


PsychRights' Litigation Against the Psychiatric Drugging of Poor Children & Youth


NARPA Annual Rights
Conference
TURNING CRISES INTO
OPPORTUNITIES
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PsychRights' Mission

- Strategic litigation campaign against forced drugging and electroshock.
- Shifted focus to the drugging of children and youth starting in 2006.




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 children & youth in State Custody Drugged
- Thousands of infants less than 1 Year Old Have Received Psychotropic Drugs
- Medicaid Reimbursement for Pediatric Psychopharmacology Through the Roof.



Efforts to Negotiate With State of Alaska Failed


- Both Legislative and Executive Branches Failed to Address the Problem
- Brought *PsychRights v. Alaska* in 2008, just after Palin Anointment



PsychRights v. State of Alaska


- Sought declaratory and injunctive relief 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: Source of Rights

- Substantive Due Process Under *DeShaney*, 489 U.S. 189 (1989)
 - "[W]hen the State takes a person into its custody and holds him there against his will, the Constitution imposes upon it a corresponding duty to assume some responsibility for his safety and general well-being. . . [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.
- Alaska Constitutional Rights
- State Statutory Rights
- Amended to Include Unlawful Under Medicaid




PsychRights v. Alaska:

- Complaint Largely Based On CriticalThinkRX.org Curriculum <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 psychopharmacology
- Meticulously Researched




PsychRights v. Alaska:
Dismissed for Lack Of Standing

- When Filed, Law Allowed “Citizen-Taxpayer” Standing if no better suited plaintiff had or was likely to bring suit.
- Alaska Supreme Court Cut Back Citizen-Taxpayer Standing in a Series of Cases, Culminating in Dismissal of *PsychRights v. Alaska*.



PsychRights v. Alaska:
Re-file in State Court?


- Could Re-file in State Court with Named Plaintiffs, but . . .
 - Attorney Fee Award Against Client if Don’t Prevail for all but Class Action Certification *Monzingo v. Alaska Air Group, Inc.*, 112 P.3d 655 (2005), & Constitutional Claims
 - Need Class Action for Systemic Relief?
 - Court Turnover since *Myers* Gives Pause



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.


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



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)

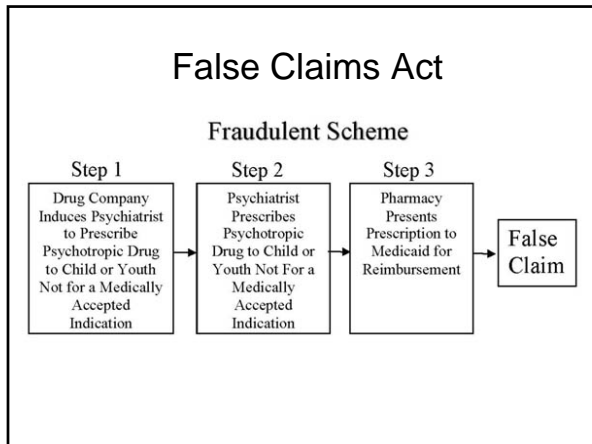


False Claims Act:
Knowingly Defined As:

- (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: Drug Co. Settlements

- Lilly/Zyprexa: \$1.4 Billion
 - *Qui Tam Relators*--\$102 million
- Pfizer/Geodon: Part of \$2.3 Billion
 - *Qui Tam Relators*--\$102 million
- AstraZeneca/Seroquel: \$520 Million
 - *Qui Tam Relators*--\$45 million
- Forest/Lexapro-Celexa: \$313 Million
 - Includes Levethroid


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Even \$Billion Settlements Against Drug Cos. Not Effective Deterrence

- 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.
- 2 in Alaska, 1 in Illinois & one to be unsealed soon in another state.

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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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DRUGDEX® Consults

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

RESPONSE
The Thomson Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

| Class | Recommendation | Description |
|---------------------|----------------------------|--|
| 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 | |

| Drug | Indication (Indications) | FDA Approval | DRUGDEX Support for Off-Label Use | DRUGDEX Reimbursement Level | |
|---|--|---|-----------------------------------|-----------------------------|--|
| Key: White Background: Medically Accepted Indication Orange Background: Pediatric Indication cited, but not supported by DRUGDEX Red Background: Pediatric Indication not cited | | | | | |
| | Colitis de la Tenon's syndrome | Yes (12 years and older) | | | |
| | Neurotic disorder | Yes | | Yes (1) | |
| Drug (Indication): | Depression, Central Nervous System Agent, Serotonin Reuptake Inhibitor | | | Yes (1) | |
| | Panic disorder | Yes | | Yes (1) | |
| | Posttraumatic stress disorder | Yes | | Yes (1) | |
| Drug (Indication): | 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) | | | |
| | Generalized Anxiety Disorder | Yes | | Yes (1) | |
| | Panic Disorder | Yes | | Yes (1) | |
| | Posttraumatic Stress Disorder | Yes | | Yes (1) | |
| | Major Depressive Disorder | Yes | | Yes (1) | |
| Off-label (Indication): | Amphetamine Related, Central Nervous System Agent, CNS Stimulant | | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years to 12 years old (extended release) and 8 years old and up (immediate release)) | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 8 years and up, and Ritalin/CR, DR only) | | | |
| | Hyperactivity | Yes | | Yes (1) | |
| | Panic disorder | Yes | | Yes (1) | |
| | Feeding related to coordination (incoordination) disorder, childhood | Yes | | Yes (1) | |
| | Conduct disorder | Yes | | Yes (1) | |
| | Disruptive behavior disorder | Yes | | Yes (1) | |
| | Specialty (Indication): | Antipsychotic, Neuroleptic | | | |
| | | Bipolar Disorder - Inability | Yes (for 8 years old and up) | | |
| Bipolar Disorder | | Yes (for 10 years old and up) | | | |
| Manic depression | | Yes (for 13 years old and up, Olanzapine) | | | |
| Manic depression - Mixed episode | | Yes | | Yes (1) | |
| Manic depression - Depressive episode | Yes | | Yes (1) | | |
| Manic depression - Mixed episode | Yes | | Yes (1) | | |
| Manic depression - Depressive episode | Yes | | Yes (1) | | |




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.
 - Reality is Extreme Deference

31 USC §3730(c)

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False Claims Act: Other Requirements

- Public Disclosure Bar 31 USC §3730(e)(4)(A)
- First to File Rule 31 USC 3730(e)(3)
- Civil Rule 9(b) "Particularity" Requirement Applies
- Attorney required.
- Six Year Statute of Limitations

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Medicaid Fraud Initiative: Status

- *ex rel PsychRights & Griffin v. Matsutani et al.* (Alaska), Dismissed Under Public Disclosure Bar
 - On Appeal—Oral Argument October 12th
 - Trial Court Held Public Disclosure of Industry-Wide Fraud Triggered Public Disclosure Bar.
 - 9th Circuit Has Held Public Disclosure of Industry-Wide Fraud Does Not Trigger Public Disclosure Bar
- *ex rel Nicholson v. Spigelman et al.*, (Illinois)
 - US Motion to Dismiss Granted – Extreme Deference
 - Caught US lying about Not Enough at Stake, but Court Agreed Defendants Did Not Have Significant Assets
 - Not Appealed
- Case In Other State About to Come Out from Under Seal
- Recruiting Lawyers to Take Other Cases.

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Potential Federal 42 USC §1983 Case

- Same Remedy as *PsychRights v. Alaska*
- Local P&A Declined to Take Case
- Will Therefore Need Named Plaintiff
- Need Class Action?
- Include State Causes of Action?
- Need Big Name Co-Counsel (per S. Stefan)
- Need Big Budget (per S. Stefan)



Q & A