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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ALASKA

UNITED STATES OF AMERICA Ex rel. Law Project for Psychiatric Rights, an Alaskan non-profit corp.,	)	
Plaintiff,	)	Case No. 3:09-cv-0080-TMB
OSAMU H. MATSUTANI, MD., et al.,	)	
Defendants.	)	

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS UNDER RULES 12(B)(1) AND 12(H)(3) FOR LACK OF SUBJECT MATTER JURISDICTION UNDER THE FALSE CLAIMS ACT'S PUBLIC DISCLOSURE BAR, 31 U.S.C. § 3730(E)(4)(A)

Because the allegations in this False Claims Act ("FCA") *qui tam* case are based on publicly disclosed information and the relator, The Law Project for Psychiatric Rights

("PsychRights"), offers no insider information, the Court has no subject matter jurisdiction under the FCA's public disclosure bar. Accordingly, the Court should dismiss the case with prejudice.[1]

I. INTRODUCTION

A district court lacks subject matter jurisdiction over a FCA case in which the government has not intervened if the facts supporting the allegations were publicly disclosed before the relator filed the case and the relator is not an original source (i.e., does not have direct and independent insider knowledge) of the allegations.[2]

The relator in this case, PsychRights, which is run by its counsel, James Gottstein, has a mission "to mount a strategic campaign against forced psychiatric drugging and electroshock in the United States akin to what Thurgood Marshall and the NAACP mounted in the 40's and 50's on behalf of African American Civil Rights."[3] As part of this mission, PsychRights wants to

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[1] Defendants bring this motion pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(h)(3). A motion to dismiss for lack of subject matter jurisdiction may be raised at any time, and the court may consider evidence outside the pleadings to determine whether subject-matter jurisdiction exists. *See Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006); *Gemtel Corp. v. Cmty Redevelopment Agency*, 23 F.3d 1542, 1544 n.1 (9th Cir. 1994) (noting that the district court properly considered various public documents submitted in granting motion to dismiss for lack of subject matter jurisdiction and that this did not convert the motion to dismiss to a motion for summary judgment).

[2] *See* 31 U.S.C. § 3730(e)(4)(A) ("No court shall have jurisdiction over an action under [the FCA] based upon the public disclosure of allegations or transactions . . ., unless the action is brought by the Attorney General or the person bringing the action is an original source of the information."); *United States ex rel. Meyer v. Horizon Health Corp.*, 565 F.3d 1195, 1199 (9th Cir. 2009). The recently passed Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (PPACA), amended the public disclosure bar, but not retroactively. Because the provision in place when PsychRights filed its Complaint will govern, defendants will cite to that and the relevant law in this brief.

[3] PsychRights.org, Recent News/Highlighted Items, http://psychrights.org/index.htm., (last visited April 2, 2010), Ex. 1.

stop physicians from prescribing psychotropic medications to pediatric patients or at least put limits on the use of these medications. PsychRights filed a state court case to accomplish this goal directly, but the case was dismissed for lack of proper standing, and is currently on appeal.[4]

Thwarted in that previous case, PsychRights chose a more circuitous route in the present case. Focusing on claims to the Alaska Medicaid Program and Alaska Children's Health Insurance Program ("CHIP") for psychotropic medications prescribed and dispensed to pediatric patients (i.e., under 18 years old), PsychRights accuses thirty-two defendants of submitting or causing to be submitted "false or fraudulent" claims to the federal agency that provides partial funding to the Medicaid and CHIP programs. Brandishing an incorrect interpretation of select provisions of the Social Security Act, PsychRights alleges that the defendants submitted or caused to be submitted claims that were not supposed to be covered by the Medicaid program and CHIP. Although physicians may prescribe medications off-label (i.e., for indications or conditions beyond those specifically approved by the FDA), PsychRights claims that defendants should have not provided those medications to Medicaid or CHIP patients.[5]

Regardless of whether PsychRights's theory could be legally valid, this Court has no jurisdiction over this case under the FCA's public disclosure bar. First, PsychRights is alone in

[4] *See Law Project for Psychiatric Rights v. State of Alaska, et al.*, No. 3AN 08-10115 CI (Alaska Sup. Ct. 3rd Judicial Dist., June 17, 2009) *appeal docketed*, No. S-13558 (Alaska June 30, 2009) (seeking declaratory and injunctive relief that Alaskan children have the right not to be administered psychotropic drugs unless and until certain requirements are met).

[5] This theory is expressed only in the broadest sense in the Complaint. As noted in Defendants' Rule 9(b) Motion To Dismiss, the Complaint fails to specify any particular patient, prescription, or claim.

representing the federal government here. The U.S. Department of Justice chose not to intervene in the case.[6]

Second, the allegations in this case were publicly disclosed long before PsychRights filed its Complaint. Letters from 2007 and 2008 between the State of Utah and the Federal Centers for Medicare & Medicaid Services ("CMS"), which even appear on PsychRights's website, addressed precisely the issue about which PsychRights complains. The internet offers many public reports alleging that physicians have been over-medicating pediatric patients, including Medicaid beneficiaries, with psychotropic agents and have been using the medications for off-label purposes not supported by the relevant drug compendia. Public reports, including PsychRights's previously filed state-court lawsuit against the State of Alaska and other previously filed cases, also leave no doubt that Medicaid knowingly paid for this type of prescribed medication. On top of these publicly disclosed allegations, PsychRights merely

[6] The Justice Department may have chosen to decline intervention because the Centers for Medicare & Medicaid Services ("CMS") has expressly sanctioned the submission of the types of claims that PsychRights challenges here. *See* 2007-08 correspondence between Utah and CMS, Ex. 2 ("Section 1927 of the Social Security Act (the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations. Section 1927(d) of the Act authorizes States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in section 1927(k)(6) of the Act), however, it does not explicitly require them to do so."); CMS Medicaid Drug Rebate Release No. 141 (May 4, 2006), Ex. 3 ("Section 1927(k)(5) defines 'medically accepted indication' to mean any use for a covered outpatient drug which is approved by the Food and Drug Administration, or a use which is supported by one or more citations included or approved for inclusion in the compendia specified in subsection (g)(1)(B)(II) . . . . The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II). Prior approval policies may be put in place, but prior authorization cannot be used to deny the off-label indications supported by citations included or approved for inclusion in the above-referenced compendia.").

reiterates its and Utah's interpretation of the most public of sources, a statute, to argue that Medicaid (and accordingly CHIP) should not have covered those claims.

Third, PsychRights must, but cannot, show that it was an original source of the public disclosures. As a matter of law, as a corporate organization (rather than an individual), PsychRights cannot be an original source under the FCA. In addition, and putting aside that legal infirmity, the facts doom any claim that PsychRights is an original source. PsychRights makes no claim to have direct or independent knowledge of these allegations and indeed cannot as it was not a Medicaid beneficiary or guardian of one, was not (and did not work for) a physician or a pharmacy, and did not work for either State medical assistance program. PsychRights simply has no direct and independent knowledge of the relevant facts, as the FCA requires.

For these reasons, this Court has no subject matter jurisdiction over this case, and thus, the entire case should be dismissed with prejudice.[7]

II. BACKGROUND

A. Procedural History

PsychRights filed this action on April 27, 2009. (Dkt. #1.) The U.S. government swiftly declined intervention. (Dkt. #14.) The Complaint was unsealed on January 25, 2010. (Dkt. #16.)

B. Public Disclosures

PsychRights's allegations were publicly disclosed prior to PsychRights filing its Complaint in this case.

[7] *See* 31 U.S.C. § 3730(e)(4)(A).

1. Utah and the federal government's investigation and communications.

In 2007-08, the State of Utah's Attorney General's Office and CMS exchanged letters regarding Utah's investigation into the allegation that "many state Medicaid programs are liberally reimbursing – and presumably receiving Federal Financial Participation ('FFP') – for outpatient drugs used for indications that are neither FDA-approved nor supported in the relevant compendia."[8] PsychRights's own website contains this series of letters.[9] These letters specifically described (and notified CMS of) the type of fraudulent conduct that PsychRights alleges in this case. CMS, however, concluded that the provision of the Social Security Act cited by Utah (and PsychRights in this case) "authorizes" but "does not explicitly require" "States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in section 1927(k)(6) of the Act . . . ."[10]

2. PsychRights's dismissed case against Alaska.

In September 2008, PsychRights filed a lawsuit in the Alaska superior court against the State of Alaska seeking declaratory and injunctive relief to prevent the administration of psychotropic drugs to Alaskan children unless and until: (1) evidence-based psychosocial interventions have been exhausted; (2) benefits of the drugs outweigh the risks; (3) the person

[8] Ex. 2.

[9] PsychRights.org, PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth, http://psychrights.org/education/ModelQuiTam/ModelQuiTam.htm#UtahAG, (last visited April 5, 2010), Ex. 4.

[10] Ex. 2.

authorizing administration of the drugs is fully informed of the risks and benefits; and (4) monitoring safeguards are in place.[11]

In its amendment to the complaint filed on November 24, 2008, PsychRights made the exact allegation that it is making in this case:

> 22. It is unlawful to for the State to use Medicaid to pay for outpatient drug prescriptions except for indications approved by the Food and Drug Administration (FDA) or included in the following compendia:
>
> (a) American Hospital Formulary Service Drug Information,
>
> (b) United States Pharmacopeia-Drug Information (or its successor publications), or
>
> (c) DRUGDEX Information System.[12]

PsychRights further alleged in that case that Alaska Medicaid did, in fact, authorize these alleged illegal claims.[13]

PsychRights's state court case also contains several other allegations that demonstrate that the allegations in its current complaint were previously publicly disclosed. Indeed, paragraphs 23-30 of the Amended Complaint describe Alaska state legislature hearings from as early as 2004 concerning the use of allegedly unapproved psychotropic medications on children in state custody.[14] Additionally, in its Amended Complaint, PsychRights candidly states that

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[11] ¶ 1 of April 3, 2009 Amended Complaint in *Law Project for Psychiatric Rights v. State of Alaska, et al.*, No. 3AN 08-10115 CI, Ex. 5.

[12] Amend. to ¶¶ 22, 236 of Complaint, Ex. 6.

[13] Ex. 5, ¶¶ 218-36.

[14] *Id.* ¶¶ 23-30.

most of the allegations relating to the allegedly improper use of psychotropic medications on children were taken from the "Critical Think Rx Curriculum," which was developed and published as part of the "Critical Think Rx" program under a grant from the Attorneys General Consumer and Prescriber Grant Program of which the Attorney General of the State of Alaska is a participant.[15]

PsychRights's case was dismissed by the superior court because PsychRights lacked standing to assert this cause of action.[16] PsychRights appealed the dismissal, and the appeal is currently fully briefed before the Alaska Supreme Court.[17]

3. Other court cases

Previous cases have also included allegations that allegedly false claims for off-label, non-compendium drug prescriptions have been paid by Medicaid. Most notably, in *United States ex rel. Franklin v. Parke-Davis*, No. 96-11651-PBS, 2003 U.S. Dist. LEXIS 15754 (D. Mass. Aug. 22, 2002), the relator alleged that claims for off-label, non-compendium supported uses of the drug Neurontin (one of the drugs named in PsychRights's Complaint) to the 50 state Medicaid programs (including Alaska Medicaid) constituted "false" claims for purposes of the FCA.[18] The defendant in that case, the relator's former employer, Parke-Davis, was alleged to have promoted Neurontin for uses not approved by the FDA which resulted in the alleged

[15] *Id.* ¶¶ 31-36.

[16] *Id.*

[17] *See Law Project for Psychiatric Rights v. State of Alaska, et al.*, No. S-13558 (Alaska).

[18] *Parke-Davis*, 2003 U.S. Dist. LEXIS 15754, at 1-2.

ineligible Medicaid payments for the drug.[19] As in this case, the government declined to intervene in *Parke-Davis*.[20]

4. News reports of alleged inappropriate off-label use of psychotropics on pediatric Medicaid beneficiaries.

Numerous reports in the news media have commented about the allegedly inappropriate off-label use of psychotropic medications on children, while also pointing out that these children are often Medicaid recipients. The following are just a small sample of these articles:

- *Johnny get your pills — Are we overmedicating our kids*, Salon.com (June 17, 1999) (available at http://www.salon.com/health/feature/1999/06/17/antidepressants) ("In Michigan, in 1996, investigators looking through records of state Medicaid patients found 157 children aged 3 or younger who had been given any of 22 different psychotropic medications for attention deficit disorder.") (Ex. 7);

- *Attention Deficit: Is it in the Genes?*, Business Week (Nov. 22, 1999) (available at http://www.businessweek.com/archives/1999/b3656091.arc.htm) ("researchers reviewed 15 months' worth of Medicaid billing records and found that 233 children between the ages of one and three were diagnosed with ADHD. . . [N]early 60% of those toddlers were treated with psychotropic medications such as Ritalin and Prozac, though little is known about the impact of such drugs on children so young.") (Ex. 8);

- *Some infants get medication despite advice of experts*, Chicago Sun-Times (Apr. 21, 2002) ("A study published in the Journal of the American Medical Association in 2000 found that almost 1.5 percent of children 2 to 4 enrolled in Medicaid programs and a particular managed care group were taking psychotropic drugs such as Ritalin or Prozac, an anti-depressant'" for off-label uses.) (Ex. 9);

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[19] *Id.*

[20] *Id.* at *2. The *Parke-Davis* court never specifically resolved the question of whether off-label non-compendium prescriptions can be reimbursable under Medicaid, but it did indicate that relator's interpretation of the relevant statutes was likely incorrect and that defendant's interpretation that states may choose to exclude or include these types of claims was better supported by the basic rules of statutory construction. *Id.* at *7-8.

- *The Psychotropic Drugging of Florida's Medicaid Children*, Citizens Commission on Human Rights of Florida (2006)(available at http://www.cchr.org/media/pdfs/The_Psychotropic_Drugging_of_Floridas-Medicaid_Children.pdf ("most off-label prescriptions for children may not be covered under Medicaid, and such reimbursements constitute Medicaid fraud.") (Ex. 10);

- *Tyke-Psych Push*, The New York Post (March 9, 2008) ("New York's Medicaid program paid nearly $90 million in 2006 for two dozen psychiatric drugs for kids . . .most have not been tested adequately on kids or approved by the Food and Drug Administration for their use. Doctors may prescribe them to children or teens 'off-label.'") (Ex. 11); and

- *Rep. McDermott announces hearing on utilization of psychotropic medication for children in foster care*, US Fed News (Mar. 12, 2008) ("One recent study found that psychotropic drug treatment was three or four times more common for youth in foster care than for other children receiving health care services through the Medicaid program. Additionally, children in foster care are often prescribed multiple psychotropic medications, and sometimes these drugs are used for off-label purposes . . . .") (Ex. 12).

Several articles describe an investigation into the off-label use of psychotropic drugs for children, launched by the Texas Comptroller Carole Keeton Strayhorn, as a head of a Medicaid fraud task force.[21]

III. ARGUMENT

The FCA's public disclosure bar denies courts subject matter jurisdiction over suits based on "allegations or transactions" that have been "public[ly] disclos[ed]," unless the relator "is an

[21] *See, e.g.*, *Drug fraud alleged in foster care*, The Dallas Morning News (Nov 13, 2004), Ex. 13; *Strayhorn to investigate alleged drug fraud in foster care*, Associated Press (Nov. 12, 2004), Ex. 14; *Comptroller Strayhorn's response to statement by Texas Medical Association, States News Service* (Nov. 12, 2004), Ex. 15; *Texas comptroller to investigate possible prescription drug fraud abuse*, The Brownsville Herald (Nov. 13, 2004), Ex. 16.

original source of the information."[22] Accordingly, the "threshold question in a False Claims Act case is whether the statute bars jurisdiction."[23] This is a two-tiered inquiry: (1) the court must first determine whether there has been a prior public disclosure; and (2) if there has been such a public disclosure, the court then must determine whether the relator is an "original source" of each public disclosure within the meaning of Section 3730(e)(4)(B).[24] The relator bears the burden of establishing subject matter jurisdiction.[25]

A. The Complaint's Allegations Were Previously Publicly Disclosed.

The Ninth Circuit uses a two-part test to determine if there has been a public disclosure under the FCA. First, the court determines whether the public disclosure originated in one of the sources enumerated in the statute:[26]

- A criminal, civil, or administrative hearing, including prior civil complaints brought by the same relator.[27]
- A federal or state congressional, administrative or government report, hearing, audit, statement, or investigation.[28]

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[22] 31 U.S.C. § 3730(e)(4)(A). *See also Graham County Soil and Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. ___, No. 08-304, slip. op. at 11 (Mar. 30, 2010) ("It is the fact of 'public disclosure'—not Federal Government creation or receipt—that is the touchstone of § 3730(e)(4)(A).").

[23] *U.S. ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13, 20 (1st Cir. 2009) (citing *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 727 (1st Cir. 2007)).

[24] *See Meyer*, 565 F.3d at 1199.

[25] *Id.*

[26] *Id.*; 31 U.S.C. § 3730(e)(4)(A).

[27] *See Meyer*, 565 F.3d at 1199; *United States ex rel. Bly-Magee v. Premo*, 470 F.3d 914, 917 (9th Cir. 2006).

- The "news media," which includes newspapers, magazines, and other publications that "disseminate information to the public in a periodic manner" and "are as generally accessible to any other strangers to the fraud as would be a newspaper article."[29]

A disclosure to even one individual outside of the government makes the disclosure "public."[30] Furthermore, the "elements of the fraud allegation need not be made public in a single document,"[31] but rather can come from multiple sources, which are "considered as a whole."[32]

Second, if the first part of the test is met, the court must determine whether the complaint is "based upon" the public disclosure.[33] "[A] claim is 'based upon' a public disclosure when the claim repeats allegations that have already been disclosed to the public."[34] The publicly

(continued…)

[28] *See Bly-Magee*, 470 at 917-18 (following the 8th Circuit in holding that non-federal reports, audits, and investigations qualify as public disclosures); *see also Hays v. Hoffman*, 325 F.3d 982, 988 (8th Cir. 2003) (Medicaid audits prepared by a state agency qualify as public disclosures).

[29] *United States ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc.*, 186 F. Supp. 2d 458, 463 (S.D.N.Y. 2002), *aff'd*, 53 F. App'x 153 (2d Cir. 2002).

[30] *See Seal 1 v. Seal A*, 255 F.3d 1154, 1161-62 (9th Cir. 2001).

[31] *United States v. Catholic Healthcare W.*, 445 F.3d 1147, 1152 n.1 (9th Cir. 2006).

[32] *United States ex rel. Reagan v. E. Tex. Med. Ctr. Reg'l Healthcare Sys.*, 384 F.3d 168, 174 n.8 (5th Cir. 2004); *see also Dingle v. Bioport Corp.*, 388 F.3d 209, 214 (6th Cir. 2004) ("The fact that the information comes from different disclosures is irrelevant."); *A-1 Ambulance Serv., Inc. v. Cal.*, 202 F.3d 1238, 1244-45 (9th Cir. 2000) (holding that, when taken together, the contents of multiple administrative proceedings were sufficient to constitute public disclosure).

[33] 31 U.S.C. § 3730(e)(4)(A).

[34] *United States ex rel. Biddle v. Bd. of Trustees of Leland Stanford, Jr. Univ.*, 161 F.3d 533, 536-40 (9th Cir. 1998) (rejecting relator's argument that "based upon" means "derived from," and affirming district court's dismissal of case for lack of subject matter jurisdiction).

disclosed facts need be only substantially similar to, not identical with, the relator's allegations.[35] Defining "substantially similar," the Ninth Circuit has held that, "the substance of the disclosure need not contain an explicit 'allegation' of fraud; the jurisdictional bar is raised so long as the material elements of the allegedly fraudulent 'transaction' are disclosed in the public domain."[36] A disclosure meets this requirement if it "'set[s] the government squarely on the trail of fraud' such that it would not have been difficult for the government to identify [the defendant] as a potential wrongdoer."[37]

1. The investigation and communications by Utah and CMS are public disclosures.

The letters between Utah and CMS pre-date the Complaint in this case and discuss a government investigation, which is a category of public disclosures specifically listed in the FCA.[38] Furthermore, PsychRights' possession of the letters (and their public display on its website) proves that the allegations were publicly disclosed.[39] There can be no doubt that

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[35] *See Meyer*, 565 F.3d at 1199; *United States ex rel. Lujan v. Hughes Aircraft Co*., 243 F.3d 1181, 1189 (9th Cir. 2001).

[36] *A-1 Ambulance Serv.*, 202 F.3d at 1243.

[37] *In re Pharm. Indus. AWP Litig.*, 538 F. Supp.2d 367, 383 n.10 (N.D.N.Y. 2008) (citing authorities); *see also In re Nat. Gas Royalties Qui Tam*, 562 F.3d 1032, 1043 (10th Cir. 2009); *United States ex rel. Gear v. Emergency Med. Assocs. Ill., Inc.* 436 F.3d 726, 729 (7th Cir. 2006) ("We are unpersuaded by an argument that for there to be public disclosure, the specific defendants named in the lawsuit must have been identified in the public records.").

[38] While the federal government participated in that investigation, the letters are public disclosures even if they are classified as reflecting a state investigation. *See Graham County Soil*, slip op. at 12 (holding that the FCA public disclosure bar included state and local reports, audits, and investigations).

[39] *See Seal 1*, 255 F.3d at 1161-62 (disclosures of a government investigation to even one individual outside of the government is sufficient to make the disclosure "public").

PsychRights's case is based upon this public disclosure as the investigation and letters were about precisely the same issue raised by PsychRights in this case.

2. The State of Alaska case is a public disclosure.

The Ninth Circuit has specifically held that an earlier complaint brought by the same relator may constitute a public disclosure.[40] PsychRights's state court case disclosed the same allegations that PsychRights makes in the present case.

3. Other court cases, including *Parke-Davis*, are public disclosures.

Again, civil court proceedings are one of the enumerated categories of public disclosures.[41] The *Parke-Davis* case put the federal government squarely on notice that Medicaid claims were being made for off-label, non-compendium supported prescriptions. This is the exact type of alleged fraud that PsychRights pleads in this case seven years later.

4. The myriad articles in the press are public disclosures.

PsychRights cannot contest that the articles cited in Section II, B. 4, *supra*, are public disclosures. They all appeared in the public media. PsychRights even has several of them on its public website, www.psychrights.org. Moreover, the articles disclosed the allegations that PsychRights makes in this case: that psychotropic medications were being prescribed off-label to pediatric patients for indications that may not be listed as approved by the compendia; and that

[40] *See Bly-Magee*, 470 F.3d at 916.

[41] 31 U.S.C. § 3730(e)(4)(A).

many of those prescriptions were dispensed to Medicaid patients and billed to and paid by Medicaid.[42]

B. PsychRights Is Not an Original Source of the Complaint's Allegations.

Because the allegations in the Complaint were publicly disclosed, this Court has no jurisdiction over this case unless PsychRights can demonstrate that it was an original source of these disclosures.[43] PsychRights cannot meet this burden here.

The requirement that a relator be an "original source" of the complaint's allegations is founded on the notion that "[a] whistleblower sounds the alarm; he does not echo it."[44] "[T]he paradigm qui tam case is one in which an insider at a private company brings an action against

[42] The sparse allegations against TR Healthcare derive not from any information discovered by PsychRights, but – as referenced in PsychRights' March 29, 2010 discovery motion – from a 2003 Wall Street Journal article. *See* Dkt. No 80, Ex. 2 (the "WSJ Article"). The WSJ Article purported to review DrugDex's approach to analyzing off-label uses of drugs and noted that TR Healthcare also offered continuing medical education services ("CME") (a business that it is no longer engaged in). Plaintiff's few factual allegations in the Complaint relating to TR Healthcare are pulled practically verbatim from the WSJ Article. *Compare* Compl. ¶ 193 ("One of Thomson's scientific and health-care division's biggest operations is running continuing medical education seminars paid by pharmaceutical companies which promote off-label prescribing of such drug companies' drugs ….") *with* WSJ Article ("One of the division's biggest operations is running "continuing medical education" seminars for the pharmaceutical industry … Off-label uses of drugs are a frequent topic at medical-education seminars."), Compl. ¶ 192 ("In 2002, Thomson's scientific and health-care divisions, which includes DRUGDEX, accounted for $780 million of Thomson's $7.8 Billion in revenue.") with WSJ Article ("Thomson's scientific and health-care divisions, which includes DrugDex, accounted for $780 million of the company's $7.8 billion in revenue last year."). Aside from the facts taken from the WSJ Article, the Complaint is devoid of any facts relating to TR Healthcare.

[43] *See* 31 U.S.C. § 3730(e)(4).

[44] *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1475 (9th Cir.) (quotation omitted); *see also United States ex rel.O'Keeffe v. Sverdup Corp.*, 131 F. Supp. 2d 87, 93 (D. Mass. 2001) (noting that "there may be a point at which a private investigator 'should be termed a busybody and turned away at the courthouse steps'") (quoting *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1017 (7th Cir. 1999)).

his own employer."[45] "Legislative history also suggests that Congress envisioned only this paradigm suit when enacting this version of the *qui tam* provisions."[46]

In light of these policy concerns, Congress defined "original source" under the FCA as follows: "an *individual* who has *direct and independent knowledge* of the information on which the allegations are based and has *voluntarily provided the information to the Government* before filing an action under this section which is based on the information."[47]

The Ninth Circuit adds to this standard that the relator must have "had a hand in the public disclosure of the allegations that are part of [its] suit."[48] Thus, the Ninth Circuit has summarized the standard as follows:

> To qualify as an original source, a relator must show that he or she [1] has direct and independent knowledge of the information on which the allegations are based, [2] voluntarily provided the information to the government before filing his or her qui tam action, and [3] had a hand in the public disclosure of allegations that are a part of . . . [the] suit.[49]

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[45] *United States ex rel. Fine v. Chevron, U.S.A., Inc.*, 72 F.3d 740, 742 (9th Cir. 1995).

[46] *Id. See also United States v. Johnson Controls, Inc.*, 457 F.3d 1009, 1017 (9th Cir. 2006) (with the FCA Congress meant to encourage whistleblowers who were aware of fraud against the government, but "discourage 'parasitic' suits brought by individuals with no information of their own to contribute"); *Wang v. Johnson Controls., Inc.*, 975 F.2d at 1412, 1419 (9th Cir. 1992) ("Q*ui tam* suits are meant to encourage insiders privy to a fraud on the government to blow the whistle on the crime.").

[47] 31 U.S.C. § 3730(e)(4)(B) (emphasis added). *See also Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 467-79 (2007) (finding that the relator was not an original source under the meaning of the statute).

[48] *United States ex rel. Zaretsky v. Johnson Controls, Inc.*, 457 F.3d 1009, 1013 (9th Cir. 2006) (quoting *Wang v. FMC Corp*., 975 F.2d 1412, 1418 (9th Cir. 1992)).

[49] *Lujan v. Hughes Aircraft Co*., 162 F.3d 1027, 1033 (9th Cir. 1998) (internal quotation marks omitted).

Here, PsychRights cannot show that it is an "original source" of the information contained in the Complaint. First, as a preliminary manner, PsychRights is not an individual and therefore cannot be an "original source" under the statute's plain language. Second, PsychRights – an advocacy organization, and not a Medicaid beneficiary, a physician, or a pharmacy or Medicaid employee – cannot show that it has the requisite direct and independent knowledge of the allegations in its Complaint. Finally, relator did not, as required, have a hand in many of the public disclosures of allegations underlying this suit.

1. PsychRights, as a corporate entity, cannot be an "original source" under the FCA.

PsychRights, a corporation, is not an "individual" and therefore cannot be an original source under the FCA. The FCA draws this distinction between "person," which includes a corporation, and "individual," which does not. The statute permits that "a person may bring a civil action" under the FCA, that "a person shall have the right to continue as a party to the action" if the Government does not intervene and that there is no jurisdiction over publicly-disclosed allegations unless "the person bringing the action is an original source of the information."[50] The FCA's next subparagraph makes clear, however, that "'original source' means an individual who has direct and independent knowledge . . . ."[51]

The term "person" under the FCA is statutorily defined to "include corporations, companies, associations, firms, partnerships, societies, and joint stock companies, as well as

[50] 31 U.S.C. § 3730(b)(1), (c)(1), (e)(4)(A).

[51] *Id.* § 3730(e)(4)(B).

individuals."[52] As the statutory definition of "person" indicates, an "individual" is distinct from a "corporation," and therefore cannot be a "corporation."[53] Indeed, the First Circuit found that similar language in a statute that likewise "define[d] 'person' to include 'individuals, partnerships, and corporations," showed that "the term [individual] was not meant to include corporations."[54]

Congress's decision to avoid the standard term "person" in 31 U.S.C. § 3730(e)(4)(B) and instead require an original source to be an "individual" must be presumed as meaningful and deliberate, particularly given its repeated use of the more-inclusive term "person" elsewhere in the same section and paragraph.[55] Indeed, such a requirement is logical given that an original source must have "direct," and not second-hand, knowledge of the information upon which the claims are based.[56]

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[52] 1 U.S.C. § 1; *see also, e.g.*, *Vt. Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 782 (2000) (looking to 1 U.S.C. § 1 in defining scope of term "person" under FCA).

[53] *See* 1 U.S.C. § 1.

[54] *In re Spookyworld, Inc.*, 346 F.3d 1, 7 (1st Cir. 2003). *See also Lee v. ABC Carpet & Home*, 236 F.R.D. 193, 198 (S.D.N.Y. 2006) (holding that where the statutory term "person" was defined as "an individual, partnership, association, [or] corporation," the term "'individual' . . . does not include corporations").

[55] *See* 1 John T. Boese, *Civil False Claims and* Qui Tam *Actions*, § 4.02[D], at 4-108.8 (3d ed. 2009-1 supp.) (noting that an "organization may be absolutely barred from bringing suits in cases of public disclosure," as "the original source rule does not refer to the relator as the 'person' . . . but as the 'individual'").

[56] *O'Keeffe*, 131 F. Supp. 2d at 95.

Likewise, defining an "original source" as an "individual" is consistent with the "paradigm of the inside whistleblower" that the False Claims Act is to encourage.[57] By contrast, the legislative history does not discuss anything that could overcome the presumption that the use of the term "individual" rather than "person" was deliberate.

Given that language and the policy considerations, PsychRights is not, by definition, an original source of the Complaint's allegations.

2. PsychRights cannot be an original source because it does not have direct and independent knowledge of the facts alleged in its complaint and did not have a hand in the public disclosures.

Even if PsychRights could qualify as an original source, the court would still lack jurisdiction because PsychRights lacks the requisite "direct and independent knowledge of the information on which the allegations are based,"[58] and did not have "'a hand in the public disclosure of the allegations that are part of [his] suit.'"[59]

To prove direct knowledge, "the relator must show that he had firsthand knowledge of the alleged fraud, and that he obtained this knowledge through his own labor unmediated by anything else."[60] To prove independent knowledge, the relator must have had knowledge "about

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[57] *Id.* at 93.

[58] 31 U.S.C. § 3730(e)(4)(B); *see also Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 471-472 (2007).

[59] *Zaretsky*, 457 F.3d at 1013 (alteration in original) (quoting *Wang v. FMC Corp.*, 975 F.2d 1412, 1418 (9th Cir. 1992)); *see also Lujan*, 162 F.3d at 1033.

[60] *Meyer*, 565 F.3d at 1202 (quoting *Alcan Elec. & Eng'g, Inc.*, 197 F.3d 1014, 1020 (9th Cir. 1999)); *see also Bly-Magee*, 470 F.3d at 917 (rejecting claim that relator was original source through her investigation as executive director of the Southern California Rehabilitation Services because she failed "to show that she had direct knowledge of a scheme to submit false claims").

the allegations before that information [was] publicly disclosed."[61] "Secondhand information, speculation, background information, or collateral research do not satisfy a relator's burden of establishing the requisite knowledge."[62] Likewise, "[t]he fact that a relator has background information or unique expertise allowing him to understand the significance of publicly disclosed allegations and transactions is also insufficient."[63] Perhaps most important for this case:

> [A] person who obtains secondhand information from an individual who has direct knowledge of the alleged fraud does not himself possess direct knowledge and therefore is not an original source. [T]o be independent, the relator's knowledge must not be derivative of the information of others, even if those others may qualify as original sources.[64]

PsychRights clearly was not, and could not have been, an original source of the information alleged in the Complaint. Notably absent from the Complaint is the kind of direct and independent knowledge that an original source would have (and not coincidentally the kind of information needed to satisfy Rule 9(b)): The facts showing exactly who, what, where, when, how and why.

The only individuals involved in the alleged fraudulent transaction are the nurses and doctors who saw the patients and wrote the prescriptions, the Medicaid beneficiaries who received the prescriptions, the pharmacists who dispensed the prescriptions, and the Medicaid officials who approved and pay the claims. PsychRights is none of these. It appears that,

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[61] *Meyer*, 565 F.3d at 1202.

[62] *In re Natural Gas Royalties*, 562 F.3d 1032, 1045 (10th Cir. 2009).

[63] *Id.*

[64] *Hays*, 325 F.3d at 990-91 (internal quotations and citations omitted).

instead, PsychRights learned about children being prescribed psychotropic medications, off-label, through the media or through some other indirect means. PsychRights simply deduced that Medicaid was allegedly improperly paying for these claims from the public fact that many of the children prescribed these medications are covered by Medicaid and from its purported (albeit incorrect) understanding of the law concerning Medicaid payments for off-label uses of medications. This simply does not constitute direct and independent knowledge under the FCA.[65] Finally, Psych Rights did not have a "hand" or "play a role" in the Utah-CMS communications or the articles.[66]

IV. CONCLUSION

The FCA's public disclosure bar precludes subject matter jurisdiction in this case. For the reasons stated in this memorandum, the Court should dismiss the Complaint with prejudice.

DATED: April 5, 2010

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[65] *See, e.g., Natural Gas*, 562 F.3d at 1045.

[66] *See United States v. Johnson Controls, Inc.*, 457 F.3d 1009, 1018 (9th Cir. 2006). That PsychRights had a hand in its previous amended allegations in its state court case is wholly inadequate. PsychRights otherwise fails to meet the requirements to be an original source of those allegations.

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CERTIFICATE OF SERVICE

I hereby certify that on the 5th day of April, 2010, a copy of the foregoing **Memorandum in Support of Motion to Dismiss under Rules 12(b)(1) ad 12(h)(3) for Lack of Subject Matter Jurisdiction Under the False Claims Act's Public Disclosure Bar, 31 U.S.C. § 3730(e)(4)(a)** was served electronically on Allen Frank Clendaniel; Brewster H. Jamieson; Carolyn Heyman-Layne; Cheryl Mandala; Daniel W. Hickey; David B. Robbins; Evan Craig Zoldan; Gary M. Guarino; Howard S. Trickey; James B. Gottstein; James E. Torgerson; John J. Tiemessen; Matthew K. Peterson; Linda Johnson; Matthew W. Claiman; R. Scott Taylor; Renee M. Howard; Richard D. Monkman; Kay E. Maassen Gouwens; Robert C. Bundy; Sanford M. Gibbs; Stacie L. Kraly, Vance A. Sanders and Howard A. Lazar.

s/ Jeffrey M. Feldman

MOTION TO DISMISS UNDER RULE 12(b)(1) AND 12(h)(3) FOR LACK OF SUBJECT MATTER JURISDICTION UNDER THE FALSE CLAIMS ACT'S PUBLIC DISCLOSURE BAR 31 U.S.C. § 3730(E)(4)(A)

INDEX TO EXHIBITS

PsychRights®

Law Project for Psychiatric Rights

The Law Project for Psychiatric Rights (PsychRights) is a non-profit, tax exempt 501(c)(3) public interest law firm whose mission is to mount a strategic legal campaign against forced psychiatric drugging and electroshock in the United States akin to what Thurgood Marshall and the NAACP mounted in the 40's and 50's on behalf of African American civil rights. The public mental health system is creating a huge class of chronic mental patients through forcing them to take ineffective, yet extremely harmful drugs.

There are now two ways to make on-line tax deductible donations

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DONATE NOW THROUGH Network for Good

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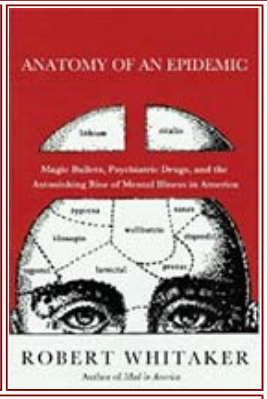
Currently, due to massive growth in psychiatric drugging of children and youth and the current targeting of them for even more psychiatric drugging, PsychRights has made attacking this problem a priority. Children are virtually always forced to take these drugs because it is the adults in their lives who are making the decision. This is an unfolding national tragedy of immense proportions.

Anatomy of an Epidemic: Magic Bullets, Psychiatric Drugs, and the Astonishing Rise of Mental Illness in America, by Robert Whitaker, to be published April 13, 2010.



NARPA 2010 Annual Rights Conference
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Recent News/Highlighted Items

- *United States ex rel Law Project for Psychiatric Rights v. Matsutani, et al.*, USDCAK Case No. 3:09-cv-80-TMB
  - Massive Medicaid Fraud Lawsuit Unsealed, January 25, 2010.
  - PsychRights Files for Order Prohibiting State of Alaska from Continuing to Perpetrate Medicaid Fraud, March 25, 2010.
  - Lawyer takes on psychiatric industry for over-prescribing foster children, by Rhonda McBride, *KTUU*, February 11, 201
- PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth
  - Model Complaint
  - Medically Accepted Indications Chart
- *Law Project for Psychiatric Rights v. State of Alaska, et al.* Case No. 3AN 08-10115 CI, a lawsuit to stop the massive over-drug Alaska's children & youth.
  - Alaska Supreme Court oral argument set for April 14, 2010 at 11:00 am, 303 K Street in Anchorage.
- Forced Drugging Defense Package **(4.5 Megabytes)**
  - Microsoft Word version of pleadings
- The "clickable" Whitaker Affidavit
- Dr. Grace E. Jackson Affidavit, including brain damage
- Civil Minutes Order Denying Motion to Dismiss by Sandoz and Eli Lilly on the grounds that the FDA would not have allowed a concerning Prozac's suicide risks and that a generic manufacturer is not allowed to voluntarily revise its warning label, in *Dorse Sandoz, Inc., et al.*, Case No. CV 06-7821, (C.D.Cal., March 26, 2010).Top Scientist Calls for Ethics Cleanup Around "Big Pha

USA Today, March 23, 2010.

- Medicating the military: Use of psychiatric drugs has spiked; concerns surface about suicide, other dangers, by Andrew Tilghma Brendan McGarry, *Army Times*, March 17, 2010.
- FDA Warns Psychiatrist Who Treated Dead Foster Child, by Carol Marbin Miller, *The Miami Herald*, March 16, 2010.
- Pregnant women warned over Prozac risk to foetus, *The London Times*, March 12, 2010.
- J&J Pushed Risperdal for Elderly After U.S. Warning, Files Show, by Margaret Cronin Fisk, Jef Feeley and David Voreacos, *Bloomberg*, March 10, 2010.
- Nursing home drug use puts many at risk Antipsychotics given to some with dementia, by Kay Lazar, Boston Globe, March 8, 2
- Are Veterans Being Given Deadly Cocktails to Treat PTSD? by Martha Rosenberg, *AlterNet*, March 6, 2010.
- It's not too late to save 'normal':Psychiatry's latest DSM goes too far in creating new mental disorders, by Allen Frances, *Los An Times* (opinion), March 1, 2010.
- Cold Case Files - Paxil Birth Defects, by Evelyn Pringle, *Scoop*, March 2, 2010
- New York Is Ordered to Move Mentally Ill Out of Group Homes, by A.G. Sulzberger, *The New York Times*, March 1, 2010.
  - Court Decision, March 1, 2010
  - Court Order, March 1, 2010
- AstraZeneca Tied Studies to Marketing, Witness Says, by Jef Feeley and Margaret Cronin Fisk, Business Week, February 23, 2(
- Mother Guilty of Murder--Pediatric Bipolar Disorder Innocent, by By Lawrence Diller, M.D., *Psychology Today*, February 20, 2
- Suing Doctors Who Use Drugs as Chemical Straitjackets for Children, *Alison Bass Blog*, February 8, 2010.
- Child Psychiatric Diagnosis on Trial, by Peter Aldhous, *New Scientist*, February 16, 2010.
- Revising Book on Disorders of the Mind, by Benedict Carey, *The New York Times*, February 10, 2010.
- Ghostwriting at Elite Academic Medical Centers in the United States, by Jeffrey R. Lacasse, Jonathan Leo, *Public Library of Sc* (PLoS), Vol 7, Iss 2 (2010).
- AstraZeneca Facing 26,000 Lawsuits Over Seroquel, by Jeff Feeley and Margaret Cronin Fisk, *Bloomberg News*, February 3, 20
- Unsealed or Otherwise Formerly Confidential Documents
- Forced Drugging of Bill Bigley
  - One Drug, Two Faces, *New York Times*, March 25, 2008.
- The Zyprexa Papers Scandal
- Involuntary Commitment and Forced Psychiatric Drugging in the Trial Courts: Rights Violations as a Matter of Course, by Jame (Jim) Gottstein, 25 *Alaska L. Rev.* 51 (2008).
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- Report on Multi-Faceted Grass-Roots Efforts To Bring About Meaningful Change To Alaska's Mental Health Program
- *Bigley v. Alaska Psychiatric Institute*, S-13116, Alaska Supreme Court Opinion No. 6374, May 22, 2009.
- *Wetherhorn v. Alaska Psychiatric Institute*, Opinion No. 6091, ruling Alaska's gravely disabled criteria unconstitutional (requiri state prove the person unable to survive safely in freedom).
- *Myers v. Alaska Psychiatric Institute*, Opinion No. 6021, June 30, 2006, ruling Alaska's forced psychiatric drugging regime unconstitutional.
- Anatomy of an Epidemic: Psychiatric Drugs and the Astonishing Rise of Mental Illness in America, by Robert Whitaker, *Ethica Psychology and Psychiatry*, Volume 7, Number I: 23-35 Spring 2005.
- Jim Gottstein Legal Defense Fund
- MindFreedom Shield Program
- Allen Jones' Full Whistle-Blower Report on Drug Company influence on states' drug purchases.

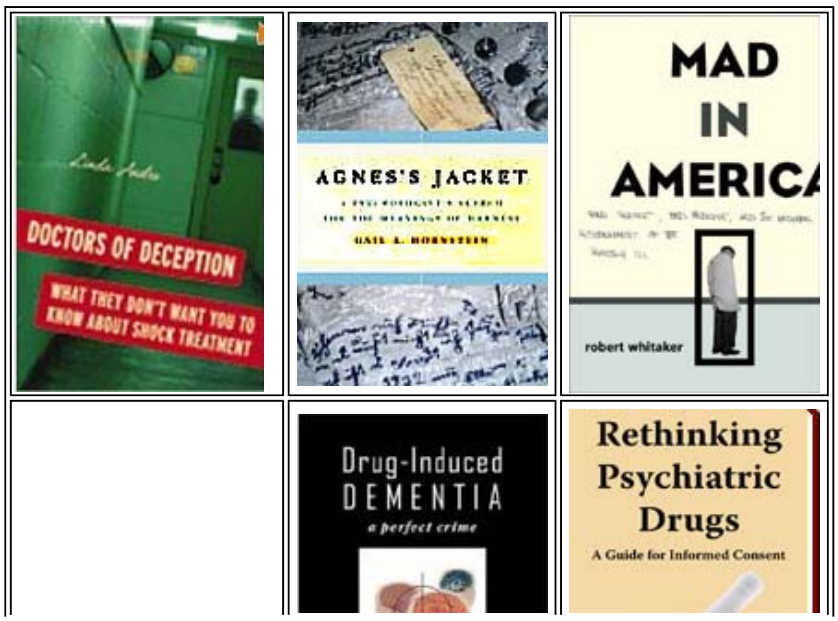
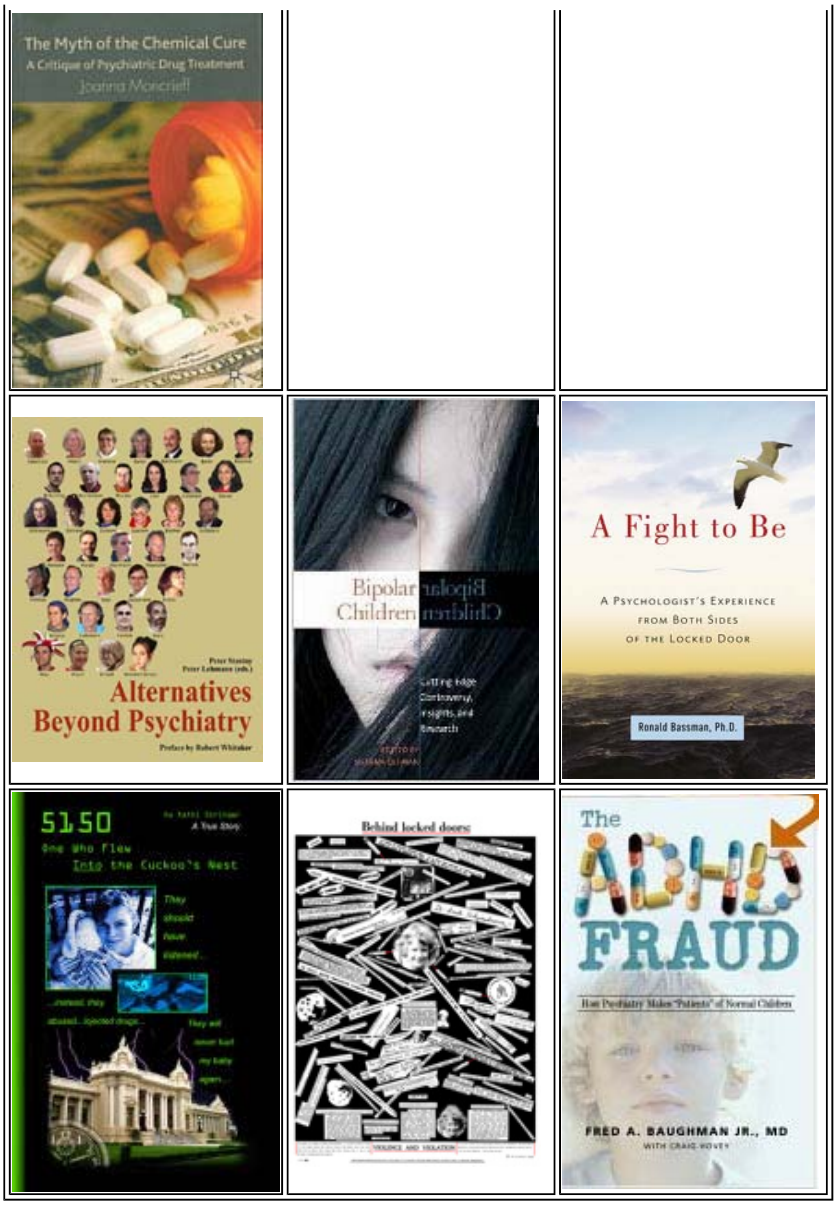


Exhibit 1, Page 2 of 3
Motion to Dismiss Under
Rule 12(b)(1) and 12(h)(3)
Case No. 3:09-cv-00080-TMB



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Re: Request for clarification regarding Medicaid "covered outpatient drugs"

Dear Dr. Phurrough:

In working on state actions recently against various pharmaceutical manufacturers for off-label promotion causing the filing of false Medicaid claims, it has come to our attention that many state Medicaid programs are liberally reimbursing -- and presumably receiving Federal Financial Participation ("FFP") -- for outpatient drugs used for indications that are neither FDA-approved nor supported in the relevant compendia. Clarification on the permissible scope of FFP-eligible reimbursement by state Medicaid programs for covered outpatient drugs is critically important.

More specifically, §1927 of the Social Security Act (42 U.S. Code §1396r-8, often referred to as OBRA '90) provides:

- in subsection (k)(3) that the term "covered outpatient drug" excludes "a drug or biological used for a medical indication which is not a medically accepted indication."
- in subsection (k)(6) that the term "medically accepted indication" means any use approved by the FDA or "supported" in one or more specified compendia
- in subsection (g)(1)(B)(i) that the specified compendia are American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications) and the DRUGDEX Information System

ISSUE #1: ***Does CMS interpret federal law to restrict FFP for state Medicaid programs to uses of otherwise "covered outpatient drugs" that are either FDA-approved or supported in the specified compendia?***

ISSUE #2: ***If the answer to question #1 is yes, has the federal government delegated to the states any authority to approve exceptions, i.e., to expand FFP-eligible Medicaid prescription drug coverage?*** *(e.g., May a state grant its Drug Utilization Review Board the authority to approve FFP-eligible Medicaid reimbursement for off-label indications not supported in the specified compendia?)*

Your clarification regarding these Medicaid drug coverage issues is respectfully requested.

Very truly yours,

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/DRS

cc: David Frank, Director, Medicaid Integrity Group

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December 17, 2007

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Re: Improper Off-Label Indications - definition of "covered outpatient drugs"

Dear Mr. Smith:

Thank you for your reply dated December 6, 2007, in which you stated that "the Social Security Act does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter," namely for uses other than "medically accepted indications" (i.e., for uses not FDA-approved or "supported" in the specified compendia).

With all due respect, I beg to differ and direct your attention to Section 1927(k)(3) regarding a specific exception to the definition of "covered outpatient drug." In pertinent part it states that the term "covered outpatient drug" (which would otherwise be eligible for Medicaid Federal Financial Participation) **does not include "a drug or biological used for a medical indication which is not a medically accepted indication.**"

This federal statute defining the term "covered outpatient drug" clearly delineates that Medicaid drugs are covered only so long as they are used for "medically accepted indications." Congress apparently intended that Medicaid not be so restrictive as to prohibit all off-label use, but that it not be so expansive as to cover experimental uses not yet medically accepted. The criterion Congress chose for permissible off-label use was that the particular use be "supported" in at least one of the specified compendia [(k)(6)].

Frankly, I do not see how CMS can ignore this unambiguous statutory definition of "covered outpatient drug." I conclude from your letter that CMS, while ignoring the clear statutory definition, is focusing on the Limitations subsection (d) that lists permissible restrictions, including prescribed uses not for a medically accepted indication at subsection (d)(1)(B)(i).

ATTORNEY GENERAL'S OFFICE • MEDICAID FRAUD CONTROL UNIT • 5272 SO. COLLEGE DRIVE, #200 • MURRAY, UTAH 84123 • TEL: (801) 281-1259 • FAX: (801) 281-1250

Apparently an inference is being drawn from this subsection that, since a State may exclude coverage for a prescribed use that is not a medically accepted indication, it is not required to do so. But for the clear, unambiguous definition of "covered outpatient drug," it would appear to be reasonable to draw such an inference; however, as a principle of statutory construction, a mere negative inference from a Limitations section (the purpose of which is to identify restrictions to coverage, not to expand coverage) does not trump a clear delineation of coverage in the definitional section.

I strongly encourage you to run this issue by your legal counsel and am confident that they will conclude that the clear, unambiguous definition of "covered outpatient drug" means that States are eligible for Federal Financial Participation with respect to drugs that are reimbursed only for "medically accepted indications," i.e., only for uses either approved by the FDA or "supported" in the specified compendia.

A "poster child" example of exactly why this issue is important not only for cost considerations, but also for patient safety, is the atypical antipsychotic drug Zyprexa manufactured by Eli Lilly. For about 10 years it has been at or near the highest dollar volume drug reimbursed by Medicaid nationwide. It is only approved for schizophrenia and bipolar disorder in adults, a very narrow segment of the population. It has been widely reported that approximately 50% of utilization is off-label, including for infants and toddlers. Based on recent lawsuit settlements totaling over a billion dollars and involving thousands of Zyprexa users, the drug causes substantial weight gain and diabetes in a significant percentage of cases. In other words, Medicaid is not only paying for a very expensive drug for uses that are not "medically accepted indications," but its reimbursement of this drug is resulting in many Medicaid recipients developing diabetes, a life-threatening condition with many adverse health complications for the individuals and a significant cost burden on taxpayers for treating these complications.

I implore you to look into this drug coverage issue resulting in substantial overpayments and jeopardizing the health and safety of hundreds of thousands of Medicaid recipients.

Very truly yours,

David R. Stallard

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CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations
Disabled and Elderly Health Programs Group (DEHPG)

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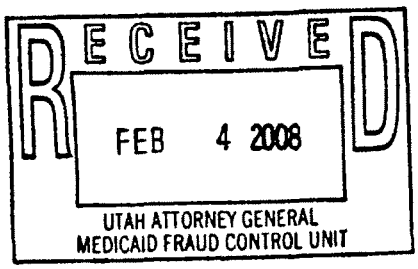

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Dear Mr. Stallard:

Thank you for your letter expressing further concerns regarding the Utah Medicaid Program's coverage of outpatient drugs. I've been asked to respond to you directly since this program area is the responsibility of my group.

I wish to confirm that our previous response to you is correct. As we noted in that response, the State may limit coverage for drugs to medically accepted indications. To verify what Utah has chosen to do for coverage of a particular drug, we again suggest you contact State personnel and review the State's approved State plan and policies on the specific coverage of drugs, including Zyprexa.

I hope this information adequately addresses your concerns.

Sincerely,

for Gale P. Arden
Director

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

DEC 6 2007

RECEIVED
DEC 10 2007
UTAH ATTORNEY GENERAL
MEDICAID FRAUD CONTROL UNIT

David R. Stallard, CPA
Assistant Attorney General
Office of the Attorney General
5272 S. College Drive, #200
Murray, Utah 84123

Dear Mr. Stallard:

Thank you for your recent letter to Dr. Steve E. Phurrough regarding clarification of reimbursement by Medicaid for covered outpatient drugs. Your letter has been forwarded to me for response.

Section 1927 of the Social Security Act (the Act) does not provide definitive policy on the coverage of Medicaid drugs for the uses you describe in your letter, nor have we addressed this issue in implementing Federal regulations. Section 1927(d) of the Act authorizes States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication (as defined in section 1927(k)(6) of the Act), however, it does not explicitly require them to do so. States are responsible for defining this coverage in their approved Medicaid State plan and implementing policies. To determine the indications for the coverage of a drug, you would need to review the State's approved plan and policies on the specific coverage of that drug.

I appreciate your concern regarding the necessity for proper reimbursement under the Medicaid drug program.

Sincerely,

Bill Fasouk for
Dennis G. Smith
Director

May 4, 2006

MEDICAID DRUG REBATE PROGRAM **RELEASE #141**

For State Medicaid Directors

COMPENDIA CLARIFICATION

The Deficit Reduction Act of 2005, Pub. L. 109-171, amended the drug rebate provisions to include a reference to certain successor publications. Specifically, the amendment, effective February 8, 2006, clarified that the reference to the United States Pharmacopoeia-Drug Information in section 1927(g)(1)(B)(II) includes its successor publications.

We are also reiterating the definition of medically accepted indication. Section 1927(k)(5) defines "medically accepted indication" to mean any use for a covered outpatient drug which is approved by the Food and Drug Administration, or a use which is supported by one or more citations included or approved for inclusion in the compendia specified in subsection (g)(1)(B)(II) – the American Hospital Formulary Service Drug Information, United States Pharmacopoeia-Drug Information (or its successor publications), and the DRUGDEX Information System. The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II). Prior approval policies may be put in place, but prior authorization cannot be used to deny the off-label indications supported by citations included or approved for inclusion in the above-referenced compendia.

/s/
Edward C. Gendron
Director
Finance, Systems and Budget Group

cc:
All State Drug Rebate Technical Contacts
All Regional Administrators

PsychRights®
Law Project for Psychiatric Rights

PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth

Model Medicaid Fraud Complaint

United States ex rel Law Project for Psychiatric Rights v. Matsutani, et al.

Summary	Analysis Medicaid False Claims Act	**Model Qui Tam Complaint**	Links	Utah Attorney General Correspondence

February 24, 2010 Webinar on PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth

Summary

The massive psychiatric drugging of America's children, particularly poor, disadvantaged children & youth through Medicaid and in foster care is an unfolding public health catastrophe of massive proportions. This catastrophe is being caused by the fraudulent promotion of these harmful practices by pharmaceutical companies sacrificing children and youth's health, futures and lives on the altar of corporate profits. In 2009, Eli Lilly agreed to pay $1.4 Billion in criminal and civil penalties for such off-label promotion of Zyprexa and Pfizer agreed to pay $2.3 Billion for the illegal off-label promotion of Geodon and other drugs, yet the practice has not stopped. It is merely a cost of doing business to these pharmaceutical Goliaths and, in fact, caps their liability for these crimes. Most importantly, these settlements have not stopped the practice of child psychiatrists and other prescribers giving these drugs to children and youth and Medicaid continuing to pay for these fraudulent claims.

PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth is designed to address this problem by having lawsuits brought against the doctors prescribing these harmful, ineffective drugs, their employers, and the pharmacies filling these prescriptions and submitting them to Medicaid for reimbursement. Once one sues over specific offending prescriptions, all of such prescriptions can be brought in, which means that any psychiatrist on the losing end of such a lawsuit will almost certainly be bankrupted, because each offending prescription carries a penalty of between $5,500 and $11,000. This is why it is expected that once this financial exposure becomes known to the prescribers they will quit the practice. Each prescriber may have a million dollars or few, at most, to lose, but the pharmacies' financial exposure can run into the hundreds of millions of dollars and it is hoped this will attract attorneys to take these cases. Anyone with knowledge of specific offending prescriptions can sue on behalf of the government to recover for such Medicaid Fraud, and receive a percentage of the recovery, if any.

Of course, it can be expected that the defendants will vigorously contest everything, and there are no guarantees of success. However, PsychRights believes what is presented here is accurate. PsychRights has published a PowerPoint Presentation that goes through the requirements and identifies the major issues.

The Model Qui Tam Complaint PsychRights has put together is set up for former foster youth to sue the doctors who prescribed the drugs to them, their employers, and the pharmacy(ies) submitting the false claims, but it can be easily modified for anyone else to file such a complaint, such as parents, teachers, therapists, etc. **PsychRights stands ready to to help people interested in bringing such suits and interested people can e-mail us, or call at (907) 274-7686, or write to 406 G Street, Suite 206, Anchorage, AK 99501.**

Analysis

Medicaid

In 42 USC 1396R-8(k)(3), as relevant here, Congress prohibited reimbursement under Medicaid for any outpatient drugs "used for a medical indication which is not a medically accepted indication." 42 USC 1396R-8(k)(6) then defines "medically accepted indication" as follows:

> The term “medically accepted indication” means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 301 et seq.], or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i) of this section.

42 USC 1396R-8(g)(1)(B)(i), in turn, designates the Compendia as:

> (I) American Hospital Formulary Service Drug Information;
> (II) United States Pharmacopeia-Drug Information (or its successor publications); and
> (III) the DRUGDEX Information System

An indication not approved by the FDA is often referred to as "off-label." Congress didn't prohibit reimbursement by Medicaid for all off-label prescriptions, but specifically limited reimbursement for off-label prescriptions to those that have sufficient scientific "support," as documented in one of the Compendia. A couple of illustrations: Geodon is not (yet) approved for any use in children and not supported by any citation in any of the Compendia. Thus, any Geodon prescriptions to children and youth submitted to Medicaid constitute fraud. Similarly, I have seen neuroleptics such as Abilify, Risperdal, Seroquel, & Zyprexa, prescribed for "Oppositional Defiant Disorder," and even for sleep. Such prescriptions are not for "medically accepted indications," and thus automatically constitute Medicaid Fraud.

There are a a lot of technical requirements that must be met, such as the lawsuit must be based on "non-public" information, which in this case is satisfied by having knowledge of offending prescriptions and the cases must initially be filed under seal (in secret).

False Claims Act

Under the False Claims Act:

- It is a False Claim to knowingly (A) present, or cause to be presented, a false or fraudulent claim

for payment or approval, or (B) 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)

- "Knowingly" is defined as (i) actual knowledge; (ii) deliberate ignorance of the truth or falsity; or (iii) reckless disregard of the truth or falsity, and no proof of intent to defraud is required. 31 U.S.C. §3729(b)(1)(a)
  - Every Medicaid provider is presumed to know what Medicaid's billing and coverage policies require. *Heckler v. Community Health Services*, 467 U.S. 51, 63-64 (1984).
  - Claims of ignorance are an untenable bases for the doctor's failure to live up to his duty to familiarize himself with the Medicaid requirements and observe his legal duty to submit truthful claims. *United States v. Nazon*, 940 F.2d 255, 259 (7th Cir. 1991).
  - "The applicant for public funds has a duty to read the regulations or be otherwise informed of the basic requirements of eligibility." *Coop. Grain*, 476 F.2d 47, 55-60.

Links

- *United States ex rel Law Project for Psychiatric Rights v. Matsutani, et al.*
- PowerPoint Presentation: PsychRights' Medicaid Fraud Initiative Against Psychiatric Drugging of Children & Youth.
- Medically Accepted Indications Chart
- CriticalThinkRx Curriculum
- Report on Mental Health Services and Foster Care, by Facing Foster Care in Alaska.
- PsychRights Launches Campaign Against Medicaid Fraud With Model Lawsuit, July 27, 2009.
  - Model Qui Tam Complaint
  - Microsoft Word Version
- Massive Medicaid Fraud Exposed: PsychRights Calls on Members of Congress for Assistance, May 5, 2009.
  - Letter to Senator Charles Grassly
  - Letter to Senator Herb Kohl
  - Letter to Congressman Henry Waxman
  - Letter to Congressman Bart Stupak
  - Letter to Congressman John Dingell
  - Letter to Congressman Barney Frank

Utah Attorney General's Office Correspondence

- October 22, 2007, letter from Utah Assistant Attorney General David Stallard to the Centers for Medicare & Medicaid Services (Medicaid)
- December 6, 2007, response from Medicaid to Utah Assistant Attorney General David Stallard
- December 17, 2007, follow-up letter from Utah Assistant Attorney General David Stallard to Medicaid
- January 30, response from Medicaid to Utah Assistant Attorney General David Stallard

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Last modified 2/7/2010

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

Law Project for Psychiatric Rights,
Plaintiff,
vs.
State of Alaska, *et al*,
Defendants

RECD APR 16 2009

Case No. 3AN 08-10115CI

ORDER GRANTING
MOTION FOR LEAVE TO AMEND COMPLAINT
(Citizen-Taxpayer Standing/Medicaid Injunction)

Having reviewed the Motion for Leave to Amend Complaint (Citizen-Taxpayer Standing/Medicaid Injunction) filed April 3, 2009, by Plaintiff, the Law Project for Psychiatric Rights, and any responses thereto, including the conditional non-opposition with reservation it is hereby ORDERED that the motion is GRANTED.

DATED this 14th day of April, 2009.

Jack W. Smith
Superior court Judge

I certify that on 4-15-09 a copy of the above was mailed to each of the following at their addresses of record. Gottstein, Kaaly, Bakalar

Secretary/Deputy Clerk

LAW PROJECT FOR PSYCHIATRIC RIGHTS, APR - 3 2009
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

COPY
Original Received
APR 03 2009
Clerk of the Trial Courts

Law Project for Psychiatric Rights,	)	
	)	
Plaintiff,	)	
vs.	)	
	)	Case No. 3AN 08-10115CI
State of Alaska, *et al*,	)	
	)	
Defendants	)	

MOTION FOR LEAVE TO AMEND COMPLAINT
(Citizen-Taxpayer Standing/Medicaid Injunction)

COMES NOW, Plaintiff in the above captioned action, and hereby moves to amend the Amended Complaint, as follows:

1. Insert, ", and has citizen-taxpayer standing to bring this action" at the end of Paragraph 4.

2. Add a new paragraph, ¶236, as follows:

236. The State approves and applies for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:

(a) are not medically necessary, or

(b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (i) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or

(c) both.

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

3. Amend ¶B of the Prayer for Relief to read as follows:

B. Permanently enjoin the defendants and their successors from:

1. authorizing or paying for the administration of psychotropic drugs to Alaskan children and youth without conformance with Paragraph A of this prayer for relief, and

2. approving or applying for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:

(a) are not medically necessary, or

(b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (i) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or

(c) both.

This motion is accompanied by a memorandum in support hereof.

DATED: April 3, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

LAW PROJECT FOR PSYCHIATRIC RIGHTS, an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENT OF HEALTH AND SOCIAL SERVICES, WILLIAM HOGAN, Commissioner, Department of Health and Social Services, TAMMY SANDOVAL, Director of the Office of Children's Services, STEVE McCOMB, Director of the Division of Juvenile Justice, MELISSA WITZLER STONE, Director of the Division of Behavioral Health, RON ADLER, Director/CEO of the Alaska Psychiatric Institute, WILLIAM STREUR, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants,

Case No. 3AN 08-10115CI

AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

(Administration of Psychotropic Medication to Children and Youth in the Custody of, or Paid for by, the State of Alaska)

TABLE OF CONTENTS

INTRODUCTION

1. This is an action to,

(a) obtain a declaratory judgment 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 of the risks and potential benefits, and

(iv) close monitoring of, and appropriate means of responding to, treatment emergent effects are in place,

(b) permanently enjoin the defendants and their successors from authorizing or paying for the administration of psychotropic drugs to Alaskan children and youth without conformance with subparagraph (a) of this paragraph 1, and

(c) obtain an order

(i) requiring an independent reassessment of each Alaskan child or youth to whom defendants have authorized the administration or payment of psychotropic drugs for conformance with subparagraph (a) of this paragraph 1 by a qualified contractor appointed and monitored by the Court, or a Special Master, to be paid by defendant State of Alaska, appointed for that purpose,

and

(ii) for each child for whom it is found the administration of or payment for psychotropic drugs is taking place out of conformance with subparagraph (a) of this paragraph 1, that immediate remedial action be commenced to prudently eliminate or reduce such administration of or payment for psychotropic drugs and diligently pursued to completion.

JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to AS 22.10.020

3. Venue is proper under Rule 3 of the Alaska Rules of Civil Procedure.

PARTIES

4. Plaintiff, the Law Project for Psychiatric Rights, an Alaska non-profit corporation (PsychRights®), is a public interest law firm whose mission is to mount a strategic litigation campaign against forced psychiatric drugging and electroshock.

5. Defendant State of Alaska, is the state of Alaska, one of the United States of America (State), which through various of its agencies, agents and delegees, (a) pays for the administration of psychotropic drugs to Alaskan children and youth and (b) has taken, does take, and will take Alaskan children and youth into care and custody and assume control over them, including authorizing the administration of psychotropic drugs.

6. Defendant Sarah Palin is the Governor of the State and has ultimate responsibility for its operation, including its agencies, agents and delegees who (a) pay for the administration of psychotropic drugs to Alaskan children and youth, and (b) take

Alaskan children and youth into care and custody and assume control over them, including authorizing the administration of psychotropic drugs.

7. Defendant Alaska Department of Health and Social Services is the agency of the State of Alaska that primarily (a) pays for the administration of psychotropic drugs to Alaskan children and youth, and (b) has taken, does take, and will take Alaskan children and youth into care and custody and assume control over them, including authorizing the administration of psychotropic drugs.

8. Defendant William Hogan, is the Commissioner of the State of Alaska's Department of Health and Social Services, one of the agencies which (a) pays for the administration of psychotropic drugs to Alaskan children and youth, and (b) has taken, does take, and will take Alaskan children and youth into care and custody and assume control over them, including authorizing the administration of psychotropic drugs.

9. Defendant Tammy Sandoval, is the Director of the Office of Children's Services (OCS), within the Department of Health and Social Services, one of the agencies which (a) pays for the administration of psychotropic drugs to Alaskan children and youth, and (b) has taken, does take, and will take Alaskan children and youth into care and custody and assume control over them, including authorizing the administration of psychotropic drugs.

10. Defendant Steve McComb is the Director of the Division of Juvenile Justice within the Department of Health and Social Services, one of the agencies which (a) pays for the administration of psychotropic drugs to Alaskan children and youth, and (b) has taken, does take, and will take Alaskan children and youth into care and custody and

assume control over them, including authorizing the administration of psychotropic drugs.

11. Defendant Melissa Witzler Stone is the Director of the Division of Behavioral Health, which has programs in which Alaskan children and youth are administered psychotropic drugs.

12. Defendant Ron Adler is the Director/Chief Executive Officer of the Alaska Psychiatric Institute, an inpatient psychiatric hospital that administers psychotropic drugs to Alaskan youth.

13. Defendant William Struer is a Deputy Commissioner of the Alaska Department of Health and Social Services and the Director of the Division of Health Care Services, which pays for the administration of psychotropic drugs to Alaskan children and youth.

CHILDREN AND YOUTH'S CONSTITUTIONAL RIGHTS NOT TO BE ADMINISTERED PSYCHOTROPIC DRUGS UNLESS IT IS IN THEIR BEST INTERESTS AND THERE ARE NO LESS INTRUSIVE ALTERNATIVES

14. Because decisions to administer psychotropic medication to children and youth are not made by the children and youth themselves, the administration of such medication is involuntary as to them.

15. Under the Alaska Constitution 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.

16. Under the Alaska Constitution Alaskan minors have the right to enforce their own fundamental constitutional rights.

17. Under the Fourteenth Amendment to the Constitution of the United States, Alaskan children and youth have the right not to be harmed by the actions of, or through, the State of Alaska, its employees, delegees and agents.

18. Alaskan children and youth have one or more other constitutional rights not to be harmed by the actions of, or through, the State, its employees, delegees, and agents.

CHILDREN AND YOUTH'S STATUTORY RIGHTS WHEN IN STATE CUSTODY

19. Under AS 47.10.084(a) and AS 47.12.150(a), when a child is in state custody, as a child in need of aid pursuant to AS 47.10 or a delinquent minor under AS 47.12, the Alaska Department of Health and Social Services and its delegees have a duty to 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.

20. Decisions by the Alaska Department of Health and Social Services and its delegees with respect to fulfilling their duties under AS 47.10.084(a) and AS 47.12.150(a) to meet the emotional, mental, and social needs of the child and to protect, nurture, train, and discipline children and youth in their custody and provide them with education and medical care must be made on the basis of what is in the best interests of the children and youth.

21. Under AS 47.14.100(d)(1), the Alaska Department of Health and Social Services has a duty to pay the costs of habilitative and rehabilitative treatment and services for children and youth diagnosed with a mental illness.

MEDICAID PAYMENT FOR OUTPATIENT PRESCRIPTIONS IS NOT ALLOWED UNLESS APPROVED FOR THE INDICATION BY THE FDA OR INCLUDED IN CERTAIN MEDICAL COMPENDIA

22. It is unlawful to for the State to use Medicaid to pay for outpatient drug /when medically necessary and prescriptions except for indications approved by the Food and Drug Administration (FDA) or included in the following compendia:

(a) American Hospital Formulary Service Drug Information,

(b) United States Pharmacopeia-Drug Information (or its successor publications), or

(c) DRUGDEX Information System.

THE LAW PROJECT FOR PSYCHIATRIC RIGHTS' RAISING THE ALARM TO AND DEMANDING CORRECTIVE ACTION BY GOVERNMENT OFFICIALS HAS BEEN IGNORED

23. By letter dated December 10, 2004, to Alaska State Senator Fred Dyson and Alaska State Representative Peggy Wilson, who were holding hearings regarding OCS, with a copy to then Commissioner of the Alaska Department of Health and Social Services, Joel Gilbertson, James B. (Jim) Gottstein, president of the Law Project for Psychiatric Rights, requested they look into the situation in Alaska, writing in part:

> [I]t is almost certain a large number of children in state custody are on dangerous psychotropic medications that have never been approved for children. The worst of these drugs are the neuroleptics, including the newer ones, called "atypicals." These medications make it tremendously difficult for children to ever grow up to lead normal lives. They cause, rather than

> cure mental illness. It has been found in other states that a large number of children in foster care or outright custody are on these drugs in order to control their behavior, rather than help them deal with the traumas in their lives that are causing the troubling behavior.

See, Exhibit A.

24. On August 14, 2006, Mr. Gottstein spoke with then Commissioner of the Alaska Department of Health and Social Services, Karleen Jackson (Commissioner Jackson), about the problem of the State's pervasive psychiatric drugging of children and youth in State custody.

25. On February 8, 2007, Mr. Gottstein testified before the Judiciary Committee of the Alaska House of Representatives that children and youth in State custody were being pervasively over-drugged with psychotropic drugs to their extreme harm.

26. On March 9, 2007, Mr. Gottstein e-mailed members of the Judiciary Committee of the Alaska House of Representatives, with copies to Governor Palin, other legislators and various interested parties, conveying additional information, including that, as far as he knew, Alaska was not even keeping track of the extent to which it was administering psychotropic drugs to Alaskan children and youth and stating his hope that Alaska would voluntarily do something about the serious harm it is inflicting on Alaskan children and youth in State custody by administering psychotropic drugs to them. *See*, Exhibit B.

27. On March 14, 2007, Mr. Gottstein e-mailed defendant Governor Palin, among other things, about children and youth in custody in other states dying from the administration of psychotropic drugs, and stating:

> The massive over-drugging of America's children is a titanic health catastrophe caused by the government's failure to protect its most precious citizens, who rely on the adults in their lives to shield them from harm, not inflict it upon them. Perhaps the worst of all is the State inflicting this harm on children it has taken from their homes "for their own good."
>
> Please correct this situation.

See, Exhibit C.

28. By letter dated March 22, 2007, Commissioner Jackson responded to Mr. Gottstein's e-mail to Governor Palin in a March 14, 2007, e-mail stating in pertinent part:

> Indications for the use of psychotropic medications in children includes, but is not limited to, symptoms consistent with psychosis, Bipolar Disorder, severe depression, Attention Deficit Hyperactivity Disorder (ADHD), and, in certain situations, severe behavioral disturbances. Concern should be raised when multiple medications of one class are used or when doses are prescribed which are considered high for this population. Concern should also be raised when it appears that these medications are being used for behavioral control alone, or to hasten a response to inpatient treatment or, for that matter, outpatient or residential treatment.
>
> The State of Alaska, in cooperation with First Health Corporation, has for the past 3 1/2 years utilized a behavioral pharmacy management system that compares evidence-based and consensus based practice guidelines to the prescribing practices of Alaskan clinicians. If discrepancies are identified, the company uses a combined approach of education and peer consultation to address specific concerns. Since this program started, there have been changes made in prescribing practices with the goal being improved care for Alaska's children.
>
> The Office of Children's Services (OCS) operates under policy which requires that caseworkers must staff medication recommendations for children on their caseloads with their Supervisor and their regional Psychiatric Nurse prior to giving consent to the treatment provider. The OCS Psychiatric Nurses have weekly contacts with the professionals treating OCS children in acute care settings, i.e., North Star, Alaska Psychiatric Institute, Providence Discovery, and in residential treatment centers. OCS caseworkers and Psychiatric Nurses also participate in monthly treatment plans for children in the residential treatment facilities.

> A medication can be increased or decreased for a child in custody, but cannot be started without the OCS' knowledge and consent.

See, Exhibit D.

29. By letter dated February 4, 2008, Mr. Gottstein wrote Governor Palin, with copies to the Attorney General, Commissioner Jackson, defendants Hogan and Stone, and others, conveying scientific evidence regarding the harm being done to children and youth by the massive over-prescribing of psychotropic drugs to them, and stating:

> It is a huge betrayal of trust for the State to take custody of children and then subject them to such harmful, often life-ruining, drugs. They have almost always already been subjected to abuse or otherwise had very difficult lives before the State assumes custody, and then saddles them with a mental illness diagnosis and drugs them. The extent of this State inflicted child abuse is an emergency and should be corrected immediately.
>
> Children are virtually always forced to take these drugs because, with rare exception, it is not their choice. PsychRights believes the children, themselves, have the legal right to not be subject to such harmful treatment at the hands of the State of Alaska. We are therefore evaluating what legal remedies might be available to them. However, instead of going down that route, it would be my great preference to be able to work together to solve this problem. It is for this reason that I am reaching out to you again on this issue.

See, Exhibit E.[1]

30. By letter dated March 4, 2008, Commissioner Jackson responded to her courtesy copy of Mr. Gottstein's February 4, 2008 letter to Governor Palin, in part, as follows:

> The Office of Children's Services (OCS) policy 6.3.1 clearly states that administration of psychotropic medication, or any drugs prescribed for mental illness or behavioral problems, falls under the definition of major medical care. This reflects the fact that administration of these medications is viewed in a serious manner. The OCS policy further states, "Parental

[1] This letter is incorrectly dated 2007, rather than 2008, which is noted on the Exhibit.

> permission or a court order is also required for administration of psychotropic medication. If parental rights have been terminated, the assigned worker may approve administration of psychotropic medication following consultation with the supervisor, OCS regional psychiatric nurse and GAL. The consultation and resulting decision should be documented in the case file."
>
> The policy does allow a physician or nurse to immediately administer medication if this is necessary to preserve the life of the child or prevent significant physical harm to the child or another person. Crisis administration of medications should be for a very brief duration of time and the assigned worker should be immediately informed. The worker should notify the parent of any medication administered on a crisis basis and the regional psychiatric nurse should review the circumstances regarding the administration to ensure adherence to policy. . . .
>
> Thank you for advocating for the rights of Alaska's children.

See, Exhibit F.

31. In early June of 2008, "Critical ThinkRx, A Critical Curriculum on Psychotropic Medications" (Critical ThinkRx), David Cohen PhD, principal investigator, was released.

32. 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 the prescription drug Neurontin, one of the anticonvulsants/anti-seizure drugs marketed as mood stabilizers described below, in order to give guidance to people making decisions regarding authorizing the administration of psychotropic drugs to children and youth.

33. The Attorney General of the State of Alaska is one of the participants in the Attorneys General Consumer and Prescriber Grant Program.

34. On June 11, 2008, Mr. Gottstein e-mailed then Acting Commissioner, defendant Hogan, with copies to the Attorney General of the State of Alaska, and among others, defendants Melissa Stone and Tammy Sandoval, as follows:

> In a last-ditch effort to avoid litigation as I begin drafting my complaint seeking a declaratory judgment and injunction against the state of Alaska for its massively harmful psychiatric drugging of children it has taken into custody, I thought I would draw your attention to a terrific, just launched, on line program about this issue, called CriticalThinkRx. Paid for by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of Neurontin®, CriticalThinkRx was developed specifically for non-medical personnel making decisions about giving psychiatric drugs to children. In other words, it was put together so that people such as those working for the State of Alaska authorizing the psychiatric drugging of children subject to State control are able to make informed decisions.
>
> By this e-mail, I am requesting (demanding) the State implement such a program for informed decision making regarding the administration of psychiatric drugs to children it has taken into custody.
>
> Frankly, even if the State continues to ignore this problem, it might as well start looking at the CriticalThinkRx program now because it will be faced with this same information in the lawsuit. More importantly, the State should use the information to change what it is doing to the children whom it has taken into custody and subjecting to what can quite legitimately be characterized as State-inflicted child abuse. I suspect you take umbrage at this characterization and think it is an exaggeration, but it is an accurate one. It is a huge betrayal by the State of this most vulnerable population and should be stopped immediately.
>
> As you know, PsychRights has tried for years to get the State to address the problem of it's very harmful program of psychiatrically drugging kids it has taken into custody. See, http://psychrights.org/States/Alaska/Kids/Kids.htm
>
> I hope the State will now recognize the problem and immediately take steps to correct it. Unfortunately, based on past experience, my guess is this will not happen. Therefore, I am proceeding with developing the lawsuit unless I hear otherwise from you and we work out a satisfactory program to address this crisis, such as one consistent with CriticalThinkRx, that does

> not inflict such damage on Alaska's children for whom the State has taken responsibility.

See, Exhibit G.

35. Despite Plaintiff's repeated requests, no substantive negotiations between Plaintiff and any State personnel regarding the administration of and payment for psychotropic drugs to Alaskan children and youth have taken place.

THE "CRITICAL THINKRX" CURRICULUM

36. Most of the allegations in the below sections on the FDA Drug Approval Process, Undue Drug Company Influence, Pediatric Psychotropic Prescribing Practices, Neuroleptics, Antidepressants, Stimulants and Anticonvulsants Promoted as "Mood Stabilizers" and Evidence-Based, Less Intrusive Alternatives: Psychosocial Interventions, and all of the allegations in the below section "Critical ThinkRx Specifications," are from the Critical ThinkRx Curriculum.

The FDA Drug Approval Process

37. The legal availability of a psychotropic drug and its approval by the United States Food and Drug Administration (FDA) for prescription by medical practitioners does not, in itself, signify that it is safe or effective for use with children and youth diagnosed with a mental illness.

38. The FDA's Center for Drug Evaluation and Research (CDER) oversees testing and approval of medications for the FDA, but conducts no drug trials of its own.

39. Drug companies pay for and conduct all tests and trials considered by CDER in the drug approval process, and CDER judges a drug's efficacy and safety based on the

data submitted by the sponsoring drug company (Sponsor) in support of what is called a New Drug Application (NDA).

40. When the FDA approves a drug for a specific use (Approved Use), it means it has reviewed limited data on safety and efficacy for one indication, usually in one population or age group.

41. Fees paid by drug companies (User Fees) now make up over half of CDER's budget.

42. Since User Fees were initiated in 1992, the FDA has slashed its own testing laboratories and network of independent drug-safety experts.

43. To approve a drug, the FDA requires only two "Phase III trials," or large multi-site, randomized comparisons of active drug to placebo that result in positive findings, even if there are more Phase III trials that result in negative findings.

44. For purposes of drug approval by the FDA, "efficacy" means the drug has shown less than a 5 percent chance of being worse than placebo; it does not mean the drug has shown it helps a patient's condition or works better than another drug or non-drug intervention.

45. Each FDA-approved drug has a "Label," in which findings from the pre-clinical (laboratory and animal) and clinical (human) trials are summarized, the exact content secretly negotiated by the FDA and the Sponsor.

46. In developing drugs for physical diseases, researchers start with a target of drug action identified by understanding how a disease affects the body at the cellular and molecular levels and target identified biological anomalies.

47. Completely unlike drugs for physical diseases, potential psychotropic or psychiatric drugs are selected for human trials based on their effects on animal behavior and expected effects on people's complaints and behavior.

48. Experts in the field admit (a) there are no biomarkers for psychiatric illness, (b) they do not understand the supposed neurobiology or genetic underpinnings of psychiatric disorders, (c) they do not understand the developmental factors and causes of mental illness, (d) there are few good animal models for psychiatric research, and (e) all of these problems are worse when diagnosing and researching treatments in children and youth.

49. There are many problems with the design and conduct of clinical trials of psychotropic drugs, resulting in the trials' inability to provide a valid basis to determine the drugs' genuine benefits and risks.

50. Trials at all phases neglect most psychoactive effects of the drug being studied because the researchers focus on measuring narrowly selected complaints and behavior, leaving main psychological alterations produced by the drug unknown.

51. Phase II and III trials are short, typically lasting only three to eight weeks, with up to 70 percent of the subjects dropping out before the trials' end, detecting only some of the acute effects and few that emerge over a longer time frame.

52. Clinical trial subjects are incorrectly assumed to have the same "disorder," such as depression, or Major Depressive Disorder, where 200 distinct symptom combinations are considered to be the same "disorder," and the same subjects usually

meet criteria for several different psychiatric diagnoses, resulting in an invalid comparison of treatments.

53. Because active placebos causing physical sensations are usually not used, clinical trial subjects, as well as the researchers, can often determine whether subjects are being given a placebo or the drug being tested, i.e, "breaking the blind," thus destroying the scientific validity of the trial.

54. In clinical trials comparing a new drug to an older one, very high doses of the older drug are often used, producing more side effects for the older drug, and resulting in the intentionally misleading conclusion that the newer drug is safer than the older one.

55. Primary outcomes of most psychiatric drug clinical trials are rated by the researchers rather than the subjects, ignoring relevant measures, such as in the Phase III pediatric trials of antidepressants where not one of ten parent or child rated scales showed advantages for antidepressant use over placebo.

56. Sponsors routinely remove prospective subjects who respond to placebo from clinical trials, making the results invalid.

57. Adverse effects of the drugs occurring during clinical trials are carelessly investigated, at best, resulting in a false impression of a drug's safety.

58. During clinical trials, adverse events are often miscoded by the Sponsor.

59. During clinical trials, adverse events are often arbitrarily determined to be unrelated to the drug being studied, and ignored.

60. Sponsors announce in their study protocols that they will gather data for weeks after clinical trial subjects stop treatment, but do not submit these data to the FDA

even though subjects often rate their experience differently once the mind-altering drug has been discontinued.

61. While the FDA often officially "requires" Sponsors to conduct trials once the drugs have been approved in what is known as the "post marketing phase" or "Phase IV Trials," as of late 2006, more than 70 percent of these promised post marketing or Phase IV trials had not even been started by Sponsors.

62. Sponsors often design drug studies solely to get positive results.

63. Sponsors often suppress and distort negative results.

64. Sponsors often publish purported positive results multiple times to give the appearance the results have been replicated multiple times.

65. 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.

66. In 90 percent of studies pitting one newer neuroleptic against another, the best drug was the Sponsor's drug.

67. 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.

68. The foregoing problems and limitations, and other problems and limitations of drug trials, give clinicians and policymakers false, misleading, and incomplete ideas about how these medications can help and how they can harm people.

69. Because of the foregoing problems and limitations, and other problems and limitations of drug trials, FDA approval of a psychotropic drug, by itself, does not substantiate that the approved drug is either safe or efficacious.

70. An accurate portrait of the benefits and risks of FDA-approved drugs is not achieved until the drug has been in use for many years by many people.

Undue Drug Company Influence Over Prescribing Practices

71. Drug company marketing of psychiatric drugs targets all types of participants potentially involved in prescribing these drugs, or in making them available for prescription, to children and youth.

72. Drug companies influence physicians to prescribe psychiatric drugs to children and youth through, among other things:

(a) Free meals,

(b) Free drug samples,

(c) Providing free continuing medical education, which states require of physicians to maintain their licenses,

(d) Payments for lecturing, consulting and research,

(e) Publishing misleading articles in medical journals,

(f) Funding their professional organizations' activities,

(g) Advertising in professional journals,

(h) Paying doctors to serve on "expert committees" that create and promote guidelines for drug treatments used by other doctors, and

(i) 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.

73. Drug companies influence consumers, or the lay public, to seek specific drugs from physicians through, among other things:

(d) Direct-to-consumer advertising of prescription drugs on national television and popular magazines,

(e) "Disease awareness" campaigns,

(f) Funding "patient advocacy" groups,

(g) Websites purporting to provide objective information, and

(h) Online promotions.

74. Drug companies influence medical and health "experts" to evaluate drugs positively through, among other things:

(a) Paying researchers, and their academic institutions, to run clinical trials and develop treatment guidelines, and

(b) Paying researchers and academics to lend their names to articles they have not written in a practice called "ghostwriting."

75. Drug companies often require researchers to sign secrecy agreements whereby the drug companies are able to suppress negative information about their products from publication.

Pediatric Psychotropic Prescribing

76. 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.

77. 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.

78. Prescriptions of psychotropic drugs to youths tripled in the 1990s and are still rising.

79. 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.

80. Seventy-Five percent of all medication administered to children and youth is prescribed for uses not approved by the Food and Drug Administration.

81. At least forty percent of all psychiatric drug treatments today involve polypharmacy.[2]

82. Most psychotropic medication classes lack scientific evidence of their efficacy or safety in children and youth.

83. The FDA only evaluates trials testing a single drug, not drug combinations, ie, "polypharmacy."

[2] As employed herein, "polypharmacy" means concomitant or multiple psychotropic medication use.

84. No studies have established the safety and efficacy of polypharmacy in children and youth.

85. Almost all psychiatric drugs have been shown to cause brain damage in the form of abnormal cell growth, cell death and other detrimental effects, which is especially harmful for growing and developing children and youth.

86. Psychotropic drugs given to children and youth cause "behavioral toxicity."[3]

87. Psychotropic drugs given to children and youth suppress learning and cognition and produce cognitive neurotoxicty, interfering with the basic mental development of the child, which adverse effects often do not go away after the drugs are withdrawn.

88. No studies show that the administration of psychotropic drugs to children and youth increases learning or academic performance in the long term.

89. Adverse drug effects are often confused with symptoms of disorders, leading to the addition of inappropriate diagnoses, increased doses of current medications, and even more complex drug regimens.

90. Nine of ten children and youth seeing a child psychiatrist receive psychotropic medication.

91. Use of most classes of psychotropic drugs among 2-4 year-olds, or preschoolers, continues to increase with almost half of those receiving prescriptions given two or more medications simultaneously.

[3] As employed herein, "behavioral toxicity" means drug-induced adverse effects and behavioral changes, including apathy, agitation, aggression, mania, suicidal ideation and psychosis.

92. Thousands of infants less than one year of age have received psychotropic medications.

93. The fastest increases have been in newer drugs, which by definition have little or no established efficacy or safety profiles.

94. Treatment of preschoolers with psychiatric drugs has barely been studied.

95. There is insufficient evidence on the administration of psychotropic drugs to preschoolers to provide guidelines for treatment, establish efficacy of treatment, guarantee safe use, or evaluate short- and long-term consequences on development of drug prescriptions to preschoolers.

96. Children and youth in child welfare settings are two and three times more likely to be medicated than children and youth in the general community.

97. Medicaid-enrolled children and youth are more likely to receive psychotropic medication, be treated with multiple medications, and receive medications as sole treatment for psychiatric diagnoses than other children and youth.

98. After controlling for demographic and clinical factors, youths in group homes are twice as likely to be administered psychotropic medications than youths in therapeutic foster care.

99. Both because minority and poor children and youth are more likely to be involved in child protection and foster care placements and because the drugs are paid for by Medicaid and other governmental programs, these children and youth are given more psychotropic drugs than other children and youth.

100. In 2006, the FDA strengthened its warnings about stimulants, which are routinely given to children after a diagnosis of Attention Deficit Hyperactivity Disorder (ADHD), because of more evidence they cause cardiovascular problems, psychosis and hallucinations at usual prescribed doses.

101. In 2004, the FDA issued a "Public Health Advisory" about all antidepressants, warning these drugs cause anxiety and panic attacks, agitation and insomnia, irritability and hostility, impulsivity and severe restlessness, and mania and hypomania after the British equivalent of the FDA banned the use of all antidepressants except Prozac in children and youth under 18.

102. Currently the FDA requires a "Black Box" warning on the label for all antidepressants, stating, "WARNING Suicidality and Antidepressant Drugs—Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in short-term studies in children, youth, and young adults, with Major Depressive Disorder and other psychiatric disorders."

103. Between 1993 and 2002, the number of non-institutionalized six to eighteen year olds on neuroleptics, also misleadingly called "antipsychotics," increased from 50,000 to 532,000.

104. Nationwide, neuroleptics are typically prescribed to children for non-psychotic conditions.

105. Seventy-seven to eighty-six percent of youths taking neuroleptics do so with other prescribed psychotropic drugs.

106. In the 1996-2001 time period, neuroleptic use in children increased the most dramatically in Medicaid populations, with prescriptions increasing 61 percent for preschool children, 93 percent for children aged six to twelve, and 116 percent for youth aged thirteen to eighteen.

107. Children are particularly vulnerable to harm from psychiatric drugs because their brains and bodies are developing.

108. There is little or no empirical evidence to support the use of drug interventions in traumatized children and youth.

109. Fewer than ten percent of psychotropic drugs are FDA-approved for any psychiatric use in children.

110. The use of psychiatric drugs in children and youth far exceeds the evidence of safety and effectiveness.

Neuroleptics

111. The following "second-generation" of neuroleptics have been approved for the following pediatric uses:

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		

112. The following first-generation neuroleptics have been approved for the following pediatric uses:

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+

113. Neuroleptics have been used to treat psychoses since the 1950s despite high toxicity and limited effectiveness.

114. Starting in the 1990s, the newer, more expensive, second-generation neuroleptics were heavily promoted as safer and more effective than the first-generation neuroleptics.

115. In 2005, in the largest ever study regarding the treatment of people diagnosed with schizophrenia, the Clinical Antipsychotic Trials of Intervention Effectiveness (CATIE) study, conducted by the National Institute of Mental Health, it was found that the second-generation neuroleptics were neither more effective nor better tolerated than the older drugs and that seventy five percent of patients quit either type of drug within eighteen months due to inefficacy or intolerable side effects, or both.

116. Neuroleptics are most often prescribed to children and youth to suppress aggression and agitation, which are common reactions to abuse and the trauma of being removed from their homes and families, rather than for psychosis.

117. The latest randomized-controlled trial of neuroleptics for aggression, which had no drug company sponsorship, found inert placebo more effective than Haldol a first-generation neuroleptic, or Risperdal, a second-generation neuroleptic, in reducing aggression in patients with intellectual disability.

118. There are few clinical trials of second-generation neuroleptics for pediatric use, and most existing trials are short-term with the results favoring the funder's drugs.

119. Overall, current prescriptions of neuroleptics to children and youth overwhelmingly exceed the available evidence for safety and effectiveness.

120. No studies show that second-generation neuroleptics are safe or effective for children and youth.

121. The dopamine-blocking action of all neuroleptics is believed to account for the following observed main effects:

(a) Indifference, sedation, drowsiness and apathy;

(b) Reduced spontaneity and affect;

(c) Reduced ability to monitor one's state;

(d) Increased abnormal movements;

(e) Cognitive and motor impairments;

(f) Confusion and memory problems; and

(g) Depression, mood swings and agitation.

122. The following observed effects of neuroleptics are regularly misconstrued as therapeutic by physicians and other practitioners:

(a) Increased indifference, including to psychotic symptoms,

(b) Reduced spontaneity and affect,

(c) Reduced ability to monitor one's state, and

(d) Increased compliance with social norms.

123. The following are undesirable observed behavioral effects of neuroleptics:

(a) Cognitive and motor impairments,

(b) Sedation and drowsiness,

(c) Confusion and memory problems,

(d) Anxiety,

(e) Depression and mood swings,

(f) Abnormal thinking, and

(g) Hostility and aggression.

124. The following are undesirable observed physical effects of neuroleptics:

(a) Weight gain and high blood sugar (second-generation),

(b) Extrapyramidal symptoms (abnormal movements of all body parts),

(c) Diabetes (second-generation) and other endocrine problems, to which children and youth are more susceptible,

(d) Cardiac problems,

(e) Liver problems and jaundice,

(f) Neuroleptic malignant syndrome, which occurs at a rate of one to two percent per year, is often fatal, can occur with any neuroleptic, at any dose, at any time, characterized by extreme muscular rigidity, high fever and altered consciousness,

(g) Stroke, and

(h) Death.

125. Exrapyramidal symptoms (involuntary abnormal movements) caused by both first and second-generation neuroleptics include:

(a) Akathisia, an inner distress, often manifested by rocking, pacing and agitation, and known to cause extreme violence including suicide and homicide;

(b) Dystonia, which are sudden, bizarre, sustained muscle spasms and cramps;

(c) Dyskinesia, which consists of uncontrollable, disfiguring, rhythmic movements of the face, mouth and tongue and sometimes of the extremities;

(d) Parkinsonism, which manifests as rigid muscles, slowed movement, loss of facial expression, unsteady gait and drooling.

126. Long-lasting extrapyramidal symptoms affect twelve to thirteen percent of children who receive first-generation neuroleptics for more than three months.

127. The rate of acute extrapyramidal symptoms affecting children who receive second-generation neuroleptics has not been extensively studied, but from what is known, it appears the rates are comparable to the first-generation neuroleptics.

128. Among the extrapyramidal symptoms caused by both the first and second-generation neuroleptics is often irreversible Tardive Dyskinesia, resulting from the brain damage caused by the neuroleptics, characterized by (a) disfiguring and stigmatizing involuntary movements, (b) difficulties in walking, sitting still, eating and speaking and (c) impaired nonverbal function.

129. Tardive Dyskinesia is such a common, serious and severe negative effect of neuroleptics that AS 47.30.837(d)(2)(B) requires specific information about it being taken into account when seeking informed consent.

130. The second-generation neuroleptics cause elevated prolactin levels, resulting in sexual and menstrual disturbances, infertility and decreased bone density, and which has resulted in severe gynecomastia (the development of abnormal breast tissue) in both boys and girls, but particularly disturbing and disfiguring for boys.

131. Fifty percent of patients on second-generation neuroleptics gain twenty percent of their weight, primarily as fat, that has been linked to what is called "Metabolic Syndrome," which dramatically increases the risk of obesity, elevated blood sugar and diabetes, elevated cholesterol and blood lipids, and hypertension.

132. All the second-generation neuroleptics also cause potentially lethal pancreatitis.

133. Withdrawal of children and youth from neuroleptics often results in very disturbed behavior worse than anything experienced prior to starting on the medication.

134. Between 1998 and 2005, Clozaril (clozapine) was reported to the FDA as suspected to have caused the death of 3,277 people, Risperdal (risperidone) 1,093 and Zyprexa (olanzapine) 1,005.

135. Currently, second-generation neuroleptics carry the following FDA "Black Box" warnings:

All Second Generation Neuroleptics	Increased mortality in frail elderly
Clozaril	Serious risk of agranulocytosis (severe drop in white blood cells), seizures, myocarditis and other cardiovascular and respiratory effects
Seroquel	Suicidality in children and adolescents

136. One study showed a lifespan decrease of twenty-five years for people diagnosed with schizophrenia who take these medications chronically.

137. Another study showed a 20 fold increase in suicide rates for patients diagnosed with schizophrenia who were treated with neuroleptics from 1994-1998 compared to those in the period from 1875-1924.

138. Experts recommend that neuroleptics not be considered first-line treatment for childhood trauma because of their serious adverse effects.

Antidepressants

139. The following antidepressants have been approved for the following pediatric uses:

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+

140. Meta-analyses of controlled clinical trials of antidepressants submitted to the FDA by Sponsors show 75 percent to 82 percent of the response, as measured by clinician-rated scales, was duplicated by placebo.

141. Fifty Seven percent of the antidepressant controlled clinical trials submitted to the FDA failed to show a difference between the drug and placebo.

142. Only three of fifteen (20%) published and unpublished controlled pediatric trials of the newer selective serotonin reuptake inhibitor (SSRI) antidepressants found the drugs more effective than placebo in depressed children and no trial found the drugs better as measured by the children themselves or their parents observing them.

143. There is no evidence that the older tricyclics or monoamine oxidase inhibitor (MAO) antidepressants have any efficacy with depressed youths.

144. Tricyclic antidepressants commonly produce abnormalities in cardiovascular function in children and there are reports of cardiac arrest and death in children.

145. Short term desirable observed effects of the newer SSRI antidepressants at usual doses include:

(a) Increased physical activity,

(b) Elevated mood,

(c) Decreased expressions of distress, such as crying and hopelessness, and

(d) Improved sleep and appetite.

146. Undesirable observed behavioral effects of antidepressants include:

(a) Anxiety and nervousness,

(b) Agitation and irritability,

(c) Mood swings, including mania,

(d) Aggressiveness,

(e) Thoughts of suicide,

(f) Apathy, and

(g) Attempted and actual suicide.

147. Undesirable observed physical effects of antidepressants include:

(a) Gastrointestinal distress (nausea, vomiting, stomach pain, constipation, diarrhea),

(b) Sexual problems (loss of libido, anorgasmia, erectile dysfunction),

(c) Sleep disruption (insomnia, hypersomnia), which is particularly problematic in growing children,

(d) Urinary retention,

(e) Blurred vision,

(f) Weight gain, and

(g) Headaches and dizziness.

148. The following six clusters of withdrawal effects are likely upon abrupt discontinuation of SSRIs:

(a) Neurosensory effects (vertigo, tingling and burning),

(b) Neuromotor effects (tremor, spasms, visual changes),

(c) Gastrointestinal effects (nausea, vomiting, diarrhea, weight loss),

(d) Neuropsychiatric effects (anxiety, depression, crying spells, irritability, suicidal thinking),

(e) Vasomotor effects (heavy sweating, flushing), and

(f) Insomnia, vivid dreaming and fatigue.

149. In 2005, the FDA issued a "Black Box" warning of suicidality in children and adolescents, that "Antidepressants increased the risk of suicidal thinking and behavior (suicidality)."

150. Later, in 2007, the FDA extended the warning on suicidality to young adults, aged eighteen to twenty-four.

151. The FDA also warns of increased agitation, irritability, aggression, worsening anxiety, severe restlessness, and other unusual behaviors in youth treated with antidepressants.

152. Continuing to expose children and youth to antidepressant drugs who experience one or more of the negative effects they induce, such as mania, is likely to lead to those effects being misinterpreted as psychiatric symptoms and increases in dosage or additional drugs when reducing or stopping the offending drug would solve the problem.

Stimulants

153. The following stimulants have been approved for the following pediatric uses:

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		

154. The drugs set forth in the preceding paragraph show minimal, if any, long-term efficacy in general life domains of the child, including social and academic success.

155. The following are short-term observed desirable effects of the stimulants at usual doses:

(a) Increase alertness and wakefulness,

(b) Induce sense of well-being (euphoria), and

(c) Improve accuracy on brief physical and mental tasks.

156. The following are effects of the stimulants regularly misconstrued as therapeutic in children and youth by physicians and other practitioners:

(e) Increased repetitive, persistent behavior,

(f) Decreased exploration and social behavior, and

(g) Increased compliance with the wishes of adults in their lives.

157. The following are undesirable observed behavioral effects of stimulants:

(a) Nervousness and restlessness,

(b) Insomnia,

(c) Agitation,

(d) Depression, including a "zombie" look,

(e) Irritability and aggression,

(f) Psychological dependence, and

(g) Mania and psychosis.

158. The following are undesirable observed physical effects of stimulants:

(a) Increased blood pressure,

(b) Dizziness and headaches,

(c) Palpitations,

(d) Stomach cramps and nausea,

(e) Appetite and weight loss,

(f) Stunted growth, including stunted brain growth,

(g) Brain atrophy, and

(h) Cardiac arrest.

159. Decreases in growth caused by the stimulants given to children and youth are a result of their impact on the brain and pituitary gland disrupting growth hormone production and average three fourths of an inch and 6 pounds without evidence the affected children and youth will make up the stunted growth even after stopping the stimulant(s).

160. Brain dysfunctions induced by stimulants include the following:

(a) Reduced blood flow,

(b) Reduced Oxygen supply,

(c) Reduced energy utilization,

(d) Persistent biochemical imbalances,

(e) Persistent sensitization (increased reactivity to stimulants),

(f) Permanent distortion of brain cell structure and function,

(g) Brain cell death and tissue shrinkage,

(h) Cytotoxicity with chromosomal abnormalities,

(i) Dependence and tolerance, and

(j) Withdrawal symptoms.

161. Stimulants prescribed to children and youth are Drug Enforcement Administration "Schedule II Drugs," which means they result in tolerance, dependence and abuse.

162. Children and youth prescribed stimulants are more prone to use cocaine and smoke cigarettes as young adults than children and youth who were not prescribed stimulants.

163. In 2006, the FDA warned that stimulants increase aggression, mania and/or psychotic symptoms, including hallucinations, as well as the risk of sudden death in patients with heart problems.

164. The FDA "black box" warning for Adderall (amphetamine and dextroamphetamine), which is prescribed to millions of American children and youth, reads: "Amphetamines have a high potential for abuse. Administration of amphetamines for prolonged periods of time may lead to drug dependence." The warning also states: "Misuse of amphetamines may cause sudden death and serious cardiovascular adverse events."

165. The Surgeon General's Report on Mental Health, the American Psychological Association report, and a review of over 2,200 studies of ADHD treatment did not find these drugs safe or effective.

Anticonvulstants Promoted as "Mood Stabilizers"

166. Starting in the 1980s and 1990s, due to dissatisfaction with lithium and neuroleptics in the treatment of people diagnosed with Bipolar Disorder, previously

known as Manic Depressive Illness, drug companies promoted the use of anticonvulsants, i.e., antiepileptics and antiseizure drugs, for people diagnosed with Bipolar Disorder.

167. None of these drugs, including Tegretol, Equetro, Neurontin, Lamictal, Depakene, Depakote, Topamax, Trileptal, and Gabitril have been approved for pediatric psychiatric indications.

168. The following anticonvulsants carry the following FDA "Black Box Warnings:"

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

169. A 40-fold increase in the diagnosis of pediatric Bipolar Disorder over ten years ensued upon the promotion of these drugs for children and youth given this diagnosis.

170. No studies confirm the efficacy and safety of anticonvulsants to treat children diagnosed with Bipolar Disorder.

171. No anticonvulsant has been approved by the FDA for any psychiatric indication in children or youth.

172. More than ninety percent of children diagnosed with Bipolar Disorder receive more than one psychoactive drug and less than forty percent receive any psychotherapy.

173. In an open trial of lithium divalproex or carbamezepine (Tegretol) on youth, in which fifty eight percent received at least one of the two drugs plus a stimulant, an atypical neuroleptic, or an antidepressant, half of all participants did not respond to the drug treatment.

174. In 2008, the FDA warned that anticonvulsants double the risk of suicidal behavior or ideation, with treatment of epilepsy having the highest risk, ruling out psychiatric status as a confounding variable.

175. Desired observed behavioral effects of anticonvulsants include:

(a) Reducing aggression and impulsivity, and

(b) Calming restlessness and excitability.

176. Undesired observed behavioral effects of anticonvulsants include:

(a) Depression and sedation,

(b) Hostility and irritability,

(c) Aggression and violence,

(d) Anxiety and nervousness,

(e) Hyperactivity,

(f) Abnormal thinking,

(g) Confusion and amnesia,

(h) Slurred speech, and

(i) Sedation and sleepiness.

177. Undesired observed physical effects of anticonvulsants include:

(a) Nausea and dizziness,

(b) Vomiting and abdominal pain,

(c) Headaches and tremors,

(d) Fatal skin rashes,

(e) Hypothyroidism,

(f) Blood disorders,

(g) Pancreatitis, liver disease,

(h) Birth defects and menstrual irregularities, and

(i) Withdrawal seizures.

Evidence-Based, Less Intrusive Alternatives: Psychosocial Interventions

178. "Evidence-Based Practice" in medicine and in non-medical helping professions has been defined as the integration of best research evidence, clinical judgment, and client preferences and values.

179. Criteria for judging an intervention as an Evidence-Based Practice, such as the administration of psychotropic medication to children and youth, include (a) whether it has a sound theoretical basis, (b) whether it carries a low risk of harm or an acceptable risk-benefit ratio, (c) whether unbiased research supporting the intervention exists, and (d) whether the decision maker, the child or youth and/or the child or youth's parent(s) or guardian concur.

180. In order for an intervention such as the administration of a psychotropic drug(s) to a child or youth to be an Evidence Based Practice, the intervention must have

at least some unbiased observations or tests supporting its usefulness with the particular problem sought to be addressed, taking into account the age of the child or youth.

181. Published evidence is often biased, being influenced by funding sources, researcher biases and conventional wisdom.

182. Children and youth experience loss and trauma because of disrupted attachments to biological parents, which result in foster care placements, both with and without termination of parental rights.

183. Children and youth experience emotional disruption from out-of-home placement, from their difficulty adjusting to a foster care setting, from experiencing unsettling multiple foster care placements, multiple school placements, high turnover of caregivers, as well as sometimes experiencing more trauma and physical and or sexual abuse in foster care, step families, group homes, residential treatment centers, and psychiatric hospitals.

184. The brains of children develop in a socially dependent manner, through secure attachments and consistent, competent adults attuned to the needs of the children.

185. Trauma, abuse and neglect disrupt a child's ability to form secure attachments, impair brain development and regulation, make self-control difficult and alter the child's identity and sense of self.

186. The ability to function well despite living or having lived in such adversity rests mainly on normal cognitive development and involvement from a caring, competent adult.

187. Risk and protective factors in the foster child, foster-families, agencies, and birth family all interact to produce positive or negative spirals of development.

188. Understanding children and youth's resilience helps create interventions that produce positive turning points in children and youth's lives.

189. Three key elements in positive outcomes for children and youth in foster care settings are (a) having a secure base where the child or youth has a strengthening sense of security and is able to use his or her foster parents as a secure base, (b) having a sense of permanence where the foster placement is stable and foster-parents offer family membership, and (c) positive social functioning in which the child or youth is functioning well in school and with peers.

190. Treatment goals for children and youth in state custody who are presenting emotional and/or behavioral problems should be to (a) enhance their sense of personal control and self-efficacy, (b) maintain an adequate level of functioning, and (c) increase their ability to master, rather than avoid, experiences that trigger intrusive re-experiencing, numbing, or hyper-arousal sensations.

191. Proven effective alternatives to psychotropic medication for children's emotional and/or behavioral problems include (a) consistent, structured, supportive adult supervision, (b) opportunities for self-expression and physical activity to give them a sense of mastery over their minds and bodies, and (c) a stable academic environment where they master both academic basics and more complicated academic material.

192. Activities that have been proven helpful for children's emotional and/or behavioral problems include (a) teaching problem solving and pro-social skills, (b)

modeling appropriate behaviors, (c) teaching self-management, and (d) helping them learn to comply and follow rules.

193. Interactions that have been shown to be helpful for children's emotional and/or behavioral problems include (a) desensitizing hyper-reactivity, (b) promoting self-calming and modulation of arousal states, (c) organizing sustained attention, and (d) facilitating organized, purposeful activity.

194. Interventions that have been shown helpful for children and youth's emotional and/or behavioral problems include (a) Cognitive-Behavioral Therapy (CBT), (b) Interpersonal Psychotherapy, (c) Psychodynamic Psychotherapy, (d)Exposure-based Contingency Management, and (e) Problem-solving and Coping-Skills Training.

195. In addition to the foregoing, family-based behavioral interventions are effective for children and youth diagnosed with disruptive and conduct disorders.

196. In addition to the foregoing, effective psychosocial treatments shown to be helpful for children diagnosed with Bipolar Disorder and Schizophrenia include (a) Child and Family Focused CBT, combined with interpersonal and "social rhythm" therapy to stabilize mood, activities and sleep, and (b) Community support and social acceptance through day programs and sports and cultural activities.

197. Effective parenting is the most powerful way to reduce child and youth problem behaviors.

198. The types of parenting training with the strongest evidence base are (a) Parent Management Training (PMT), (b) Problem-Solving Skills Training (PSST), (c) Brief Strategic Family Therapy (BSFT), and (d) Functional Family Therapy (FFT).

199. The goals of such parent training include (a) promoting parent competencies and strengthening parent-child bonds, (b) increased consistency, predictability and fairness of parents, and (c) producing positive behavior change in their children.

200. Maltreatment is consistently linked to aggressive behavior in children and youth, with a history of trauma being virtually universal in youth diagnosed with conduct disorders.

201. Children and youth in foster care have socio-emotional problems three to ten times more often than other children and youth.

202. Coercive interactions, including the administration of psychotropic drugs, result in escalation of aggressive behaviors.

203. A large evidence base supports behavioral interventions for children diagnosed with ADHD, including parenting training, social skills training and school-based services, resulting in at least as positive outcomes as stimulant medications without the attendant physical harm.

204. Mentoring has been defined as a relatively long term, non-expert relationship between a child and non-parental adult, based on acceptance and support, aiming to foster the child's potential, where change is a desired but not predetermined goal.

205. Strong evidence exists that mentoring programs have significant positive effects, with community-based programs being more effective than school based programs.

206. Mentoring in foster care settings has been found particularly helpful for children and youth placed in foster homes by providing a bridge to employment and

higher education and helping with problems surrounding transitioning from foster care, sometimes called "aging out."

207. Factors found to be important in mentoring children and youth in foster care include (a) frequent contacts, (b) emotional closeness, also called "attunement," (c) relatively long duration, (d) structured activities, and (e) ongoing training for the mentors.

208. Sensitive mentoring has been found to increase self-esteem and well-being, reduce aggression, and open new relationships beyond the foster care system, significantly reducing negative outcomes as youth "age out" of the foster care system.

209. Mentoring also reduces the likelihood of children and youth in foster care committing violent offences through "having someone to count on when needed," which softens the impact of trauma.

210. Medicalizing children and youth's distress and disability is part of mainstream mental health practice, defining their distress and disability as disorders or diseases, and managing them with medical means, pathologizing their behavior and ignoring the context of their experiences leading to the problem behavior.

211. Understanding rather than diagnosing, changes the meaning of distressing behaviors and can lead practitioners to adopt less harmful and more helpful interventions.

"CriticalThink Rx" Specifications

212. The Critical ThinkRx program specifies that certain questions should be considered before a legitimate determination to authorize the administration of psychotropic medication to children and youth can be made.

213. The Critical ThinkRx Program specifies that the following questions should be asked and answered about the child or youth to whom the administration of psychotropic drugs is contemplated:

(a) What are the client's symptoms or observed behaviors of concern, who has observed them?

(b) Has the client experienced any recent or chronic life events or stressors that may contribute to the problems?

(c) Could any of the client's problems be caused by a current medication?

(d) Does the client's psychiatric diagnosis truly reflect the client's problems? Is the diagnosis useful to plan for interventions with this client?

(e) What interventions have been tried to address client's problems? By whom, and with what results?

(f) Are alternative interventions available to address the client's problems? Why have they not yet been tried?

(g) Why is medication being prescribed for this client? What other medication has been prescribed currently or in the past?

(h) How long before we see improvements? How will the improvements be measured?

(i) How long will the patient be on the medication? How will a decision to stop be made?

(j) If client is a minor, is the medication designed to benefit the child, or the child's caregivers?

214. The Critical ThinkRx Program specifies that the following questions should be asked and answered about psychotropic medication proposed for administration to a child or youth:

(a) Why is this particular medication prescribed for this client?

(b) 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?

(c) 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?

(d) 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?

(e) What is the recommended dosage? How often will the medication be taken? Who will administer it?

(f) Has this medication been shown to induce tolerance and/or dependence? What withdrawal effects may be expected when it is discontinued?

(g) Do any laboratory tests need to be done before, during, or after use of this medication?

(h) Are there other medications or foods the child should avoid while on this medication?

(i) What are the potential positive and adverse effects of this medication?

(j) 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?

(k) How will the use of medication impact other interventions being provided?

(l) How much does this medication cost? Who is paying for it? Are there cheaper, safer, generic versions of this medication?

215. The Critical ThinkRx Program specifies that the following questions should be asked and answered about the prescriber who is proposing that the administration of psychotropic medication to a child or youth be authorized:

(a) What is the experience of the physician prescribing the medication?

(b) Would you consider the physician's prescribing habits cautious and conservative?

(c) Does this physician have any financial relationships with pharmaceutical companies? Have these been disclosed to patients?

(d) 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?

(e) Is there an adequate monitoring schedule and follow-up in place?

(f) 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?

216. The Critical ThinkRx Program specifies that the following questions should be asked and answered by the decision maker, termed "therapist," when considering whether to authorize the administration of psychotropic medication to children and youth or youth:

(a) Has a comprehensive assessment (e.g., biopsychosocial, holistic, integral) been conducted? Does it offer plausible reasons for the client's problems?

(b) Are there other explanations for the client's behavior?

(c) 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?

(d) Do I know how the client/client's family feel about the use of medication?

(e) What is my role and has it been clearly delineated with all other providers?

(f) Has the client/client's family been provided with all the information necessary to provide informed consent? Do they understand their choices?

(g) 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?

(h) Will I be able to educate my client about these effects so he/she can raise concerns with the prescribing physician?

(i) What alternative services/interventions does this family need or want?

(j) Can I provide these or help them obtain access?

217. The Critical ThinkRx Program specifies that children and youth not be administered psychotropic drugs unless and until,

(i) Evidence-based psychosocial interventions have been exhausted,

(ii) Rationally anticipated benefits outweigh the risks,

(iii) The person or entity authorizing administration of the drug(s) is fully informed, and

(iv) Close monitoring of and appropriate responses to, treatment emergent effects are in place.

DEFENDANTS' AUTHORIZING AND PAYING FOR THE ADMINISTRATION OF PSYCHOTROPIC DRUGS TO CHILDREN AND YOUTH IS ILL-INFORMED AND EXTREMELY HARMFUL

218. The Defendants' practice of authorizing and paying for the administration of psychotropic drugs to children and youth far exceeds evidence of safety and effectiveness.

219. Defendants' reliance on prescribers in authorizing and paying for the administration of psychotropic drugs to Alaskan children and youth is improper, constituting a violation of their right to competent and informed decision making by Defendants.

220. Competent and informed decisions regarding the administration of or payment for psychotropic drugs to children and youth and informed consent, include, at a minimum, consideration of:

(a) the child or youth's diagnosis and prognosis, or their predominant symptoms, with and without the medication;

(b) the proposed medication, its purpose, the method of its administration, the recommended ranges of dosages, possible side effects and benefits, ways to treat side effects, and risks of other conditions, such as Tardive Dyskinesia;

(c) the child's history, including medication history and previous side effects from medication;

(d) interactions with other drugs, including over-the-counter drugs, street drugs, and alcohol; and

(e) alternative treatments and their risks, side effects, and benefits, including the risks of nontreatment.

221. Defendants' authorization and payment for the administration of psychotropic drugs to Alaskan children and youth is not based on competent and knowledgeable decision making and informed consent.

222. Defendants' authorization and payment for the administration of psychotropic drugs to Alaskan children and youth is rarely in the best interest of the child or youth.

223. Defendants' authorization and payment for the administration of psychotropic drugs to Alaskan children and youth is often to suppress their negative emotions leading to disruptive actions— especially under stressful conditions that tax the child or youth’s adaptive capacities.

224. Children and youth are commonly administered psychotropic medication to suppress impulsive aggression.

225. Defendants' authorization and payment for the administration of psychotropic drugs to Alaskan children and youth is often for the convenience of the adult or adults in the child's or youth's life.

226. Defendants' authorization and payment for the administration of psychotropic drugs to Alaskan children and youth is rarely, if ever, based on a valid assessment of the potential benefits and risk of harm.

227. Defendants' authorization and payment for the administration of psychotropic drugs to Alaskan children and youth rarely, if ever, occurs after the less intrusive evidence-based psychosocial interventions set forth in the above section on Evidence-Based, Less Intrusive Alternatives: Psychosocial Intervention have been tried, let alone exhausted.

228. Defendants' authorization and payment for the administration of psychotropic drugs to Alaskan children and youth always, or almost always, occurs without close monitoring of, and appropriate means of responding to, treatment emergent effects being in place.

229. From April 1, 2007, through June 30, 2007, at least 1,033 Alaskan children and youth under the age of 18 receiving Medicaid benefits were prescribed second-generation neuroleptics.

230. From April 1, 2007, through June 30, 2007, at least 1,578 Alaskan children and youth under the age of 18 receiving Medicaid benefits were prescribed stimulants.

231. From April 1, 2007, through June 30, 2007, at least 293 Alaskan children and youth under the age of 18 receiving Medicaid benefits were prescribed supposedly non-stimulant drugs such as atomoxetine hydrochloride (Strattera).

232. From April 1, 2007, through June 30, 2007, at least 871 Alaskan children and youth under the age of 18 receiving Medicaid benefits were prescribed antidepressants.

233. From April 1, 2007, through June 30, 2007, at least 15 Alaskan children and youth under the age of 18 receiving Medicaid benefits were prescribed first-generation neuroleptics.

234. From April 1, 2007, through June 30, 2007, at least 723 Alaskan children and youth under the age of 18 receiving Medicaid benefits were prescribed anticonvulsants marketed as mood stabilizers.

235. From April 1, 2007, through June 30, 2007, at least 470 Alaskan children and youth under the age of 18 receiving Medicaid benefits were prescribed noradrenergic agonists, most likely Clonidine to counteract problems caused by the administration of neuroleptics.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, the Law Project for Psychiatric Rights, an Alaska non-profit corporation, requests the Court enter the following relief:

A. Issue a declaratory judgment that Alaskan children and youth have the constitutional and statutory 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 of the risks and potential benefits, and

(iv) close monitoring of, and appropriate means of responding to, treatment emergent effects are in place.

B. Permanently enjoin the defendants and their successors from authorizing or paying for the administration of psychotropic drugs to Alaskan children and youth without conformance with Paragraph A of this prayer for relief.

C. Order that

(i) all children and youth in state custody currently being administered psychotropic drugs, and

(ii) all children and youth to whom the state of Alaska currently pays for the administration of psychotropic drugs

be reassessed in accordance, and brought into compliance, with the specifications of Critical ThinkRx, as set forth above, by a contractor knowledgeable of the Critical ThinkRx curriculum and ready, willing and able to implement the Critical ThinkRx specifications, appointed and monitored by the Court, or a Special Master to be paid for by the State, appointed for that purpose.

D. Award Plaintiff costs and attorney's fees.

E. Such other relief as the court finds just in the premises.

DATED: September 29, 2008.

Law Project for Psychiatric Rights, an Alaskan non-profit corporation

By: _____
James B. Gottstein, ABA # 7811100

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December 10, 2004

Sen. Fred Dyson
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Eagle River, AK 99577
(fax) 694-1015

State Capitol, Room 121
Juneau, AK 99801-1182

Rep. Peggy Wilson
PO Box 109
Wrangell, AK 99929
(fax) 907-874-3055

State Capitol, Room 104
Juneau, AK 99801-1182

Re: Office of Children's Services

Dear Sen. Dyson and Rep. Wilson:

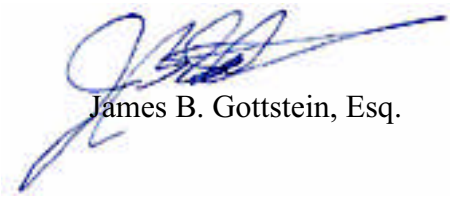
I am pleased you are holding hearings regarding the Office of Children's Services and the difficulties they have had in protecting children it seems they should have known about and acted upon. I am, however, writing about another side of the coin. That is there is increasing reason to believe children taken into custody by OCS are being abused on a large scale.

More specifically, it is almost certain a large number of children in state custody are on dangerous psychotropic medications that have never been approved for children. The worst of these drugs are the neuroleptics, including the newer ones, called "atypicals." These medications make it tremendously difficult for children to ever grow up to lead normal lives. They cause, rather than cure mental illness. It has been found in other states that a large number of children in foster care or outright custody are on these drugs in order to control their behavior, rather than help them deal with the traumas in their lives that are causing the troubling behavior.

When a psychiatrist employed by the State of Pennsylvania to perform a quality assurance review there defied his orders not to look into prescribing practices, he was fired. He found four children had died from improper prescribing. Thousands more are merely being harmed for life. There is every reason to believe the same thing is happening to Alaska kids.

In my view, your committee should look into the situation here in Alaska. Please feel free to contact me with any questions or if you would like further information.

Yours truly,



James B. Gottstein, Esq.

Commissioner Joel Gilbertson

Exhibit A

X-Mailer: QUALCOMM Windows Eudora Version 7.0.1.0
Date: Fri, 09 Mar 2007 17:13:32 -0900
To: Representative_Jay_Ramras@legis.state.ak.us,
Representative_Nancy_Dahlstrom@legis.state.ak.us,
Representative_John_Coghill@legis.state.ak.us,
Representative_Bob_Lynn@legis.state.ak.us,
Representative_Ralph_Samuels@legis.state.ak.us,
Representative_Max_Gruenberg@legis.state.ak.us,
Representative_Lindsey_Holmes@legis.state.ak.us
From: Jim Gottstein <jim.gottstein@psychrights.org>
Subject: Follow-Up: Over Drugging of Kids in State Custody
Cc: sarah_palin@gov.state.ak.us,Senator_Bettye_Davis@legis.state.ak.us,
Representative_Peggy_Wilson@legis.state.ak.us,
Representative_Bob_Roses@legis.state.ak.us,
Representative_Sharon_Cissna@legis.state.ak.us,
Representative_Anna_Fairclough@legis.state.ak.us,
Representative_Mark_Neuman@legis.state.ak.us,
Representative_Berta_Gardner@legis.state.ak.us,
Senator_Joe_Thomas@legis.state.ak.us,
Senator_John_Cowdery@legis.state.ak.us,
Senator_Kim_Elton@legis.state.ak.us,
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Jim Gottstein <jim.gottstein@psychrights.org>

Dear Members of the House Judiciary Committee:

When I testified to the committee on February 8th, one of the things I reported on was the pervasive over-drugging of kids in state custody with psychiatric drugs not approved for children and in combinations that had never even been studied. Representative Coghill challenged me on whether I had any proof and I informed the committee that as far as I knew the State is not keeping track of this extremely important information, but that based on what is being found in other states that have looked into it, approximately 70% of the children in state custody are on psychiatric drugs, many in especially harmful combinations. There is every reason to believe the same is happening to Alaska kids. I wrote to Senator Dyson and Representative Wilson about this issue in December of 2004.
http://psychrights.org/States/Alaska/Kids/OCSHearingltr.pdf

Thus, this is not a new issue about a problem negatively impacting many Alaskan children, but it is being ignored as far as I can tell. There is an article today by Evelyn Pringle at http://www.lawyersandsettlements.com/articles/00660/zyprexa-medical-costs.html , which includes a description of some of what is happening in other states. I have reproduced a couple of passages from the article below:

> In the summer of 2002, psychiatrist, Dr Kruszewski, was employed with the Pennsylvania Department of Public Welfare, and charged with reviewing psychiatric

care provided by state-funded agencies to identify waste, fraud, and abuse. He was also responsible for reviewing the deaths of individuals in state care who died under suspicious circumstances in facilities inside and outside of Pennsylvania.
Early in his investigation, Dr Kruszewski noticed that almost all of the patients under state care were on drug cocktails consisting of antipsychotics, antidepressants, and anticonvulsants. The populations he found drugged most often, he said, were children in state care, the disabled, people in state prisons, and children in the juvenile justice system.

For instance, he says, Neurontin was only approved for controlling seizures, but "was being prescribed for anxiety, social phobia, PTSD, oppositional defiant behavior, and attention deficit disorder with no evidence to support these uses."
When he informed his superiors about the high rate of off-label prescribing and warned about the risk of liability to the state of Pennsylvania if it continued, he was told, "it is none of your business."
In June 2003, Dr Kruszewski inspected a facility in Oklahoma that housed children from Pennsylvania after an unexpected death of a child, and found children were being overmedicated and housed in deplorable living conditions, in addition to being sexually and physically abused by staff and kept in unnecessary restraints and seclusion.
In a report, Dr Kruszewski recommended removing the children from the facility, "in order to protect other innocent individuals from morbid and mortal consequences of severe over-medication, including chemical restraints; emotional, physical and sexual abuse; seclusion; and dirty and inadequate living conditions."
A day later, Dr Kruszewski was accused of "trying to dig up dirt," and was subsequently fired in July 2004, because he refused to keep quiet and accept that it was none of his business, he says.

* * *

TMAP required doctors to prescribe atypicals rather than the older, less expensive antipsychotics. "The plan," Mr Jones explains, "was part of a larger scheme designed to infiltrate public institutions to influence prescribing practices in which drug companies bought the opinions of a few key doctors and state policymakers, and opened the door for spending billions of tax dollars on dangerous drugs."

The Texas lawsuit describes exactly how the TMAP preferred drug list was developed in Texas in 1997, and according to the complaint, Dr Shon traveled around the country at J&J's expense to convince officials in other states to adopt the TMAP model, which is now used in 17 states.

The lawsuit says, J&J promoted Risperdal by influencing policymakers with trips, perks, travel expenses, speaking fees and other payments and that Risperdal was recommended as the drug of choice for children, even though it was not approved for use with children.

TMAP was highly successful in getting doctors to prescribe atypicals to kids. According to an investigation of psychiatric drug use by Texas children on Medicaid, ACS-Heritage, a medical consulting firm, found 19,404 teens were prescribed an antipsychotic in July or August of 2004, with nearly 98% being atypicals.

ACS also found that more than half of the doses were inappropriately high, almost half of the prescriptions did not appear to have diagnoses warranting their use, and one-third of the children were on two or more drugs.

The Texas lawsuit alleges that J&J concealed Risperdal's link to hyperglycemia, stroke,

and renal failure, to qualify for reimbursement under Medicaid, and that Texas seeks to recover money paid to purchase the drug for off-label uses and the cost of medical care for the people injured by Risperdal.

It is my hope Alaska will voluntarily do something about the serious harm it is inflicting on kids it is taking from their families on the grounds that they are not safe, and also those it is having locked up and drugged in what are called "Residential Treatment Facilities."

Note New E-mail Address

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Psych Rights ®
Law Project for Psychiatric Rights

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of unwarranted forced psychiatric drugging. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Extensive information about this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

X-Mailer: QUALCOMM Windows Eudora Version 7.0.1.0
Date: Wed, 14 Mar 2007 09:31:04 -0800
To: sarah_palin@gov.state.ak.us,Representative_Jay_Ramras@legis.state.ak.us,
Representative_Nancy_Dahlstrom@legis.state.ak.us,
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karleen_jackson@health.state.ak.us,Stacy_Toner@health.state.ak.us
From: Jim Gottstein <jim.gottstein@psychrights.org>
Subject: Follow-Up: Over Drugging of Kids in State Custody
Cc: "Demer, Lisa" <LDemer@adn.com>,
"Bruce Whittington" <Bruce.Whittington@PsychRights.Org>,
"DJRICCIO-aol.com" <DJRICCIO@aol.com>,lloydross1@worldnet.att.net,
kreffrem@pro-ns.net,ARONWOLF@aol.com,
Jim Gottstein <jim.gottstein@psychrights.org>,
Vera Sharav <veracare@ahrp.org>,
"list-psychrights.org" <list@psychrights.org>,
Senator_Johnny_Ellis@legis.state.ak.us,
"Susan Musante" <susan@soteria-alaska.com>,mgstone@arctic.net

Dear Governor Palin and other Alaska Mental Health Policy Makers,

I wrote to most of you last Friday about Alaska's over-drugging of children in state custody:

> [A]s far as I knew the State is not keeping track of this extremely important information, but that based on what is being found in other states that have looked into it, approximately 70% of the children in state custody are on psychiatric drugs, many in especially harmful combinations. There is every reason to believe the same is happening to Alaska kids. I wrote to Senator Dyson and Representative Wilson about this issue in December of 2004.
> http://psychrights.org/States/Alaska/Kids/OCSHearingltr.pdf
>
> Thus, this is not a new issue about a problem negatively impacting many Alaskan children, but it is being ignored as far as I can tell.

I included some information about what has been happening in other states, including kids being killed by these drugs. Yesterday, as reported by the Alliance for Human Resource Protection (AHRP) today, the AP issued a report about this problem (below). **This is state inflicted child abuse.** It is **your responsibility** to investigate what the State of Alaska is doing to children in its custody as well as in "residential treatment centers" and stop this abuse.

The massive over-drugging of America's children is a titantic health catastrophe caused by the government's failure to protect its most precious citizens, who rely on the adults in their lives to shield them from harm, not inflict it upon them. Perhaps the worst of all is the State inflicting this harm on children it has taken from their homes "for their own good."

Please correct this situation.

ALLIANCE FOR HUMAN RESEARCH PROTECTION (AHRP)
Promoting Openness, Full Disclosure, and Accountability
www.ahrp.org and http://ahrp.blogspot.com

FYI

The chemical abuse of U.S. children in foster care represent the collapse of civilized medicine.

The Associated Press report (below) provides but a glimpse into a world of wantonly prescribed psychotropic drugs for children.
Children are being chemically assaulted under the guise of "treatment."
Psychiatrists under the influence of drug manufacturers are misusing their prescribing license all across the U.S when they prescribe toxic combinations of psychotropic drugs for helpless children.

"The picture is bleak, and rooted in profound human suffering."
That was the stinging verdict of a report on psychiatric treatment of foster children, including the misuse of medication issued by outgoing Texas state comptroller Carole Keeton Strayhorn in December. The report recommended hiring a full-time medical director for foster children and requiring prior approval for certain prescriptions.
http://www.window.state.tx.us/specialrpt/hccfoster06

In New York--"Children who are having normal reactions to the trauma of being separated from their families are often misdiagnosed or overdiagnosed as suffering from psychiatric problems, and the system is too quick to medicate," said Mike Arsham of the Child Welfare Organizing Project. '

'It's a chemical sledgehammer that makes children easier to manage."

Among the New York parents sharing that view is Carlos Boyet, who says his son was routinely and unnecessarily medicated, at one point suffering an overdose, while bouncing through several foster homes as a toddler.

The boy, Jeremy, had been taken away from Boyet's ex-girlfriend; Boyet eventually established paternity and was able to gain custody of his son, then 6, in 2005. "It's crazy," Boyet said.

"A child is acting out because he was moved away from his parent, and you're going to medicate him because of that? It's not right."

"There is such a lack of good psychiatric services, and you have the pharmaceutical companies and managed care companies saying, 'Medicate, Medicate,'" Abramovitz said. "That's all they want psychiatrists to do. They don't pay for anything else."

Referring collectively to child psychiatrists, he added, "We do not want to be pill-vending machines. But the alternatives aren't there."

Carole Keeton Strayhorn's son, the former head of the FDA, Dr. Mark McClellan, testifies before the Senate HELP committee tomorrow about drug safety. The FDA bears some responsibility for failing to prevent the widespread abusive prescribing of psychotropic drug combinations for children. Inasmuch as these drugs and drug combinations have not been tested for safety or approved for use in children, the FDA could have but failed to use its authority to ban their use.

ALLIANCE FOR HUMAN RESEARCH PROTECTION (AHRP)
Promoting Openness, Full Disclosure, and Accountability
www.ahrp.org and http://ahrp.blogspot.com

Contact: Vera Hassner Sharav
212-595-8974
veracare@ahrp.org

~~~~~~

March 13, 2007
A Dilemma: Medications for Foster Kids
By THE ASSOCIATED PRESS
Filed at 3:51 p.m. ET

NEW YORK (AP) -- Coast to coast, states are wrestling with how best to treat the legions of emotionally troubled foster children in their care. Critics contend that powerful psychiatric drugs are overused and say poor record-keeping masks the scope of the problem.
Nationwide, there are more than 500,000 children in foster care at any one time, and more than half have mental illness or serious behavioral problems, according to the Child Welfare League of America.

"The child welfare system wasn't prepared for the deluge of kids that have mental health problems," said Dr. Chris Bellonci, a child psychiatrist in Needham, Mass. "By default, it's become a mental health delivery system
~~~~~~

and it's ill-equipped to do that."
Some states have taken broad action -- often in response to overdose tragedies, lawsuits or damning investigations. California requires court review of any psychotropic drug prescription for a foster child; Illinois has designated a prominent child psychiatrist to oversee such reviews.

In other states, however, experts say the issue is not being adequately addressed and basic data is lacking that would show the extent of medication usage.

"It's a problem that's really ugly, and growing under a rock, and no one wants to turn the rock over," said Dr. Michael Naylor, the psychiatrist in charge of Illinois' review program, who recently struggled to get responses from other states for a paper he is writing on the topic.
Some parents and advocacy groups say child welfare authorities routinely resort to drugs to pacify foster children without fully considering non-medication options. Among the aggrieved parents is Sheri McMahon of Fargo, N.D., whose son Willy was in foster care for 28 months from 2001 to 2003 because of an inspector's ruling that their home was substandard.

McMahon said Willy, now 17, had been diagnosed with multiple disorders and was taking an antidepressant when he entered foster care. But she said that in a residential foster-care facility, he was placed on five psychotropic medications simultaneously -- becoming sleepy and overweight and developing breathing difficulties.

"When he came back home, his pediatrician and psychiatrist expressed concern about the number and doses of medications," McMahon said. "It took many months to get them down to a level where he had a chance of attending school regularly."

Child psychiatrists say a shortage of funds and resources complicate the already daunting task of effectively diagnosing and treating mental illness in foster children. One problem, Bellonci said, is a nationwide shortage of child psychiatrists, often leaving pediatricians to handle complex behavioral problems.

Bellonci helped Tennessee's Department of Children's Services -- the target of a sweeping lawsuit -- overhaul its procedures for psychotropic drugs after an investigation found that 25 percent of foster children were taking them, often without legal consent. Tennessee's policies are now considered among the best, encouraging expert reviews of prescriptions and urging prescribing doctors to consult with the youth, caseworkers and the biological and foster parents before deciding on medication.

The issue is very much alive in several other states. Among them:

--In Florida, child welfare officials will be reporting to the legislature within weeks on the effects of a 2005 bill that tightened rules on when foster children can be given psychotropic drugs. The law requires prior consent of a foster child's parents or a court order before such drugs can

be used. The bill's approval followed a report concluding that mood-altering drugs were being prescribed to 25 percent of Florida's foster children.

--In Texas, outgoing state comptroller Carole Keeton Strayhorn issued a stinging report in December on psychiatric treatment of foster children, including the use of medication. "The picture is bleak, and rooted in profound human suffering," said the report, which recommended hiring a full-time medical director for foster children and requiring prior approval for certain prescriptions. Some activists say the recommendations, 48 in all, are unlikely to be embraced by the task force studying them; state health officials say use of psychotropic drugs for foster children is already declining because of guidelines adopted in 2005.

--In California, Assemblywoman Noreen Evans introduced a bill last month that would require the state to collect the necessary data to show whether foster children are being overmedicated. "Many foster youth have told me that they are given pills instead of counseling," Evans said. "The state doesn't track who receives prescriptions and why. We need to do that in order to prevent abuses."

Oversight and data collection is complicated in California because the medication regulations are handled by county courts. Dr. George Fouras, a psychiatrist hired to review foster-care prescriptions for San Francisco County, said the overwhelming majority of medication decisions are proper, and he has rejected only four out of many hundreds. But he said child-welfare systems nationwide are overloaded, sometimes tempting authorities to look for quick fixes instead of ensuring detailed mental-health evaluations.

--In New York City, the public advocate -- who serves in a watchdog role -- asked child welfare officials three years ago for data on the use of psychotropic drugs in the foster care system. The data is still not available, although Assistant Commissioner Angel Mendoza of the city's Administration for Children's Services said a database should be ready later this year.

Mendoza said his agency has strict procedures governing the use of powerful medications; activists nonetheless worry that they are used too often. "Children who are having normal reactions to the trauma of being separated from their families are often misdiagnosed or overdiagnosed as suffering from psychiatric problems, and the system is too quick to medicate," said Mike Arsham of the Child Welfare Organizing Project. "It's a chemical sledgehammer that makes children easier to manage."

Among the New York parents sharing that view is Carlos Boyet, who says his son was routinely and unnecessarily medicated, at one point suffering an overdose, while bouncing through several foster homes as a toddler.

The boy, Jeremy, had been taken away from Boyet's ex-girlfriend; Boyet eventually established paternity and was able to gain custody of his son, then 6, in 2005. "It's crazy," Boyet said. "A child is acting out because

he was moved away from his parent, and you're going to medicate him because of that? It's not right."

Some child psychiatrists are concerned about a possible overreaction against the use of psychotropic drugs, saying many foster children genuinely need them. However, leading psychiatrists acknowledge the many hurdles to coming up with thorough, thoughtful diagnoses for children who have been wrested from their own families, often shift through multiple foster homes and perhaps have no appropriate blood relative with whom to consult regarding treatment.

"More times than not, kids do not get a really adequate psychiatric evaluation," said Dr. Robert Abramovitz of the New York-based Jewish Board of Family and Children's Services.

"There is such a lack of good psychiatric services, and you have the pharmaceutical companies and managed care companies saying, 'Medicate, Medicate,'" Abramovitz said. "That's all they want psychiatrists to do. They don't pay for anything else."
Referring collectively to child psychiatrists, he added, "We do not want to be pill-vending machines. But the alternatives aren't there."

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Note New E-mail Address

James B. (Jim) Gottstein, Esq.

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jim.gottstein@psychrights.org
http://psychrights.org/

Psych Rights ®
Law Project for
Psychiatric Rights

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of unwarranted forced psychiatric drugging. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Extensive information about this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

STATE OF ALASKA
DEPT. OF HEALTH AND SOCIAL SERVICES
OFFICE OF THE COMMISSIONER

SARAH PALIN, GOVERNOR

P.O. BOX 110601
JUNEAU, ALASKA 99811-0601
PHONE: (907) 465-3030
FAX: (907) 465-3068

March 22, 2007

RECEIVED
MAR 27 2007

James B. (Jim) Gottstein, Esq.
Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501

Dear Mr. Gottstein:

Thank you for your March 14, 2007 e-mail regarding the concern that children in State custody are being over medicated.

Indications for the use of psychotropic medications in children includes, but is not limited to, symptoms consistent with psychosis, bipolar disorder, severe depression, Attention Deficit Hyperactivity Disorder (ADHD), and, in certain situations, severe behavioral disturbances. Concern should be raised when multiple medications of one class are used or when doses are prescribed which are considered high for this population. Concern should also be raised when it appears that these medications are being used for behavioral control alone, or to hasten a response to inpatient treatment or, for that matter, outpatient or residential treatment.

The State of Alaska, in cooperation with First Health Corporation, has for the past 3 ½ years utilized a behavioral pharmacy management system that compares evidence-based and consensus-based practice guidelines to the prescribing practices of Alaskan clinicians. If discrepancies are identified, the company uses a combined approach of education and peer consultation to address specific concerns. Since this program started, there have been changes made in prescribing practices with the goal being improved care for Alaska's children.

The Office of Children's Services (OCS) operates under policy which requires that caseworkers must staff medication recommendations for children on their caseloads with their Supervisor and their regional Psychiatric Nurse prior to giving consent to the treatment provider. The OCS Psychiatric Nurses have weekly contacts with the professionals treating OCS children in acute care settings, i.e., North Star, Alaska Psychiatric Institute, Providence Discovery, and in residential treatment centers. OCS caseworkers and Psychiatric Nurses also participate in monthly treatment plans for children in the residential treatment facilities.

A medication can be increased or decreased for a child in custody, but cannot be started without the OCS' knowledge and consent.

Persons with concerns about a specific child in State custody being over medicated should contact the OCS at (907) 465-3191 to report the pertinent information. Thank you for bringing this matter to my attention.

Sincerely,

Karleen K. Jackson, Ph.D.
Commissioner

cc: Anna Kim, Special Staff Assistant, Office of the Governor

Psychiatric Rights, Inc.

February 4, ~~2007~~ (should be 2008)

Governor Sarah Palin
PO Box 110001
Juneau, AK 99811-0001

Re: Alaska's Psychiatric Drugging of Children in It's Custody

Dear Governor Palin:

I am the President and CEO of the Law Project for Psychiatric Rights (PsychRights), founded in late 2002 to mount a strategic litigation campaign against unwarranted forced psychiatric drugging. The reason for undertaking this mission is, contrary to the story sold by the pharmaceutical industry, these drugs:

(1) have limited effectiveness, especially for those upon whom they are forced,
(2) are causing great harm, including reducing life spans to the point where people in the public mental health system taking these drugs have a 25 year reduced lifespan,
(3) decrease, rather than increase public safety, and
(4) at least double the number of people categorized as chronically mentally ill.[1]

The latter, of course, causes great unnecessary expense to the State because almost all of these people end up as Medicaid recipients and a large percentage receive Alaska Adult Public Assistance.

In 2006 PsychRights won its first Alaska Supreme Court case, *Myers v. Alaska Psychiatric Institute*, 138 P.3d 238, in which the Court held Alaska's statutory forced psychiatric drugging regime unconstitutional, requiring, before the State may constitutionally force adults to take these drugs against their will it must prove the forced drugging is in the patient's best interest and there are no less intrusive alternatives.[2]

The terrible consequences of adult forced drugging is bad enough, but due to what is probably illegal pharmaceutical company "off-label" promotion of these drugs for use on children,[3] in recent years there has been an explosion in the administration of the most powerful, most harmful, and most debilitating psychiatric drugs to children in state custody. In connection with this, I am enclosing a copy of *Bipolar Children: Cutting Edge Controversy, Insights, and Research*, Sharna Olfman, Ed., which describes the great harm being done through the 40 times increase in the rate of diagnosing children with bipolar disorder.

It is a huge betrayal of trust for the State to take custody of children and then subject them to such harmful, often life-ruining, drugs. They have almost always already been subjected

[1] *See*, enclosed copy of affidavit of Robert Whitaker.
[2] PsychRights won its second Alaska Supreme Court case in 2007, *Wetherhorn v. Alaska Psychiatric Institute*, 156 P.3d 371, which held involuntarily committing someone as being gravely disabled under the definition in AS 47.30.915(7)(B) is constitutional only if construed to require a level of incapacity so substantial the respondent is incapable of surviving safely in freedom.
[3] *See*, enclosed article by David Healy and Joanna Le Noury.

406 G Street, Suite 206, Anchorage, Alaska 99501 ~ (907) 274-7686 Phone ~ (907) 274-9493 Fax

to abuse or otherwise had very difficult lives before the State assumes custody, and then saddles them with a mental illness diagnosis and drugs them. The extent of this State inflicted child abuse is an emergency and should be corrected immediately.[4]

Children are virtually always forced to take these drugs because, with rare exception, it is not their choice. PsychRights believes the children, themselves, have the legal right to not be subject to such harmful treatment at the hands of the State of Alaska. We are therefore evaluating what legal remedies might be available to them. However, instead of going down that route, it would be my great preference to be able to work together to solve this problem. It is for this reason that I am reaching out to you again on this issue.

Yours truly,

James B. (Jim) Gottstein, Esq.

Enc. 1. *Bipolar Children: Cutting Edge Controversy, Insights, and Research*, Sharna Olfman, Ed.
2. *Pediatric bipolar disorder: An object of study in the creation of an illness*, by David Healy and Joanna Le Noury
3. Affidavit of Robert Whitaker

cc Talis Colberg (w/o book)
Karleen Jackson (w/o book)
Sen. Bettye Davis
Sen. Hollis French
Rep. Jay Ramras
Rep. Les Gara (w/o book)
Rep. Berta Gardner (w/o book)
Rep. Sharon Cissna (w/o book)
Rep. Max Gruenberg (w/o book)
William Hogan (w/o book)
Melissa Stone (w/o book)
Anna Kim

[4] I know calling it State inflicted child abuse seems extreme, but is warranted.

STATE OF ALASKA
DEPT. OF HEALTH AND SOCIAL SERVICES
OFFICE OF THE COMMISSIONER

SARAH PALIN, GOVERNOR

P.O. BOX 110601
JUNEAU, ALASKA 99811-0601
PHONE: (907) 465-3030
FAX: (907) 465-3068

March 4, 2008

RECEIVED
MAR 0 6 2008

James B. (Jim) Gottstein, Esq.
PsychRights
406 G Street, Suite 206
Anchorage, AK 99501

Dear Mr. Gottstein:

Thank you for my courtesy copy of the letter and attachments you addressed to Governor Palin regarding unwarranted psychiatric drugging and the potential over-diagnosis of bipolar disorder of children in the custody of Alaska's Department of Health and Social Services.

The Office of Children's Services (OCS) policy 6.3.1 clearly states that administration of psychotropic medication, or any drugs prescribed for mental illness of behavioral problems, falls under the definition of major medical care. This reflects the fact that administration of these medications is viewed in a serious manner. The OCS policy further states, "Parental permission or a court order is also required for administration of psychotropic medication. If parental rights have been terminated, the assigned worker may approve administration of psychotropic medication following consultation with the supervisor, OCS regional psychiatric nurse and GAL. The consultation and resulting decision should be documented in the case file."

The policy does allow a physician or nurse to immediately administer medication if this is necessary to preserve the life of the child or prevent significant physical harm to the child or another person. Crisis administration of medications should be for a very brief duration of time and the assigned worker should be immediately informed. The worker should notify the parent of any medication administered on a crisis basis and the regional psychiatric nurse should review the circumstances regarding the administration to ensure adherence to policy.

Regarding the increase in the diagnosis of pediatric bipolar disorder, I appreciate you raising this concern. Your attached article is being forwarded to the regional psychiatric nurses within the OCS for their review and consideration.

The OCS is currently reviewing all policies and procedures. Please be encouraged to submit any future recommendations you might have regarding administration of psychotropic medications to:

Kristie Swanson
Office of Children's Services
PO Box 110630
Juneau, AK 99811

Thank you for advocating for the rights of Alaska's children.

Sincerely,

Karleen K. Jackson, Ph.D.
Commissioner

cc: Governor Sarah Palin
Talis Colberg, Attorney General
Anna Kim, Special Staff Assistant, Office of the Governor
William Hogan, Deputy Commissioner
Tammy Sandoval, Director, Office of Children's Services
Melissa Stone, Director, Division of Behavioral Health

Subject: CriticalThinkRx & the Psychiatric Drugging of Children in State Custody
From: Jim Gottstein <jim.gottstein@psychrights.org>
Date: Wed, 11 Jun 2008 11:49:14 -0800
To: william.hogan@alaska.gov
CC: melissa.stone@alaska.gov, talis.colberg@alaska.gov, Jim Gottstein <jim.gottstein@psychrights.org>, sarah.palin@alaska.gov, jeff_jessee@mhta.revenue.state.ak.us, tammy.sandoval@alaska.gov, anna.kim@alaska.gov, LDemer@adn.com, nancy.gordon@alaska.gov, "Toomey, Sheila" <SToomey@adn.com>, doolittle@acsalaska.net

Dear Mr. Hogan:

In a last-ditch effort to avoid litigation as I begin drafting my complaint seeking a declaratory judgment and injunction against the state of Alaska for its massively harmful psychiatric drugging of children it has taken into custody, I thought I would draw your attention to a terrific, just launched, on line program about this issue, called CriticalThinkRx. Paid for by a grant from the Attorneys General Consumer and Prescriber Grant Program, funded by the multi-state settlement of consumer fraud claims regarding the marketing of Neurontin®, CriticalThinkRx was developed specifically for non-medical personnel making decisions about giving psychiatric drugs to children. In other words, it was put together so that people such as those working for the State of Alaska authorizing the psychiatric drugging of children subject to State control are able to make informed decisions.

By this e-mail, I am requesting (demanding) the State implement such a program for informed decision making regarding the administration of psychiatric drugs to children it has taken into custody.

Frankly, even if the State continues to ignore this problem, it might as well start looking at the CriticalThinkRx program now because it will be faced with this same information in the lawsuit. More importantly, the State should use the information to change what it is doing to the children whom it has taken into custody and subjecting to what can quite legitimately be characterized as State-inflicted child abuse. I suspect you take umbrage at this characterization and think it is an exaggeration, but it is an accurate one. It is a huge betrayal by the State of this most vulnerable population and should be stopped immediately.

As you know, PsychRights has tried for years to get the State to address the problem of it's very harmful program of psychiatrically drugging kids it has taken into custody. *See*, http://psychrights.org/States/Alaska/Kids/Kids.htm

I hope the State will now recognize the problem and immediately take steps to correct it. Unfortunately, based on past experience, my guess is this will not happen. Therefore, I am proceeding with developing the lawsuit unless I hear otherwise from you and we work out a satisfactory program to address this crisis, such as one consistent with CriticalThinkRx, that does not inflict such damage on Alaska's children for whom the State has taken responsibility.

--

James B. (Jim) Gottstein, Esq.
President/CEO

Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501
USA
Phone: (907) 274-7686 Fax: (907) 274-9493
jim.gottstein[[at]]psychrights.org
http://psychrights.org/

PsychRights®

Law Project for Psychiatric Rights

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Extensive information about this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation,

Plaintiff,

vs.

STATE OF ALASKA, *et al.*,

Defendants,

Case No. 3AN 08-10115CI

COPY
Original Received
NOV 24 2008
Clerk of the Trial Courts

AMENDMENT TO PARAGRAPH 22 OF AMENDED COMPLAINT

COMES NOW, Plaintiff in the above captioned action, and hereby amends paragraph 22 of its amended complaint to read as follows:

22. It is unlawful to for the State to use Medicaid to pay for outpatient drug prescriptions except when medically necessary and for indications approved by the Food and Drug Administration (FDA) or included in the following compendia:

(a) American Hospital Formulary Service Drug Information,

(b) United States Pharmacopeia-Drug Information (or its successor publications), or

(c) DRUGDEX Information System.

DATED: November 24, 2008.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

Law Project for Psychiatric Rights, Plaintiff, vs. State of Alaska, *et al*, Defendants	)	Case No. 3AN 08-10115CI

MEMORANDUM IN SUPPORT OF
MOTION FOR LEAVE TO AMEND COMPLAINT
(Citizen-Taxpayer Standing/Medicaid Injunction)

Plaintiff, the Law Project for Psychiatric Rights (PsychRights®), has moved to amend the Amended Complaint, as follows:

1. Insert, ", and has citizen-taxpayer standing to bring this action" at the end of Paragraph 4. (Citizen-Taxpayer Amendment).

2. Add a new paragraph, ¶236, as follows:

> 236. The State approves and applies for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:
>
> (a) are not medically necessary, or
>
> (b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (i) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or
>
> (c) both.

(Medicaid Violation Allegation).

3. Amend ¶B of the Prayer for Relief to read as follows:

B. Permanently enjoin the defendants and their successors from:

1. authorizing or paying for the administration of psychotropic drugs to Alaskan children and youth without conformance with Paragraph A of this prayer for relief, and

2. approving or applying for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that:

(a) are not medically necessary, or

(b) for indications that are not approved by the Food and Drug Administration (FDA) or included in (i) the American Hospital Formulary Service Drug Information, (ii) the United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System, or

(c) both.

(Medicaid Violation Injunction).

These three amendments are technical in nature and the desirability of making them arose out of the briefing on the Motion for Judgment on the Pleadings filed by the defendants, State of Alaska, *et al* (State) and dated March 12, 2009. In its Opposition to Motion for Judgment on the Pleadings, filed March 31, 2009, which is hereby incorporated herein by reference, PsychRights indicated that this motion for leave to amend would be forthcoming.[1]

A. CITIZEN-TAXPAYER AMENDMENT

In its Motion for Judgment on the Pleadings, the State apparently made the

[1] *See*, pages 3-4 and note 63.

argument that the current complaint in this action was deficient for failing to allege that PsychRights has citizen-taxpayer standing. Assuming *arguendo*, that the Amended Complaint is technically insufficient for failing to include the allegation that PsychRights has citizen-taxpayer standing, the Citizen-Taxpayer Amendment makes the allegation. It appears allowance of such an amendment is mandatory under *Prentzel v. State, Dept. of Public Safety*.[2]

B. MEDICAID VIOLATION AMENDMENT

Footnote 63 of PsychRights Opposition to Motion for Judgment on the Pleadings states:

> In reviewing the status of the pleadings, PsychRights realized it should add to the relief requested to effectuate ¶22 of the Amended Complaint, to wit that the State be enjoined from paying for outpatient psychiatric drugs for anything other than indications approved by the Food and Drug Administration (FDA) or included in the following compendia: (a) American Hospital Formulary Service Drug Information, (b) United States Pharmacopeia-Drug Information (or its successor publications), or (c) DRUGDEX Information System. A motion to amend the complaint to include this relief will be forthcoming shortly.

In preparing such amendment PsychRights realized that in addition to amending the Prayer for Relief, the complaint in this action could be benefitted by including a specific allegation that the above Medicaid requirement is being violated. The Medication Violation Amendment accomplishes this. There are many other allegations that indirectly establish the State's violations of Medicaid rules, but it seems desirable to include the explicit allegation of the Medicaid Violation Amendment.

---

[2] 53 P.3d 587, 590-91 (Alaska 2002).

In *Prentzel*,[3] the Alaska Supreme Court held, "a party should be permitted to amend if there is no showing that amending would cause injustice." There is no injustice here. The State has been on notice of the Medicaid violation claim since the Amended Complaint was filed in September, 2008, when the current ¶22 was added.

C. MEDICAID VIOLATION INJUNCTION

The third amendment, the Medicaid Violation Injunction, adds to the Prayer for Relief the appropriate remedy for the State's alleged violation of Medicaid requirements. The requested injunction against such violation is the logical relief and could be ordered under the "Such other relief as the court finds just in the premises," prayer for relief,[4] but it seems desirable to also include the proposed explicit language. The same lack of injustice standard with respect to the Medicaid Violation Allegation applies here and the amendment to add it to the prayer for relief should be permitted.[5]

D. CONCLUSION

For the foregoing reasons, PsychRights Motion for Leave to Amend Complaint (Citizen-Taxpayer Standing/Medicaid Injunction) should be granted.

DATED: April 3, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein, ABA # 7811100

[3] 53 P.3d at 590-91.
[4] §E. of the Prayer for Relief.
[5] *Prentzel*, 53 P.3d at 590-91.

TOPIC:
Children

Editor:
UPDATED: TODAY

THURSDAY, JUN 17, 1999 09:00 EDT

Johnny get your pills

Are we overmedicating our kids?

BY ROB WATERS

Some of the names in this story have been changed to protect the sources' privacy.

Jimmy Spence was in fourth grade when his strange new behavior started: He began jerking his head and limbs uncontrollably and making strange blowing sounds with his mouth. During lunch at his school in Milford, Conn., his arm would suddenly jump and smack into someone next to him. Jimmy would hang his head in embarrassment as the kids around him laughed.

Partly to control these tics, a psychiatrist prescribed an antidepressant, Wellbutrin, which Jimmy began taking twice a day. Ironically, the tics were most likely a side effect of another medication Jimmy had started taking three years earlier, when he was 6: Ritalin, the stimulant taken by millions of American kids who are considered hyperactive.

Looking back, it's hard to say exactly when Jimmy's problems began. When he was 3, his mother and father separated. He felt suddenly lonely, and thought he didn't fit in with his parents' new partners. Entering school didn't help; in class he was restless, unable to concentrate or stay in his seat. His teacher urged Jimmy's mother to seek professional help and when she did, the psychologist diagnosed Jimmy with attention deficit hyperactivity disorder (ADHD) and suggested Ritalin. Within a week, Jimmy was taking two pills a day.

Jimmy disliked the medications. The Ritalin left him with wild mood swings when it wore off in the afternoon. And he dreaded the sense that everyone at school knew about his problems. "The kids were always making fun of me," he remembers. "It would be like, 'That kid's stupid, he's on Ritalin.'" Jimmy begged his mother to stop the Ritalin, and at one point, she agreed. But school officials told her that if she didn't keep Jimmy on medication he would not be allowed to attend school for more than half a day. Nancy, a single mother, gave in.

Later, when the Wellbutrin was added to Jimmy's daily regimen, it had little effect. The twitching continued, one time jerking his head so forcefully that the school nurse feared he would snap his neck. Jimmy went to therapists, psychiatrists, even a neurologist, but never saw anyone long enough to form a connection. He was variously diagnosed with ADHD, bipolar disorder and a mood disorder. Another doctor took him off Ritalin and put him on a different stimulant, Cylert, while continuing the antidepressant. Still the tics continued.

By the fall of 1996 Jimmy, then 11, was in a funk. He hated going to school in the morning, and came home nearly every day to hide in his bedroom and cry. "I felt like nobody liked me, everything was just like -- like downpours," he says. One afternoon, his mother went into his room and found a note scrawled on the wall. "Somebody help me, I want to die," it said. She called the psychiatrist Jimmy saw occasionally, who switched him from Wellbutrin to Zoloft, an antidepressant similar to Prozac. But within a week, Jimmy

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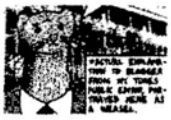
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degenerated. He ran in the street, ignoring traffic, threw lit matches around the house and imagined conversations that never occurred.

Alarmed, his mother grappled with questions she'd been asking herself for years. Were these medications really helping her son? Should she continue to make him take them, or challenge the school and medical authorities who seemed so confident of their course?

A decade after it vaulted into our consciousness, America's love affair with Prozac (and other new antidepressants) has worked its way down the age ladder. Last year, more than 2.5 million prescriptions for antidepressants were written for children and adolescents, according to IMS Health, a research firm that tracks prescription drug sales. That's a jump of nearly 60 percent since 1993 -- despite the fact that most of these drugs have not been approved by the Food and Drug Administration for use with children, and that no one knows what the long-term effects might be on developing brains. Prozac and its chemical cousins, the so-called serotonin selective re-uptake inhibitors (or SSRIs), have led the charge: SSRI prescriptions for kids nearly tripled in the last five years.

Many children have no doubt been helped by these drugs. But it also seems clear that powerful medications are being given far too easily to some children, fueled by a variety of forces, from managed care to overworked parents. In a culture addicted to drugs, but reluctant to address children's pain unless they start shooting up schools, it's become easier and cheaper to deal with troubled kids by medicating them than by providing the personal attention of a sympathetic professional.

These days, antidepressants are being prescribed not just by psychiatrists but by pediatricians and family doctors. In a survey released last month by researchers at the University of North Carolina, nearly three of four pediatricians and family practitioners in North Carolina said they had prescribed antidepressants to children or adolescents; nearly a third had recently (within the past six months) prescribed the medications to kids between 6 and 12. And, more alarming, only 8 percent of the doctors said they were adequately trained in the management of childhood depression; just 16 percent said they were comfortable treating depressed kids.

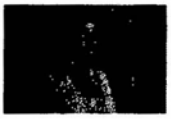
In an unpublished study from 1996-97, researchers with Kaiser Permanente, the nation's largest HMO, found that more than 65 percent of children under 15 who were seen for depression in Kaiser clinics in Portland, Ore., were prescribed antidepressants by their pediatrician or family doctor. But perhaps the most shocking research finding is this: In Michigan, in 1996, investigators looking through records of state Medicaid patients found 157 children aged 3 or younger who had been given any of 22 different psychotropic medications for attention deficit disorder.

To Peter Jensen, the associate director of child and adolescent research with the National Institute of Mental Health, the idea of pediatricians dispensing antidepressants is troubling. "The average pediatric visit is now 13 minutes," Jensen says. "The kind of evaluation that's necessary to tell whether a child is clinically depressed goes beyond what a pediatrician in an office practice has the time or training to do."

For years, research on the safety and effectiveness of these medications for children has lagged behind their use. In recent years, that's changed somewhat and most experts now believe that SSRIs are safe for kids -- in the short run. Psychiatrists like them because they see them as "clean" drugs that regulate mood by adjusting levels of the brain chemical serotonin, while leaving other systems of the brain untouched. They're difficult to overdose on, and they cause relatively few immediate side effects -- most commonly anxiety, nausea, and insomnia.

Some parents like the drugs because of their alluring promise to "fix" kids, while perhaps sparing a family in turmoil the emotional rigors of counseling. And managed-care companies may like medications most of all, for one simple reason: They appear to be cheaper than therapy.

Indeed, many psychiatrists, pediatricians, and therapists say they feel pushed to use medications both by managed care and by the difficulty of



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getting a child into therapy. "The pressure to use medication has increased enormously," says Joe Woolston, medical director of the children's inpatient psychiatric unit at Yale/New Haven Hospital in Connecticut. "Every single day, we have at least one case where the managed-care reviewer says to us, 'If you don't start the child on medications within 24 hours after admission, we will not fund another day of hospital.'"

"For some of these children these medications may be lifesaving," says Peter Jensen. "For other children, the psychological treatments may be more appropriate. But if there are constraints -- financial considerations or managed care saying you have to use a drug -- well that's really unethical. That's wrong."

Phoebe Cirio, a child psychologist in St. Louis, says most managed-care companies initially authorize a therapist to spend four to six sessions with a child; the therapist must then convince case managers to authorize more treatment. "If you can't say clearly that such-and-such symptom is better, they'll say, 'Well, maybe we need to refer to a psychiatrist for assessment of underlying depression.' Managed care sees this as a cheap way to get rid of the problem. They think of antidepressants as equivalent to antibiotics--let's get in there and kill the germs." Psychologists can't do effective therapy that quickly, Cirio adds. "You have to talk to the parents, to establish rapport with the child," she says. "Four or six sessions is a totally inappropriate time frame."

Mary Lou Sharrar, an Oakland, Calif., therapist who works extensively with children, says she's gotten so much pressure to limit the number of sessions with young patients, and to refer them for medication, that she now avoids working with children on managed-care plans.

Managed-care executives see things differently. Saul Feldman, a psychiatrist and chief executive officer of United Behavioral Health, which manages mental health and substance abuse benefits for 15 million people around the country, credits managed care with putting a stop to a widespread abuse in the 1980s, when thousands of children were inappropriately hospitalized in for-profit psychiatric hospitals. He acknowledges that some managed-care firms may try to rush kids out of therapy. "But," he adds, "I think it's absolutely inappropriate to push kids onto meds if the sole objective for doing so is economic. That's unethical and it's not done here."

Jerry Rushton, the pediatrician who led the North Carolina survey, says he and his colleagues in primary care often feel trapped when they try to plan treatment for children. When they see a child in pain, they want to provide immediate help. But they know if they refer the child for therapy, it can take months to get approval and to set up an appointment; insurance benefits can be denied; the child and parents may not follow up.

"It's a dilemma," Rushton says. "You don't want to harm kids by giving them medications when we're unsure about the effects. But you also don't want them to go untreated and put them at risk for suicide or failure in school. So sometimes you start them on the meds and you wait and you hope."

So far, three drugs -- the SSRIs Luvox and Zoloft, and an older antidepressant, Anafranil -- have been approved by the FDA for children and adolescents suffering from obsessive-compulsive disorder. Typically, fewer than half of the children on these drugs improve. A study of Zoloft reported in the Journal of the American Medical Association last year found that 42 percent of the children taking the drug improved, compared to 26 percent on placebos. No medications have been approved for children diagnosed as depressed.

But drugs don't have to be approved for children to be used by them; any drug that has cleared the FDA for one group of patients can be prescribed to anyone for any reason at a doctor's discretion. This so-called "off-label" prescribing of antidepressants to children is based on research that is quite limited. So far, the best study of depressed children was led by Graham Emslie of the University of Texas Southwestern Medical Center. His 1997 report found that when Prozac was given for eight weeks to 96 depressed children between 7 and 17 years old, 56 percent showed improvement, compared to 33 percent taking placebos. But even with the improvement,

two-thirds of the kids on Prozac still had significant symptoms of depression at the end of the eight weeks. And, says Emslie, "The children who got medication seem as likely to have a recurrence as those who didn't." Hardly a ringing endorsement.

But how applicable are these studies to real-world conditions? Clinical trials in research settings include extensive visits between children and clinicians. Such visits, Emslie says, are an important part of the therapeutic process. But in the busy world of managed care, doctors frequently dispense medication without providing therapy or meeting regularly with the patient -- because they don't have the time or the training. Jimmy Spence, for example, was taking stimulants and antidepressants, but would often go months at a time without being seen for an evaluation, much less for psychotherapy.

More studies are under way, funded by drug companies and the NIMH. They will seek to show that the drugs are safe in the short term and are at least moderately effective. The studies should provide greater insight into how the drugs work in the short term. But they could also be a double-edged sword: If the testing leads the FDA to approve antidepressants for children, doctors will prescribe them more often. And that could further erode support for counseling in favor of a pharmaceutical fix.

Government approval would also free drug companies to direct their marketing efforts at children. Some would argue that they already are. Eli Lilly, the maker of Prozac, has waged a peppy -- and controversial -- advertising campaign, placing simple, high-contrast advertisements in women's and children's magazines across the country. One featured a child-like drawing of a dark cloud with the slogan "Depression hurts" next to a bright sun and the slogan "Prozac can help."

Some families view the new antidepressants as godsends. When Robert Schwartz, a Long Island dentist, walked into the office of child psychiatrist Harold Koplewicz five years ago with son Alex in tow, Schwartz was a desperate man. Then 4 years old, Alex was a dark-eyed boy with a winning smile and an affectionate manner. But he could hardly speak, had not yet mastered toilet training and often would get so agitated he'd clench and unclench his fists for minutes at a time. He fixated on switches and buttons, turning them on and off repeatedly, but couldn't focus on building blocks or other children's toys long enough to play with them.

Alex's problems first came to his parents' attention when he was an infant. His pediatrician noticed that Alex's growth had slowed substantially starting at the age of 5 months. He ordered a blood test, which revealed a thyroid deficiency. Alex began taking synthetic thyroid medication, but his growth and development were already delayed. At 6 months, he couldn't roll over; at 10 months, he couldn't crawl. Not until he was 18 months old was he able to walk on his own.

Alex continued to miss developmental milestones, and his parents grew increasingly concerned. They took him to numerous clinicians, including a speech pathologist, psychologists and a neurologist. He was diagnosed with a pervasive developmental disorder, a condition that can severely retard a child's social and communication skills. He started attending a special education preschool, but was making little progress. Then his father took him to see Koplewicz.

Koplewicz read Alex's file and reports, and within five minutes of meeting him, was recommending a treatment plan centered around the use of Ritalin to help Alex focus his attention. The next morning, just before dressing him for school, Schwartz gave his son the first half-pill. The impact was almost immediate. "It was like a metamorphosis occurred before my eyes," his father recalled. "I gave him the first pill at 8 a.m. and within 20 minutes, he wanted to pull up his pants by himself, which is something he'd never done before."

But the Ritalin also intensified Alex's anxiety: He began to urinate in his pants, and to jump at the sounds of traffic. To moderate the anxiety, Koplewicz added a low dose of liquid Prozac to Alex's growing drug regimen.

Since then, Alex's progress has been slow but steady, held back for a while by his parent's divorce three years ago. Today, Alex, now 9, goes to a special education program in his local school district and, twice a week, attends an after-school social and recreation program. He also sees a psychologist two or three times a month, who works with him on ways to modify his behavior and assists his teacher with classroom strategies. But the central component of his treatment continues to be medication: He's now up to four drugs a day, a combination of antidepressants and stimulants.

"Without the medication," says his father, "he'd still be where he was at 4, or we might have to be considering an institution." He continues to see Koplewicz every two or three months so the doctor can adjust his medication. "It's like a recipe," says Schwartz, "and you're constantly tweaking it to try to get the perfect combination." Alex, his father says, will probably need medication for the rest of his life.

What if he stops taking them? Koplewicz is blunt in his warnings of what can eventually befall children who need medications but don't take them. "Bad things can occur. You will drop out of school 10 times more frequently if you have ADHD [that goes untreated]. You are at higher risk of killing yourself if you're depressed without an antidepressant. You will more likely do substances -- medicate yourself -- if you're depressed and don't get treatment. There is an adverse effect to not taking medicine which I don't think parents recognize."

Koplewicz makes these pronouncements from his perch as director of New York University's Child Study Center, where he has emerged as one of the leading advocates of psychiatric medications for children. He argues that medication is the best way to help many children who have what he calls biologically based brain disorders. "There are 5 or 6 million kids who could potentially benefit from SSRIs," Koplewicz says. "I actually think we're not medicating kids enough."

Koplewicz and his staff see thousands of families each year, many of whom (like the Schwartzes) have spent years trying to navigate the disjointed services offered by school districts and public mental health programs. By the time they get to the NYU center, many parents are mired in guilt and despair. The charismatic doctor, who has written a book called "It's Nobody's Fault," has a message they find appealing: "I say that psychiatric illness is not caused by bad parenting. It is not that your mother got divorced, or that your father didn't wipe you the right way. It really is DNA roulette: You got blue eyes, blond hair, sometimes a musical ear, but sometimes you get the predisposition for depression."

But some psychiatrists and many psychologists -- even those who believe in the judicious use of medications for children -- worry that the drugs are being overused. "Many people feel the pressure to make a change and have a result quickly," says Mark DeAntonio, a psychiatrist who directs the adolescent inpatient unit at UCLA Neuropsychiatric Institute. "It's faster to write a prescription than to sit down and talk to people and find out what's really going on."

Morris Johnson, a child therapist and former intake director of the Philadelphia Guidance Center, sees a place for medications in extreme circumstances -- "if a kid is acting out, or trying to kill people in the family. But if you don't get to what's causing those symptoms in the first place; the kid just ends up coming back once the medication runs out. Medication is being used as a replacement for therapy and I think that's a major mistake."

And then there's the question of long-term effects: Will these drugs cause problems down the line? Joan Moreau, a child psychiatrist in Williamsport, Pa., has prescribed the new SSRIs to children as young as 6, but not without some real worries. "What if 20 years after people start taking them, they get senile or lose the capacity to reproduce?" she asks. "We just don't know because the medications aren't older than 10 years."

Because of these concerns, Moreau tries to wean children from medications as soon as she can, and encourages parents to use psychotherapy as well. "If you can help someone change the way they think and feel, that will serve

them well in the long term," she says.

As she watched her son Jimmy falling apart, Nancy Spence wrestled with how best to help him. In the end, she made the decision Jimmy had been requesting for years: "I said, 'I want him off all these medications. I want to know who Jimmy really is.' It had been six years and I'd had enough."

It took three weeks to wean Jimmy from the medications. Within a week, he began to feel better, and to feel his depression lift. Today, two and a half years later, Jimmy is still off antidepressants, but takes a blood pressure medication to control his tics.

In the kitchen of his small, tidy home, Jimmy sits, listening to the rap group Wu-Tang Clan on a headset. He answers some questions, haltingly at first, but after a while, the stocky adolescent opens up, raising his head from beneath his baseball cap to make occasional eye contact. Pushing the headphones off his ears, he walks over to the kitchen cupboard and pulls three old pill bottles off the shelf. "These medications," he says, setting them down on the kitchen table, "they made me uncomfortable to where I just didn't like me."

Today, Jimmy said, he feels happier and more in control, though he still copes with bouts of depression that tend to strike near the winter holidays. "I'm popular, I like school better and I like my life better," he says. Then he pulls the headphones back down and moves his head slightly to the music.

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Attention Deficit: Is It in the Genes?

New research suggests it is. Now a reliable test and more treatment options are in sight

Many parents have long suspected that their lively kids are being diagnosed, too quickly, as victims of attention deficit hyperactivity disorder. A new study suggests they're right. At Michigan State University, researchers reviewed 15 months' worth of Medicaid billing records and found that 233 children between the ages of one and three were diagnosed with ADHD--an alarming age to be judged for a disorder that can be hard to diagnose even in school-age kids. Even more troubling, nearly 60% of those toddlers were treated with psychotropic medications such as Ritalin and Prozac, though little is known about the impact of such drugs on children so young. "I don't think we can give a simple diagnosis of ADHD in a child of this age," warns Dr. Marsha D. Rappley, associate professor of pediatrics at Michigan State.

That may change in the next few years. Right now there is no objective diagnostic test for ADHD that can point to a biological malfunction, though some 3 million children and 4 million adults in the U.S. are thought to suffer from it. ADHD is characterized by a persistent pattern of impulsive behavior, inability to pay attention, and hyperactivity. The most common treatment is Novartis' Ritalin, a mild stimulant that helps the brain disregard distracting stimuli.

Over the years, doctors have blamed the condition on a dysfunctional home environment, brain damage at birth, even refined sugar and food additives. All these theories have been disproved. But highly sophisticated brain-scanning technology seems to have finally honed in on the biological cause. Researchers now blame a genetically induced imbalance of the brain chemical dopamine.

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Dopamine modulates the activity of neurons associated with emotions and movement. People who carry the gene associated with ADHD apparently overproduce dopamine, which impairs their self-control and inhibitions. Based on this discovery, a diagnostic test is now in clinical trials that may be able to finally determine exactly who does and does not have the disorder.

Boston Life Sciences Inc., a small biotech startup in Boston, has developed an agent, Altropane, that binds to the brain cells that create dopamine. When used with a relatively simple brain-scanning method called single photon emission computer tomography (SPECT), doctors can determine if patients have the elevated number of dopamine-producing neurons associated with ADHD. Altropane is already in the final stage of clinical trials as a diagnostic agent with Parkinson's disease, caused when the brain cells that produce dopamine die off.

PREVALENT DISORDER. Dr. Alan J. Fisch- man, director of nuclear medicine at Massachusetts General Hospital, says preliminary studies of adult patients with longstanding ADHD found that all had a much higher level of dopamine-producing neurons than non-ADHD adults of the same age. He cautions that the test must be still be tried on a far larger population, but early results hold out promise for a method that would allow both a quick, accurate diagnosis and a treatment individually tailored to the patient's dopamine imbalance.

An accurate ADHD test would likely be in huge demand. Various studies have estimated that between 3% and 9.5% of all school-age children worldwide have the disorder, and half of these children manifest symptoms throughout their lives. But despite its prevalence, ADHD is one of the most controversial childhood disorders. A panel of experts convened a year ago by the National Institutes of Health to settle on treatment standards for ADHD concluded that it had too little information to form a consensus. "There is no consistency in treatment, diagnosis, or follow-up for children with ADHD," lamented panel chair Dr. David J. Kupfer, professor of psychiatry at the University of Pittsburgh School of Medicine. "It is a major public health problem."

The situation creates an paradox. "I think what's going on is that ADHD is overdiagnosed and undertreated," says Dr. Joseph Biederman, director of the pediatric psychopharmacology unit at Mass General. Because many of the symptoms of ADHD are similar to other psychological problems, doctors not trained to recognize the disorder may slap the ADHD label on any hard-to-handle kid. This is particularly true for boys, who are diagnosed with ADHD five to nine times as often as girls. Dr. Mark A. Stein, director of the ADHD program at Children's National Medical Center in Washington, D.C., says about 40% of the children referred to him have been misdiagnosed by doctors who did not bother to test for such problems as sleep disorders, depression, even mild retardation. "We waste so much money by not trying to figure out exactly what their problem is," says Stein.

ADDICTION FEARS. Even if a good test is devised, there still needs to be a consensus on treatment. Less than half of all kids diagnosed with ADHD take Ritalin, despite its proven effectiveness and limited side effects. Parents often resist Ritalin therapy because they don't like their children taking pills throughout the day, and they fear addiction. However, a recent four-year study by Biederman of boys diagnosed with ADHD found that those treated with Ritalin or similar stimulants were three times less likely as untreated boys to develop later substance abuse problems.

Some newer ADHD drugs in development could be more popular with parents, says Piper Jaffray Inc. analyst Peter L. Ginsburg. Celgene Corp.'s Attenade and Alza Corp.'s Concerta are both longer-acting versions of the same stimulant used in Ritalin, so do not need to be taken as often. Shire Richwood Inc.'s Adderall, an amphetamine, has also proven effective against ADHD. Ginsburg estimates that these drugs should broaden demand, boosting sales of ADHD treatment in the U.S. from $300 million a year now to between $800 million and $1 billion by 2003. And with a new diagnostic test, parents and doctors alike could be more confident that the right kids are getting the proper therapy.

By Catherine Arnst in New York

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April 21, 2002 Sunday

SECTION: NEWS SPECIAL EDITION; Pg. 14

LENGTH: 594 words

HEADLINE: Some infants get medication despite advice of experts

BYLINE: Mark Skertic

BODY:

Nobody knows what long-term damage drugs such as Ritalin can do to the fast-growing brains of very small children. For that reason alone, federal regulators and pharmaceutical companies don't recommend giving these drugs to children under 6.

That hasn't stopped some local doctors. A Sun-Times analysis of prescriptions written in the Chicago area over 18 months reveals 4,145 prescriptions for Ritalin and other forms of methylphenidate for children age 5 and younger. Of those, 53 were written for infants who had not yet reached their first birthday.

The numbers add up to just a small fraction of such drugs prescribed locally, but even just a handful of such prescriptions raises professional concerns. None of those babies, experts say, could possibly have the attention span or cognitive skills to demonstrate symptoms of attention deficit/hyperactivity disorder.

There is simply no medical justification for giving these drugs to a child who can't yet walk, said Dr. Lawrence Diller, a California pediatrician and author of *Running on Ritalin: A Physician Reflects on Children, Society and Performance in a Pill.*

In his 22 years as a doctor, Diller said, he has prescribed methylphenidate to just two 4-year-olds and about a dozen 5-year-olds. It is not, he said, a step any doctor should take lightly. The companies that make the drugs have cautioned doctors against giving them to very small children, and have never even ordered studies on the effects.

That has not prevented at least some doctors from using the drugs for any age group, though. Such use is called "off label," because it is something not listed on the U.S. Food and Drug Administration's approved label detailing proper use.

"Where's the line between normal and abusive? How do you identify ADHD in a toddler?" Diller asked. "I can't see a justification for it. But I can see the exhausted mom and the harried doctor wondering what else they can do."

A study published in the Journal of the American Medical Association in 2000 found that almost 1.5 percent of children 2 to 4 enrolled in Medicaid programs and a particular managed care group were taking psychotropic drugs such as Ritalin or Prozac, an anti- depressant.

The study shocked many in the medical community, and prompted an angry rebuke of his peers from Dr. Joseph Coyle, chairman of the department of Psychiatry at Harvard Medical School.

It "appears that behaviorally disturbed children are now increasingly subjected to quick and inexpensive pharmacological fixes," instead of remedies that bring together families, pediatricians, psychiatrists and others to help children in need," Coyle said when the study was published.

But Thomas Phelan, a psychologist in west suburban Glen Ellyn, cautions against prohibiting such strong medication for very young children.

"I've used meds on kids 3, 4, 5, but a couple things need to be in place," he said. "They have to be really off the wall, and the parents have to have made a real try at a behavior management system."

In extreme cases, children who can't control their behavior can be a danger, Phelan said. "Some of the worst worries are the kids who are overly aggressive--not only for parents, but for other children."

AMOUNT OF RITALIN DISPENSED TO KIDS

This chart shows the number of units of Ritalin and other methylphenidates dispensed to children under 18 in the Chicago area from April 1, 2000, through Oct. 31, 2001. Boys receive much more medication than girls, and 10-year-olds are most likely to get the drugs.

GRAPHIC: See also related stories, charts pages 11 to 16. CHART; See below. GRAPHS; See roll microfilm.

LOAD-DATE: May 16, 2002

Citizens Commission on Human Rights of Florida

THE PSYCHOTROPIC DRUGGING OF FLORIDA'S MEDICAID CHILDREN

A WHITE PAPER

EXECUTIVE SUMMARY

In July 2003, the Florida Statewide Advocacy Council disclosed in their "Red Item Report" that an inexplicable **55% of foster children** in the state of Florida had been put on powerful mind altering psychotropic drugs.

Prompted by this report, the Citizens Commission on Human Rights in Florida (CCHR) launched an investigation into the current number of Florida children prescribed psychotropic drugs through the State's Medicaid Program.

CCHR's investigation has brought to light several startling trends. Foremost among these is the radical increase in the number of children receiving Medicaid benefits in Florida that are being prescribed psychotropic drugs.

In just five years, the annual number of children placed on these powerful mind-altering drugs has increased by an alarming **528%**.

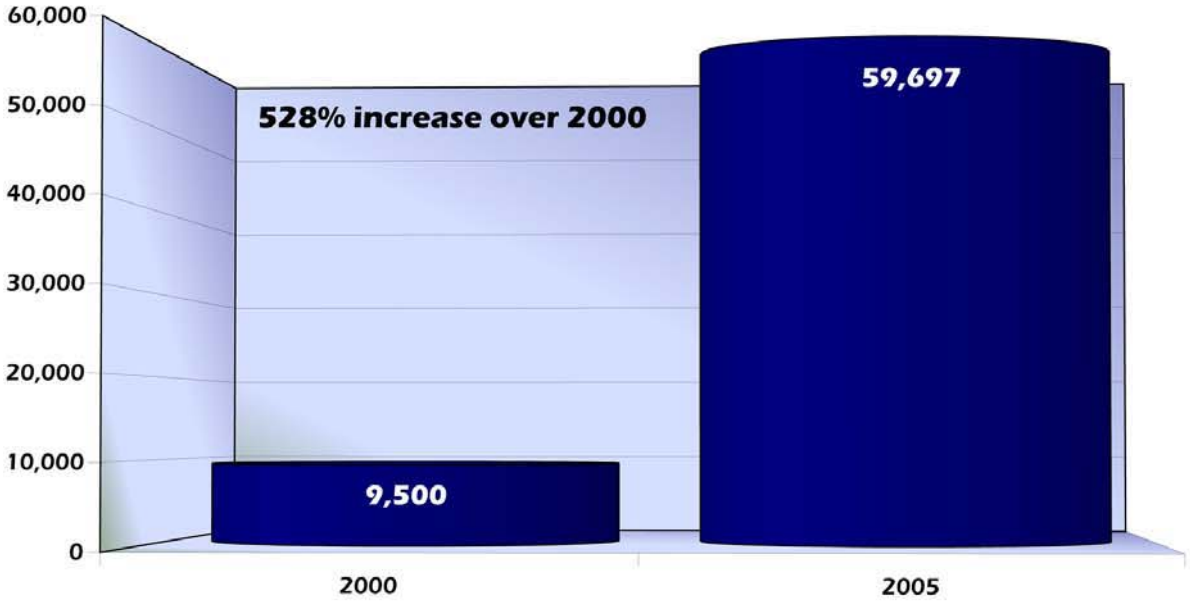
- **59,697 Medicaid children were put on psychotropic drugs in the year 2005 as compared to 9,500 children in the year 2000 (a 528% increase).**

- **62% (37,142 children) were prescribed "off label" psychotropic drugs (not tested or approved for children).**

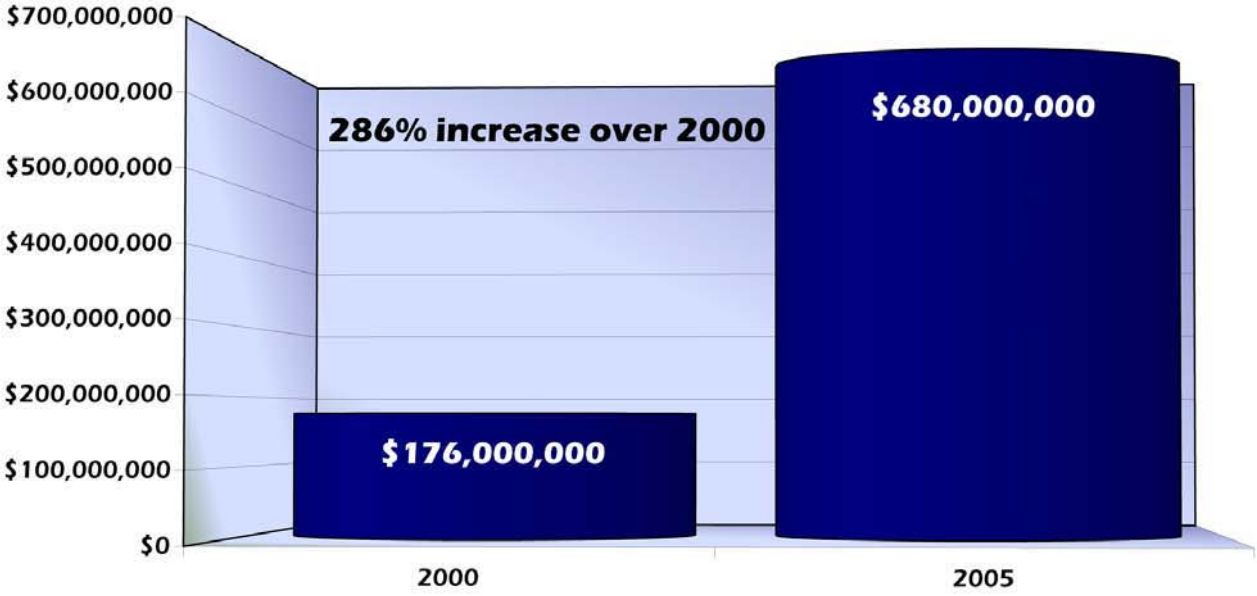
    - **4,556 of the children given "off label" drugs were 5 years old or less.**
    - **1,728 of the children were infants (3 years of age or less) and were prescribed these dangerous "off label" drugs.**

- **19,080 children were given "antipsychotic" drugs. (4,556 of these children were five years of age or younger)**
- **15,240 children were prescribed 3 or more different psychotropic drugs.**
- **1,953 infants and toddlers (3 years of age or less) were put on powerful psychotropic drugs such as antidepressants and Ritalin.**
- **260 infants and toddlers (3 years of age or less) were routinely prescribed 4 or more psychotropic drugs. (Most of the drugs were "off label" and have not been tested or approved for infants.)**
- **351 children were written 50 or more prescriptions.**
- **One child was issued 111 prescriptions in just one year.**
- **In the state of Florida alone, $680,000,000 of Medicaid funds was expended on "behavioral health drugs" in 2005, which represents a 286% increase in five years.**

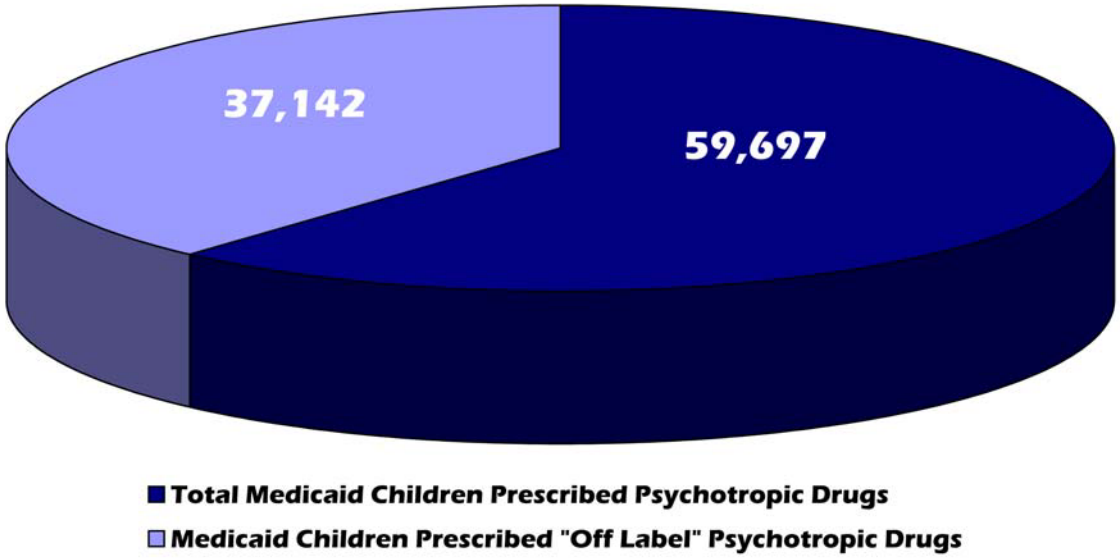
Number of Medicaid Children Supplied Psychotropic Drugs



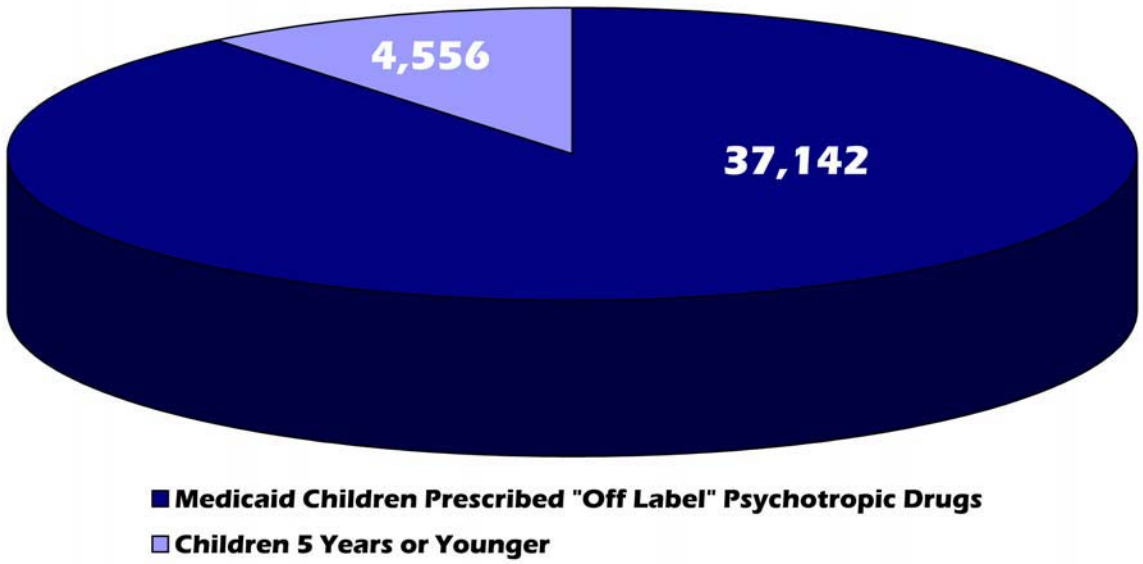
Medicaid Funds Expended on Behavioral Health Drugs



Children Prescribed "Off Label" Psychotropic Drugs



"Off Label" Prescriptions Given to Children 5 Years or Less in 2005



DOCUMENTED SIDE EFFECTS OF DRUGS BEING PRESCRIBED TO INFANTS, TODDLERS AND CHILDREN

STIMULANT SIDE EFFECTS:

- Abdominal pain
- Aggression
- Angina (sudden acute pain)
- Anorexia
- Blood pressure and pulse changes
- Blurred vision
- Depression
- Dizziness
- Drowsiness
- Fever
- Hallucinations
- Headaches
- Heart palpitations
- Hypersensitivity
- Increased irritability
- Insomnia
- Involuntary tics and twitching called Tourette's Syndrome
- Liver problems
- Loss of appetite
- Mental/mood changes
- Moodiness
- Nausea
- Nervousness
- Psychosis
- Restlessness
- Seizures
- Stomach pain
- Stunted growth
- Suicidal thoughts
- Tachycardia (heart irregularity)
- Toxic psychosis
- Unusual weakness or tiredness
- Violent behavior
- Vomiting
- Weight loss
- "Zombie" demeanor

ANTIDEPRESSANT SIDE EFFECTS:

- Agitation
- Akathisia (severe restlessness)
- Anxiety
- Bizarre dreams
- Confusion
- Delusions
- Emotional numbing
- Hallucinations
- Headache
- Heart attacks
- Hostility
- Hypomania (abnormal excitement)
- Insomnia
- Loss of appetite
- Mania
- Memory lapses
- Nausea
- Panic attacks
- Paranoia
- Psychotic Episodes
- Seizures
- Suicidal thoughts or behavior
- Violent behavior
- Weight loss
- Withdrawal symptoms include deeper depression

ANTIPSYCHOTIC SIDE EFFECTS:

- Akathisia
- Abnormal gait (manner of walking)
- Blindness
- Blood disorders
- Blood-sugar abnormalities
- Blurred vision
- Cardiac arrest
- Confusion
- Death from liver failure
- Depression
- Diabetes
- Drowsiness
- Extreme inner-anxiety
- Fatal blood clots
- Headache
- Heart arrhythmia
- Heart failure
- Heart palpitation
- Heat stroke
- Hemorrhage
- Hostility
- Hyperglycemia (abnormally high blood sugar)
- Hypoglycemia (abnormally low blood sugar)
- Insomnia
- Light-headedness
- Manic reaction
- Muscle rigidity
- Nausea
- Nervousness
- Nightmares
- Painful skin rashes
- Pancreatitis (inflammation of pancreas, a gland near the stomach that helps digestion)
- Poor concentration
- Seizures
- Sleepiness
- Spasms
- Suicidal thoughts
- Swollen and leaking breasts
- Tachycardia (heart irregularity)
- Tardive dyskinesia
- Tremors
- Violence
- Vomiting
- Weakness
- Weight gain

ANTIANXIETY DRUG SIDE EFFECTS:

- Acute hyperexcited states
- Aggressive behavior
- Agitation
- Akathisia
- Amnesia
- Anxiety
- Coma
- Confusion
- Depression
- Disorientation
- Drowsiness
- Epileptic seizures and death
- Excitability
- Extreme restlessness
- Fear
- Hallucinations
- Hostility
- Hysteria
- Insomnia
- Irritability
- Jaundice
- Lethargy
- Liver problems
- Memory impairment
- Muscle tremors
- Nausea
- Nervousness
- Nightmares
- Psychosis
- Rage
- Sedation
- Severe depression
- Sleep disturbances
- Suicidal attempt

INTRODUCTION

In response to information published in an investigation conducted by the Florida Statewide Advocacy Council (SAC) into the widespread psychotropic drugging of foster children, the Citizens Commission on Human Rights Florida (CCHR) launched an investigation to ascertain the full scope of an escalating trend to prescribe psychotropic drugs to minor children in Florida's Medicaid Program. CCHR's findings were even more disturbing than expected and in fact disclosed that since the report period investigated by the SAC report, the number of Medicaid children prescribed psychotropic drugs has increased an alarming **528%.**

In July 2003, the Florida Statewide Advocacy Council ("SAC") published a Red Item Report on the widespread administration of psychotropic drugs to children in foster care. The SAC investigation found that **55%** of Florida children under foster care were being treated with psychotropic drugs.

The SAC report also stated that, *"information received from the Agency for Health Care Administration (AHCA) revealed that* ***more than 9,500 children in Florida on Medicaid had been treated with psychotropic drugs in the year 2000****."* [1]

The SAC expressed particular concern that many children as young as five years old or less were being drugged through Medicaid, and in that context stated:

> *"...the use of psychotropic drugs by preschoolers was a disturbing discovery, since most of these drugs have not been approved for use in young children by the Federal Food and Drug Administration (FDA). While physicians are permitted to prescribe medications in ways that have not received FDA approval, there is very little data on the possible long-term consequences of using these drugs at such an early age. Further, diagnosing mental illness in children at such a young age is extremely difficult as these children are unable to describe their symptoms adequately, if at all."* [2]
>
> Further, in relation to all foster children being treated with psychotropic medication, the report stated, *"There was little documentation that appropriate* ***written informed consent*** *to give these medications to minor children was obtained from parents or guardians."* [3]

The SAC report highlighted the very real danger of the use of these drugs by children:

> *"Side effects of these drugs are very serious and include decreased blood flow to the brain, cardiac arrhythmias, disruption of growth*

> *hormone leading to suppression of growth in the body and brain of a child, weight loss, permanent neurological tics, dystonia, addiction and abuse, including withdrawal reactions, psychosis, depression, insomnia, agitation and social withdrawal, suicidal tendencies, possible atrophy in the brain, worsening of the very symptoms the drugs are supposed to improve, and decreased ability to learn, tardive dyskinesia and malignant neuroleptic syndrome. The FDA is currently reviewing reports of a possible increased risk of suicidal thinking and suicide attempts in children and adolescents under the age of 18 treated with the drug, Paxil."* [4] [5]

The SAC report concluded that "unnecessary dispensing of psychotropic medication remains a threat" to Florida's foster children and made recommendations including implementing a quality assurance program to monitor the use of these drugs in foster children and ensuring "appropriate standardized written informed consent is obtained prior to starting any child on psychotropic medication."

In the 2005 legislative session, a new law was created which instituted additional controls on the use of these drugs with foster children including a procedure for obtaining informed consent from parents or guardians. The drugging of Florida's children is much farther reaching than our foster children. While instituting controls and informed consent requirements for the foster children was long overdue, even longer overdue is instituting these same requirements for all children in Florida, particularly the underprivileged who are normally served through the Medicaid program.

THE CURRENT INVESTIGATION

In 2006 the Citizens Commission on Human Rights of Florida (CCHR) investigated the current state of the problem as described in the 2003 SAC report. While CCHR was denied access to records of Florida foster children, Florida Medicaid records for the year 2005 were obtained through a public records request.

In response to CCHR's request, the Agency for Health Care Administration (AHCA) produced a Microsoft Access database labeled, "Florida Medicaid – CY2005 – Recipients Under 19 Years, Behavioral Drug Scripts."

The database included five separate sections, listing prescriptions in the categories of ADHD drugs, anti-anxiety drugs, anticonvulsants, antidepressants and anti-psychotics.

Each database contained all prescriptions for that category of drug, with columns of data as follows:

- A unique ID number for each child
- Age of each child
- Gender of the child
- Drug name and dosage
- The prescribing physician's name, license number and location

The findings demonstrate a very real and escalating problem not just among foster children but all Florida children receiving care through Medicaid.

FLORIDA MEDICAID CHILDREN

In summary, an analysis of the 2005 Florida Medicaid facts revealed the following:

- 59,697 children were prescribed psychotropic drugs. Of these, 7,444 were 5 years old or younger.

- 520,348 total psychotropic drug prescriptions were written for Medicaid children.

- 19,080 children were prescribed antipsychotic drugs. 4,556 were five years old or younger.

- 15,240 children were prescribed 3 or more *different* psychotropic drugs during the year.

- 351 children were written 50 or more different prescriptions during 2005. One child was written 111 prescriptions.

Given the earlier data contained in the SAC Report also obtained from the AHCA that 9,500 children on Medicaid in Florida were treated with psychotropic drugs in 2000, this new figure of 59,697 represents an increase of **528%** in just five years.

A significant increase in the number of infants prescribed psychotropic drugs has also occurred. Of the 59,697 children put on these drugs, 1,953, or 3% of the children were aged 3 years or younger. This is compared to the 1% of Medicaid children found in the 2003 SAC report.

CCHR's study also revealed that **260 infants and toddlers (ages 0-3) were prescribed four or more different psychotropic drugs, including many potent antidepressants, such as Effexor, Wellbutrin and Doxepin, none of which have been tested or approved for use with children.**

INDIVIDUAL PHYSICIANS

Three doctors wrote more than 5,000 prescriptions each for psychotropic drugs given to Medicaid children. Nine doctors prescribed the drugs to 500 or more children and 227 doctors prescribed them to 100 or more children. It is difficult to imagine a doctor who could fill over 50 prescriptions for psychotropic drugs every day to children, each working day of the year, but that in fact is what is being claimed.

The most voluminous prescriber is Dr. Mohammed Bhaghani, a psychiatrist in Clermont, Florida. Dr. Bhaghani, who received his medical degree from Dow Medical College, University of Karachi, Pakistan. Dr. Bhaghani billed Medicaid for a total of 5,572 psychotropic drug prescriptions for 735 different children ages 1 to 18. This represents an average of 7.5 prescriptions per child under his care. Dr. Bhaghani issued a total of 2,236 prescriptions for anti-psychotic drugs, 1,427 prescriptions for ADHD drugs, and 1,191 prescriptions for anti-depressants.

MEDICAID SPENDING

According to a presentation at a December 2003 conference of the National Mental Health Association, the cost of Medicaid in State budgets has more than doubled in 10 years and now consumes about 25% of every State budget. The fastest growing category of Medicaid expense is pharmacy with national Medicaid pharmacy expenditures in 2002 reaching $24 billion. The fastest growing drug classes within the Medicaid pharmacy budget is behavioral health drugs (anti-psychotics, anti-convulsants/mood stabilizers, anti-depressants, anti-anxiety agents and sedative hypnotics).

In Florida, Medicaid spending on behavioral health drugs for the year 2004-2005 was $680,000,000, which represented a 286% increase over spending just five years earlier.[6] In comparison, the 528% increase in drug usage by Medicaid children in Florida over the same five years demonstrates that child drugging is a significant factor in the increase in Medicaid spending in Florida.

"OFF LABEL" DRUGS

CCHR's investigation found that 57% of the psychotropic prescriptions for Florida Medicaid children in 2005 were prescribed "off-label", and that 37,142 children were irresponsibly given off-label drugs. Medicaid children in Florida are being used as subjects in a gigantic experiment, although the "results" are not being codified, reported or analyzed. [7]

When the FDA approves a prescription drug, it clearly states the manner in which it can be used, including the age of patients to which prescriptions may be made, standard dosage, and the conditions which may be treated with that drug. This approval process is based on the testing conducted on the drug. Use of the drug in patients in a manner, or for an age or condition that was not tested and approved is called "off label". A physician *may* prescribe medications off-label to patients at the physician's discretion.

Almost all psychotropic drug prescriptions for preschool children are considered "off label". That means that the drug is being prescribed for populations for which no standards of dosage have been established, or for medical conditions for which the product is not indicated and has not been tested.[8]

A recent study published in the Archives of Internal Medicine found that 21 percent of the 725 million prescriptions written in 2001 in the United States were for off-label uses. Further, the study found that most of the off-label uses lacked strong scientific justification, such as a clinical trial and were based solely on observational studies or no discernable evidence whatsoever. In psychiatry, the researchers found that 96 percent of off-label prescriptions lacked strong scientific support.[9]

More 2005 Florida Medicaid "off label" Prescription Facts:

- 4,556 children and infants, 5 years old or less, were prescribed "off label" **antipsychotic** drugs.

- 37,142 children received "off label" psychotropic drugs. This represents more than 60% of the total of 59,697 children put on psychotropic drugs.

- **1,728 of the "off label" prescriptions written were given to infants 3 years of age or less.**

MEDICAID FRAUD

Further, most off-label prescriptions for children may not be covered under Medicaid, and such reimbursements constitute Medicaid fraud. 42 U.S.C. 1396r-8(d)(1)(B)(i), authorizes a State to exclude Medicaid coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication.

Medicaid reimbursement for prescription drugs in Florida requires that the drug be both medically necessary and prescribed for medically accepted indications and dosages as found in the FDA approved drug labeling or in specifically named drug compendia, i.e. *Drug Facts and Comparisons, USP-Drug Information, AMA Drug Evaluations, AHFS-Drug Information, or DRUGDEX*

Information System. (see *Prescribed Drug Services Coverage, Limitations and Reimbursement Handbook* [Florida Handbook], page 9-2.)

The 2005 Florida Medicaid records reveal that more than 60% of the psychiatric drug prescriptions for children age 0-18 that were reimbursed by Medicaid were neither medically necessary or prescribed for a medically accepted indication because they were prescribed for children younger than permitted either under the drug label or the above named compendia. Assuming an average cost of $100 per prescription (likely underestimated), that comes to some $25 million in Medicaid fraud from child drugging.

ILLEGAL USE OF PRESCRIPTION DRUGS

It is undisputed that the legal use of prescription drugs is increasing at an alarming rate. In the ten years between 1992 and 2002, the number of prescriptions filled for "controlled" prescription drugs increased by 154 percent. This dramatic increase occurred while the U.S. population increased by only 13 percent and the number of prescriptions written for "non-controlled" drugs increased by just 57 percent.

Increases in "controlled" drug prescriptions correlate with the increases seen in the illegal use of prescription drugs. During this same period, there was a 90 percent increase (from 7.8 million to 14.8 million) in the number of people who admitted abusing controlled prescription drugs. Also, there was a 203 percent increase among 12-17-year olds abusing these drugs and a 78 percent increase among adults. By the year 2003, these numbers had comparably risen to 212 percent for teens and 81 percent for adults.

Prescription drug abuse accounts for 30% of the Nation's drug problem and is fast overtaking drugs like marijuana and cocaine. Controlled prescription drugs like OxyContin, Ritalin and Valium are now the fourth most abused substances in America behind only marijuana, alcohol and tobacco.[10] The sharp increase in controlled prescription drug abuse is twice the increase seen in the number of people abusing marijuana, it is five times the increase in the number abusing cocaine and 60 times the increase in the number of people abusing heroin. Particularly alarming is the 212 percent increase that occurred between1992 to 2003 in the number of 12 to 17 year olds abusing controlled prescription drugs. An increasing number of these are teens trying drugs for the first time.

In 2002, Florida experienced 9,116 drug overdose deaths. Of these, 3,324 deaths (36%) were caused by prescription drugs. In 2002, Florida suffered more deaths from the prescription Schedule IV benzodiazepines than cocaine. Illegal prescription drugs now constitute the fastest growing segment of the illicit drug market.[11]

DRUGS LINKED TO CHILD SUICIDES

An increasing number of recent retrospective studies have found that a great many psychotropic drugs are associated with increased suicidality in children. In response to these published findings, CCHR conducted an investigation to determine if there is a significant causal link between taking psychotropic drugs, receiving psychiatric/mental health treatment and suicide. The study looked at Florida youth who committed suicide during a five-year period.

The study looked for children, 18 years or younger, who committed suicide either a) with psychotropic drugs in their system at the time of death, b) with a history of use of psychotropic drugs, or c) with a history of psychological, psychiatric or other mental health treatment.

Public records requests were submitted to each of 24 medical examiner districts in Florida requesting a list of every death of 18 year olds or younger who committed suicide from 2000 to 2004 (a 5 year period). A total of 252 cased histories were thereby obtained.

It was found that a total of 52% (131 cases) of the child suicides during this five-year period either used psychotropic drugs or had a history of psychiatric treatment.[12] Psychotropic drug use was verified in 38.1% of the suicides (96 cases). An additional 13.9% of suicides had a verified history of psychological, psychiatric or mental health treatment (35 cases).

The number of children who commit suicide and who are using or have used psychotropic medication validate recent strong FDA warnings for both stimulants and antidepressants that are being prescribed to children. Furthermore, it raises serious questions regarding the efficacy, risk and comparable worth of the use of psychotropic medication in children.

INFORMED CONSENT

Black's Law Dictionary defines "informed consent" as "A person's agreement to allow something to happen, made with full knowledge of the risks involved and the alternatives."[13] Informed consent to any sort of medical treatment is a fundamental right and is required by law and by oath for medical doctors. Doctor's should insist that patients, or their parents or guardians in the case of children, provide informed consent prior to any program of treatment. However, it is proving impractical and unreliable to rely on doctors or pharmaceutical companies, whose financial gain depends on the patient accepting treatment as recommended, to be responsible for obtaining genuine and properly deliberated, informed consent.

As most Medicaid children are school aged, it is highly probable that their referral to a psychiatrist or other medical doctor who prescribed psychotropic drugs came through the public school system. Any student who is suspected by school personnel to be emotionally or mentally disabled is required to be evaluated by the school under the Individuals with Disabilities Education Act (IDEA).

IDEA contains a specific requirement that "informed consent" be obtained from parents prior to any evaluation or treatment of their children through the public school system.[14] The IDEA 2004 Regulations, updated August 2006, and published in the Federal Register, strengthen informed consent requirements and specifically require public schools, **"to make reasonable efforts to obtain the informed consent from the parent for an initial evaluation".** The new rules clarify that references to "consent" throughout the regulations means, "**informed consent"**, and that for a public agency to meet the "**reasonable efforts requirement,"** the agency "**must document its attempts to obtain parental consent."**[15]

CCHR conducted a survey of Florida School Districts and found that in practice, informed consent is *not* being obtained from parents prior to evaluation. Parents *are* required to sign a consent form that articulates their legal rights, and the legal rights of the school to override their consent. However, true informed consent by definition is not being obtained from most Florida parents. Parents of children who are being evaluated for apparent behavioral or emotional dysfunction as reported by teachers, are not being told or provided information on the risks or consequences of psychological or psychiatric evaluation or treatment, including the many disastrous side effects of psychotropic drugs on children.

In short, Florida Schools are non-compliant with IDEA informed consent requirements.

It was the classification of ADHD as a disability under IDEA in 1991 by the U.S. Department of Education which likely contributed to the skyrocketing epidemic-like increase in the prescription of Ritalin and other ADHD drugs to children.[16] Therefore, it is only appropriate that IDEA regulations are applied to ensure that parents are properly informed and can best determine whether their children should risk psychotropic drugs or pursue non-drug approaches to handling children's problems with attention and learning.

RECOMMENDATIONS

1. The Florida Attorney General Medicaid Fraud Unit should investigate the prescription of psychotropic drugs to children which are either medically unnecessary or not for accepted medical indications and the concerned physicians should be held accountable.

2. Stronger warnings are needed for all medical doctors in Florida of the requirements that prescription drugs covered by Medicaid must be both medically necessary and for a medically accepted indication, and exactly what this means.

3. Exactly as recommended by the Statewide Advocacy Council in 2003, we recommend, "that appropriate standardized written informed consent is obtained prior to starting any child on psychotropic medication." We further recommend that the Florida Legislature enact law, which provides the content of informed consent required for students referred by public schools for evaluation as emotional, mental or behavioral disabled under IDEA.

4. AHCA or the Florida Department of Children and Families need to develop a system for monitoring the use of these drugs in children and investigating doctors who are heavy prescribers.[17]

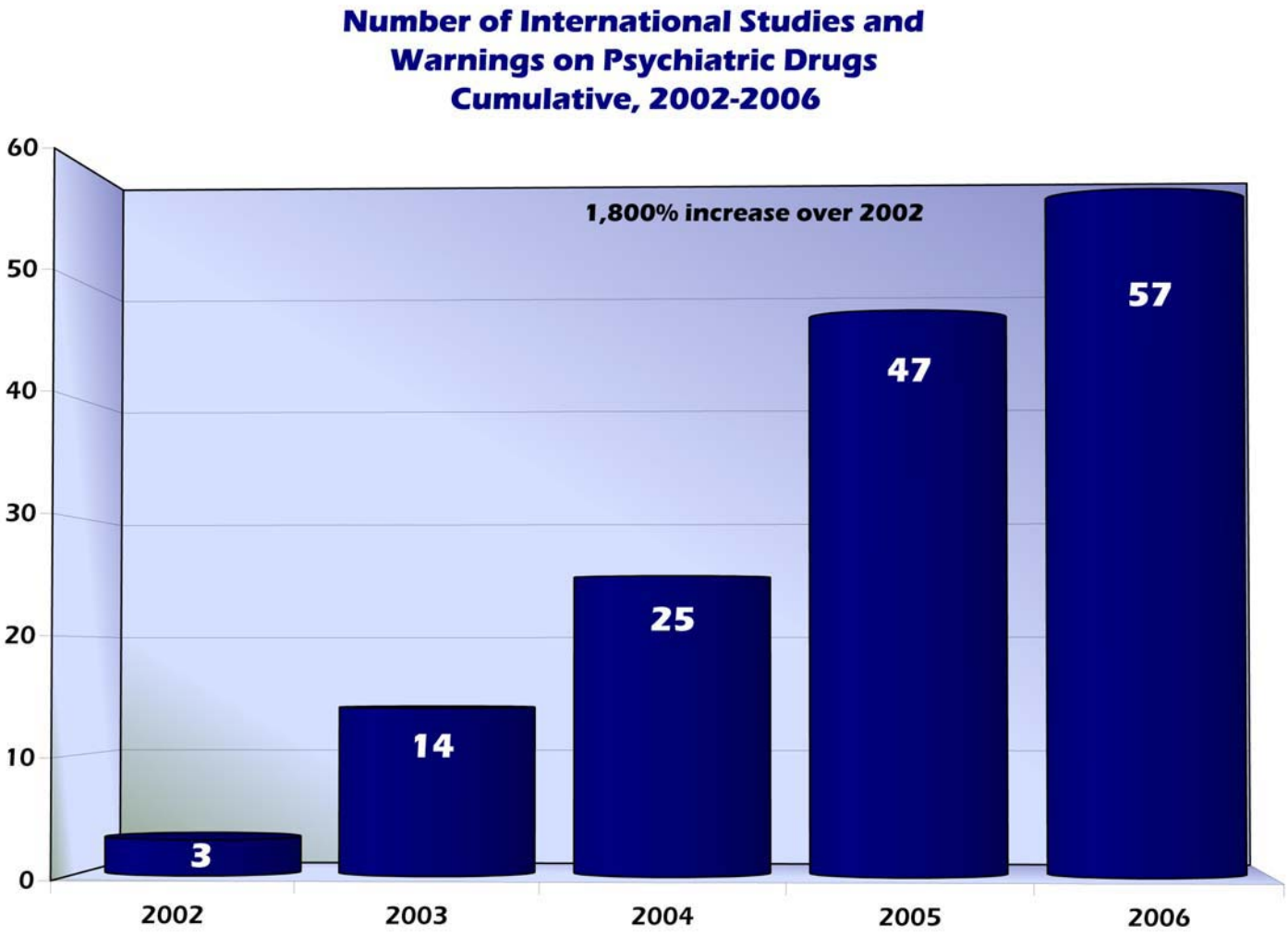
5. The Florida Department of Health should require that medical doctors and pharmacies provide parents and guardians report forms to report any adverse reactions for drugs to the FDA and any other relevant regulatory agencies.

6. The Florida Department of Law Enforcement and the Medical Examiners Commission should require Medical Examiners report toxicology analyses that indicate psychotropic drug use in suicides to the FDA as an adverse reaction report to any psychotropic drug which a suicide victim has been using.

References

[1] "Psychotropic Drug Use in Foster Care," Florida Statewide Advocacy Council, Red Item Report, July 2003, p. 3.
[2] *Ibid.*
[3] *Ibid.*
[4] *Ibid.*
[5] On October 15, 2004 the FDA placed the most serious level of warning, the "black box", on virtually all antidepressants, that they could cause suicidal thoughts and actions in persons under age 18. See the Appendix for additional information on health warnings associated with psychotropic drugs.
[6] Medicaid Formulary Presentation, Aug. 18, 2005, Florida Council for Community Mental Health.
[7] As stated by Dr. John March, a professor of child and adolescent psychiatry at Duke University, in the article "Antipsychotic Drug Care for Children Soars" *New York Times*, June 6, 2006: "We are using these medications and don't know how they work, if they work, or at what cost. It amounts to a huge experiment with the lives of American kids, and what it tells us is that we've got to do something other than we're doing now."
[8] Greenhill LL, "The use of psychotropic medication in preschoolers: indications, safety, and efficacy," *Canadian Journal of Psychiatry*, Vol. 43, No. 6 (Aug. 1998), p.576-7.
[9] Radley, David C., et. al., "Off-label Prescribing Among Office-Based Physicians," *Archives of Internal Medicine*, 2006;166:1021-1026.
[10] Califano, Joseph, "Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S.," The National Center on Addiction and Substance Abuse, Columbia University, July 2005.
[11] 2005 Report of the Florida Office of Drug Control, James McDonough, Director.
[12] Suicides of Young Persons in Florida Associated with Psychotropic Drugs – A Five-Year Study, February 2006, By Ken Kramer.
[13] Black's Law Dictionary, Seventh Edition, 1999.
[14] 20 U.S.C. § 1414 (a) (1) (C) (I).
[15] 34CFR300.
[16] The situation was clearly articulated in February 2002 by Robert Holland, Senior Fellow of the Lexington Institute, in his article, "The Reaction Against Ritalin": "The United Nations reported that the U.S. was manufacturing and consuming 90 percent of the world's supply of Ritalin, a powerful stimulant that's been on Schedule II of the Controlled Substances Act since 1971. Between 1991 and 1999, domestic sales of Ritalin increased 500 percent. Some critics believe a 1991 federal Department of Education decision to classify attention deficit (hyperactivity) disorder (ADHD or ADD) as a learning disability for which schools could receive reimbursement under the Individuals With Disabilities Education Act (IDEA) contributed to this questionable Ritalin boom. It is impossible to look at the explosive increase in Ritalin use in the USA over the past decade without concluding that something more than student behavior is out of control."
[17] A Department of Children and Families (DCF) report of February 2005, which appeared to have been an attempt to lessen the seriousness of the SAC report of 2003, found that 5,137, or 25%, of the State's foster children were being treated with psychotropic drugs, prompting concerns that the medication is inappropriate, too costly and simply dangerous. DCF notified 442 doctors involved in prescribing the drugs to 1,273 children that they were engaging in "questionable" practices. It is not known whether or not DCF ever conducted an investigation of these doctors, but the magnitude of the 2005 report pales in comparison to the instant report with almost 60,000 Medicaid children being prescribed these drugs.

APPENDIX



2004

February 2: FDA official Dr. Andrew D. Mosholder testified before the FDA's Psychopharmacological Advisory Committee on the Office of Drug Safety Data Resources for the Study of Suicidal Events, warning that children being prescribed the newer antidepressants were at risk of suicide.

March 22: The FDA warned that Prozac-like antidepressants (called Selective Serotonin Reuptake Inhibitors or SSRIs) could cause "anxiety, agitation, panic attacks, insomnia, irritability, hostility, impulsivity, akathisia [severe restlessness], hypomania [abnormal excitement] and mania [psychosis characterized by exalted feelings, delusions of grandeur]."

June: The Australian Therapeutic Goods Administration published an Adverse Drug Reactions Bulletin reporting that the latest antipsychotics could increase the risk of diabetes.

June: The FDA ordered that the packaging for the stimulant Adderall include a warning about sudden cardiovascular deaths, especially in children with underlying heart disease.

August 20: A Columbia University review of the pediatric (child) clinical trials of Zoloft, Celexa, Effexor, Wellbutrin, Paxil and Prozac, found that young people who took them could experience suicidal thoughts or actions.

September 21: Following a BBC news report on antidepressants causing aggression and homicidal behavior, the British Healthcare Products Regulatory Authority advised that it had issued guidelines that children should not be given most SSRIs because clinical trial data showed an increased rate of harmful outcomes, including hostility.

October 15: The FDA ordered a "black box" warning for antidepressants that they could cause suicidal thoughts and actions in under 18 year olds taking them.

October 21: The New Zealand Medicines Adverse Reactions Committee recommended that old and new antidepressants not be administered to patients less than 18 years of age because of the potential risk of suicide.

December: The Australian Therapeutic Goods Administration children and adolescents prescribed SSRI antidepressants should be carefully monitored for the emergence of suicidal ideation. In a recent study involving Prozac, it said, there was an increase in adverse psychiatric events (acts and ideation [thoughts] of suicide, self-harm, aggression, violence.)

December 9: The European Medicines Agency's Committee for Medicinal Products for Human Use confirmed that product information should be changed for antidepressants to warn of the risk of suicide-related behavior in children and adolescents and of withdrawal reactions on stopping treatment.

December 17: The FDA required that packaging for the "ADHD" drug Straterra carry a new warning advising, "Severe liver damage may progress to liver failure resulting in death or the need for a liver transplant in a small percentage of patients."

2005

February 9: Health Canada, the Canadian counterpart of the FDA, suspended marketing of Adderall XR (Extended Release, given once a day) due to reports of 20 sudden unexplained deaths (14 in children) and 12 strokes (2 in children) in patients taking Adderall or Adderall XR.

February 18: A study published in the *British Medical Journal* determined that adults taking SSRI antidepressants were more than twice as likely to attempt suicide as patients given placebo.

April: The British House of Commons (Parliament) Health Committee issued a damning report that SSRI antidepressants had been "indiscriminately prescribed on a grand scale" and that drug companies have marketed the drugs without punishment to treat "unhappiness [that] is part of the spectrum of human experience, not a medical condition."

April 11: The FDA warned that antipsychotic drugs in elderly patients could increase the risk of death.

April 21: A national non-government organization, Partnership for a Drug-Free America, released its findings of a study that determined that 10% of teens (2.3 million) had abused the stimulants Ritalin and Adderall.

April 25: The European Medicines Agency's Committee for Medicinal Products for Human Use reaffirmed that *all* the latest antidepressants could cause increased suicide-related behavior and hostility in young people.

June 28: The FDA announced its intention to make labeling changes to Concerta and other Ritalin products to include the side effects: "visual hallucinations, suicidal ideation [ideas], psychotic behavior, as well as aggression or violent behavior."

June 30: The FDA warned that the latest antidepressant Cymbalta could increase suicidal thinking or behavior in pediatric patients taking it.

June 30: The FDA also warned about a potential increased risk of suicidal behavior in adults taking antidepressants, broadening its earlier warning that related only to children and adolescents taking the drugs.

July 1: An FDA "Talk Paper" said that it had requested antidepressant manufacturers to provide all information from their clinical trials on possible increased suicidal behavior in adults taking the drugs.

July 7: The National Center on Addiction and Substance Abuse at Columbia University issued a report called "Under the Counter: The Diversion and Abuse of Controlled Prescription Drugs in the U.S." that determined 15 million Americans were getting high on painkillers and psychiatric drugs such as the tranquilizer Xanax and the stimulants Ritalin and Adderall. Between 1992 and 2003, the number of 12 to 17 year olds abusing these drugs had risen 212%. Teens who abused prescription drugs were 12 times likelier to use heroin, 15 times likelier to use Ecstasy and 21 times likelier to use cocaine, compared to teens that did not abuse such drugs.

July 16: The *British Medical Journal* published a study, "Efficacy of antidepressants in adults," by Joanna Moncrieff, senior lecturer in psychiatry at University College London who found that antidepressants were no more effective than a placebo (fake pill) and do not reduce depression. In a media interview on the study, Dr. Moncrieff stated, "The bottom line is that we really don't have any good evidence that these drugs work."

August: The Australian Therapeutic Goods Administration found a relationship between antidepressants and suicidality, akathisia (severe restlessness), agitation, nervousness and anxiety in adults. Similar symptoms could occur during withdrawal from the drugs, it determined.

August 19: The European Medicines Agency's Committee for Medicinal Products for Human Use issued its strongest warning against child antidepressant use, stating that the drugs caused suicide attempts and thoughts, aggression, hostility, aggression, oppositional behavior and anger.

August 22: Norwegian researchers found that patients taking antidepressants were seven times more likely to experience suicide than those taking placebo.

September 7: The Australian Therapeutic Goods Administration warned that antidepressant use during pregnancy could cause "withdrawal effects that can be severe or life-threatening."

September 13: The Oregon Health & Science University, Evidence-Based Practice Center published the findings of its review of 2,287 studies—virtually every study ever conducted on "ADHD" drugs—and found that there were no trials showing the effectiveness of these drugs and that there was a lack of evidence that they could affect "academic performance, risky behaviors, social achievements, etc." Further, "We found no evidence on long-term safety of drugs used to treat ADHD in young children" or "adolescents."

September 22: Dr. Jeffrey Lieberman of Columbia University and other researchers published a federally funded study in the *New England Journal of Medicine* about the effectiveness of certain antipsychotic drugs, comparing an older generation of antipsychotics with several newer ones. Far from proving effectiveness, of the 1,493 patients who had participated, 74% discontinued their antipsychotic drugs before the end of their treatment due to inefficacy, intolerable side effects or other reasons. After 18 months of taking Zyprexa, 64% of the patients taking this stopped, most commonly because it caused sleepiness, weight gain or neurological symptoms like stiffness and tremors.

September 26: *The Italian Gazette* (official news agency of the Italian government) published a resolution of the Agenzia Italiana del Farmaco (Italian Drug Agency, equivalent to the FDA) ordering a warning label for older (tricyclic) antidepressants that the drugs should not be prescribed for under 18 year olds. They also determined that they were associated with heart attacks in people of *any* age.

September 27: The FDA warned that Paxil and other antidepressants taken during the first trimester of pregnancy could cause increased risk of major birth defects, including heart malformations in newborn infants.

September 28: The British National Health Service's Institute for Health and Clinical Excellence released a Clinical Guideline for treatment of "Depression in Children and Young People." It advised "all antidepressant drugs have significant risks when given to children and young people" and instead, they should be "offered advice on the benefits of regular exercise," "sleep hygiene," "nutrition and the benefits of a balanced diet."

September 29: The FDA directed Eli Lilly & Co. to revise Strattera labeling to include a boxed warning about the increased risk of suicidal thinking in children and adolescents taking it.

September 29: The UK Medicines and Healthcare Products Regulatory Agency issued a press release that it had begun a review of the risks of Strattera in light of the FDA's direction.

October: The sales and marketing of the stimulant Cylert were stopped in the U.S. because of the risk of liver damage that could lead to death.

October 17: The FDA ordered Eli Lilly & Co. to add a warning to the packaging of its antidepressant Cymbalta, that it could cause liver damage.

October 19: A study in the *Journal of the American Medical Association* concluded that atypical (newer) antipsychotic drugs could increase the risk of death in elderly people.

October 24: The FDA withdrew Cylert from the market because of its "overall risk of liver toxicity" and liver failure.

November: The FDA approved updated labeling for the antidepressant Effexor XR which noted that this antidepressant can cause homicidal ideation.

December 1: Researchers found that 18% of nearly 23,000 elderly patients taking the older antipsychotics died within the first six months of taking them.

December 8: The FDA warned that Paxil taken by pregnant women in their first trimester may cause birth defects, including heart malformations.

2006

January 5: The FDA said it had received reports of sudden deaths, strokes, heart attacks and hypertension (high blood pressure) in both children and adults taking "ADHD" drugs and asked its Drug Safety and Risk Management advisory committee to examine the potential of cardiovascular (heart) risks of the drugs.

February 4: A University of Texas study published in *Pediatric Neurology* reported cardiovascular problems in people taking stimulants.

February 5: An analysis of World Health Organization medical records found that infants whose mothers took antidepressants while pregnant could suffer withdrawal effects.

February 6: A study published in the *Archives of Pediatrics and Adolescent Medicine* determined that nearly one-third of newborn infants whose mothers took SSRI antidepressants during pregnancy experienced withdrawal symptoms that included high-pitched crying, tremors and disturbed sleep.

February 9: The FDA's Drug Safety and Risk Management Advisory Committee urged that the strongest "black box" warning be issued for stimulants, including Ritalin, Adderall and Concerta and that they may cause heart attacks, strokes and sudden death.

February 11: The Australian Therapeutic Goods Administration announced it would review the FDA advisory committee recommendation for stronger warnings against stimulants.

February 20: British authorities warned that the "ADHD" drug Strattera was associated with seizures and potentially lengthening period of the time between heartbeats.

February 25: A study in the journal, *Drug and Alcohol Dependence*, and reported in *The Washington Post* revealed that seven million Americans were estimated to have abused stimulant drugs and a substantial amount of teenagers and young adults now appeared to show signs of addiction.

March 10: Health Canada issued a warning that pregnant women taking SSRIs and other newer antidepressants placed newborns at risk of developing a rare lung and heart condition.

March 22-23: Two FDA advisory panels held hearings into the risk of stimulants and another new "ADHD" drug called Sparlon. Between January 2000 and June 30, 2005, the FDA had

received almost 1,000 reports of kids experiencing psychosis or mania while taking the drugs. The first panel recommended stronger warnings against stimulants, emphasizing these on special handouts called "Med Guides" that doctors must give to patients with *each* prescription. The second committee recommended not to approve Sparlon, which the manufacturer, Cephalon, estimated would lose them $100 million in drug sales.

March 28: The Australian Therapeutic Goods Administration announced its review of reports of 400 adverse reactions to stimulants in children taking them. CCHR had filed a Freedom of Information Act request with the TGA to obtain the reports and released this to the media that ran the story internationally.

May 1: An *American Journal of Psychiatry* study revealed that elderly people prescribed antidepressants such as Prozac, Paxil, and Zoloft are almost five times more likely to commit suicide during the first month on the drugs than those given other classes of antidepressants.

May 3: FDA adverse drug reaction reports linked 45 child deaths to new antipsychotic drugs. There were also more than 1,300 reports of other potentially life-threatening adverse reactions such as convulsions and low white blood cell count.

May 12: GlaxoSmithKline, the manufacturer of Paxil, sent a letter to doctors warning that its antidepressant increases the risk of suicide in adults. It was the first warning of its kind by a manufacturer.

July 19: The FDA said antidepressant packaging should carry warnings that they may cause a fatal lung condition in newborns whose mothers took SSRI antidepressants during pregnancy. Migraine sufferers also need to be warned that combining migraine drugs with SSRIs could result in a life-threatening condition called serotonin syndrome.

August: The *Archives of General Psychiatry* published a study by Mark Olfson, MD, MPH; Steven C. Marcus, PhD; David Shaffer, MD, on "Antidepressant Drug Therapy and Suicide in Severely Depressed Children and Adults." The study determined that children taking antidepressants were 1.52 times more likely to attempt suicide and 15 times ore likely to succeed in the attempt than those not taking the drugs.

August 21: The FDA issued a Black Box warning on the ADHD drug Dexedrine, as the drug causes sudden death in children and adolescents with structural cardiac abnormalities or other serious heart problems.

August 21: The FDA ordered warnings on all ADHD drugs. The warnings include: "Sudden deaths, strokes and myocardial infarction [heart attack] have been reported in adults taking stimulant drugs at usual doses." In addition to appearing on Ritalin, the warnings will be put on the labels of Adderall and Concerta. The warning will also state that one in a thousand children on the drugs suffers from hallucinations.

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The New York Post

March 9, 2008 Sunday

SECTION: All Editions; Pg. 2

LENGTH: 319 words

HEADLINE: TYKE-PSYCH PUSH

BYLINE: SUSAN EDELMAN

BODY:

Alarmed at the growing use of psychiatric drugs for children, a key New York lawmaker wants to set up regional centers to advise pediatricians on treating kids' mental and emotional problems.

State Sen. Thomas Morahan (R-Rockland County) will present a bill to the Mental Health Committee Wednesday to create at least three child-psychiatry centers where doctors statewide can call for consultations on troubled kids.

Under the plan, teams consisting of a psychiatrist, a social worker and a "care coordinator" would discuss the child's problem, make referrals and provide other support services to the family.

Based on a pioneering program in Massachusetts, the New York plan is aimed at helping troubled children who may be suffering untreated, and at choosing safe treatments.

Morahan said he acted in response to an investigative report in The Post last month that New York's Medicaid program paid nearly $90 million in 2006 for two dozen psychiatric drugs for kids. The state says that covered 55,700 children 18 and under.

More kids in New York and nationwide are taking powerful anti-psychotics and antidepressants - while most have not been tested adequately on kids or approved by the Food and Drug Administration for their use. Doctors may prescribe them to children or teens "off-label."

Morahan blasted the FDA policy. "They permit these drugs to be prescribed, regardless what the label says," said spokesman Ron Levine. "Many pediatricians may not be aware of the ramifications of psychotropic drugs on the market."

Some of the drugs cause severe - and dangerous - side effects, including Parkinson's-like movement disorders, weight gain, breast growth in boys, and suicidal tendencies. Experts warn that some kids may be misdiagnosed or overmedicated to control behavior problems.

State Health Department officials told The Post they do not require a diagnosis when paying for the drugs.

GRAPHIC: FLASHBACK: Last month's Post story.

LOAD-DATE: March 12, 2008

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US Fed News

March 12, 2008 Wednesday 6:45 AM EST

LENGTH: 924 words

HEADLINE: REP. MCDERMOTT ANNOUNCES HEARING ON UTILIZATION OF PSYCHOTROPIC MEDICATION FOR CHILDREN IN FOSTER CARE

BYLINE: US Fed News

DATELINE: WASHINGTON

BODY:

The House Ways & Means Committee issued the following statement:

Congressman Jim McDermott (D-WA), Chairman of the Subcommittee on Income Security and Family Support, today announced a hearing to examine the use of psychotropic drugs for children in the foster care system. The hearing will take place on Wednesday, March 12, 2008, at 2:00 p.m. in room B-318 Rayburn House Office Building.

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the subcommittee and for inclusion in the printed record of the hearing.

BACKGROUND:

Psychotropic medications have been increasingly prescribed for children in recent years, but the use of these drugs appears to be particularly elevated for children in foster care. One recent study found that psychotropic drug treatment was three or four times more common for youth in foster care than for other children receiving health care services through the Medicaid program. Additionally, children in foster care are often prescribed multiple psychotropic medications, and sometimes these drugs are used for off-label purposes (i.e., meaning their effects have not been demonstrated in children). These medicines are most commonly used to treat depression, anxiety and attention-deficit/hyperactivity disorder.

While the trauma associated with coming into foster care may increase some children's need for certain prescription drugs, the high rate of use of psychotropic medications in foster care has raised concerns regarding the monitoring of these drugs and whether a continuum of treatment services is being provided to these children beyond medication. It appears only a minority of States have established methods to formally regulate the use and administration of these medications among children in their care.

In announcing the hearing, Chairman McDermott stated, "Some children in foster care need and benefit from psychotropic medication. But these drugs should not be used as a shortcut to treat foster children when more effective treatments, including counseling, might provide long-term benefits. We need to carefully oversee the prescription of these medicines, especially when it comes to placing foster children on multiple drugs or prescribing medication for off-label use."

FOCUS OF THE HEARING:

REP. MCDERMOTT ANNOUNCES HEARING ON UTILIZATION OF PSYCHOTROPIC MEDICATION FOR CHILDREN IN FOSTER CARE US Fed News March 12, 2008 Wednesday 6:45 AM EST

The hearing will examine the use of prescription psychotropic drugs among children in the foster care system.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, http://waysandmeans.house.gov, select "110th Congress" from the menu entitled, "Hearing Archives" (http://waysandmeans.house.gov/Hearings.asp?congress=18). Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You MUST REPLY to the email and ATTACH your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business March 26, 2008. Finally, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225-1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at http://waysandmeans.house.gov.

LOAD-DATE: April 6, 2008

1 of 1 DOCUMENT

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THE DALLAS MORNING NEWS

November 13, 2004 Saturday
SECOND EDITION

SECTION: NEWS; Pg. 4A

LENGTH: 494 words

HEADLINE: Drug fraud alleged in foster care Strayhorn believes kids are getting unnecessary psychiatric medication

BYLINE: ROBERT T. GARRETT, Austin Bureau

DATELINE: AUSTIN

BODY:

AUSTIN - Comptroller Carole Keeton Strayhorn suspects foster children are being given psychiatric drugs so they're more docile, or so doctors and drug companies can make a buck.

Mrs. Strayhorn on Friday demanded a year's worth of records on drugs given to foster children, and she vowed to investigate and share evidence of fraud with the Legislature and the Health and Human Services Commission.

The comptroller cited her authority as the head of a Medicaid fraud task force that advises the commission.

She immediately drew skepticism from the Texas Medical Association and political rival Gov. Rick Perry that her investigation will be either helpful or necessary.

But two mothers of children placed by the state into foster care praised Mrs. Strayhorn's effort, saying her year-old crusade against misuse of mental health drugs among the state's 17,000 foster children had helped save the lives of their children.

"If it wouldn't have been for the care and concern of the comptroller, Mrs. Strayhorn, my daughter would not be alive today," said Elain Philpott of Port Neches.

Ms. Philpott said an unnecessary antipsychotic drug dulled her 15-year-old daughter's senses and caused other problems during the six years she was in foster care.

Mrs. Strayhorn said up to $4 million a year might be wasted on drugs given to foster children for mental illnesses

such as schizophrenia, bipolar disorder and depression.

"Children as young as 3 are receiving powerful, mind-altering drugs," she said.

Commission spokeswoman Jennifer Harris said it has launched a two-track review of whether poor children on Medicaid - including foster children - receive proper medicine for mental illness.

One is an ongoing review of drug claims by its beefed-up anti-fraud unit. The other is a review of "clinical data" on mentally disturbed children who receive Medicaid to see if policies need to be changed or if doctors need continuing education about mental health drugs.

Dr. John Holcomb of the Texas Medical Association said Mrs. Strayhorn has "a serious misunderstanding" of whether off-label use of drugs is appropriate.

"Hogwash," retorted the comptroller, whose son, Mark McClellan, runs the Food and Drug Administration. "I understand the use of off-label drugs, and I understand that most of these drugs are not approved for use in children."

She questioned actions by two Texas doctors who aren't psychiatrists but have prescribed mental health medications to foster children. A third, she said, co-owns a pharmacy that dispenses the drugs.

"It is not uncommon for some [foster] children to have up to 14 different prescriptions," she said.

Mrs. Strayhorn began reviewing foster care last year after stories in The Dallas Morning News found problems with the state's financial oversight of some foster care operators.

Ms. Harris said Mrs. Strayhorn will get the requested data "as long as it doesn't violate federal law protecting a patient's confidentiality."

E-mail rtgarrett@dallasnews.com

GRAPHIC: PHOTO(S): Carole Keeton Strayhorn

LOAD-DATE: November 13, 2004

FOCUS - 9 of 14 DOCUMENTS

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The Associated Press State & Local Wire

November 12, 2004, Friday, BC cycle

SECTION: State and Regional

LENGTH: 550 words

HEADLINE: Strayhorn to investigate drug fraud in foster care system

BYLINE: By NATALIE GOTT, Associated Press Writer

DATELINE: AUSTIN

BODY:

Texas is spending an estimated $4 million a year on mind-altering drugs for foster care children, Comptroller Carole Keeton Strayhorn said Friday as she announced a study into possible Medicaid prescription drug fraud.

She called on the Health and Human Services Commission to release to her a year's worth of prescription drug and claims data for foster children so she can determine whether the drugs are "being prescribed to make the children more submissive or to line the pockets of unscrupulous and uncaring doctors and pharmaceutical companies, or both."

Her office reviewed a month's worth of data from November 2003 that Strayhorn said showed a pattern of questionable prescription practices in the foster care system. She noted that it is common for some children to have up to 14 different prescriptions, and her office said that at least one 3-year-old foster child was prescribed a mind-altering psychotropic drug.

Strayhorn said that one doctor prescribing the drugs for foster children has ownership in a pharmacy located in the doctor's office. She also said that a radiologist in San Antonio prescribed such medications for children in El Paso, and that an ophthalmologist also prescribed the medications.

"As a mama and a grandmama, I am concerned with the health and well being of our foster kids," Strayhorn said. "And, as comptroller, I'm also concerned with potential Medicaid prescription drug fraud and abuse in the system because of the high cost of many of these prescriptions."

The Health and Human Services Commission already is reviewing the use of Medicaid drug claims and psychotropic drug use in children, HHSC spokeswoman Jennifer Harris said.

Harris noted that a preliminary study on the issue released last month by the HHSC inspector general analyzed Medicaid drug claim data from July and August. The report's initial findings raised some serious concerns, and HHSC already is taking immediate action, Harris said.

"While the original study looked at all Medicaid claims, we're concerned about the real lives and people behind the paperwork and benefit claims - the individual child, their diagnosis and health, as well (as) any providers who may be abusing the system," Harris said.

The comptroller's office review of the November 2003 data showed that $272,331 was spent on 1,129 antipsychotic prescriptions and $74,201 was spent on 1,167 antidepressants for foster care children that month.

Strayhorn said that many of the psychotropic drugs being prescribed to children are not labeled for use in children and have serious side effects.

"While I acknowledge documented success stories in the pharmacological treatment of children with psychotropic drugs, I believe that these powerful agents must be used with caution and prudence," Strayhorn said.

Dr. John Holcomb of the Texas Medical Association said most medications used in pediatrics are used off-label and perfectly appropriately and that his group cannot tell without examining the medical records whether the medicines Strayhorn discussed were prescribed correctly.

"Her study does not put the information in a clinical context, so we can not make clinical judgments. Nor can she," Holcomb said.

On the Net:

http://www.window.state.tx.us/

LOAD-DATE: November 13, 2004

FOCUS - 11 of 14 DOCUMENTS

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November 12, 2004 Friday

LENGTH: 289 words

HEADLINE: COMPTROLLER STRAYHORN'S RESPONSE TO STATEMENT BY TEXAS MEDICAL ASSOCIATION

BYLINE: States News Service

DATELINE: Austin, Texas

BODY:

The following information was released by the Office of Texas Comptroller of Public Accounts:

"Hogwash," Comptroller Strayhorn said. "I understand the use of off-label drugs and I understand that most of these drugs are not approved for use in children according to the FDA.
"I also understand that no child needs to be on 14 different drugs and I severely question a three-year-old being put on Risperdal and a radiologist in San Antonio prescribing psychotropic drugs to children in El Paso."
Statement from John R. Holcomb, MD, Texas Medical Association
"Texas Medical Association does not condone fraud or any other criminal activity, especially if committed by members of the medical profession," said John R. Holcomb, MD, chair of TMA's Ad Hoc Committee on Medicaid. "And to paraphrase Comptroller Strayhorn, 'As physicians, we are concerned with the health and well-being of our foster kids.'"
Texas physicians also support federal and state officials in their work to eliminate all genuine fraud within the Medicare and Medicaid programs.
"Comptroller Strayhorn, however, is starting off with a serious misunderstanding of the informed, off-label use of prescription drugs," Dr. Holcomb said. "In fact, most medications used in pediatrics are used off-label and perfectly appropriately. We obviously cannot tell without close examination of the medical records whether all of the medications the comptroller is discussing were prescribed correctly. Her study does not put the information in a clinical context, so we cannot make clinical judgments. Nor can she.
"The physicians of Texas would love to work with Mrs. Strayhorn to improve the lives of the forgotten children in the Texas foster care system."

LOAD-DATE: December 6, 2004

FOCUS - 8 of 14 DOCUMENTS

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The Brownsville Herald

November 13, 2004, Saturday

KR-ACC-NO: BV-DRUG-FRAUD-20041113

LENGTH: 413 words

HEADLINE: Texas comptroller to investigate possible prescription drug fraud, abuse

BYLINE: By Elizabeth Pierson

BODY:

AUSTIN, Texas -- The Texas state comptroller on Tuesday announced she would investigate possible fraud and abuse of prescription drugs in the foster care system.

Fraud and abuse harms children unnecessarily placed on psychotropic drugs and costs the state at least $ 4 million a year, said Texas Comptroller Carole Keeton Strayhorn.

She plans to request one year of records from the Health and Human Services to review prescription drug and claims data for foster children.

"It appears that large numbers of psychotropic drugs are being prescribed by our foster care system even though the Food and Drug Administration has not approved them for use in our children," she said.

Strayhorn is not the first state official to investigate the use of psychotropic drugs. The issue has been discussed in several legislative committee hearings and was the subject of inquiry by the inspector general's office.

Strayhorn became aware of the issue in detail after her April report, "Forgotten Children," in which she looked at one month of data regarding the use of psychotropic drugs by children in the foster care system.

She was particularly upset that children as young as 3 years old were being given psychotropic medications, she said. There are 1.7 million children on Medicaid in Texas, and 26,000 of them are foster children, she said.

But psychiatrists, including the only private-practice, full-time child psychiatrist in the Rio Grande Valley, have testified in front of legislators that sometimes the drugs can help children immensely when nothing else can.

The Texas Medical Association released a statement on Friday saying its doctors are concerned with the health of Texas foster children, and will do anything to help state officials eliminate genuine fraud.

However, Strayhorn misunderstands the off-label use of prescription drugs, said Dr. John R. Holcomb, chair of the ad hoc TMA committee on Medicaid.

Most medications not approved by the FDA for children are appropriately prescribed, he said.

"We obviously cannot tell without close examination of the medical records whether all of the medications the comptroller is discussing were prescribed correctly," Holcomb said in a statement. "Her study does not put the information in a clinical context, so we cannot make clinical judgments. Nor can she."

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JOURNAL-CODE: BV

LOAD-DATE: November 13, 2004