

smith

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)

REC'D APR 16 2009

Case No. 3AN 08-10115CI

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

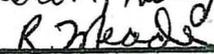
Having reviewed the Motion for Leave to Amend Complaint (Citizen-Taxpayer Standing/Medicaid Injunction) filed April 3, 2009, by Plaintiff, the Law Project for Psychiatric Rights, and any responses thereto, *including the conditional non-opposition with reservation*, it is hereby ORDERED that the motion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

DATED this 14th day of April, 2009.



Jack W. Smith
Superior court Judge

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

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

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)

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Clerk of the Trial Courts
Case No. 3AN 08-10115CI

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.

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

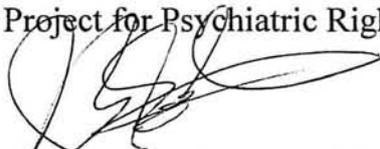
B. Permanently enjoin the defendants and their successors from:

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

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)

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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 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 neurotoxicity, 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	aripiprazole	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	imipramine		
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 (MAOI) 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.

Anticonvulsants 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 agranulocytosis 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 carbamazepine (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

PsychRights

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.

406 G Street, Suite 206, Anchorage, Alaska 99501
(907) 274-7686 Phone ~ (907) 274-9493 Fax
<http://psychrights.org>

December 10, 2004

Sen. Fred Dyson
10928 Eagle River Road Suite 238
Eagle River, AK 99577
(fax) 694-1015

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

State Capitol, Room 121
Juneau, AK 99801-1182

State Capitol, Room 104
Juneau, AK 99801-1182

Re: Office of Children's Services

Dear Sen. Dyson and Rep. Wilson:

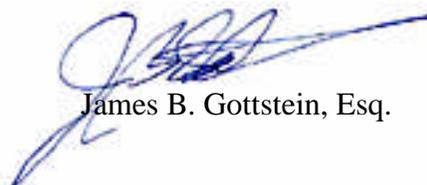
I am pleased you are holding hearings regarding the Office of Children's Services and the difficulties they have had in protecting children it seems they should have known about and acted upon. I am, however, writing about another side of the coin. That is there is increasing reason to believe children 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_Betty_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,
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 kreffrem@pro-ns.net, ARONWOLF@aol.com, doolittle@ptialaska.net,
 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

James B. (Jim) Gottstein, Esq.

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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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 Representative_Lindsey_Holmes@legis.state.ak.us,
 Senator_Betty_Davis@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 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.

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.

Law Project for Psychiatric Rights  
406 G Street, Suite 206  
Anchorage, Alaska 99501  
USA  
Phone: (907) 274-7686) Fax: (907) 274-9493  
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

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

RECEIVED  
MAR 27 2007

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.

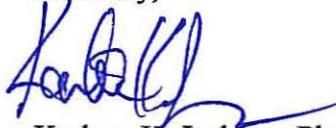
The Office of Children's Services (OCS) operates under policy which requires that caseworkers must staff medication recommendations for children on their caseloads with their Supervisor and their regional Psychiatric Nurse prior to giving consent to the treatment provider. The OCS Psychiatric Nurses 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.

James B. (Jim) Gottstein, Esq.  
Law Project for Psychiatric Rights  
March 22, 2007  
Page 2

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,

A handwritten signature in blue ink, appearing to read 'Karleen K. Jackson', with a long horizontal flourish extending to the right.

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.<sup>1</sup>

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.<sup>2</sup>

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,<sup>3</sup> 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

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<sup>1</sup> See, enclosed copy of [affidavit of Robert Whitaker](#).

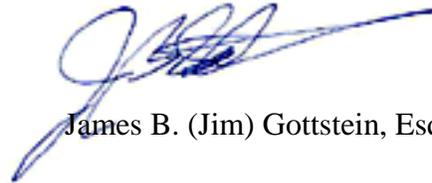
<sup>2</sup> PsychRights won its second Alaska Supreme Court case in 2007, [\*Wetherhorn v. Alaska Psychiatric Institute\*](#), 156 P.3d 371, which held involuntarily committing someone as being gravely disabled under the definition in AS 47.30.915(7)(B) is constitutional only if construed to require a level of incapacity so substantial the respondent is incapable of surviving safely in freedom.

<sup>3</sup> See, [enclosed article by David Healy and Joanna Le Noury](#).

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.<sup>4</sup>

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

---

<sup>4</sup> 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 06 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.

James B. (Jim) Gottstein  
PsychRights  
March 4, 2008  
Page 2

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®**

Exhibit G, page 1 of 2

**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.