Litigating Against the Psychiatric Drugging of Children & Youth

ICSPP 2009 Conference

Difficult Children and Families:

Understanding Instead of Diagnosing;
Evidence Based Interventions;
Support Instead of Just Medications

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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.

Identified Approaches

- Direct Suit Against States
  - *PsychRights v. Alaska*
- False Claims Act (*Qui Tam*)
  - Model *Qui Tam* Complaint
- Challenge FDA Approvals
  - Citizen's Petition under 21 CFR 10.30

PsychRights v. State of Alaska

- Lawsuit Against State & Responsible Officials, seeking an injunction that Alaskan children and youth have the right not to be administered psychotropic drugs unless and until,
  i. evidence-based psychosocial interventions have been exhausted,
  ii. rationally anticipated benefits of psychotropic drug treatment outweigh the risks,
  iii. the person or entity authorizing administration of the drug(s) is fully informed, and
  iv. close monitoring of, and appropriate means of responding to, treatment emergent effects are in place.

Complaint Available at http://psychrights.org

PsychRights v. Alaska: Remedies Sought

- Declaratory Judgment that Children & Youth Have These Rights
- Injunction Against the State Authorizing or Paying for Pediatric Psychopharmacology Unless Satisfies Criteria
- Review & Correct Current Pediatric Psychopharmacology

PsychRights v. Alaska: Status

- Dismissed for Lack of Standing
- On Appeal
- But Developed Medicaid Fraud Approach as a Result

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 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 this 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
- Promotion of Geodon for use in children for non-medically accepted indications.
  - Stephen Sheller, one of the *relators'* attorneys
  - Stefan Kruszewski, MD, one of the *relators*

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"
- Stephen Sheller, one of attorneys

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

False Claims Act:
Other Liable Parties

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

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

* Will probably have an FDA approval soon, if not already

False Claims Act:
Other Pediatric non-Medically Accepted Indications (*per se* Medicaid Fraud)

- Virtually All Polypharmacy?
- Otherwise, have to check specific diagnosis with Drugdex (as a practical matter)
  - Doubt, for example, Oppositional Defiance Disorder is a medically accepted indication for any neuroleptic, but seen it prescribed

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)

Suing Prescribers, Their Employers & the Pharmacies May Stop it in Its Tracks

But . . .

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:
(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:
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:
Questions (to be litigated)

- What does "support" in a compendia mean?
  - Drugdex Codes
    - Can a positive report of "3 mentally deficient children & adolescents" receiving Depakote generating a IIb rating constitute "support?"
  - Is almost all polypharmacy a violation?
- Can Prescribers, Employers & Pharmacies be charged with knowledge?
  - If sued, can't claim ignorance for future.
- What does Non-Public Mean?
  - Are Offending Prescriptions Sufficient ?
- What does allegations or transactions mean?

False Claims Act:
Miscellaneous

- Attorney required.
- Six Year Statute of Limitations

False Claims Act:
Model Complaint

- Drafted for former foster youth, but anyone with non-public information (i.e., specific prescriptions) can bring.

Challenging FDA Approvals
(21 CFR 10.30)

- Risperdal Pediatric Approval Fraud Most Dramatic at This Point
  - Harvard's Biederman
    - Promised research results supporting pediatric use if Johnson/Janssen funded Center
- Need Substantial Funding to Pursue

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