MEDICATING CHILDREN & YOUTH: EXCEEDING SCIENCE AND THE LAW

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Law Project For Psychiatric Rights (PsychRights®)

- Public Interest Law Firm
- Mission: Mount Strategic Litigation Campaign Against Forced Psychiatric Drugging and Electroshock.
- Adopted Drugging of Children & Youth as Priority Few Years Ago

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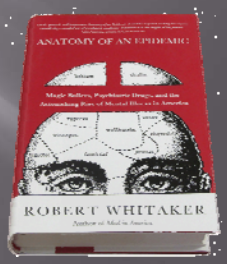
Critical Think Rx *A prescription for critical thinking about psychotropic medications*



Critical Think Rx *A prescription for critical thinking about psychotropic medications*

The "Critical Think Rx" program was developed under a grant from the Attorneys General Consumer and Prescriber Grant Program through the multi-state settlement of consumer fraud claims regarding the marketing of Neurontin, to give guidance to people making decisions regarding authorizing the administration of psychotropic drugs to children and youth.

Medicating Children & Youth

- Mainstream mental health practice endorses a "medical model" of mental illness that supports medicating children and youth with little or no evidence of the drugs' safety or efficacy.
- Mainstream mental health practice endorses medicating children and youth for mental illness when there is considerable disagreement and lack of scientific evidence about psychiatric diagnoses in children and youth.
- Prescriptions of psychotropic drugs to youths tripled in the 1990s and are still rising.
- The proportion of children and youth prescribed psychiatric drugs is 2 to 20 times higher in the United States, Canada, and Australia than in any other developed nations.

Medicating Children & Youth (Cont.)

- Seventy-Five percent of all medication administered to children and youth is prescribed for uses not approved by the Food and Drug Administration.
- At least forty percent of all psychiatric drug treatments today involve polypharmacy.
- Most psychotropic medication classes lack scientific evidence of their efficacy or safety in children and youth.
- The FDA only evaluates trials testing a single drug, not drug combinations, ie, "polypharmacy."
- No studies have established the safety and efficacy of polypharmacy in children and youth.

Food & Drug Administration

- FDA requires only two positive trials even if there are more trials that result in negative findings.
- For FDA, "efficacy" means less than a 5 percent chance of being worse than placebo
  - does not mean the drug has shown it helps a patient's condition or works better than another drug or non-drug intervention.

Clinical Trials

- Drug companies (sponsors) routinely remove prospective subjects who respond to placebo from clinical trials, making the results invalid.
- Adverse effects of the drugs occurring during clinical trials are carelessly investigated, at best, resulting in a false impression of a drug's safety.
- During clinical trials, adverse events are often miscoded by the Sponsor.
- During clinical trials, adverse events are often arbitrarily determined to be unrelated to the drug being studied, and ignored.

Clinical Trials (Cont)

- Sponsors often design drug studies solely to get positive results.
- Sponsors often suppress and distort negative results.
- Sponsors often publish purported positive results multiple times to give the appearance the results have been replicated multiple times.
- In conducting clinical trials, sponsors now extensively use Contract Research Organizations, which are private, for profit companies who get paid to achieve positive results for the Sponsors.
- In 90 percent of studies pitting one newer neuroleptic against another, the best drug was the Sponsor's drug.
- Sponsors keep negative data about their drugs secret, claiming they are trade secrets or otherwise entitled to be kept secret from prescribers and other people making decisions on whether to give them to children and youth.

Publishing Studies Multiple Times

SCIENCE EX MACHINA

In striking contrast to these publication difficulties, when marketing sertraline (Zoloft), Pfizer's efforts were geared to producing an average of two to three articles per month in significant journals,[50] many of which appear to have been ghostwritten.[51] In the case of the three leading SSRIs combined, this would mean six to nine articles per month—two per week. In the case of Lilly's Zyprexa, the four clinical trials that brought this drug on the market gave rise to 234 publications, all advocating the efficacy of the compound with none containing data on the increases in glucose or cholesterol levels or rates of suicide found in these trials that have since become the subject of legal actions.[52]

Pharmageddon, page 125

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Long-Term Results from NIMH's MTA Study

- At end of 14 months, "carefully crafted medication management" had proven to be superior to behavioral treatment in terms of reducing core ADHD symptoms. There was a hint that medicated children also did better on reading tests.
- At the end of 36 months, "medication use was a significant marker not of beneficial outcome, but of deterioration. That is, participants using medication in the 24-to-36 month period actually showed increased symptomatology during that interval relative to those not taking medication." Medicated children were also slightly smaller, and had higher delinquency scores.
- At end of six years, medication use was "associated with worse hyperactivity-impulsivity and oppositional defiant disorder symptoms," and with greater "overall functional impairment."

Sources: The MTA Cooperative Group, "A 14-month randomized clinical trial of treatment strategies for attention-deficit/hyperactivity disorder, " *Archives of General Psychiatry* 56 (1999):1073-86. Jensen, "A 3-year follow-up of the NIMH MTA study," *J Amer Academy of Child & Adolescent Psychiatry* 46 (2006):989-1002. Molina, "MTA at 8 years," *J Amer Academy of Child & Adolescent Psychiatry 48 (2009):484-500.*

MTA Study Conclusion

"We had thought that children medicated longer would have better outcomes. That didn't happen to be the case. There were no beneficial effects, none. In the short term, [medication] will help the child behave better, in the long run it won't. And that information should be made very clear to parents."

--MTA Investigator William Pelham, University at Buffalo

Daily Telegraph, "ADHD drugs could stunt growth, " Nov. 12, 2007.

A Meta-Analysis of the Literature, 2005

In a review of 2,287 studies:

There is "no good quality evidence on the use of drugs to affect outcomes relating to global academic performance, consequences of risky behaviors, social achievements, etc."

-- Drug Effectiveness Review Project
Oregon Health and Science University, 2005

Source: McDonagh, "Drug class review on pharmacologic treatment for ADHD," 2006, http://www.ohsu.edu/drugeffectiveness

Adverse Effects From ADHD Medications

- **Physical:** Drowsiness, appetite loss, lethargy, insomnia, headaches, abdominal pain, motor abnormalities, tics, jaw clenching, skin problems, liver disorders, weight loss, growth suppression, hypertension, and sudden cardiac death.
- **Emotional:** Depression, apathy, a general dullness, mood swings, crying jags, irritability, anxiety, and a sense of hostility from the world.
- **Psychiatric:** Obsessive-compulsive symptoms, mania, paranoia, psychotic episodes, and hallucinations.

Adverse Effects of SSRIs in Children

- **Physical:** Insomnia, sexual dysfunction, headaches, gastrointestinal problems, dizziness, tremors, nervousness, muscle cramps, muscle weakness, seizures, and akathisia (associated with increased risk of suicide).
- **Emotional/Psychiatric:** Psychosis, mania, behavioral toxicity, panic attacks, anxiety, apathy, an emotional dulling. Also, doubling of risk of suicidal acts.

Adverse Effects With Atypicals

- Psychosis.
- University of Maryland: Nine percent of children treated with antipsychotics for median time of 484 days developed tardive dyskinesia.
- Brain shrinkage and cognitive decline long-term.
- Metabolic dysfunction, obesity, type-II diabetes, hormonal abnormalities, movement disorders, cardiovascular problems, emotional blunting, sedation, and cognitive problems. Adverse events worse in children and adolescents than in adults.
- Early death

Drug- Caused Pathways to Bipolar Diagnosis

Stimulants → Bipolar Diagnosis

- In Canadian study, six percent of ADHD children treated with stimulants for average of 21 months developed psychotic symptoms.
- In a study of 195 bipolar children, Demitri Papolos found that 65% had "hypomanic, manic and aggressive reactions to stimulant medications."
- University of Cincinnati reported that 21 of 34 adolescent patients hospitalized for mania had been on stimulants "prior to the onset of an affective episode."

Source: Cherland, "Psychotic side effects of psychostimulants," *Canadian Journal of Psychiatry* 44 (1999):811-13. Papolos, "Bipolar disorder, co-occuring conditions, and the need for extreme caution before initiating drug treatment." *Bipolar Child Newsletter* 1 (Nov.-1999). DelBello, "Prior stimulant treatment in adolescents with bipolar disorder," *Bipolar Disorders* 3 (2001):53-57.

Antidepressants → Bipolar Diagnosis

- In first pediatric trial of Prozac, 6% of treated children suffered a manic episode; none in placebo group.
- Harvard University researchers find that 25% of children treated for depression convert to bipolar within four years.
- Washington University researchers report that within 10 years, 50% of prepubertal children treated for depression convert to bipolar illness.

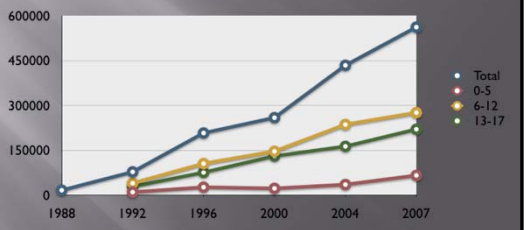
Source: Emslie, "A double-blind, randomized, placebo-controlled trial of fluoxetine in children and adolescents with depression," *Arch of General Psychiatry* 54 (1997):1031-37. Martin, "Age effects on antidepressant-induced manic conversion," *Arch of Pediatrics & Adolescent Medicine* 158 (2004):773-80. Faedda, "Pediatric onset bipolar disorder," *Harvard Review of Psychiatry* 3 (1995): 171-95. Geller, "Bipolar disorder at prospective follow-up of adults who had prepubertal major depressive disorder," *Amer J of Psychiatry* 158 (2001):125-7.

Summary of Long-term Harms from Psychotropics in Children and Youth

- Increased risk of disability (bipolar pathway)
- Physical ailments
- Emotional lethargy
- Cognitive decline
- Early death

Psychiatric Drugs & Children: A Monumental Disaster

Children on SSI Disability Due to Mental Illness



Prior to 1992, the government's SSI reports did not break down recipients into subgroups by age. Source: Social Security Administration reports, 1988-2007.

Module 8 – Alternatives to Medication: Evidence Based Psychosocial Interventions

- Deconstructing the Diagnosis: What is this Child's Problem in Behavioral Terms?
  - Environmental Influences
  - Understanding rather than diagnosing
- Empirically-Supported Psychosocial Interventions
  - Focus: Trauma, Resilience & Child Welfare

Rights of Children Under US Constitution

- Under the Fourteenth Amendment to the Constitution of the United States, children and youth in state custody have the right to be protected by and not harmed by the state.

> [W]hen the State by the affirmative exercise of its power so restrains an individual's liberty that it renders him unable to care for himself, and at the same time fails to provide for his basic human needs-*e.g.*, food, clothing, shelter, medical care, and reasonable safety-it transgresses the substantive limits on state action set by the Eighth Amendment and the Due Process Clause

DeShaney v. Winnebago County Dept. of Social Services, 489 U.S. 189, 109 S.Ct. 998, 103 L.Ed.2d 249, 57 USLW 4218 (1989)

Rights of Children Under Federal Civil Rights Law

42 USC § 1983 -- Civil action for deprivation of rights

Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proper proceeding for redress, except that in any action brought against a judicial officer for an act or omission taken in such officer's judicial capacity, injunctive relief shall not be granted unless a declaratory decree was violated or declaratory relief was unavailable.

Rights of Children Under Alaska Constitution

Under the Alaska Constitution

- minors have the right to enforce their own fundamental constitutional rights.
- involuntary administration of psychotropic drugs infringes upon fundamental constitutional rights, and before the State may administer such drugs, (a) there must be a compelling state interest in doing so, (b) the action must be in the best interests of the person, and (c) there must be no less intrusive alternatives.

Rights of Children & Youth In State Custody Under State Statutes

Alaska Department of Health and Social Services (DHSS) has duty to:

- Make Decisions in Best Interests of Child or Youth
- "care for the child, including meeting the emotional, mental, and social needs of the child, and to protect, nurture, train, and discipline the child and provide the child with education and medical care."
- Pay the costs of habilitative and rehabilitative treatment and services for children and youth diagnosed with a mental illness.

AS 47.14.100(d)(1), AS 47.10.084(a) and AS 47.12.150(a)

Rights of Children Under International Law

1971 UN Convention on Psychotropic Substances (1971 Convention-US Is Signatory)

- psychotropic drugs limited to medical and scientific purposes
- prohibits advertising of psychotropic drugs to the general public with due regard to constitutional provisions

UN Convention on the Rights of the Child (Child Rights Convention) -- Not Ratified But May Be Binding

- Government Decisions Must Be Based on Best Interests of Child
- Children Have Own Rights

PsychRights v. Alaska

Sought Injunction that psychotropic drugs not be administered to children and youth unless and until,

- evidence-based psychosocial interventions have been exhausted,
- rationally anticipated benefits of psychotropic drug treatment outweigh the risks,
- the person or entity authorizing administration of the drug(s) is fully informed, and
- close monitoring of, and appropriate means of responding to, treatment emergent effects are in place

- Alaska Supreme Court Ruled No Standing in 2010

42 U.S.C § 1983 Action

- PsychRights Potentially to File for *PsychRights v.* Alaska Type Relief in Federal Court Under 42 USC § 1983
- State Official/Employee Defendants
  - CPS Workers
  - Query: Are the Doctors Liable?
- Foster Parents Could Also Be Defendants

False Claims Act

- Civil War Era Statute to Address Rampant Fraud Against Government
- Amended in 2009 & 2010 to Counteract Hostile Judges
- Allows citizens to bring suit on behalf of the government and share in recovery if any.
- Plaintiffs Called "Relators" (for the King)

31 U.S.C §3729, et seq.

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False Claims Act (Medicaid Fraud Initiative)

- Medicaid Coverage Limited to "Medically Accepted Indications"
  - FDA Approved + Compendia "Supported"
- Designed to Stop Harmful Practice by Causing Doctors to Realize Inviting Financial Ruin if Continue
  - $5,500 minimum fine per prescription
- Model Complaint
  - Former Foster Youth *Relators*
  - Other Possibilities

$Billion Settlements Against Drug Manufacturers Not Stopping Massive, Inappropriate Psychiatric Drugging of Poor 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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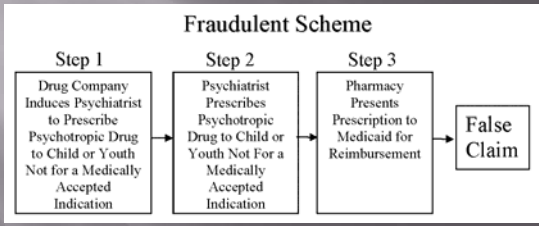
Fraudulent Scheme



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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
- Mental Health Workers Could Also Be Defendants

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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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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: Pre- 2010 Public Disclosure Bar

"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)

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False Claims Act: Current Public Disclosure Bar

- **(4)(A)** The court shall dismiss an action or claim under this section, unless opposed by the Government, if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed--
  - **(i)** in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;
  - **(ii)** in a congressional, Government Accountability Office, or other Federal report, hearing, audit, or investigation; or
  - **(iii)** 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)

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Matsutani Decision:

- If the Government Doesn't Care, Why Should We?
- Explicitly Non-Precedential, but
- Immunizes those defendants not only for past, but future false claims, unless
- Government Prosecutes, Intervenes, or Objects to Dismissal.

Medicaid Fraud Initiative Not Knocked Out

Questions?

Suggested Reading

- *Anatomy of an Epidemic*, by Robert Whitaker (2010 – in press).
- *Drugging Our Children*, Sharna Olfman & Brent Robbins, Eds. (2012)
- *Mad in America: Bad Science, Bad Medicine and the Enduring Mistreatment of the Mentally Ill*, by Robert Whitaker (2001)
- *Alternatives Beyond Psychiatry*, Peter Lehman & Peter Stastny, MD, Editors (2007).
- *Pharmageddon*, David Healy, MD (2012)
- *Agnes's Jacket: A Psychologist's Search for the Meaning of Madness*, by Gail Hornstein, PhD, Rodale Books, 2009.
- *Drug Induced Dementia*, Grace E. Jackson, MD, Author House, 2009.
- *A Fight to Be: A Psychologist's Experience from Both Sides of the Locked Door*, Ronald Bassman, Ph.D. (2007)
- *Rethinking Psychiatric Drugs: A Guide to Informed Consent*, by Grace E. Jackson, MD, (2005)
- *Brain Disabling Treatments in Psychiatry: Drugs, Electroshock, and the Role of the FDA*, Ed. 2 (2008) by Peter Breggin, MD.

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Suggested Reading (cont.)

- *Community Mental Health: A Practical Guide* (1994) by Loren Mosher and Lorenzo Burti
- *Soteria: Through Madness to Deliverance*, by Loren Mosher and Voyce Hendrix with Deborah Fort (2004
- *Psychotherapy of Schizophrenia: The Treatment of Choice* (Jason Aronson, 1996), by Bertram P. Karon and Gary R. Vandenbos
- *Schizophrenia: A Scientific Delusion*, by Mary Boyle, Ph.D. (2002)
- *Let Them Eat Prozac*, by David Healy, MD. (2006).
- *Creating Mental Illness*, by Allan V. Horwitz (2002).
- *Commonsense Rebellion*, by Bruce E. Levine (2001)
- *Blaming the Brain : The Truth About Drugs and Mental Health* (1998) by Elliot Valenstein
- *Escape From Psychiatry*, by Clover (1999)
- *How to Become a Schizophrenic: The Case Against Biological Psychiatry*, 3d Ed., by John Modrow (2003)
- Other books at http://psychrights.org/Market/storefront.htm