

## 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.

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## 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.

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

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## False Claims Act

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

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31 U.S.C §3729, et seq.

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## 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)

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## 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)

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## False Claims Act: AstraZeneca/Seroquel Settlement (April, 2010)

- \$520 Million *Qui Tam* Recovery
  - Promotion of Seroquel off-label use, including in children for non-medically accepted indications.
- *Qui Tam Relators* James Wetta and Stephan Kruszewski, MD, split \$45 million

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## Pfizer/Geodon Settlement (September, 2009)

- 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. 8

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## Lilly/Zyprexa Settlement (January, 2009)

- \$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”

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## 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

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## 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.

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## 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

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

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

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**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.

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**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

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**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)

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**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)

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**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)

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## **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.

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31 USC §3730(c)

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## **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."

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31 USC §3730(e)(4)(A)

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## **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."

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31 USC §3730(e)(3)

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## **False Claims Act: Miscellaneous**

- Attorney required.
- Six Year Statute of Limitations

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## ***U.S. ex rel Griffin v. Martino, Family Centered Services & Safeway***

- Unsealed May 17, 2010
- Based on Model Complaint
- Defendants
  - Psychiatrist
  - MH Agency
  - Pharmacy

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- USDC AK 3:09-cv-246

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## ***US ex rel PsychRights v. Matsutani, et al. Additional Defendants (Unsealed January 25, 2010)***

- 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

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

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
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<b>Key:</b>	<b>White Background: Medically Accepted Indication</b>
	<b>Orange Background: Pediatric Indication cited, but not supported by DRUGDEX</b>
	<b>Red Background: No Pediatric FDA Approval or DRUGDEX citation</b>

<b>Abilify</b> (Aripiprazole) - Antipsychotic				
	Autistic disorder-Psychomotor agitation	Yes (6-17)		
	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)		

<b>Adderall</b> (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 (immediate release only))		

<b>Ambien</b> (zolpidem) - nonbarbiturate Hypnotic				
	Insomnia, Short-term treatment	No		Class III

<b>Anafranil</b> (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent				
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)		
	Depression	No		Class IIb

<b>Ativan</b> (lorazepam) - Antianxiety, Anticonvulsant, Benzodiazepine, Short or Intermediate Acting, Skeletal Muscle Relaxant.				
	Anxiety	Yes, oral only, 12 years and older		
	Chemotherapy-induced nausea and vomiting; Prophylaxis	No	Class IIa	
	Insomnia, due to anxiety or situational stress	Yes		
	Seizure	No	Class IIa	
	Status epilepticus	No	Class IIa	
	Premedication for anesthetic procedure	No		Class IIb
	Sedation	No		Class IIb
	Seizure, drug-induced; Prophylaxis	No		Class IIb

<b>Buspar</b> (buspirone) - Antianxiety, Azaspirodeconedione				
	Anxiety	No		Class III
	Autistic disorder	No		Class IIb
	Behavioral syndrome	No		Class IIb
	Pervasive developmental disorder	No		Class IIb

<b>Celexa</b> (citalopram) - Antidepressant, Serotonin Reuptake Inhibitor				
	Depression	No		None
	Obsessive-compulsive disorder	No		Class IIb
	Panic disorder	No		Class IIb
	posttraumatic stress disorder	No		Class IIb

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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
<b>Clozaril</b> (clozapine) – Antipsychotic; Dibenzodiazepine				
	Bipolar I Disorder	No		Class IIb
	Schizophrenia, Treatment Resistant	No		cited, with no recommendation level
<b>Concerta</b> (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 III
	Traumatic Brain Injury	No		Class IIb
<b>Cymbalta</b> (duloxetine) - Antidepressant; Central Nervous System Agent; Neuropathic Pain Agent; Serotonin/Norepinephrine Reuptake Inhibitor				
<b>Dalmane</b> (flurazepam) - Benzodiazepine, Long Acting, Hypnotic				
	Insomnia	Yes, 15 years and older		
<b>Depakote/Depakene</b> (valproate/valproic acid) – Anticonvulsant; Antimigraine; Valproic Acid (class)				
	Absence Seizure, Simple and Complex	Yes (10 years and older)		
	Complex Partial Epileptic Seizure	Yes (10 years and older)		
	Seizure, Multiple seizure types; Adjunct	Yes (10 years and older)		
	Bipolar I disorder, Maintenance	No		Class IIb
	Bipolar II disorder, Maintenance	No		Class IIb
	Chorea	No		Class IIb
	Febrile Seizure	No		Class IIb
	Mania	No		Class III
	Manic bipolar I disorder	No		Class IIb
	Mental Disorder - Mood Disorder	No		Class IIb
	Migraine; Prophylaxis	No		Class IIb
	Status epilepticus	No		Class IIb
	West syndrome	No		Class IIb
<b>Desyrel</b> (trazodone) - Antidepressant; Triazolopyridine				
	Migraine, Pediatric; Prophylaxis	No		Class III
<b>Dexedrine</b> (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)		
<b>Effexor</b> (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
	Social Phobia	No		Class IIb
<b>Focalin</b> (dexmethylphenidate) - Amphetamine Related; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years and older)		
<b>Geodon</b> (ziprasidone) - Antipsychotic; Benzisothiazoyl				

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

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level	
<b>Haldol</b> (haloperidol) - Antipsychotic; Butyrophenone; Dopamine Antagonis	Gilles de la Tourette's syndrome	Yes (for 3 years old and up)	It does not appear the injectible form (decanoate) is FDA approved for any pediatric use, nor is it supported by DRUGDEX for any indication.		
	Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy	Yes (for 3 years old and up)			
	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)			
	Agitation	No			Class IIb
	Migraine	No			Class III
<b>Invega</b> (paliperidone) - Antipsychotic; Benzisoxazole					
<b>Klonopin</b> (clonazepam) - anti-anxiety, Anticonvulsant, Benzodiazepine, Short or Intermediate Acting					
	Seizure	Yes, up to 10 years or up to 30 kg			
	Gilles de la Tourette's syndrome	No		Class IIb	
	Hyperreflexia	No		Class IIb	
	Nocturnal epilepsy	No		Class IIb	
	Panic disorder	No		Class IIb	
	Status epilepticus	No		Class IIb	
<b>Lamictal</b> (lamotrigine) - Anticonvulsant; Phenyltriazine					
	Convulsions in the newborn, Intractable	No		Class IIa	
	Epilepsy, Refractory	No		Class IIa	
	Lennox-Gastaut syndrome; Adjunct	yes (2 years and older)			
	Partial seizure, Adjunct or monotherapy	yes (13 years and older, extended-release only; 2 years and older, chewable dispersible)			
	Tonic-clonic seizure, Primary generalized; Adjunct	yes (2 years and older)			
	Absence seizure; Adjunct	No		Class IIb	
	Bipolar Disorder, Depressed Phase	No		Class IIb	
	Infantile neuronal ceroid lipofuscinosis	No		Class IIb	
	Juvenile myoclonic epilepsy	No		Class III	
	Paroxysmal choreoathetosis, Paroxysmal	No		Class IIb	
	Rett's disorder	No		Class IIb	
	Status epilepticus	No		Class IIb	
	West syndrome	No		Class IIb	
<b>Lexapro</b> (escitalopram) - Antianxiety, Antidepressant, Serotonin Reuptake Inhibitor					
	Major Depressive Disorder	Yes (for 12 years old and up)			
<b>Limbitrol</b> (chlordiazepoxide/amitriptyline) - Tricyclic Antidepressant/Benzodiazepine Combination					
<b>Lunesta</b> (eszopiclone) - Nonbarbiturate Hypnotic					
<b>Luvox</b> (fluvoxamine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor					
	Obsessive-Compulsive Disorder	Yes (for 8 years old and up and immediate release formula only)			
	Asperger's Disorder	No		Class IIb	

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

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
<b>Mellaril</b> (thioridazine) - Antipsychotic; Phenothiazine; Piperidine	Schizophrenia, Refractory	Yes		
	Behavioral Syndrome	No		Class III
<b>Moban</b> (molindone) - antipsychotic, Dihydroindolone	Schizophrenia	Yes, 12 years and older		
	Aggressive behavior, In children	No		Class IIb
<b>Neurontin</b> (gabapentin) anticonvulsant	Partial seizure; Adjunct	Yes (3- 12 years old)		
	Complex Regional Pain Syndrome, Type 1	No		Class IIb
	Neuropathic Pain	No		Class IIb
	Partial Seizure	No		Class IIb
	Partial Seizure, Refractory	No		Class III
	Phantom Limb Syndrome	No		Class IIb
<b>Orap</b> (pimozide) - Antipsychotic; Diphenylbutylpiperidine; Dopamine Antagonist	Gilles de la Tourette's syndrome	Yes (12 years and older)		
	Anorexia Nervosa	No		Class III
<b>Paxil</b> (paroxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor	Panic disorder	No		Class IIb
	Trichotillomania	No		Class IIb
<b>Pristiq</b> (desvenlafaxine) Antidepressant, Serotonin/Norepinephrine Reuptake Inhibitor				
<b>Prozac</b> (fluoxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor	Major Depressive Disorder	Yes (for 8 years old and up)		
	Obsessive-Compulsive Disorder	Yes (for 7 years old and up)		
	Anxiety Disorder of Childhood	No		Class IIb
	Autistic disorder	No		None
	Bulimia nervosa	No		Class IIb
	Vasovagal syncope; Prophylaxis	No		Class III
<b>Restoril</b> (temazepam) - Antianxiety, Benzodiazepine, Short or Intermediate Acting, Hypnotic				
<b>Ritalin</b> (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years to 12 years old)(extended 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)		
	Autistic disorder	No		Class IIb
	Finding related to coordination / incoordination - Impaired cognition	No		Class IIb
	Schizophrenia	No		Class III
	Traumatic Brain Injury	No		Class IIb
	<b>Risperdal</b> (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)		
	Behavioral syndrome - Mental retardation	No		Class IIb
	Gilles de la Tourette's syndrome	No		Class IIb
	Pervasive developmental disorder	No		Class IIb



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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
<b>Rozerem</b> (ramelteon) - Melatonin Receptor Agonist, Nonbarbiturate Hypnotic				
<b>Seroquel</b> (QUETIAPINE) - Antipsychotic; Dibenzothiazepine				
	Bipolar disorder, maintenance	Yes, 10-17 regular release only (12/4/09)		
	Manic bipolar I disorder	Yes, 10-17 regular release only (12/4/09)		
	Schizophrenia	Yes 13-17, regular release only (12/4/09)		
	Gilles de la Tourette's syndrome	No		Class IIb
<b>Sinequan</b> (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)		
	Pruritus (Moderate), Due to atopic dermatitis or lichen simplex chronicus	No		Class IIb
<b>Sonata (zaleplon) - Nonbarbiturate Hypnotic</b>				
<b>Strattera</b> (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
<b>Symbyax</b> (fluoxetine hydrochloride/olanzapine) - Antidepressant; Antipsychotic				
<b>Tegretol</b> (carbamazepine) - Anticonvulsant; Antimanic; Dibenzazepine Carboxamide; Neuropathic Pain Agent				
	Epilepsy, Partial, Generalized, and Mixed types	Yes		
	Apraxia			None
	Chorea			Class IIb
	Migraine; Prophylaxis			Class IIb
	Myokymia			Class IIb
	Neuropathy, General			Class IIb
	Schwartz-Jampel syndrome			Class IIb
<b>Tofranil</b> (imipramine) - Antidepressant; Antidepressant, Tricyclic; Urinary Enuresis Agent				
	Nocturnal enuresis	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type	No		Class III
	Depression	No		Class IIb
	Schizophrenia, Adjunct	No		Class III
	Separation Anxiety Disorder of Childhood	No		Class III
	Trichotillomania	No		Class IIb
	Urinary incontinence	No		Class IIb
<b>Topamax</b> (topiramate) - anticonvulsant, Fructopyranose Sulfamate				
	Lennox-Gastaut syndrome; Adjunct	Yes, 2 years and older		
	Partial seizure, Initial monotherapy	Yes, 10 years and older		
	Partial seizure; Adjunct	Yes, 10 years and older		
	Tonic-clonic seizure, Primary generalized; Adjunct	Yes, 2 to 16 years old		
	Tonic-clonic seizure, Primary generalized (initial monotherapy)	Yes, 10 years and older		
	Angelman syndrome	No		Class IIb
	Migraine; Prophylaxis	No		Class IIb

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Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
	Status epilepticus	No		Class IIb
	West syndrome	No		Class IIb
<b>Tranxene</b> (clorazepate) - Antianxiety, Anticonfulsant, Benzodiazepine, Long Acting				
	Partial seizure; Adjunct	Yes, 9 years and older		
	Epilepsy	No		Class IIb
<b>Trileptal</b> (oxcarbazepine) - Anticonvulsant; Dibenzazepine Carboxamide				
	Partial Seizure, monotherapy	Yes (for 4 years old and up)		
	Partial seizure; Adjunct	Yes (for 2 years old and up)		
<b>Vyvanse</b> (lisdexamfetamine) - Amphetamine (class); CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old to 12 years)		
<b>Wellbutrin</b> (bupropion) - Aminoketone, Antidepressant, Smoking Cessation Agent				
	Attention deficit hyperactivity disorder	No		None
<b>Xanax</b> (alprazolam) - Antianxiety, Benzodiazepine, Short or Intermediate Acting				
<b>Zoloft</b> (sertraline) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Obsessive-Compulsive Disorder	Yes (6 years old and up)		
	Anorexia nervosa	No		Class III
	Generalized Anxiety Disorder	No		Class IIb
	Major Depressive Disorder	No		Class IIb
<b>Zyprexa</b> (olanzapine) - Antipsychotic; Thienobenzodiazepine				
	Bipolar 1, Disorder, Acute Mixed or Manic Episodes	Yes (ages 13-17), oral only, approved 12/4/09		
	Schizophrenia	Yes (ages 13-17), oral only, approved 12/4/09		
	Schizophrenia, Refractory	No		Class IIb
	Pervasive Developmental Disorder	No		Class IIb

**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.