CriticalThinkRx and PsychRights' Lawsuit Against State of Alaska's Drugging of Children

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Governmental Pediatric Psychopharmacology: A National Horror

- Very Powerful Drugs That Cause Great Harm
- Most Pediatric Psychopharmacology Is to Control Unwanted Behavior
- 40-Fold Increase in Bi-Polar Diagnoses
  - Used to Justify Stronger Drugs➔ Antidepressants, "Mood Stabilizers" and Neuroleptics
  - 2.5 million children are on neuroleptic drugs
- 60-80% of kids in State Custody Being Drugged
- Thousands of infants less than 1 Year Old Have Received Psychotropic Drugs
- Medicaid Reimbursement for Pediatric Psychopharmacology Has Skyrocketed.

CriticalThinkRx & PsychRights

- Two Years Ago PsychRights Adopted Addressing Problem as a Priority
- Learned Almost Year Ago that CriticalThinkRx Was in the Works
  - David Cohen, PhD, Principle Investigator
- Waited For & Shamelessly Appropriated CriticalThinkRx for Lawsuit

- http://www.criticalthinkrx.org/
- Funded by the Attorneys General Consumer and Prescriber Grant Program, arising out of the multi-state settlement of consumer fraud claims regarding the marketing of Neurontin
- Designed to educate professionals in child welfare and mental health to make informed decisions regarding authorizing pediatric psychopharmacolgy
- Meticulously Researched

CriticalThinkRx Curriculum: FDA Approval Process

- FDA Defines Efficacy as < 5% Chance Worse Than Placebo
- Need Only Two Positive Studies—A Dozen Negative Ones Doesn't Matter
- FDA Usually Approves Drug for One Use in One Population
- Does Not Signify Safe or Effective for Pediatric Use

Curriculum: Crude Drug Company Influence

- Trials Are Inherently Marketing Driven
  - Designed to Favor Drug
  - Studies Manipulated to Achieve Desired Result
- Unfavorable Data is Kept Secret
- Journals Are No Longer Reliable Sources of Information
- Baksheesh Is Everywhere
- Etc., Etc., Etc.

Example:
kshesh is Everywhere

- Free meals,
- Free drug samples,
- Providing free continuing medical education, which states require of physicians to maintain their licenses,
- Payments for lecturing, consulting and research,
- Paying "Key Opinion Leaders" to put name on articles in medical journals (Ghost Writing),
- Funding their professional organizations' activities,
- Advertising in professional journals,
- Paying doctors to serve on "expert committees" that create and promote guidelines for drug treatments used by other doctors, and
- Promotion of mental health screening programs in state and federal policy, including for children and youth in foster care that have very high false positive rates and that lead to over diagnosis and over use of these dangerous and ineffective medications.

ediatric Psychotropic Prescribing

- Mainstream MH Practice Supports "Medical Model" of MI that Supports Medicating children & Youth With Little or No Evidence of Safety or Efficacy.
- 75% of Pediatric Psychopharmacology is for unapproved Uses
- Rampant Polypharmacy Has Not Even Been Subjected to Clinical Trials
- The Drugs Cause Brain Damage and Other Serious Health Effects

Curriculum:
Evidence-Based, Less Intrusive lternatives: Psychosocial Interventions

- Tremendous Evidence Base for Evidence-Based Psychosocial Interventions.
- Foster Kids Need Help Dealing With Both What Brought them There and Foster Care Traumas
- Parents and Foster Parents Need Help in Raising Children & Youth

Example:
dence-Based Psychosocial Interventions

- Foster Care Settings that Give Feeling of Security & Stability, and Imparts Positive Social Functioning
- Consistent, Structured Supportive Adult Supervision
- Teaching Problem Solving/Taking Responsibility
- Teaching How to Deal with Strong Emotions
- Stable Academic Environment Where Able to Master Material
- Recreation & Exercise Opportunities
- Long-term Adult Mentors Outside of Foster Care, MH & School Systems
- Etc., Etc., Etc.

Curriculum:
ThinkRx Questions To Answer

- About the Client
- About the Medication
- About the Prescriber
- About the Therapist's (Decision Maker's) Role

Questions to Answer:
About the Client

- What are the client's symptoms or observed behaviors of concern, who has observed them?
- Has the client experienced any recent or chronic life events or stressors that may contribut to the problems?
- Could any of the client's problems be caused by a current medication?
- Does the client's psychiatric diagnosis truly reflect the client's problems? Is the diagnosis useful to plan for interventions with this client?
- What interventions have been tried to address client's problems? By whom, and with what results?
- Are alternative interventions available to address client's problems? Why have they not yet been tried?
- Why is medication being prescribed for this client? What other medication has been prescribed currently or in the past?
- How long before we see improvements? How will the improvements be measured?
- How long will the patient be on the medication? How will a decision to stop be made?
- If client is a minor, is the medication designed to benefit the child, or the child's caregivers?

Questions to Answer: About the Medication

- ...cation prescribed for this client?
- How long has it been on the market? Is it FDA-approved for use in children? Are there any FDA "black box" warnings about this medication?
- What is known about the helpfulness of this medication with other children with similar conditions?
- Have any studies about this drug been evaluated by the professionals working with this child? Is there scientific support for this medication's helpfulness with other children with similar conditions?
- How much scientific evidence exists to support the safety and efficacy of this drug with children, whether used alone or in combination with other psychotropic medications?
- What is the recommended dosage? How often will the medication be taken? Who will administer it?
- Has this medication been shown to induce tolerance and/or dependence? What withdrawal effects may be expected when it is discontinued?
- Do any laboratory tests need to be done before, during, after use of this medication?
- Are there other medications or foods the child should avoid while on this medication?
- What are the potential positive and adverse effects of this medication?
- How long will the effects of the medication be monitored? By whom, how, and how often? Where will the effects be documented? What should be done if a problem develops?
- How will the use of medication impact other interventions being provided?
- How much does this medication cost? Who is paying

Questions to Answer: About the Prescriber

- What is the experience of the physician prescribing the medication?
- Would you consider the physician's prescribing habits cautious and conservative?
- Does this physician have any financial relationships with pharmaceutical companies? Have these been disclosed to patients?
- Have all the risks and benefits of this medication, and those of alternative interventions, been evaluated and discussed by the physician with the client or the client's family?
- Is there an adequate monitoring schedule and follow-up in place?
- Do I or my client/client's family have the opportunity to speak regularly with the physician and other healthcare providers about the medication's effects? Should my feedback be expressed in writing?

Questions to Answer: About the About the Therapist's (Decision Maker's) Role

- Has a comprehensive assessment (e.g., biopsychosocial, holistic, integral) been conducted? Does it offer plausible reasons for the client's problems?
- Are there other explanations for the client's behavior?
- Am I familiar with all the risks and benefits of this medication, as well as those of alternate interventions? Have I discussed them with the client/client's family?
- Do I know how the client/client's family feel about the use of medication?
- What is my role and has it been clearly delineated with all other providers?
- Has the client/client's family been provided with all the information necessary to provide informed consent? Do they understand their choices?
- Do I feel confident that I can recognize the effects, adverse or otherwise, of this medication on my client? How should I record my observations?
- Will I be able to educate my client about these effects so he/she can raise concerns with the prescribing physician?
- What alternative services/interventions does this family need or want?
- Can I provide these or help them obtain access?

Pediatric PsychoPharmacology: Neuroleptics

Brand Name	Generic Name	Approved Use	Approved Ages
Risperdal	risperidone	Autism, bipolar mania, schizophrenia	5+
Abilify	aripriprazole	Schizophrenia	10+
Clozaril	clozapine	Treatment-Resistant schizophrenia	Adults only
Zyprexa	olanzapine	Bipolar mania, schizophrenia	
Seroquel	quetiapine		
Geodon	ziprasidone		
Symbyax	olanzapine & fluoxetine		
Invega	paliperidone		

Brand Name	Generic Name	Approved Use	Approved Ages
Orap	pimozide	Tourette's Disorder (for Haldol non-responders)	12+
Haldol	haloperidol	Schizophrenia, Tourette's Disorder	3+
Mellaril	thioridazine	Schizophrenia	2+

Pediatric PsychoPharmacology: Neuroleptics (Cont.)

- Most Often Prescribed to Suppress Aggression & Agitation
- Current Prescriptions of Neuroleptics to Children & Youth Far Exceeds Evidence of Safety and Effectiveness
- No Studies Show Safe or Effective for Children & Youth
- Many Physical & Psychiatric Adverse Effects (too many to list here)

Pediatric PsychoPharmacology: Antidepressants

Brand Name	Generic Name	Approved Use	Approved Ages
Sinequan	doxepin	Obsessive Compulsive Disorder (OCD)	12+
Anafranil	clomipramine		10+
Luvox	Fluvoxamine		8+
Zoloft	sertraline		6+
Tofranil	imiprimine		
Prozac	fluoxetine	Depression, OCD	7+

Pediatric PsychoPharmacology: Antidepressants (cont.)

- 75-82% of Response Duplicated by Placebo-- 57% of controlled trials failed to show a difference between drug and placebo
- Only 20% of Published and Unpublished trials Showed SSRIs More Effective than Placebo for Children & Youth
- Increase Suicidality in Children & Youth
- Increased Agitation, Irritability, Aggression, Worsening Anxiety, Severe Restlessness, and Other Unusual Behaviors in Youth
- Cause Mania in Significant Number of Children & Youth
- Continued exposure to Antidepressants after Emergence of Such Adverse Events Likely to Lead to Higher Doses and/or Administration of Neuroleptics

Pediatric PsychoPharmacology: Stimulants

Brand Name	Generic Name	Approved Use	Approved Ages
Adderal, Adderall XR, Dexedrine, Dextrostat	amphetamine, dextroamphetamine	ADHD narcolepsy	3+
Concerta, Ritalin, Daytrana, Metadate, Focalin, Focalin Xr	methylphenidate	ADHD	6+
Vyvanse	lisdextroamphetamine		
Strattera (inaccurately portrayed as a non-stimulant	atomoxetine		

Pediatric PsychoPharmacology: Stimulants (Cont.)

- Used to Suppress Unwanted Behavior
- DEA Schedule II Drug (Addiction & Abuse)
- No Long Term Benefit
- Increased blood pressure,
- Dizziness and headaches,
- Palpitations,
- Stomach cramps and nausea,
- Appetite and weight loss,
- Stunted growth, including stunted brain growth,
- Brain atrophy, and
- Cardiac arrest

Pediatric PsychoPharmacology: Anticonvulsants Promoted as "Mood Stabilizers)

Depakote	Liver toxicity (particularly for under 2 yrs of age); birth defects; pancreatitis
Tegretol	Aplastic anemia and agranulycytosis Tegretol (severe reduction in white blood cells)
Lamictal	Serious rash requiring hospitalization; Stevens-Johnson Syndrome for children under 16 yrs of age (fatal sores on mucuous membranes of mouth, nose, eyes and genitals)
All Anticonvulsants	Suicidal ideation and behavior

Pediatric PsychoPharmacology: Anticonvulsants Promoted as "Mood Stabilizers (Cont.)

- 40-fold Increase in Diagnosing Pediatric Bipolar Disorder in Ten Years Ensued Upon Promotion of These Drugs for Children & Youth
- >90% of Children & Youth Diagnosed with Bipolar Disorder Receive More than One drug
- Doubles the Risk of Suicidal Behavior or Ideation
- Nausea and dizziness, Vomiting and abdominal pain, Headaches and tremors, Fatal skin rashes, Hypothyroidism, Blood disorders, Pancreatitis, liver disease, Birth defects and menstrual irregularities, and Withdrawal seizures.

PsychRights v. State of Alaska

- Lawsuit Against State & Responsible Officials, seeking an injunction that Alaskan children and youth have the constitutional 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 (Cont.)

- Expect Concerted Fight By State
  - Motion to Dismiss for
    - Lack of Standing
    - Failure to State a Claim
    - Others
  - Big Pharma Help?
  - Stonewalling

PsychRights v. Alaska Remedies

- Declaratory Judgment that Kids Have These Rights
- Injunction Against the State Authorizing or Paying for Pediatric Psychopharmacology Unless Satisfies CriticalThinkRx Criteria
- Review & Correct Current Pediatric Psychopharmacology
- Need Workable Mechanism That Will Not Be Co-Opted

PsychRights v. Alaska Potential Interim Relief

- Lawsuits Tend To Take A Long Time so Would Like to Obtain Interim Relief
  - Preliminary Injunction
  - *Guardian Ad Litem*
  - Other?

PsychRights v. Alaska Need Help

- Worker Bees (Including Experts) to Help Analyze & Prepare
- *Pro Bono* Attorney Help
- Expert Witnesses For Written and Oral Testimony
  - Have Some Potential Already
  - Written Testimony Can establish Right to Interim Remedy(ies)
  - Telephonic Oral Testimony Normally Allowed in Alaska.
- Financial Support

We Are Not Powerless