

31 U.S.C §3729, et seq.

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Key:		White Beckground: Medically Accepted Indication Orange Background: Pediatric Indication cited, but not supported by ORUGDEX Red Background: No Pediatric 20A Approval or ORUGDEX station		
Abilify (Arip	pratolo) - Antipoychotic			
	Bipclar I Disorder - Adjunctive therapy with lifetum or valproate for Acute Marko or Mond Episodes Bipclar I Disorder, monotherapy, Marko or Mixed Episodes	Yes (for 10 yrs old and up) Yes (for 10-17 years old re joude Beneby)		
	Schizophrenia	Yes (for 13-17 years old)		
Adderall (=	rehetanise/destroarrehetanise) - Central Nervous System Age	nt: CNS Stimulant		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years old and up nr: [Immediate-release] and 8 years old and up nr: [eadended-release] drug Yes (for 6 years old and up nr: [Immediate release] drug)		
Anafranil	slompramine) - Antidepressant, Antidepressant, Tricyclic, Cent		_	
	Contractory	10	and the second	
	Obsessive-Computative Disorder	Yes (for 10 years and up)		
Clorazil de	rapine) - Antipsycholis; Dibenzodiszopine			
	Bodar Daurber	107 C	2414	



False Claims Act:

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

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

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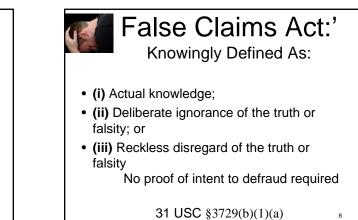


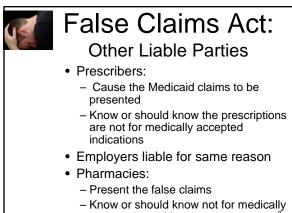
False Claims Act:

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

- Virtually All Polypharmacy?
- Otherwise, have to check specific diagnosis with Drugdex (as a practical matter)
 - Oppositional Defiance Disorder is not a medically accepted indication for any neuroleptic, but seen it prescribed

False Claims Act:	
 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)	7





accepted conditions



- Average is 13 months.

31 USC §3730(b)



· If Government doesn't intervene, Relator receives 25% to 30%.

31 USC §3730(d)

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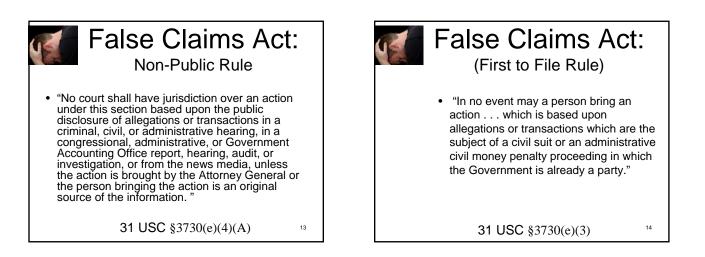


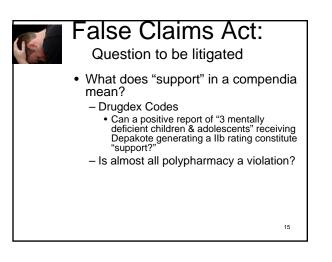
- If government intervenes and takes over case, Relator can still participate unless found to interfere with or unduly delay the Government's prosecution of the case, or be repetitious, irrelevant, or harassing
- If government does not intervene, Relator gets to proceed.
- · Government can settle or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

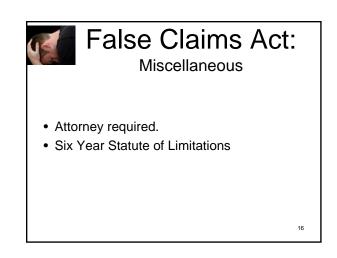
31 USC §3730(c)

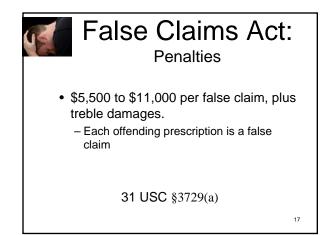
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Alaska	Psychiatric Drugging of Alaskan Children & Youth Through Medicaid				
Dates	Anti-Co Claims	Amount	2nd Generation Neuroleptics Claims Amount per Month Per Month		
12/1/2004 to 2/28/05	1,393	\$ 122,224	1,532	\$ 277,746	
1/1/2005 to 3/31/2005	1,402	\$ 123,963	1,490	\$ 285,762	
5/1/2005 to 7/31/2005	1,436	\$ 136,939	1,705	\$ 319,725	
2/1/2006 to 4/30/2006	1,240	\$ 118,954	1,492	\$ 272,717	
3/1/2006 to 5/31/2006	1,260	\$ 120,047	1,552	\$ 281,919	
4/1/2006 to 6/30/2006	1,210	\$ 114,838	1,521	\$ 272,009	
5/1/2006 to 7/31/2006	1,225	\$ 116,052	1,534	\$ 277,940	
8/1/2006 to 10/31/2006	1,252	\$ 121,346	1,648	\$ 284,966	
11/1/2006 to 1/31/2007	1,298	\$ 121,519	1,800	\$ 289,540	
1/1/2007 to 3/31/2007	1,259	\$ 121,925	1,735	\$ 288,238	
4/1/2007 to 6/30/2007	1,270	\$ 139,718	1,730	\$ 312,815	
Average	1,295	\$ 123,411	1,613	\$ 287,580	

	Damages Calculation				
	 Anticonvulsants are not Medically Accepted Indication Trivial Percentage of 2nd Generation Neuroleptics Medically Accepted Indication 				
72 Months of	Claims at \$5,500 per claim	\$	1,151,568,000		
Treble Damag	ges for 72 Months of Anti-Convulsants	\$	26,656,776		
Treble Damag	ges for 72 Months of Neuroleptics	\$	62,117,280		
	Total	\$	1,240,342,056		
	Yes, that is \$1.24	Bil	lion		
			20		

DRUGDEX® Consults

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

<u>RESPONSE</u> 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. S	trength Of Evidence
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.
В	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	able 3. Efficacy					
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective				
Class Ila		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 Ilb	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.				

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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 demonstrate 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

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 Recommendatior Level		
Vor						
<u>Key:</u>	White Background: Medically Accepte		orted by DDUCDE	v		
	Orange Background: Pediatric Indicat Red Background: No Pediatric FDA A			X		
	Red Background. No Fediatile FDA A		Itation			
Abilify (Aripipra	zole) - 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 (amph	etamine/dextroamphetamine) - Central Nervous System Agen	nt; 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 Yes (for 6 years old and up				
	Narcolepsy	re: [immediate release] drug)				
Anafranil (ala	mipramine) - Antidepressant; Antidepressant, Tricyclic; Cent	0/				
Analiann (cio	mipranine) - Andepressant, Andepressant, Theyene, Cent	rai Nervous System Agent				
	Depression	No		Class IIb		
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)				
Clorazil (clozap	ine) – Antipsychotic; Dibenzodiazepine					
<u>Clorazil</u> (clozap		Νο		Class IIb		
<u>Clorazil</u> (clozap	Bipolar I Disorder	No		Class IIb cited, with no recommendation level		
	Bipolar I Disorder Schizophrenia, Treatment Resistant	No		cited, with no		
	Bipolar I Disorder	No		cited, with no recommendation		
	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster	No n Agent; CNS Stimulant Yes (for 6 years old to 12		cited, with no recommendation		
	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Autistic Disorder	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up)		cited, with no recommendation		
	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD)	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up) re ConcertaR		cited, with no recommendation level		
	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Attentic Disorder Impaired Cognition - inding related to	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up) re ConcertaR No		cited, with no recommendation level Class IIb		
	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Autistic Disorder Impaired Cognition - inding related to coordination/ in coordination	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up) re ConcertaR No		cited, with no recommendation level Class IIb Class IIb		
<u>Concerta (</u> meth	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Autistic Disorder Impaired Cognition - inding related to coordination/ in coordination Schizophrenia	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up) re ConcertaR No No No No	Vorepinephrine Reuptake	cited, with no recommendation level Class IIb Class III Class IIII Class III		
<u>Concerta (</u> meth	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Autistic Disorder Impaired Cognition - inding related to coordination Schizophrenia Traumatic Brain Injury	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up) re ConcertaR No No No No No No	Norepinephrine Reuptake	cited, with no recommendation level Class IIb Class III Class IIII Class III		
<u>Concerta (</u> meth	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Autistic Disorder Impaired Cognition - inding related to coordination/ in coordination Schizophrenia Traumatic Brain Injury exetine) - Antidepressant; Central Nervous System Agent; Nervous System	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up) re ConcertaR No No No No No No	Norepinephrine Reuptake	cited, with no recommendation level Class IIb Class IIb Class IIII Class III		
<u>Concerta (</u> meth	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Autistic Disorder Impaired Cognition - inding related to coordination/ in coordination Schizophrenia Traumatic Brain Injury exetine) - Antidepressant; Central Nervous System Agent; Nervoic acid) – Anticonvulsant; Antimigraine; Valproic Acid (clar Absence Seizure, Simple and Complex and/or	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up) re ConcertaR No No No No No ss)	Norepinephrine Reuptake	cited, with no recommendation level Class IIb Class IIb Class IIII Class III		
<u>Concerta (</u> meth	Bipolar I Disorder Schizophrenia, Treatment Resistant ylphenidate) - Amphetamine Related; Central Nervous Syster Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Attention Deficit Hyperactivity Disorder (ADHD) Autistic Disorder Impaired Cognition - inding related to coordination/ in coordination Schizophrenia Traumatic Brain Injury externe) - Antidepressant; Central Nervous System Agent; Ner roic acid) – Anticonvulsant; Antimigraine; Valproic Acid (clar Absence Seizure, Simple and Complex and/or Complex Partial Epileptic Seizure	No n Agent; CNS Stimulant Yes (for 6 years old to 12 years old) Yes (for 6 years old and up) re ConcertaR No No No No No So Yes (10 years and older)	Norepinephrine Reuptake	cited, with no recommendation level Class IIb Class IIb Class III Class III Class III		

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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
Dexedrine (dextroan	nphetamine) - 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			
	- Antidepressant; Antidepressant, Bicyclic; Phenethylan	nine (class): Serotonin/ Norenine	nhrine Reuntake Inhibitor	
CHICAOL (Veniaraxine)	- Antidepressant, Antidepressant, Dicyclic, Filenetityian	line (class), Selotolini/ Norephie		
	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 DEPRESSION - DRUG THE		
	Social Phobia	No		Class IIb
Focalin (dexmethylph	enidate) - Amphetamine Related; CNS Stimulant			
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years and older)		
Geodon (ziprasidone)	- Antipsychotic; Benzisothiazoyl			
	- 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	
	Problematic Behavior in Children (Severe), With failure to respond non-antipsychotic medication or psychotherapy	Yes (for 3 years old and up)	(decanoate) is approved for a	any pediatric
	Psychotic Disorder	Yes (for 3 years old and up but ORAL formulations only)	use. DRUGD safety and effi	•
	Schizophrenia	Yes (for 3 years old and up but ORAL formulations only)	established.	
Invega (paliperidone)) - Antipsychotic; Benzisoxazole			
Lamictal (lamotrigin	e) - Anticonvulsant; Phenyltriazine			
	Bipolar Disorder, Depressed Phase	No		Class IIb
	Epilepsy, Refractory	No	Class IIa	
Lexapro (escitalopram)- Antianxiety, Antidepressant, Serotonin Reuptake Inhib	bitor		
		Yes (for 12 years old and		
LUVON (fluvovomina)	Major Depressive Disorder - Antidepressant; Central Nervous System Agent; Serot	up)		
(nuvoxannine) -	- Anticepressant, Centra ivervous System Agent; Seron			
	Asperger's Disorder	No		Class IIb
	Obsessive-Compulsive Disorder	Yes (for 8 years old and up and immediate release formula only)		
		"See Drug Consult Reference		

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
Mellaril (thioridazin	e) - Antipsychotic; Phenothiazine; Piperidine			
	Behavioral Syndrome	No		Class IIII
	Schizophrenia, Refractory	Yes		
Orap (pimozide) - A	ntipsychotic; Diphenylbutylpiperidine; Dopamine Antag	onist		
Paxil (paroxetine) - A	Antidepressant; Central Nervous System Agent; Serotonir	Reuptake Inhibitor		
Prozac (fluoxetine) -	Antidepressant; Central Nervous System Agent; Seroton	in Reuptake Inhibitor		
L	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 Referenc DEPRESSION - DRUG THE		
Ritalin (methylpheni	date) - Amphetamine Related; Central Nervous System A	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
Dignordal ()	Traumatic Brain Injury	No		Class IIb
Kisperuar (risperido	one) - 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 (QUETIA)	PINE) - 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)		

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
Strattera (atomoxetine	e) - Central Nervous System Agent; Norepinephrine Re	euptake Inhibitor		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD) -	No		
Complement of the second	Social phobia			Class IIb
	ydrochloride/olanzapine) - Antidepressant; Antipsycho			
Tegretol (carbamazep	ine) - Anticonvulsant; Antimanic; Dibenzazepine Carbo	oxamide; Neuropathic Pain Agen	it	
	Epilepsy, Partial, Generalized, and Mixed types	Yes		
	Migraine; Prophylaxis	163		Class IIb
	Neuropathy, General			Class IIb
Tofranil (imipramine)	- Antidepressant; Antidepressant, Tricyclic; Urinary E	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
TD 1 4 1	Schizophrenia, Adjunct	No		Class IIII
<u>Trileptal</u> (oxcarbazepi	ne) - Anticonvulsant; Dibenzazepine Carboxamide			
	Partial Seizure, monotherapy	Yes (for 4 years old and up)		
	Partial seizure; Adjunct	Yes (for 2 years old and up)		
Vyvanse (lisdexamfeta	mine) - Amphetamine (class); CNS Stimulant			
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years)		
Zoloft (sertraline) - Anti	depressant; Central Nervous System Agent; Serotonin	Reuptake Inhibitor		
r.	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 DEPRESSION - DRUG THE		
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 DEPRESSION - DRUG THE		