Medically Accepted Indication			
	Orange Background: Pediatric Indication cited, but not supported by DRUGDEX			
	Red Background: No Pediatric FDA Approval or DRUGDEX citation			
Abilify (Aripiprazole) - Antipsychotic				
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	Yes (for 10 yrs old and up)		
	Bipolar I Disorder, monotherapy, Manic or Mixed Episodes	Yes (for 10-17 years old re acute therapy)		
	Schizophrenia	Yes (for 13-17 years old)		
Adderall (amphetamine/dextroamphetamine) - Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years old and up re: [immediate-release] and 6 years old and up re: [extended-release] drug		
	Narcolepsy	Yes (for 6 years old and up re: [immediate release] drug)		
Anafranil (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent				
	Depression	No		Class IIb
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)		
Clorazil (clozapine) – Antipsychotic; Dibenzodiazepine				
	Bipolar I Disorder	No		Class IIb
	Schizophrenia, Treatment Resistant	No		cited, with no recommendation level
Concerta (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years old)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up) re ConcertaR		
	Autistic Disorder	No		Class IIb
	Impaired Cognition - inding related to coordination/ in coordination	No		Class IIb
	Schizophrenia	No		Class IIII
	Traumatic Brain Injury	No		Class IIb
Cymbalta (duloxetine) - Antidepressant; Central Nervous System Agent; Neuropathic Pain Agent; Serotonin/Norepinephrine Reuptake Inhibitor				
Depakote (valproic acid) – Anticonvulsant; Antimigraine; Valproic Acid (class)				
	Absence Seizure, Simple and Complex and/or Complex Partial Epileptic Seizure	Yes (10 years and older)		
	Mania	No		Class IIII
	Mental Disorder - Mood Disorder	No		Class IIb
	Chorea	No		Class IIb

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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Dexedrine (dextroamphetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release))		
	Narcolepsy	Yes (for 6 years old and up)		
Desyrel (*trazadone*) - Antidepressant; Triazolopyridine				
Effexor (venlafaxine) – Antidepressant; Antidepressant, Bicyclic; Phenethylamine (class); Serotonin/ Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	No		Class IIb
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
	Social Phobia	No		Class IIb
Focalin (dexmethylphenidate) - Amphetamine Related; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years and older)		
Geodon (ziprasidone) - Antipsychotic; Benzisothiazoyl				
Haldol (haloperidol) - Antipsychotic; Butyrophenone; Dopamine Antagonis				
	Agitation	No		Class IIb
	Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy	Yes (for 3 years old and up)	It does not appear the injectible form (decanoate) is FDA approved for any pediatric use. DRUGDEX says safety and efficacy not established.	
	Problematic Behavior in Children (Severe), With failure to respond non-antipsychotic medication or psychotherapy	Yes (for 3 years old and up)		
	Psychotic Disorder	Yes (for 3 years old and up but ORAL formulations only)		
	Schizophrenia	Yes (for 3 years old and up but ORAL formulations only)		
Invega (paliperidone) - Antipsychotic; Benzisoxazole				
Lamictal (lamotrigine) - Anticonvulsant; Phenyltriazine				
	Bipolar Disorder, Depressed Phase	No		Class IIb
	Epilepsy, Refractory	No	Class IIa	
Lexapro (escitalopram)- Antianxiety, Antidepressant, Serotonin Reuptake Inhibitor				
	Major Depressive Disorder	Yes (for 12 years old and up)		
Luvox (fluvoxamine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Asperger's Disorder	No		Class IIb
	Obsessive-Compulsive Disorder	Yes (for 8 years old and up and immediate release formula only)		
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		

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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Mellaril (thioridazine) - Antipsychotic; Phenothiazine; Piperidine				
	Behavioral Syndrome	No		Class IIII
	Schizophrenia, Refractory	Yes		
Orap (pimozide) - Antipsychotic; Diphenylbutylpiperidine; Dopamine Antagonist				
	Gilles de la Tourette's syndrome	Yes (12 years and older)		
	Anorexia Nervosa	No		Class III
Paxil (paroxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
Prozac (fluoxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Anxiety Disorder of Childhood	No		Class IIb
	Major Depressive Disorder	Yes (for 8 years old and up)		
	Obsessive-Compulsive Disorder	Yes (for 7 years old and up		
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
Ritalin (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years to 12 years old)(exteded release)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)(immediate release)		
	Narcolepsy	Yes (for 6 years and up, and Ritalin(R) -SR only)		
	Schizophrenia	No		Class IIII
	Traumatic Brain Injury	No		Class IIb
Risperdal (risperidone) - Antipsychotic; Benzisoxazole				
	Autistic Disorder – Irritability	Yes (for 5 years old and up)		
	Bipolar I Disorder	Yes (for 10 years old and up)		
	Schizophrenia	Yes (for 13 years old and up, ORALLY)		
Seroquel (QUETIAPINE) - Antipsychotic; Dibenzothiazepine				
	Manic episodes associated with bipolar disorder	Yes, 10-17 (12/4/09)		
	Schizophrenia	Yes 13-17 (12/4/09)		
Sinequan (doxepin) - Antianxiety Antidepressant; Antidepressant, Tricyclic; Antiulcer Dermatological Agent				
	Alcoholism - Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety - Depression - Psychoneurotic personality disorder	Yes (for 12 years old and up)		

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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Strattera (atomoxetine) - Central Nervous System Agent; Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD) - Social phobia	No		Class IIb
Symbyax (fluoxetine hydrochloride/olanzapine) - Antidepressant; Antipsychotic				
Tegretol (carbamazepine) - Anticonvulsant; Antimanic; Dibenzazepine Carboxamide; Neuropathic Pain Agent				
	Epilepsy, Partial, Generalized, and Mixed types	Yes		
	Migraine; Prophylaxis			Class IIb
	Neuropathy, General			Class IIb
Tofranil (imipramine) - Antidepressant; Antidepressant, Tricyclic; Urinary Enuresis Agent				
	Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type	No		Class IIb
	Depression	No		Class IIb
	Nocturnal enuresis	Yes (for 6 years old and up)		
	Separation Anxiety Disorder of Childhood	No		Class IIII
	Schizophrenia, Adjunct	No		Class IIII
Trileptal (*oxcarbazepine*) - Anticonvulsant; Dibenzazepine Carboxamide				
	Partial Seizure, monotherapy	Yes (for 4 years old and up)		
	Partial seizure; Adjunct	Yes (for 2 years old and up)		
Vyvanse (lisdexamfetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years)		
Zoloft (sertraline) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Obsessive-Compulsive Disorder	Yes (6 years old and up)		
	Anorexia nervosa	No		Class IIII
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		
Zyprexa (olanzapine) - Antipsychotic; Thienobenzodiazepine				
	Schizophrenia	Yes (ages 13-17), approved 12/4/09		
	manic or mixed episodes associated with bipolar I disorder	Yes (ages 13-17), approved 12/4/09		
	Bipolar 1, Disorder, Acute Mixed or Manic Episodes	Not prior to 12/4/09	Class IIa	
	Pervasive Developmental Disorder	No		Class IIb
	Severe Major Depression with Psychotic Features	"See Drug Consult Reference: PSYCHOTIC DEPRESSION - DRUG THERAPY"		

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DRUGDEX® Consults

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

RESPONSE

The Thomson Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

Table 1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminant	Evidence Inconclusive	

Table 2. Strength Of Evidence	
Category A	Category A evidence is based on data derived from: Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies. Multiple, well-done randomized clinical trials involving large numbers of patients.
Category B	Category B evidence is based on data derived from: Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).
Category C	Category C evidence is based on data derived from: Expert opinion or consensus, case reports or case series.
No Evidence	

Table 3. Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence Favors Efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is Inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective.

May reduce the frequency, number and severity of manic episodes in patients with schizoaffective disorders

c) Adult:

1) During the 26 to 51 months of VALPROIC ACID treatment of 15 patients with affective and SCHIZOAFFECTIVE DISORDERS, the authors observed reduction in the number, length and severity of affective episodes especially mania. In a few patients fragmentation of long and severe relapses into short and mild mania or depression occurred. The number and length of hospital admissions dropped in all patients (Puzynski & Klosiewicz, 1984).

2) Valproic acid, titrated to a serum level of 94 to 110 micrograms/milliliter, successfully treated AIDS-related mania in two case reports (RachBeisel & Weintraub, 1997).

3) Valproic acid 2000 milligrams/day was effective in the treatment of severe kleptomania and mixed mania refractory to fluoxetine in a 36-year-old female (Kmetz et al, 1997).

4.5.A.13 Manic bipolar I disorder

a) Overview

FDA Approval: Adult, no; Pediatric, no
Efficacy: Adult, Evidence favors efficacy
Recommendation: Adult, Class IIa
Strength of Evidence: Adult, Category B

See Drug Consult reference: RECOMMENDATION AND EVIDENCE RATINGS

b) Summary:

Valproic acid has been used for mania secondary to bipolar disorder

c) Adult:

1) Valproic acid is indicated for the treatment of the manic episodes associated with BIPOLAR DISORDER. Valproic acid is effective in the treatment of patients suffering from bipolar disorder, even in those who have failed conventional therapy (Guay, 1995)(Fawcett, 1989; Brown, 1989; Post, 1989; McElroy et al, 1989; Calabrese & Delucchi, 1989), and in bipolar disorder secondary to head injury (Pope et al, 1988).

2) Four out of 5 acutely manic patients responded to intravenous valproate loading in an open study (Grunze et al, 1999). Five bipolar I patients received valproate 1200 or 1800 milligrams on day 1 followed by dosage individualization based on side effects. Their mean baseline Bech-Rafaelson Mania Rating Scale score was 30.2 which improved to 8 by day 5. One patient had actually been unresponsive to oral valproate. On day 5 most were switched to oral dosing. The authors believe that with the intravenous loading a quick saturation of plasma-binding proteins occurred which could have contributed to a beneficial action.

3) One uncontrolled study reported improvement in 5 of 7 patients with MANIA given VALPROIC ACID (up to 1500 milligrams daily) for 6 weeks. All patients had not responded to previous therapy with LITHIUM and neuroleptics (Prasad, 1984).

4.5.A.14 Mental disorder - Mood disorder

a) Overview

FDA Approval: Adult, no; Pediatric, no
Efficacy: Adult, Evidence is inconclusive; Pediatric, Evidence is inconclusive
Recommendation: Adult, Class IIb; Pediatric, Class IIb
Strength of Evidence: Adult, Category C; Pediatric, Category C

See Drug Consult reference: RECOMMENDATION AND EVIDENCE RATINGS

b) Summary:

Useful in treatment of affective disorders in MENTALLY DEFICIENT PATIENTS

c) Adult:

1) Although data is limited, valproic acid appears useful in the management of AFFECTIVE DISORDERS in mentally deficient children and adults. Valproic acid was noted in studies to have advantages over carbamazepine, lithium, and antipsychotics for use in mentally retarded patients since it does not carry the same risks of tremor, incontinence, cognitive impairment, worsening of mood, and increased seizures associated with other classes of medication (Kastner et al, 1990; Sovner, 1989).

2) Valproic acid was useful in 5 cases of BIPOLAR DISORDER in mentally deficient adults (1 patient with Fragile X syndrome, 2 with autistic disorder, two with rapidly cycling illness) (Sovner, 1989). Valproic acid was used in doses of 1000 to 2000 milligrams daily to maintain blood levels in the usual therapeutic range of 50 to 100 mcg/mL. In 4 of these cases, therapy with antipsychotic medications was continued. Four of the 5 patients showed a significant response to valproic acid with improvements in sleep cycle, maladaptive behaviors, distractability and assaultiveness; the other patient demonstrated only a moderate response. Antipsychotic medications were successfully tapered or discontinued in all of the patients.

d) Pediatric:

1) Significant improvement was seen with valproic acid in 3 mentally deficient children and adolescents with MOOD DISORDERS characterized by irritability, aggressiveness, SELF-INJURIOUS BEHAVIOR, hyperactivity and sleep disturbance; symptoms had been unresponsive to previous therapy or the patient had been unable to tolerate side effects associated with previous medications. Valproic acid 1500 to 3000 milligrams daily, at blood levels of 78 to 111 mcg/mL, produced significant improvement in all 3 patients (Kastner et al, 1990).

4.5.A.15 Migraine; Prophylaxis

a) Overview

FDA Approval: Adult, no; Pediatric, no
Efficacy: Adult, Effective; Pediatric, Evidence favors efficacy
Recommendation: Adult, Class IIb; Pediatric, Class IIb
Strength of Evidence: Adult, Category B; Pediatric, Category B

See Drug Consult reference: RECOMMENDATION AND EVIDENCE RATINGS

b) Summary:

Provides a 50% or greater reduction in migraine frequency
Safe and effective in adults and children
Effective for prophylaxis of migraine induced by a SELECTIVE SEROTONIN REUPTAKE INHIBITOR

IN THE UNITED STATES DISTRICT COURT
_____ DISTRICT OF _____

UNITED STATES OF AMERICA *Ex rel.* _____ Plaintiff, vs. _____, _____, and _____, Defendants.	Civil Action No**.** _____ **FILED *IN CAMERA* AND UNDER SEAL** **FALSE CLAIMS ACT MEDICAID FRAUD** **JURY TRIAL DEMANDED**

PLAINTIFF'S COMPLAINT PURSUANT TO 31 U.S.C §§ 3729-3732 OF THE FEDERAL FALSE CLAIMS ACT

The United States of America, by and through *qui tam* relator _____ _____ (Relator), brings this action under 31 U.S.C §3729, *et seq.*, as amended (False Claims Act) to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States.

I. PRELIMINARY STATEMENT

1. This is an action to recover damages and civil penalties on behalf of the United States of America, for violations of the False Claims Act arising from false or fraudulent records, statements, or claims, or any combination thereof, made, used or caused to be made, used, or presented, or any combination thereof, by the defendants, their agents, employees, or co-conspirators, or any combination thereof, with respect to

false claims for outpatient psychotropic medications prescribed to children and youth for which claims were made to the federal Medicaid Program.

2. The False Claims Act was enacted during the Civil War. Congress amended the False Claims Act in 1986 to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the False Claims Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

3. 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 of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government.

4. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

5. Under Medicaid,

(a) psychiatrists and other prescribers,

(b) mental health agencies, and

(c) pharmacies,

all have specific responsibilities to prevent false claims from being presented and are liable under the False Claims Act for their role in the submission of false claims.

6. This is an action for treble damages and penalties for each false claim and each false statement under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

II. PARTIES

7. Relator, _____, was prescribed and given psychiatric medications when a minor which constitute false claims under the False Claims Act.

8. Defendant _____ (Psychiatrist), resides in the District of _____, and prescribed psychiatric medications to Relator and other children and youth when minors, knowing that claims for such medication would be submitted to Medicaid for reimbursement, and which constitute false claims under the False Claims Act.

9. Defendant _____ (Provider), transacts business in the District of _____, and

(a) submitted or caused to be submitted claims to Medicaid for psychiatric medications prescribed and given to Relator and other minors, and

(b) continues to submit or cause to be submitted claims to Medicaid for psychiatric medications prescribed and given to minors,

which constitute false claims under the False Claims Act.

10. Defendant, _____, transacts business in the District of _____, and

(a) submitted claims to Medicaid for psychiatric medications prescribed and given to Relator and other minors, and

(b) continues to submit claims to Medicaid for psychiatric medications prescribed and given to minors,

which constitute false claims under the False Claims Act.

III. JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.

12. There have been no public disclosures of the allegations or transactions contained herein that bar jurisdiction under 31 U.S.C. §3730(e).

13. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because all the defendants have at least minimum contacts with the United States, and can be found in, reside, or transact or have transacted, business in the District of _____.

14. Venue exists in the United States District Court for the District of _____ pursuant to 31 U.S.C. § 3730(b)(1) because all of the defendants have at least minimum contacts with the United States, and all the defendants can be

found in, reside, or transact or have transacted business in the District of _____.

IV. APPLICABLE LAW

A. Medicaid

15. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments.

16. Federal reimbursement for prescription drugs under the Medicaid program is, as relevant, limited to "covered outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3).

17. Outpatient drug prescriptions, as relevant, are covered under Medicaid, *i.e.*, reimbursable only if the drug is 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).

18. Every Medicaid provider must agree to comply with all Medicaid requirements.

B. False Claims Act

19. False Claims Act liability attaches to any person who knowingly presents or causes a false or fraudulent claim to be presented for payment, or to a false record or statement made to get a false or fraudulent claim paid by the government. 31 U.S.C. §3729(a)(1)&(2).

20. Under the False Claims Act, "knowing" and "knowingly" mean that a person, with respect to information:

(1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required. 31 U.S.C. §3729(b).

21. The False Claims Act is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a course of conduct that causes the government to pay a false or fraudulent claim for money.

V. ALLEGATIONS

22. Psychiatrist prescribed the psychotropic drugs on Attachment A to Relator while a minor that were not for an indication approved by the FDA or supported by one or more of the Compendia.

23. Pharmacy submitted claims to Medicaid for reimbursement for the psychotropic drugs prescribed to Relator set forth in Attachment A that were not for an indication approved by the FDA or supported by one or more of the Compendia:

VI. CAUSES OF ACTION

Count 1: Psychiatrist Liability For Uncovered Drugs

24. Psychiatrist prescribed the psychotropic drugs to Relator set forth in Attachment A, and to other minors, that are not for an indication approved by the FDA or supported by one or more of the Compendia, thereby causing claims for such prescriptions to be made to Medicaid for reimbursement

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and is liable under the False Claims Act therefor.

25. Upon information and belief, Psychiatrist continues to prescribe psychotropic drugs to minors that are not for an indication approved by the FDA or supported by one or more of the Compendia, thereby causing claims for such prescriptions to be made to Medicaid for reimbursement

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 2: Provider Liability for Uncovered Drugs

26. Provider has submitted and/or caused the submission to Medicaid and continues to submit or cause to be for reimbursement of the psychotropic drugs

prescribed to Relator set forth in Attachment A, and to other minors, that are not for an indication that is approved by the FDA or supported by one or more of the Compendia

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 3: Pharmacy Liability For Uncovered Drugs

27. Pharmacy submitted claims to Medicaid for reimbursement of outpatient pediatric prescriptions for psychotropic drugs to Relator and other minors that are not for an indication that is approved by the FDA or supported by one or more of the Compendia

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

VII. DEFENDANTS' LIABILITY

28. By virtue of the acts described above, defendants knowingly (a) submitted, and continue to submit, and/or (b) caused and/or continue cause to be submitted, false or fraudulent claims to the United States Government for payment of psychiatric drugs prescribed to Relator and other minors that are not for an indication that is approved by the FDA or supported by one or more of the Compendia.

29. The Government paid and continues to pay such false claims.

30. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, United States of America, through Relator, requests the Court enter the following relief:

A. That defendants be ordered to cease and desist from violating 31 U.S.C. §3729 *et seq*.

B. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

C. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act.

D. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

E. That Relator recover such other relief as the Court deems just and proper.

DATED: _____.

By: _____

Certificate of Service

The undersigned hereby certifies that a copy of this Complaint and written disclosure of substantially all material evidence and information Relator possesses has been served on the Government as provided in FRCP 4.

Dated: _____ _____

7/27/09

ATTACHMENT A.