IN THE SUPREME COURT FOR THE STATE OF ALASKA

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation, Appellant, vs. STATE OF ALASKA, et al., Appellees.	)	Supreme Court No. S-13558 Superior Court No. 3AN 08-10115CI

APPEAL FROM THE SUPERIOR COURT
THIRD JUDICIAL DISTRICT AT ANCHORAGE
THE HONORABLE JACK W. SMITH, PRESIDING

APPELLANT'S EXCERPT OF RECORD

James B. Gottstein (7811100)
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Attorney for Appellant
Law Project for Psychiatric Rights

Filed in the Supreme Court of
the State of Alaska, this _____
day of _____, 2009

Marilyn May, Clerk

By: _____
Deputy Clerk

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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

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(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

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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

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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.

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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.

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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

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> 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:

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> 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.

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> 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.

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> 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.

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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

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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

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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.

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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

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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

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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.

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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

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(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.

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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.

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

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

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

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

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

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

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

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

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

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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.

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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.

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

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

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

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

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

Neuroleptics

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

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

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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.

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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,

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(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,

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(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.

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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:

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

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

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

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

Antidepressants

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

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

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

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

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

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

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

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

(a) Increased physical activity,

(b) Elevated mood,

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

(d) Improved sleep and appetite.

146. Undesirable observed behavioral effects of antidepressants include:

(a) Anxiety and nervousness,

(b) Agitation and irritability,

(c) Mood swings, including mania,

(d) Aggressiveness,

(e) Thoughts of suicide,

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(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.

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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		

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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,

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(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

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(j) Withdrawal symptoms.

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

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

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

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

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

Anticonvulstants Promoted as "Mood Stabilizers"

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

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

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

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

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

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

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

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

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

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

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

175. Desired observed behavioral effects of anticonvulsants include:

(a) Reducing aggression and impulsivity, and

(b) Calming restlessness and excitability.

176. Undesired observed behavioral effects of anticonvulsants include:

(a) Depression and sedation,

(b) Hostility and irritability,

(c) Aggression and violence,

(d) Anxiety and nervousness,

(e) Hyperactivity,

(f) Abnormal thinking,

(g) Confusion and amnesia,

(h) Slurred speech, and

(i) Sedation and sleepiness.

177. Undesired observed physical effects of anticonvulsants include:

(a) Nausea and dizziness,

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(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

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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.

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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)

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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).

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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

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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.

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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?

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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?

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(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?

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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?

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(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:

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(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.

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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.

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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,

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(ii) rationally anticipated benefits of psychotropic drug treatment outweigh the risks,

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

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

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

C. Order that

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

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

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

D. Award Plaintiff costs and attorney's fees.

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

DATED: September 29, 2008.

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

By: _____
James B. Gottstein, ABA # 7811100

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http://psychrights.org

December 10, 2004

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

State Capitol, Room 121
Juneau, AK 99801-1182

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

State Capitol, Room 104
Juneau, AK 99801-1182

Re: Office of Children's Services

Dear Sen. Dyson and Rep. Wilson:

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

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

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

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

Yours truly,

James B. Gottstein, Esq.

Commissioner Joel Gilbertson

Exhibit A

X-Mailer: QUALCOMM Windows Eudora Version 7.0.1.0
Date: Fri, 09 Mar 2007 17:13:32 -0900
To: Representative_Jay_Ramras@legis.state.ak.us,
Representative_Nancy_Dahlstrom@legis.state.ak.us,
Representative_John_Coghill@legis.state.ak.us,
Representative_Bob_Lynn@legis.state.ak.us,
Representative_Ralph_Samuels@legis.state.ak.us,
Representative_Max_Gruenberg@legis.state.ak.us,
Representative_Lindsey_Holmes@legis.state.ak.us
From: Jim Gottstein <jim.gottstein@psychrights.org>
Subject: Follow-Up: Over Drugging of Kids in State Custody
Cc: sarah_palin@gov.state.ak.us,Senator_Bettye_Davis@legis.state.ak.us,
Representative_Peggy_Wilson@legis.state.ak.us,
Representative_Bob_Roses@legis.state.ak.us,
Representative_Sharon_Cissna@legis.state.ak.us,
Representative_Anna_Fairclough@legis.state.ak.us,
Representative_Mark_Neuman@legis.state.ak.us,
Representative_Berta_Gardner@legis.state.ak.us,
Senator_Joe_Thomas@legis.state.ak.us,
Senator_John_Cowdery@legis.state.ak.us,
Senator_Kim_Elton@legis.state.ak.us,
Senator_Fred_Dyson@legis.state.ak.us,
Senator_Johnny_Ellis@legis.state.ak.us,"Demer, Lisa" <LDemer@adn.com>,
"Bruce Whittington" <Bruce.Whittington@PsychRights.Org>,
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kreffrem@pro-ns.net,ARONWOLF@aol.com,doolttle@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

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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,
Representative_John_Coghill@legis.state.ak.us,
Representative_Bob_Lynn@legis.state.ak.us,
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Representative_Peggy_Wilson@legis.state.ak.us,
Representative_Bob_Roses@legis.state.ak.us,
Representative_Sharon_Cissna@legis.state.ak.us,
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karleen_jackson@health.state.ak.us,Stacy_Toner@health.state.ak.us
From: Jim Gottstein <jim.gottstein@psychrights.org>
Subject: Follow-Up: Over Drugging of Kids in State Custody
Cc: "Demer, Lisa" <LDemer@adn.com>,
"Bruce Whittington" <Bruce.Whittington@PsychRights.Org>,
"DJRICCIO-aol.com" <DJRICCIO@aol.com>,lloydross1@worldnet.att.net,
kreffrem@pro-ns.net,ARONWOLF@aol.com,
Jim Gottstein <jim.gottstein@psychrights.org>,
Vera Sharav <veracare@ahrp.org>,
"list-psychrights.org" <list@psychrights.org>,
Senator_Johnny_Ellis@legis.state.ak.us,
"Susan Musante" <susan@soteria-alaska.com>,mgstone@arctic.net

Dear Governor Palin and other Alaska Mental Health Policy Makers,

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

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

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

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

Please correct this situation.

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

FYI

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

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

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

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

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

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

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

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

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

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

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

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

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

~~~~~~

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

RECEIVED
MAR 27 2007

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

Dear Mr. Gottstein:

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

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

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

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

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

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

Sincerely,

Karleen K. Jackson, Ph.D.
Commissioner

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

Psychiatric Rights, Inc.

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

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

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

Dear Governor Palin:

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

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

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

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

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

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

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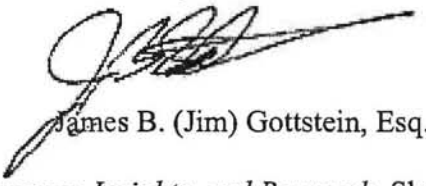
[1] *See*, enclosed copy of affidavit of Robert Whitaker.
[2] PsychRights won its second Alaska Supreme Court case in 2007, *Wetherhorn v. Alaska Psychiatric Institute*, 156 P.3d 371, which held involuntarily committing someone as being gravely disabled under the definition in AS 47.30.915(7)(B) is constitutional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

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

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

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

Yours truly,



James B. (Jim) Gottstein, Esq.

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

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

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

STATE OF ALASKA

DEPT. OF HEALTH AND SOCIAL SERVICES
OFFICE OF THE COMMISSIONER

SARAH PALIN, GOVERNOR

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

March 4, 2008

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

Dear Mr. Gottstein:

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

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

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

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

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

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

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

Sincerely,

Karleen K. Jackson, Ph.D.
Commissioner

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

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

Dear Mr. Hogan:

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

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

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

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

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

--

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

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

PsychRights®

Law Project for Psychiatric Rights

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

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

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

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMETN 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 STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

Case No. 3AN-08-10115 CI

ANSWER TO AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Defendants, the State of Alaska; Sarah Palin, Governor of the State of Alaska; the Department of Health and Social Services; William Hogan, in his official capacity as Commissioner of the Department; Tammy Sandoval, in her official capacity as Director of the Office of Children's Services' Steve McComb, in his official capacity as Director of the Division of Juvenile Justice; Melissa Stone, in her official

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

capacity as Director of the Division of Behavioral Health; Ron Adler, in his official capacity as Director of Alaska Psychiatric Institute; and William Streur, in his official capacity as Deputy Commissioner of the Department of Health and Social Services (hereinafter collectively "the state"), answer the plaintiff's Complaint for Declaratory and Injunctive Relief in the above-captioned matter as follows:

INTRODUCTION

1. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied. To the extent the paragraph alleges a legal conclusion, no response it required.

JURISDICTION AND VENUE

2. Admit.

3. Admit.

PARTIES

4. The state is without sufficient information to admit or deny the substance of this paragraph.

5. Admit that Alaska is one of the states in the United States of America. Admit that the State of Alaska pays for medically necessary medication, including psychotropic medication. Admit that under AS 47.10 and AS 47.12, the state has the authority, through a court order, to assume custody of children in need of aid. The remainder of the paragraph is denied.

6. Admit that Sarah Palin is the governor of Alaska. Admit that the State of Alaska, under the Palin Administration, pays for medically necessary medication, including psychotropic medication. Admit that under AS 47.10, the state, under the Palin Administration, has the authority, through a court order, to assume custody of children in need of aid. The remainder of the paragraph is denied.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

7. Admit that the Department of Health and Social Services is the state agency that assumes state custody over children. Admit that the Department of Health and Social Services is the state Medicaid agency and is the department responsible for paying for medically necessary medication, including psychotropic medication. Admit that the Department of Health and Social Services is the department that oversees the Office of Children's Services to assume custody through a court order of children need of aid. The remainder of the paragraph is denied.

8. Admit that William Hogan is the Commissioner of the Department of Health and Social Services. Admit that the Department of Health and Social Services is the state Medicaid agency and is the department responsible for paying for medically necessary medication, including psychotropic medication. Admit that the Department of Health and Social Services is the department that oversees the Office of Children's Services to assume custody through a court order of children need of aid. The remainder of the paragraph is denied.

9. Admit that Tammy Sandoval is the director of the Office of Children's Services. Admit that the Department of Health and Social Services is the state Medicaid agency and is the department responsible for paying for medically necessary medication, including psychotropic medication. Admit that the Department of Health and Social Services is the department that oversees the Office of Children's Services to assume custody through a court order of children need of aid. The remainder of the paragraph is denied.

10. Admit that Steve McComb is the Director of the Division of Juvenile Justice. Admit that the Department of Health and Social Services is the state Medicaid agency and is the department responsible for paying for medically necessary medication, including psychotropic medication. Admit that the Department of Health and Social Services is the department that oversees the Office of Children's Services to

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

assume custody through a court order of children need of aid. The remainder of the paragraph is denied.

11. Admit that Melissa Witzler Stone is the Director of the Division of Behavioral Health. Admit that the Department of Health and Social Services is the state Medicaid agency and is the department responsible for paying for medically necessary medication, including psychotropic medication. Admit that the Department of Health and Social Services is the department that oversees the Office of Children's Services to assume custody through a court order of children need of aid. The remainder of the paragraph is denied.

12. Admit that Ron Adler is the Director/CEO of Alaska Psychiatric Institute. Admit that the Department of Health and Social Services is the state Medicaid agency and is the department responsible for paying for medically necessary medication, including psychotropic medication. Admit that the Department of Health and Social Services is the department that oversees the Office of Children's Services to assume custody through a court order of children need of aid. The remainder of the paragraph is denied.

13. Admit that William Streur is a Deputy Commissioner of the Department of Health and Social Services and the Deputy Director of the Division of Health Care Services. Admit that the Department of Health and Social Services is the state Medicaid agency and is the department responsible for paying for medically necessary medication, including psychotropic medication. Admit that the Department of Health and Social Services is the department that oversees the Office of Children's Services to assume custody through a court order of children need of aid. The remainder of the paragraph is denied.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

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

14. This paragraph is a statement of law to which no response is required. To the extent a response is required, the paragraph is denied.

15. This paragraph is a statement of law to which no response is required.

16. This paragraph is a statement of law to which no response is required.

17. This paragraph is a statement of law to which no response is required.

18. This paragraph is a statement of law to which no response is required.

CHILDREN AND YOUTH'S STATUTORY RIGHTS WHEN IN STATE CUSTODY

19. This paragraph is a statement of law to which no response is required.

20. This paragraph is a statement of law to which no response is required.

21. This paragraph is a statement of law to which no response is required.

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

22. This paragraph is a statement of law to which no response is required.

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

23. This paragraph is a statement to which no response is required.

24. The state is without sufficient information to admit or deny the substance of this paragraph. To the extent a response is required, the paragraph is denied.

25. This paragraph is a statement to which no response is required. The legislative history speaks for itself.

26. This paragraph is a statement to which no response is required.

27. This paragraph is a statement to which no response is required.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

28. This paragraph is a statement to which no response is required.

29. This paragraph is a statement to which no response is required.

30. This paragraph is a statement to which no response is required.

31. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

32. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

33. Admit that the Attorney General's Office is a participant in the Attorneys General Consumer and Prescriber Grant Program.

34. Admit that Mr. Gottstein e-mailed a number of state officials on June 11, 2008; the remainder of the paragraph is a statement to which no response is required.

35. Admit.

THE "CRITICAL THINKRx" CURRICULUM

36. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

THE FDA DRUG APPROVAL PROCESS

37. This paragraph is a statement of law to which no response is required; to the extent a response is required, the paragraph is denied.

38. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

39. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

40. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

41. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

42. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

43. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

44. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

45. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

46. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

47. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

48. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

49. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

50. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

51. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

52. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

53. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

54. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
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PHONE: 465-3600

55. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

56. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

57. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

58. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

59. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

60. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

61. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

62. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

63. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

64. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

65. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

66. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

67. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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68. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

69. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

70. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

UNDUE DRUG COMPANY INFLUENCE OVER PRESCRIBING PRACTICES

71. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

72. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

73. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

74. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

75. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

PEDIATRIC PSYCHOTROPIC PRESCRIBING

76. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

77. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

78. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

79. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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80. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

81. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

82. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

83. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

84. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

85. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

86. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

87. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

88. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

89. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

90. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

91. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

92. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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93. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

94. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

95. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

96. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

97. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

98. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

99. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

100. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

101. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

102. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

103. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

104. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

105. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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106. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

107. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

108. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

109. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

110. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

NEUROLEPTICS

111. The paragraph is a statement of law to which no response is required.

112. The paragraph is a statement of law to which no response is required.

113. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

114. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

115. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

116. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

117. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

118. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

119. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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120. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

121. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

122. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

123. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

124. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

125. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

126. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

127. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

128. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

129. This paragraph is a statement of law to which no response is required.

130. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

131. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

132. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

133. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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134. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

135. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

136. This paragraph is a statement of law to which no response is required.

137. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

138. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

ANTIDEPRESSANTS

139. This paragraph is a statement of law to which no response is required.

140. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

141. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

142. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

143. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

144. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

145. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

146. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

147. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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148. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

149. This paragraph is a statement of law to which no response is required.

150. This paragraph is a statement of law to which no response is required.

151. This paragraph is a statement of law to which no response is required.

152. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

STIMULANTS

153. This paragraph is a statement of law to which no response is required.

154. The state is without sufficient information to admit or deny the substance of this paragraph; t therefore, it is denied.

155. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

156. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

157. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

158. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

159. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

160. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

161. This is a statement of law to which no response is required.

162. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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163. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

164. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

165. This paragraph is a statement to which no response is required. The reports and studies referenced in the paragraph speak for themselves.

ANTICONVULSANTS PROMOTED AS "MOOD STABILIZERS"

166. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

167. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

168. This paragraph is a statement of law to which no response is required.

169. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

170. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

171. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

172. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

173. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

174. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

175. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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176. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

177. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

EVIDENCE BASED, LESS INTRUSIVE ALTERNATIVES: PSYCHOSOCIAL INTERVENTIONS

178. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

179. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

180. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

181. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

182. Admit that some children may experience loss and trauma because of disrupted attachments to biological parents. The remainder of the paragraph is denied.

183. Admit that some children may experience emotional disruption. The remainder of the paragraph is denied.

184. Admit that some children may benefit from secure attachments to competent adults. The state is without sufficient information to admit or deny the remainder of the paragraph; therefore, it is denied.

185. Admit that trauma, abuse, and neglect may disrupt some children's ability to form secure attachments. The state is without sufficient information to admit or deny the remainder of the paragraph; therefore, it is denied.

186. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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187. Admit that the statements contained in this paragraph may be true for some children. The remainder of the paragraph is denied.

188. Admit that the statements contained in this paragraph may be true for some children. The remainder of the paragraph is denied.

189. Admit that the elements described in this paragraph may play a role in positive outcomes for some children in foster care. The state is without sufficient information to admit or deny the remainder of the paragraph; therefore, it is denied.

190. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

191. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

192. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

193. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

194. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

195. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

196. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

197. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

198. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

199. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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200. Admit that maltreatment may be linked to aggressive behavior in children. The state is without sufficient information to admit or deny the remainder of the paragraph; therefore, it is denied.

201. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

202. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

203. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

204. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

205. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

206. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

207. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

208. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

209. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

210. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

211. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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"CRITICAL THINK Rx" SPECIFICATIONS

212. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

213. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

214. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

215. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

216. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

217. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

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

218. Denied.

219. This paragraph contains a statement of law to which no response is required. The remainder of the paragraph is denied.

220. The state is without sufficient information to admit or deny the substance of this paragraph; therefore, it is denied.

221. Denied.

222. Denied.

223. Denied.

224. Denied.

225. Denied.

226. Denied.

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227. The state is without sufficient information to admit or deny the substance of those paragraphs in the complaint referenced in this paragraph. Accordingly, this paragraph is denied.

228. The state is without sufficient information to admit or deny the substance of those paragraphs in the complaint referenced in this paragraph. Accordingly, this paragraph is denied.

229. Admit the dates and figure described in this paragraph. The remainder of the paragraph is denied.

230. Admit the dates and figure described in this paragraph. The remainder of the paragraph is denied.

231. Admit the dates and figure described in this paragraph. The remainder of the paragraph is denied.

232. Admit the dates and figure described in this paragraph. The remainder of the paragraph is denied.

233. Admit the dates and figure described in this paragraph. The remainder of the paragraph is denied.

234. Admit the dates and figure described in this paragraph. The remainder of the paragraph is denied.

235. Admit the dates and figure described in this paragraph. The remainder of the paragraph is denied.

AFFIRMATIVE DEFENSES

1. Plaintiff is prohibited from bringing this lawsuit by the XI Amendment of the United States Constitution.

2. Plaintiff has failed to state a cause of action upon which relief can be granted.

3. Plaintiff's complaint is barred by the doctrine of laches.

4. Plaintiff's complaint is barred by the doctrine of unclean hands.

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5. Plaintiff's complaint is *res judicata*.

6. The state is entitled to official immunity.

7. The state is entitled to discretionary function immunity.

8. The state is entitled to qualified immunity.

9. Plaintiff's complaint is barred under the separation of powers doctrine.

10. Plaintiff lacks standing to bring this action.

11. The state reserves the right to assert additional defenses, which may be revealed through discovery.

12. All other applicable defenses in law and in equity.

WHEREFORE, the state requests the court order that:

1. The Plaintiff's Amended Complaint for Declaratory and Injunctive Relief be dismissed in its entirety with prejudice;

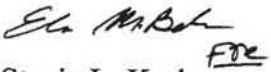
2. The state be awarded reasonable attorneys fees and costs; and

3. For such other relief as the court deems appropriate.

Dated this 13th day of October, 2008, at Juneau, Alaska.

TALIS J. COLBERG
ATTORNEY GENERAL

By: 
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: 
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

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

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation,
Plaintiff,
vs.
STATE OF ALASKA, *et al.*,
Defendants,
Case No. 3AN 08-10115CI

MOTION TO AMEND PARAGRAPH 22 OF AMENDED COMPLAINT

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

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

This motion is accompanied by a memorandum in support.

DATED: December 5, 2008.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

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

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

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation,
Plaintiff,
vs.
STATE OF ALASKA, *et al.*,
Defendants,
Case No. 3AN 08-10115CI

MEMORANDUM IN SUPPORT OF MOTION TO AMEND PARAGRAPH 22 OF AMENDED COMPLAINT

Plaintiff has moved to amend paragraph 22 of its amended complaint to read as follows:

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

The amendment inserts "when medically necessary and" in the second line.

Pursuant to the October 23, 2008, Amended Routine Pretrial Order in this case, which provides that Saturday, November 22, 2008 was the deadline to amend pleadings without motion, Plaintiff filed an Amendment to Paragraph 22 on November 24, 2008, the

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

following Monday.[1] On November 25, 2008, however, the Clerk rejected the filing saying it needed either a notice of errata or a motion to amend.[2] Therefore, Plaintiff filed a motion to amend.

For the foregoing reasons, Plaintiff respectfully requests the Court to grant his motion to amend paragraph 22 of its Amended Complaint.

DATED: December 5, 2008.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
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[1] Exhibit A.
[2] Exhibit B.

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

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

Plaintiff,

vs.

STATE OF ALASKA, *et al.*,

Defendants,

Case No. 3AN 08-10115CI

AMENDMENT TO PARAGRAPH 22 OF AMENDED COMPLAINT

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

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

(a) American Hospital Formulary Service Drug Information,

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

(c) DRUGDEX Information System.

DATED: November 24, 2008.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

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

RECD

NOV 2 [illegible] 2008

NOTICE OF DEFICIENT FILING(S)

FROM:
Alaska Court System
Nesbett Courthouse
825 W 4th Ave
Anchorage, AK 99501

DATE: November 25, 2008
CASE NO: 3AN-08-10115CI
CASE NAME: Law Project for Psychiatric Rights vs. State of Alaska et al
CLERK: SSugden
PHONE: 264-0441

TO:
JAMES B. GOTTSTEIN
406 'G' STREET, SUITE 206
ANCHORAGE, AK 99501

☐ Your documents are being returned to you.

The document(s) you submitted to the court is/are deficient. Please provide the following:

☒ **Other: The Amendment to Paragraph 22 of Amended Complaint filed on 11-24-2008 needs either a notice of errata or a motion to amend.**

Deficiencies must be corrected within 20 calendar days from the date of this notice.

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMETN 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 STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

Case No. 3AN-08-10115 CI

NON-OPPOSITION TO PLAINTIFF'S MOTION TO AMEND

Defendants State of Alaska, et al. do not oppose Plaintiff's Motion to Amend paragraph 22 of the amended complaint in the above-captioned matter.

Dated this 10th day of December, 2008, at Juneau, Alaska.

TALIS J. COLBERG
ATTORNEY GENERAL

By: 
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

SIGNATURES CONTINUED ON NEXT PAGE

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P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

By: FOR

Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

Certificate of Service

I hereby certify that on this 11th day of December, 2008, a true and correct copy of the foregoing OPPOSITION was mailed via U.S. mail, first class, postage prepaid, to the following attorney of record:

James B. Gottstein, Esq.
Law Project for Psychiatric Rights, Inc.
406 G Street, Suite 206
Anchorage, AK 99501

H. Raven Haffner, Law Office Assistant II

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

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

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation,
Plaintiff,
vs.
STATE OF ALASKA, *et al.*,
Defendants,
Case No. 3AN 08-10115CI

**ORDER GRANTING
MOTION TO AMEND PARAGRAPH 22
OF AMENDED COMPLAINT**

In consideration of Plaintiff's motion to amend paragraph 22 of its amended complaint to read as follows:

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

and any response(s), it is hereby **ORDERED**, the Motion is **GRANTED**.

DATED: Dec 17, 2008.

By: Jack Smith
Jack W. Smith
Superior Court Judge

I certify that on 12-17-08 a copy of the above was mailed to each of the following at their addresses of record. Kraly, Bakalar, Hattstein
R Meader
Secretary/Deputy Clerk

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

LAW PROJECT FOR PSYCHIATRIC RIGHS, 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 STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

REC'D MAR 16 2009

Case No. 3AN-08-10115 CI

STATE OF ALASKA'S MOTION AND MEMORANDUM IN SUPPORT OF MOTION TO STAY DISCOVERY

Pursuant to Alaska Rule of Civil Procedure 77, defendants the State of Alaska; Sarah Palin, Governor of the State of Alaska; the Department of Health and Social Services; William Hogan, in his official capacity as Commissioner of the Department; Tammy Sandoval, in her official capacity as Director of the Office of Children's Services; Steve McComb, in his official capacity as Director of the Division

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of Juvenile Justice; Melissa Stone, in her official capacity as Director of the Division of Behavioral Health; Ron Adler, in his official capacity as Director of Alaska Psychiatric Institute; and William Streur, in his official capacity as Deputy Commissioner of the Department of Health and Social Services (hereinafter collectively "the Department"), hereby move to stay discovery in the above-captioned matter. The plaintiff is currently seeking discovery in this case. However, the Department has filed contemporaneous to the instant motion a dispositive Motion for Judgment on the Pleadings pursuant to Alaska Rule of Civil Procedure 12(c). For the following reasons, the Department asks the court to stay discovery pending resolution of the Department's Civil Rule 12(c) motion.

A stay of discovery in litigation is within the discretion of the trial court and appropriate pending the court's decision on a dispositive motion.[1] This is particularly true where—as here—such a motion raises pure questions of law which discovery is not needed to resolve.[2] In such cases, and particularly where—also as here—the pending motion would dispose of the entire case, staying discovery "is an eminently logical means to prevent wasting the time and effort of all concerned, and to

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[1] *See, e.g., Karen L. v. State Dept. of Health and Social Services, Div. of Family* and Youth Services, 953 P.2d 871, 880 (Alaska 1998).

[2] *Brazos Valley Coalition for Life, Inc. v. City of Bryan, Tex.*, 421 F.3d 314, 328 (5th Cir. 2005).

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make the most efficient use of judicial resources."[3] Courts have granted government defendants' requests to stay discovery, specifically where "the burden and expense of the subject discovery outweighed its likely benefit."[4] Such motions have been resolved in favor of the government movant on threshold issues, based on the reasoning that unfettered discovery in such a context may impose "an undue burden on public officials and government agencies."[5]

In this case, a stay of discovery is appropriate because if the court grants the Department's Motion for Judgment on the Pleadings, further discovery as it relates to the Complaint in this matter will be moot.[6] If the Department's motion is denied, the regular course of discovery can resume at that point. But continued discovery while the Department's dispositive motion is pending is a waste of the parties' and the court's already-stretched resources. On February 24, 2009, the undersigned contacted plaintiff to see if the parties could agree to stay discovery pending the outcome of any

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[3] See *Chavous v. District of Columbia Financial Responsibility and Management Assistance*, 201 F.R.D. 1, 2 (D.D.C., 2001) (citing *Coastal States Gas Corp. v. Department of Energy*, 84 F.R.D. 278, 282 (D. Del.1979)).

[4] *See, e.g., Schism v. U.S.*, 316 F.3d 1259, 1301 (Fed. Cir. 2002). See also *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1091 (D.C. Cir. 1986).

[5] *Williamson v. U.S. Dept. of Agriculture*, 815 F.2d 368 (5th Cir 1987) (citing *Halperin v. Kissinger*, 606 F.2d 1192 (D.C.Cir.1979), aff'd in pertinent part, 452 U.S. 713 (1981)) (Court properly stayed discovery pending resolution of threshold governmental immunity issues).

[6] The Department's Rule 12(c) Motion seeks dismissal of the Complaint on the grounds that plaintiff has not presented the court with a justiciable case or controversy and lacks standing to sue.

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dispositive motions. Plaintiff agreed to postpone one pending deposition by a few weeks but declined to stipulate to the Department's proposed stay.

For the foregoing reasons, the Department requests that the court stay discovery pending the court's decision on the Department's contemporaneous Motion for Judgment on the Pleadings.

DATED this 12th day of March, 2009, at Juneau, Alaska.

RICHARD A. SVOBODNY
ACTING ATTORNEY GENERAL

By: _____
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: _____
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

ATTORNEY GENERAL, STATE OF ALASKA
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHS, 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 STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

REC'D MAR 16 2009

Case No. 3AN-08-10115 CI

MOTION FOR EXPEDITED CONSIDERATION

Pursuant to Alaska Rule of Civil Procedure 77(g), the State of Alaska and the remaining above-named defendants (hereinafter "the Department"), hereby move for expedited consideration of the Department's Motion to Stay Discovery, filed contemporaneously herewith. This motion is supported by the attached affidavit of counsel setting forth the facts that justify expedited consideration. A decision on this

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motion is requested by **March 19, 2009**, the date presently noticed for the first deposition in this case.

DATED this 12th day of March, 2009.

RICHARD A. SVOBODNY
ACTING ATTORNEY GENERAL

By: _____
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: _____
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

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

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

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMETN 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 STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

Case No. 3AN-08-10115 CI

AFFIDAVIT OF COUNSEL IN SUPPORT OF MOTION FOR EXPEDITED CONSIDERATION

STATE OF ALASKA)
) ss.
THIRD JUDICIAL DISTRICT)

I, Elizabeth M. Bakalar, being first duly sworn upon oath, depose and say:

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

1. I am one of the Assistant Attorneys General assigned to represent the above-named defendants ("the Department") in this matter.

2. Initially, plaintiff noticed the deposition of David Campana, state pharmacist, for the afternoon of February 26, 2009, and the Department had begun to prepare for that deposition and gather materials responsive to the accompanying *subpoena duces tecum*.

3. However, in preparing for Mr. Campana's deposition, counsel began to review the underlying Complaint more extensively and developed concerns about engaging in further discovery at that time.

4. Accordingly, on February 24, 2009, the undersigned contacted plaintiff by e-mail to convey this information and attempted to secure counsel's stipulation to stay discovery pending resolution of a dispositive motion to be filed by the Department.

5. Plaintiff agreed to postpone Mr. Campana's deposition for a few weeks, but declined to stipulate to a stay of discovery under the aforementioned terms.

6. Plaintiff has re-noticed Mr. Campana's deposition for March 19, 2009 at 1:00 p.m.

7. Plaintiff also filed its First Requests for Production on March 2, 2009, a response to which, absent a stay, is due April 2, 2009.

8. Contemporaneous to this Motion for Expedited Consideration and underlying Motion to Stay Discovery, the Department has filed a Motion for Judgment on the Pleadings pursuant to Alaska Rule of Civil Procedure 12(c), in which the Department argues that the plaintiff has failed to present a case or controversy under the Declaratory Judgment Act and lacks standing to bring this lawsuit.

9. The Department therefore would be prejudiced by having to engage in discovery when there is a pending dispositive motion that would moot the need for all discovery in the case.

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10. Based on the foregoing, and the impending discovery deadlines in this matter, the Department requests the court's expedited consideration of its Motion to Stay Discovery.

DATED: March 12, 2009

Elizabeth M. Bakalar

SUBSCRIBED AND SWORN to before me this 12th day of March, 2009.

STATE OF ALASKA
OFFICIAL SEAL
HEIDI HAFFNER
NOTARY PUBLIC
My Commission Expires With Office

Notary Public for the State of Alaska
My commission expires with office

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

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 STREUER, Deputy Commissioner, and Director of the Division of Health Care Services,

Defendants.

REC'D MAR 16 2009

Case No. 3AN-08-10115 CI

STATE OF ALASKA'S MOTION FOR JUDGMENT ON THE PLEADINGS

Pursuant to Alaska Rules of Civil Procedure 12(b)(6) and 77, defendants the State of Alaska; Sarah Palin, Governor of the State of Alaska; the Department of Health and Social Services; William Hogan, in his official capacity as Commissioner of the Department; Tammy Sandoval, in her official capacity as Director of the Office of Children's Services; Steve McComb, in his official capacity as Director of the Division

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of Juvenile Justice; Melissa Stone, in her official capacity as Director of the Division of Behavioral Health; Ron Adler, in his official capacity as Director of Alaska Psychiatric Institute; and William Streur, in his official capacity as Deputy Commissioner of the Department of Health and Social Services and Director of the Division of Health Care Services (hereinafter collectively "the Department"), hereby move for judgment on the pleadings in the above-captioned matter on the grounds that plaintiff has failed to present an actual case or controversy under the Declaratory Judgment Act and lacks standing to bring this action. This motion is supported by the attached Memorandum of Law.

DATED this 12th day of March, 2009.

RICHARD A. SVOBODNY
ACTING ATTORNEY GENERAL

By: _____
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: _____
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

ATTORNEY GENERAL, STATE OF ALASKA
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT AT ANCHORAGE

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

Plaintiff,

vs.

STATE OF ALASKA, SARAH PALIN, Governor of the State of Alaska, ALASKA DEPARTMENTOF 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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

Case No. 3AN-08-10115 CI

STATE OF ALASKA'S MEMORANDUM IN SUPPORT OF MOTION FOR JUDGMENT ON THE PLEADINGS

INTRODUCTION

Pursuant to Alaska Rules of Civil Procedure 12(b)(6) and 77, defendants the State of Alaska; Sarah Palin, Governor of the State of Alaska; the Department of Health and Social Services; William Hogan, in his official capacity as Commissioner of the Department; Tammy Sandoval, in her official capacity as Director of the Office of

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Children's Services; Steve McComb, in his official capacity as Director of the Division of Juvenile Justice; Melissa Stone, in her official capacity as Director of the Division of Behavioral Health; Ron Adler, in his official capacity as Director of Alaska Psychiatric Institute; and William Streur, in his official capacity as Deputy Commissioner of the Department of Health and Social Services and Director of the Division of Health Care Services (hereinafter collectively "the Department"), move for judgment on the pleadings in the above-captioned matter.

Plaintiff has filed an Amended Complaint for Declaratory and Injunctive Relief ("Complaint") on behalf of a nonprofit advocacy group, against a number of state defendants in their official capacities. The Complaint does not identify a single individual who has been harmed by the alleged violations in the Complaint, but makes abstract accusations and assertions regarding the administration of and payment for psychotropic medication for children in Alaska. A reading of the Complaint makes obvious that the true subject of plaintiff's grievances is not the Department, but prescribers of psychotropic pharmaceuticals, the pharmaceutical companies which produce and market them, and the overall culture of pediatric psychiatry. The implication that the Department possesses meaningful authority and control over these matters—or is in any realistic position to administer the relief requested even if the court were to order it—is a fiction.

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The Department therefore asks the court to decide one straightforward and dispositive legal question: has plaintiff demonstrated a case or controversy under Alaska's Declaratory Judgment Act and the requisite standing to bring this action? For the following reasons, the court should answer that question in the negative and dismiss the case.

FACTUAL AND PROCEDURAL BACKGROUND

I. The Department's Administration of and Payment for Psychotropic Medication to Minors in State Custody

To better frame the legal issue of standing as it relates to the plaintiff in this case, the Department provides the following factual and procedural background.

A. Administration of Psychotropic Medication to Minors in State Custody

Minors may come into state custody in one of three ways:

1. Under AS 47.10.080, the Office of Children's Services ("OCS") takes into Department custody children who have been adjudicated children in need of aid;

2. Under AS 47.12.120, the Division of Juvenile Justice ("DJJ") takes into Department custody children who have been adjudicated delinquent by a court; or

3. A minor may be ordered held at Alaska Psychiatric Institute ("API") pending evaluation and treatment pursuant to AS 47.30.

Under any of the above scenarios, any psychotropic medication prescribed to a child in Department custody is administered on an individual, case-by-case basis either through a court order or upon a release executed by the child's parent

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or guardian.[1] Employees of the Department do not have the authority to consent to the administration of psychotropic medications. The only exception to the above would be if emergency medication was warranted while the child was at API, and such situations are specifically governed by AS 47.30.

Plaintiff's Complaint also names Melissa Stone, Director of the Division of Behavioral Health ("DBH") as a defendant with respect to the administration and payment for psychotropic medication given to children in state custody. But children are not placed in the custody of DBH. Rather, children are placed in DBH-administered facilities and programs by their parents or guardians, or by DJJ or OCS after a court orders those respective agencies to take custody of a child. When a child is in a DBH-administered placement, the same analysis applies as to the prescribing and administration of psychotropic drugs. Such decisions are made on an individual, case-by-case basis either through a court order or upon a release executed by the child's parent or guardian.[2] In fact, as to children in OCS and DJJ custody, AS 47.10.084 and AS 47.12.150 govern the rights of parents and guardians as to their children, and specifically provide that parents have residual rights that include the

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1 *See* AS 47.10.084; AS 47.12.150; AS 47.30.

2 *Id.*

power to make decisions regarding "major medical treatment," which in turn explicitly includes the administration of medication used to treat a mental health disorder.[3]

In short, the administration of psychotropic medication to children in Alaska is a decision left to the parent or legal guardian of the child, or to the superior court. None of the named defendants is permitted to prescribe, authorize, or administer psychotropic medication to any child in the state absent consent from that child's parent, legal guardian, a superior court judge, or, in some circumstances, the child himself or herself. The named defendants simply do not administer psychotropic medication to children in custody in the manner portrayed by plaintiff's Complaint. Rather, there exist well-established statutory schemes—none of which is referenced in the Complaint—to seek individual approval to make such decisions.

B. Medicaid Payment for Psychotropic Medication to Minors in State Custody

Medicaid is a joint federal and state program run by the individual states that provides medical services, including prescription drugs, to certain eligible individuals. The program is elective. If a state opts to participate—as Alaska has—the state must operate the program in compliance with federal law in order to receive federal financial contributions.[4]

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[3] Under AS 25.20.025, children themselves also may consent to medical treatment under certain circumstances.

[4] *See* AS 47.07.

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With respect to Medicaid-covered pharmaceuticals of any kind prescribed to Medicaid recipients, including children in Department custody, the drug use review process stated in 7 AAC 43.593 works like authorizations under any other type of third-party insurance program. The recipient or the recipient's parent or legal guardian sees the provider, the provider determines what (if any) medication the recipient needs, the recipient takes the prescription to a pharmacy, and the pharmacy records relevant insurance and demographic information from the recipient, inputs the prescription into the computer, retrieves relevant drug information, and transmits this information to a claims processor. At this point, the prescription undergoes a clinical and eligibility review to confirm the recipient's Medicaid eligibility and determine such facts as whether the recipient has previously received the drug, the correct dosage for the recipient, the recipient's medical history, and drug interactions to determine coverage by Medicaid.[5] Again, the Department does not consent to the administration of psychotropic medications unless prescribed by a licensed provider, and there is appropriate authorization in place from a parent, a legal guardian, or a court order.

II. Plaintiff's Complaint

On September 29, 2008, plaintiff, the Law Project for Psychiatric Rights ("Psych Rights), filed the 54-page Complaint that is the subject of the instant motion. Plaintiff avers that it is an "Alaska non-profit corporation" and a "public interest law

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[5] *See* 7 AAC 43.593.

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firm whose mission is to mount a strategic litigation campaign against forced psychiatric drugging and electroshock."[6] Plaintiff's website supplies further information regarding the origins of this action, stating: "due to massive growth in psychiatric drugging of children and youth and the current targeting of them for even more psychiatric drugging, PsychRights has made attacking this problem a priority. Children are virtually always forced to take these drugs because it is the adults in their lives who are making the decision. This is an unfolding national tragedy of immense proportions."[7]

The Complaint seeks a declaratory judgment that "Alaskan children and youth" not be administered psychotropic drugs "unless and until" the Department has engaged in a series of general actions and analyses, specifically "(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."[8]

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[6] Complaint at ¶ 4. For purposes of this motion, the Department accepts that plaintiff is a nonprofit corporation registered with the State of Alaska.

[7] See http://psychrights.org/index.htm (last visited March 10, 2009).

[8] Complaint at p. 3.

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The Complaint further seeks a permanent injunction prohibiting "the defendants and their successors from authorizing or paying for the administration of psychotropic drugs to Alaskan children and youth without conformance" to the foregoing prerequisites.[9] Finally, the Complaint seeks an order requiring an "independent reassessment of each Alaskan child or youth to whom defendants have authorized the administration or payment of psychotropic drugs," in conformance with plaintiff's demands, and "for each child for whom it is found the administration of or payment for psychotropic drugs is taking place" out of conformity with said demands, order "that immediate remedial action be commenced to prudently eliminate or reduce such administration of or payment for psychotropic drugs and diligently pursued to completion."[10]

Plaintiff's lengthy Complaint goes on to make certain assertions regarding the constitutionality of psychotropic medication use, aver when such use is appropriately paid for by Medicaid, describe plaintiff's efforts to engage the legislature and the contents of a particular online curriculum critical of psychotropic medication, detail the FDA approval process for certain categories of pharmaceuticals, criticize marketing and prescribing practices for such drugs, and describe plaintiff's suggested interventions to address these issues.[11] Notwithstanding all of the above, the only

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[9] *Id.*

[10] *Id.* at pp. 3-4.

[11] *Id.* at pp. 5-54.

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specific allegations directed at the Department are contained at pages 50-52 of the Complaint, in which plaintiff claims that the Department inappropriately administered and paid for psychotropic drugs.[12] Notably, and as further discussed below, neither the Complaint nor plaintiff's website specifies whose interest plaintiff claims to represent, and on what basis.

STANDARD OF REVIEW

Alaska Rule of Civil Procedure 12(c) provides that "after the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." A Rule 12(c) motion provides the court with a "means of disposing of cases when the material facts are not in dispute and a judgment on the merits can be achieved by focusing on the content of the pleadings and any facts of which the court will take judicial notice."[13] Rule 12(c) motions are a useful means for resolving dispositive questions of law.[14] As with a motion brought under Civil Rule 12(b)(6), the court can dismiss a complaint pursuant to a Rule 12(c) motion.[15]

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12 Complaint at ¶¶ 218-228.

13 *Hebert v. Honest Bingo*, 18 P.3d 43, 46 (Alaska 2001).

14 *Id.*

15 *See, e.g., Fomby v. Whisenhunt*, 680 P.2d 787, 789 (Alaska 1984).

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ARGUMENT

I. Plaintiff Lacks the Required Case or Controversy to Bring this Action under the Declaratory Judgment Act

AS 22.10.020(g) confers upon the superior court the following jurisdiction over actions for declaratory and injunctive relief:

> In case of an *actual controversy* in the state, the superior court, upon the filing of an appropriate pleading, may declare the rights and legal relations of an interested party seeking the declaration, whether or not further relief is or could be sought. The declaration has the force and effect of a final judgment or decree and is reviewable as such. Further necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against an adverse party whose rights have been determined by the judgment.[16]

The statute explicitly requires the presence of an "actual controversy" before the court may issue declaratory relief. The Alaska Supreme Court has held that this actual controversy requirement encompasses a number of grounds upon which the court may decline to exercise jurisdiction under the Declaratory Judgment Act, including mootness, standing, and lack of ripeness.[17] As discussed below, this matter does not meet the actual controversy requirement of the Declaratory Judgment Act because the plaintiff lacks standing to sue. Therefore, the court should dismiss the Complaint.

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[16] AS 22.10.020(g) (emphasis added).

[17] *Brause v. State of Alaska et al.*, 21 P.3d 357, 358 (Alaska 2001).

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

II. Plaintiff Lacks Standing to Bring this Lawsuit

Plaintiff's Complaint asserts this court's jurisdiction under AS 22.10.020.[18] However, the court may decline to exercise its jurisdiction under that statute where a party lacks standing to sue.[19] Alaska jurisprudence interprets broadly the concept of standing to promote liberal access to the courts.[20] Indeed, a complaint seeking declaratory relief requires only "a simple statement of facts demonstrating that the superior court has jurisdiction and that an actual justiciable case or controversy is presented."[21] But standing in Alaska courts is not limitless. To the contrary, standing constitutes "a rule of judicial self-restraint based on the principle that courts should not resolve abstract questions or issue advisory opinions."[22] As noted above, the "case or controversy" requirement of the Declaratory Judgment Act includes lack of standing as

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[18] Complaint at ¶ 2. The Department admitted in its Answer that the superior court has jurisdiction under AS 22.10.020. Answer at ¶2. However, the Department also specifically raised the affirmative defense of lack of standing as a reason for the court to decline to exercise that jurisdiction. Answer at p. 22, ¶10.

[19] *Lowell v. Hayes*, 117 P.3d 745, 757 (Alaska 2005).

[20] *North Kenai Peninsula Road Maintenance Service Area v. Kenai Peninsula Borough,* 850 P.2d 636 (Alaska 1993) (citing *Moore v. State*, 553 P.2d 8, 23 (Alaska 1976); *Trustees for Alaska v. State*, 736 P.2d 324, 330 (Alaska 1987)).

[21] *Ruckle v. Anchorage School District*, 85 P.3d 1030, 1034 (Alaska 2004) (citing *Jefferson v. Asplund*, 458 P.2d 995, 999 (Alaska 1969).

[22] *Id.*

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
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a ground upon which the court can decline to exercise its jurisdiction,[23] and the Department urges the court to do so here.

The basic requirement for standing in Alaska is adversity.[24] Questions of standing are limited to whether the litigant is a "proper party to request an adjudication of a particular issue and not whether the issue itself is justiciable."[25] To this end, Alaska courts recognize two forms of standing: "interest-injury" standing and "citizen-taxpayer" standing.[26] To have interest-injury standing, the plaintiff "must have an interest adversely affected by the conduct complained of."[27] To have citizen-taxpayer standing, the plaintiff must meet certain criteria which, while liberally construed, are by no means an entitlement.[28] As discussed *infra*, plaintiff fails to show "an interest adversely affected" by the state's alleged conduct. In addition, the criteria required for citizen-taxpayer standing are well-articulated, and plaintiff fails to meet them. Even under Alaska's liberal requirements, plaintiff satisfies neither type of standing. Therefore, the Department is entitled to judgment on the pleadings.

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[23] *Id.* (citing *Bowers Office Prods., Inc. v. Univ. of Alaska*, 755 P.2d 1095, 1096 (Alaska 1988)).

[24] 850 P.2d 636 at 639-640, citing *Trustees for Alaska v. State,* 736 P.2d 324, 327 (Alaska 1987).

[25] *Gilbert v. State*, 139 P.3d 581, 587 (Alaska 2006) (citing *Moore v. State*, 553 P.2d 8 (Alaska 1976) (internal quotations omitted).

[26] 850 P.2d 636. "Citizen-taxpayer" standing is also intermittently referred to as "taxpayer-citizen" standing throughout the case law.

[27] *Id.* at n. 5.

[28] *Trustees for Alaska v. State*, 736 P.2d 324, 329 (Alaska 1987).

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A. Plaintiff Lacks Interest-Injury Standing

To establish interest-injury standing, a plaintiff must have "an interest adversely affected by the conduct complained of."[29] To ensure this requisite adversity, the plaintiff must have "a sufficient personal stake in the outcome of the controversy."[30] Although the extent of the alleged injury "need not be great," our supreme court discourages third-person representation and has "never held that standing can be created by wagering on whether *someone else's* injury will ultimately be vindicated."[31] Only in "rare cases" will the interest-injury test be read to allow standing "to protect the rights of third parties by acting in a representative capacity."[32]

In *Gilbert M. v. State*,[33] the court aired fully for the first time the circumstances under which a party may raise the rights of a third person.[34] In that case, a dependent child's grandfather lacked standing to appeal the termination of the mother's (his daughter's) parental rights to her own minor daughter. The court observed that generally, a third person may not assert another's constitutional rights.[35] The court further observed that a "special relationship between the plaintiff and the

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29 *Id.*

30 *Broeckel v. State, Dept. of Corrections*, 941 P.2d 893 (Alaska 1997) (internal quotations omitted).

31 *Foster v. State,* 752 P.2d 459, 466 (Alaska 1988) (emphasis in original).

32 *Id.*

33 139 P.3d 581 (Alaska 2006).

34 *Id.* at 587.

35 *Id.*; Complaint at ¶¶ 14-18.

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third party" must exist before standing can be established.[36] In *Gilbert M.*, the court found no such legal relationship and the plaintiff was denied standing.[37]

Here, plaintiff does not assert interest-injury standing or claim an adverse interest, nor does plaintiff claim any sort of relationship at all to any relevant individual. Plaintiff states only that it is "an Alaskan non-profit corporation" and "a public interest law firm whose mission is to mount a strategic litigation campaign against forced psychiatric drugging and electroshock."[38] This statement is *prima facie* insufficient to establish adversity. The Department cannot infer from this or anything else in the Complaint whose actual interest plaintiff purports to represent, and therefore how such an interest might be adversely affected. This deficiency is not ministerial: it makes resolution of the case—through settlement or otherwise—virtually impossible. The Department is forced to fumble about and engage in shadow boxing with a faceless litigant, and the court's task of adjudicating the parties' respective interests is frustrated.

To the extent plaintiff purports to represent the general public interest of children in state custody or other state interests, representation of those interests rests

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[36] 139 P.3d 581 at 587.

[37] *Id.* See also *Zoerb v. Chugach Elec. Ass'n, Inc.*, 798 P.2d 1258, 1261 (Alaska 1990) (plaintiff, an *employee* of an electric company, lacked standing to sue with respect to interests afforded *members* of the organization, based on plaintiff's lack of a legally protectable interest) (emphasis in original).

[38] Complaint at ¶ 4.

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with the Attorney General for the State of Alaska, the Department, and/or the parents and guardians of individual children in state custody or the children themselves—not plaintiff's law firm.[39] To the extent plaintiff purports to represent a certain class of individuals, no class action has been brought, much less certified. To the extent plaintiff purports to represent a particular individual or individuals who have allegedly been harmed by state action, no such individual has been named, and no specific harm has been alleged.

In sum, plaintiff has not asserted standing under the interest-injury doctrine, nor can the Complaint be read to infer it. Therefore, plaintiff lacks interest-injury standing.

B. Plaintiff Lacks Citizen-Taxpayer Standing

The Alaska Supreme Court has clearly articulated the requirements of citizen-taxpayer standing:

> [A] taxpayer or citizen need only show that the case in question is one of public significance and the plaintiff is appropriate in several respects. This appropriateness has three main facets: the plaintiff must not be a sham plaintiff with *no true adversity of interest*; he

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[39] *See generally* AS 44.23.020; AS 47.10.084 (the Department's legal custody of a child "imposes on the department and its authorized agents or the parents, guardian, or other suitable person the responsibility of physical care and control of the child, the determination of where and with whom the child shall live, the right and duty to protect, nurture, train and discipline the child, the duty of providing the child with food, shelter, education, and medical care, and the right and responsibility to make decisions of financial significance concerning the child. These obligations are subject to any residual parental rights and responsibilities and rights and responsibilities of a guardian if one has been appointed.").

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> or she must be capable of competently advocating his or her position; *and he or she may still be denied standing if there is a plaintiff more directly affected by the challenged conduct in question who has or is likely to bring suit.*[40]

Plaintiff does not claim citizen-taxpayer standing to bring this case, nor is plaintiff entitled to an inference of such standing as a matter of right.[41] Regardless, the Department does not dispute that plaintiff's nonprofit corporation/law firm is a legitimate advocacy organization or that the Complaint raises—at least in theory if not in fact—issues of public significance. The Department does dispute, however, that plaintiff is an appropriate party to bring this case. While the criteria for citizen-taxpayer standing in Alaska are liberal by any measure, plaintiff has shown no true adversity of interest, and there clearly exist parties more affected by the challenged conduct. Therefore, plaintiff is an inappropriate party.

The leading case in Alaska on citizen-taxpayer standing is *Trustees for Alaska v. State*.[42] In that case, a coalition of environmental, Native, and fishing groups brought a declaratory judgment action to enjoin the state from enforcing its mineral leasing system.[43] The court permitted the plaintiffs to maintain their case under the citizen-taxpayer analysis, finding in relevant part that plaintiffs were appropriate

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[40] *Ruckle v. Anchorage School District*, 85 P.3d 1030, 1034 (Alaska 2004) (emphasis added).

[41] *Trustees for Alaska v. State*, 736 P.2d 324, 329 (Alaska 1987).

[42] 736 P.2d 324 (Alaska 1987).

[43] *Id.*

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because of their status as consumers of Alaska's natural resources, their adverse interest with respect to affected mining claims, and the fact that the U.S. Attorney General—the party whom the state alleged was a more appropriate plaintiff—was not likely to sue and had an entirely different interest than existing plaintiffs in any event.[44]

Trustees for Alaska is easily distinguishable from the instant case. As discussed above, plaintiff has not demonstrated an adverse interest. Unlike the consumers of the natural resource at issue in *Trustees for Alaska*, plaintiff here does not allege to be—nor does plaintiff claim to represent or in any way be connected with—a minor Medicaid recipient or child in state custody who has been prescribed or is taking psychotropic medication. Thus, plaintiff can show no interest adverse to the conduct alleged. The above-described persons or their designees would likely be the appropriate plaintiffs in a case regarding the administration of psychotropic medication to children in state custody.[45] Their interest in the outcome of such a case would be identical to the stated interest of the existing corporate plaintiff and there is no reason

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[44] *Id.* at 330.

[45] Arguably, legislation, as opposed to litigation, is the most appropriate way to deal with such issues.

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to presume that such persons, aggrieved by some specific action, would not sue to redress it. [46]

Here, plaintiff broadly alleges that Alaska's "children and youth" (not defined in the Complaint) have the right not to be administered psychotropic drugs unless the Department complies with various requirements that plaintiff believes the Department should adopt.[47] As stated above, the only specific allegations directed at the Department are found at pages 50-52 of the Complaint, where plaintiff claims that the Department inappropriately administered and paid for psychotropic drugs to Alaska's children and youth.[48] The basis for this claim, explained only in these 11 paragraphs of the Complaint, can be simply summarized as follows: the Department's administration of and payment for these drugs exceeds evidence of safety and efficacy and is not based on competent, knowledgeable decision-making and informed consent.[49] Plaintiff makes no reference to any specific statutory violation in these paragraphs. The only reference to any potential statutory violation is found at

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[46] Citizen-taxpayer standing has been denied for less. *See, e.g., Kleven v. Yukon-Koyukuk School Dist.*, 853 P.2d 518, 526 (Alaska 1993) (former school district employee was denied citizen-taxpayer standing to air grievances against the school district on the grounds that the district's current employees were more suitable advocates better poised to raise the same grievances and there was no reason for the court to believe such individuals would not do so).

[47] Complaint at ¶ 1.

[48] *Id.* at ¶¶ 218-228.

[49] *Id.*

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paragraphs 19-21 of the Complaint, where plaintiff simply recites the Department's statutory duty to care for children in state custody.

Accordingly, there is no provision in plaintiff's Complaint—and none can be inferred—demonstrating plaintiff's required adversity of interest for purposes of establishing citizen-taxpayer standing. Plaintiff is not a child in need of aid, does not allege guardianship of such a child, and has not purported to represent a child or class of children subject to the Department's duty of care. Instead, plaintiff is engaged in a campaign to change the manner and procedure under which the Department operates without any alleged harm inflicted by the Department on plaintiff or anyone plaintiff represents. This campaign is appropriately directed to the legislature.[50]

Courts should evaluate the propriety of individual plaintiffs with respect to citizen-taxpayer standing on a case-by-case basis.[51] Such standing has been found where "no one seemed to be in a better position than the plaintiffs to complain of the illegality" of the conduct in question.[52] A policy agenda and a sweeping critique of alleged state actions perpetrated on no one in particular do not constitute the "true adversity of interest" required to maintain citizen-taxpayer standing. Surely there are

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[50] The Complaint contains several pages on plaintiff's efforts to alert the legislature to its concerns.

[51] *Ruckle v. Anchorage School District*, 85 P.3d 1030, 1037 (Alaska 2004).

[52] 736 P.2d at 328 (citing *State v. Lewis*, 559 P.2d 630 (Alaska 1977).

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more appropriate plaintiffs to raise such issues and, because of their true adversity, would presumably be able to do so in a more concrete manner.

CONCLUSION

Plaintiff's Complaint is brought on behalf of no specific individual and names Department employees who have no meaningful ability to remedy the conduct alleged or administer the relief requested. Statutory mechanisms are already in place to ensure that psychotropic medications are administered to children in Alaska in a methodical, individualized, and constitutional manner. Insofar as plaintiff takes issue with the adequacy of these existing legal mechanisms, such a grievance is more appropriately directed to the legislature, not the executive branch or the judiciary. Insofar as plaintiff disagrees with the practice of pediatric psychiatry and the culture of pharmaceutical marketing and prescribing practices related to psychotropic medication, those matters are not within the Department's meaningful control.

Plaintiff asserts no injury by the conduct complained of and therefore fails the threshold requirement for interest-injury standing. Likewise, plaintiff is a wholly inappropriate party under the citizen-taxpayer standing analysis. The court should decline to exercise jurisdiction over an abstract complaint where even minimum requirements for standing are not met.

For the foregoing reasons, plaintiff has failed to present a justiciable case or controversy and demonstrate the threshold showing of standing required to bring

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and maintain this action. The Department is entitled to judgment on the pleadings as a matter of law and the Complaint should be dismissed accordingly.

DATED this 12th day of March, 2009.

RICHARD A. SVOBODNY
ACTING ATTORNEY GENERAL

By: _____
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: _____
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

ATTORNEY GENERAL, STATE OF ALASKA
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation,
Plaintiff,
vs.
STATE OF ALASKA, *et al.*,
Defendants,
Case No. 3AN 08-10115CI

OPPOSITION TO MOTION FOR EXPEDITED CONSIDERATION

Plaintiff, the Law Project for Psychiatric Rights (PsychRights®), opposes expedited consideration of the Motion to Stay Discovery, especially on the schedule proposed by the defendants, State of Alaska, *et al* (State). The Motion for Expedited Consideration (Motion) is misleading about the necessity of a decision by March 19, 2009,[1] and about PsychRights' position on the stay, as shown by the e-mail exchanges attached hereto as Exhibits 1 and 2.

The following e-mail exchange occurred on February 24, 2009 between Ms. Bakalar, counsel for the State, and Mr. Gottstein of PsychRights:

> Jim,
>
> In preparing for Dave Campana's upcoming deposition, Stacie and I have taken a more extensive look at the complaint and we have concerns about engaging in discovery at this point. As a result of our review we are preparing a dispositive motion that we hope to file in the next two weeks. Therefore we would request that you agree to postpone Dave's deposition until after the court has ruled on our motion. If you are unable to agree to

[1] Also, instead of faxing or e-mailing a copy of the Motion, it put the Motion in the mail to PsychRights on Thursday, March 12, 2009, which was not received until the afternoon of Monday, March 16, 2009. This shortened the effective amount of time available by 4 days.

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

that postponement, we'll file an expedited motion to quash the deposition on similar grounds. We apologize for the late notice but we need to know by COB today if you can agree to this plan.

Libby[2]

PsychRights replied:

Hi Libby,

I will agree to postpone it for two weeks or maybe a bit more, but I don't think I can agree to anything that open-ended.[3]

The State responded:

Good enough Jim, we understand that concern. Thanks for your understanding and courtesy on this point and we will be in touch. Procedurally, will you be issuing a notice that cancels Thursday's deposition?[4]

PsychRights responded:

Hi Libby,

I will serve you with a re-notice of deposition for say three weeks out, which when we get closer we will presumably have another discussion about.[5]

The State responded to this as follows:

That's fine, with the understanding that we're not agreeing to a date certain at this point and re-notice will be subject to further discussions and/or motion practice as we get closer to the time. So I believe we're on the same page with how to proceed.[6]

---

[2] Exhibit 1.
[3] Exhibit 1.
[4] Exhibit 1.
[5] Exhibit 1.
[6] Exhibit 1.

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
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On Sunday, March 15, 2009, not having heard anything from the State, including not having been served with or given any notice of the State's Motion for Expedited Consideration, PsychRights e-mailed the State as follows:

> Hi Libby and Stacie
>
> I figure we should reset Mr. Campana's deposition for at least a few days after the response to our First Requests for Production are due. Do you agree? Without waiving whatever right you have to object to the deposition, do you have a preferred date and time?[7]

The next day, Monday, March 16, 2009, as PsychRights had indicated to the State it was willing to do, it has further extended the date for the deposition until April 9, 2009.[8]

Thus, the necessity of deciding the Motion to Stay Discovery by March 19, 2009 has been obviated.[9] However, it probably should be decided by April 9, 2009.

DATED: March 17, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
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Anchorage, Alaska 99501
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[7] Exhibit 2.
[8] Exhibit 3.
[9] With an "n" of two, the State seems to have established a pattern of waiting until the last minute in order to manufacture an exigency. As set forth above, the State waited until only two days before the February 26, 2009 date that had been set for Mr. Campana's deposition (to which the state had agreed) to ask for a delay and now waited so long that it is trying to force PsychRights to respond to an extremely significant motion in less than three days.

Subject: RE: Discovery in Psych Rights
From: "Bakalar, Elizabeth M (LAW)" <libby.bakalar@alaska.gov>
Date: Tue, 24 Feb 2009 16:51:10 -0900
To: Jim Gottstein <jim.gottstein@psychrights.org>
CC: "Kraly, Stacie L (LAW)" <stacie.kraly@alaska.gov>

That's fine, with the understanding that we're not agreeing to a date certain at this point and re-notice will be subject to further discussions and/or motion practice as we get closer to the time. So I believe we're on the same page with how to proceed.

Libby Bakalar
Assistant Attorney General
Office of the Attorney General
P.O. Box 110300
Juneau, Alaska 99801-0300
(907) 465-4135 (direct)
(907) 465-3600 (main)
(907) 465-2539 (fax)

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, February 24, 2009 4:17 PM
To: Bakalar, Elizabeth M (LAW)
Cc: Kraly, Stacie L (LAW); Lisa Smith
Subject: Re: Discovery in Psych Rights

Hi Libby,

I will serve you with a re-notice of deposition for say three weeks out, which when we get closer we will presumably have another discussion about.

Bakalar, Elizabeth M (LAW) wrote:
Good enough Jim, we understand that concern. Thanks for your understanding and courtesy on this point and we will be in touch. Procedurally, will you be issuing a notice that cancels Thursday's deposition?

Libby Bakalar
Assistant Attorney General
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P.O. Box 110300
Juneau, Alaska 99801-0300
(907) 465-4135 (direct)
(907) 465-3600 (main)
(907) 465-2539 (fax)

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, February 24, 2009 3:51 PM
To: Bakalar, Elizabeth M (LAW)
Cc: Kraly, Stacie L (LAW); Lisa Smith
Subject: Re: Discovery in Psych Rights

Hi Libby,

I will agree to postpone it for two weeks or maybe a bit more, but I don't think I can agree to anything that open-ended.

Bakalar, Elizabeth M (LAW) wrote:
Jim,

In preparing for Dave Campana's upcoming deposition, Stacie and I have taken a more extensive look at the complaint and we have concerns about engaging in discovery at this point. As a result of our review we are preparing a dispositive motion that we hope to file in the next two weeks. Therefore we would request that you agree to postpone Dave's deposition until after the court has ruled on our motion. If you are unable to agree to that postponement, we'll file an expedited motion to quash the deposition on similar grounds. We apologize for the late notice but we need to know by COB today if you can agree to this plan.

Libby

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--

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President/CEO

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jim.gottstein[[at]]psychrights.org
http://psychrights.org/

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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.

--

James B. (Jim) Gottstein, Esq.

Subject: David Campana Deposition
From: Jim Gottstein <jim.gottstein@psychrights.org>
Date: Sun, 15 Mar 2009 15:09:30 -0800
To: "Bakalar, Elizabeth M (LAW)" <libby.bakalar@alaska.gov>, Stacie Kraly <stacie.kraly@alaska.gov>
CC: v.colca@psychrights.org, Lisa Smith <Lisa@psychrights.org>

Hi Libby and Stacie

I figure we should reset Mr. Campana's deposition for at least a few days after the response to our First Requests for Production are due. Do you agree? Without waiving whatever right you have to object to the deposition, do you have a preferred date and time?
--

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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.

Exhibit 2

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
AT ANCHORGE

Law Project for Psychiatric Rights, Inc., Plaintiff(s) vs. State of Alaska, et al., Defendant(s)	)	**RE-NOTICE OF TAKING DEPOSITION DAVID CAMPANA**

Case No. 3AN 08-10115 CI

TO:

Elizabeth M. Bakalar/Stacie L. Kraly
Attorney General's Office
P.O. Box 110300
Juneau, AK 99811-0300

PLEASE TAKE NOTICE that on behalf of Law Project for Psychiatric Rights, Plaintiff, the deposition of David Campana has been changed to 1:00 PM on the 9th day of April, 2009, at the offices of the Law Project for Psychiatric Rights, 406 G Street, Suite 206, Anchorage, Alaska 99501, before a court reporter. The designation of materials to be produced is attached and you are invited to attend.

DATED: March 16, 2009.

Law Project for Psychiatric Rights Inc.

By: _____
James B. Gottstein, Esq.
ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
406 G Street, Suite 206
Anchorage, Alaska 99501
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Attachment to David Campana Subpoena Duces Tecum

All documentation of computerized records relating to payment (or reimbursement) by Medicaid for psychotropic drugs prescribed to children and youth who have or had claims for payment (or reimbursement) for psychotropic drugs from January 1, 1999, to date, including but not limited to:

(1) Manuals,
(2) File format,
(3) File structure,
(4) The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
(5) Examples of all report types.

I certify that on 3-18-09 Faxed a copy of the above was mailed to each of the following at their addresses of record. Bakalar, Gottstein
R. Meade [illegible]
Secretary/Deputy Clerk

MAR 16 2009

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

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

LAW PROJECT FOR PSYCHIATRIC RIGHS, 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 STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

REC'D MAR 19 2009

Case No. 3AN-08-10115 CI

ORDER GRANTING STATE OF ALASKA'S MOTION FOR EXPEDITED CONSIDERATION

Having reviewed the State of Alaska's Motion for Expedited Consideration of its underlying Motion to Stay Discovery, ~~and any responses thereto,~~

IT IS SO ORDERED: as a matter of judicial economy and in the interests of justice

Expedited consideration of said motion is GRANTED.*

DATED this 18th day of March, 2009.

Jack Smith

Superior Court Judge
Jack W. Smith

* Plaintiff should file any opposition to the motion to stay in [illegible] defendant to reply in normal time. Pending resolution of that motion, all discovery is stayed. Opposition to the Motion for Judgment on the Pleadings should be filed in normal time.

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

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation, Plaintiff, vs. STATE OF ALASKA, *et al.*, Defendants.	)

Case No. 3AN 08-10115CI

OPPOSITION TO MOTION TO STAY DISCOVERY

Plaintiff, the Law Project for Psychiatric Rights (PsychRights®), opposes the Motion to Stay Discovery (Motion for Stay) filed by defendants State of Alaska, *et al.*, (State). The Motion for Stay seeks a stay of all discovery pending determination of the State's contemporaneously filed Motion for Judgment on the Pleadings.

The State's Motion for Stay is fundamentally flawed in two respects. First, the burden and expense of the subject discovery does not outweigh its immense benefit to Alaskan children and youth. The evidence is overwhelming that current pediatric prescribing practices are improvident, largely ineffective, extremely harmful, and non-pharmacological approaches are far better. The evidence sought to be obtained regards the actual practice of pediatric psychopharmacology to Alaskan children and youth in State custody and through Medicaid, and the extent of the harm being done. The planned discovery is anticipated to produce evidence entitling PsychRights to one or more preliminary injunctions and at least partial summary judgment as to declaratory relief. The harm being done to Alaskan children and youth should not be extended because of a stay of discovery. Contrary to the State's abdication of responsibility in its Motion for

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Judgment on the Pleadings, it has the affirmative duty to protect the safety of children and youth in its custody. The fulfillment of this duty should not be further delayed.

Second, contrary to the State's assertion, the pending Motion for Judgment on the Pleadings is not likely to dispose of the entire case. The sole legal basis asserted is lack of standing, which is in itself unmeritorious and in any event, can be addressed by naming additional plaintiffs. In addition, the Motion for Judgment on the Pleadings complains about a lack of specificity in the Amended Complaint and goes outside the pleadings. Under such circumstances discovery must be allowed to proceed.

I. The Standards for Staying Discovery

In support of its Motion for Stay the State argues that a stay of discovery is within the discretion of the Court and appropriate pending determination of a dispositive motion, citing to the Alaska case of *Karen L. v. State Dept. of Health and Social Services, Div. of Family and Youth Services*,[1] and some federal cases.

However, *Karen L.* is completely inapplicable because it involves the situation where government officials were sued personally and not, as here, in their official capacity. In *Karen L.*, the question was whether discovery could be stayed pending a determination of official immunity. PsychRights found no other Alaska cases concerning when or under what circumstances a stay of discovery might be warranted and the State cited none in their motion. However, the federal cases cited by the State do not support its position that discovery should be stayed here.

[1] 953 P.2d 871, 879 (Alaska 1998).

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In *Chavous v. District of Columbia Financial Responsibility and Management Assistance*,[2] the district court held:

> A trial court "ordinarily should not stay discovery which is necessary to gather facts in order to defend against [a] motion [to dismiss]." ("discovery should precede consideration of dispositive motions when the facts sought to be discovered are relevant to consideration of the particular motion at hand.").[3]

In *Williamson v. U.S. Dept. of Agriculture*,[4] also cited by the State, the Fifth Circuit held "if discovery could uncover one or more substantial fact issues, appellant was entitled to reasonable discovery to do so," and that in such circumstances a stay of discovery would be an abuse of discretion.

The cases cited by the State have reviewed and considered the specific discovery requests and determined there was no prejudice in staying discovery.[5] Here, the State seeks a blanket stay of discovery without showing any of the discovery is in any way unwarranted, or even burdensome, let alone that it would not lead to evidence that might be relevant to the Motion for Judgment on the Pleadings.[6] As will be shown below, the

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[2] 201 F.R.D. 1, 3 (D.D.C., 2001).
[3] Citation omitted.
[4] 815 F.2d 368, 373 (C.A.5 1987).
[5] *Karen L. v. State Dept. of Health and Social Services, Div. of Family and Youth Services*, 953 P.2d 871, 879 (Alaska 1998); *Schism v. U.S.*, 316 F.3d 1259, 1300 (C.A.Fed.2002); *Brazos Valley Coalition for Life, Inc. v. City of Bryan*, 421 F.3d 314, 327 (C.A.5 2005); *James Madison Ltd. by Hecht v. Ludwig*, 82 F.3d 1085, 1096 (C.A.D.C. 1996); *Chavous v. District of Columbia Financial Responsibility*, 201 F.R.D. 1 (D.D.C. 2001).
[6] Since the dispositive motion is one for judgment on the pleadings pursuant to Civil Rule 12(c), the presumption is that discovery would not be relevant. However, the State's Motion for Judgment on the Pleadings goes outside the pleadings. In addition, the Motion for Judgment on Pleadings complains about a lack of specificity in the Amended Complaint and the discovery PsychRights will be seeking can supply such specificity.

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discovery requested to date is extremely modest and PsychRights has fashioned a focused discovery plan proceeding in a logical order. Delaying discovery will lengthen the time that Alaskan children and youth will not have the opportunity to have a motion for preliminary injunction filed on their behalf and a delay of much time could be very counterproductive by necessitating broader, less focused and less ordered discovery requests in order to get it done before the trial date.

Ultimately, as the district court in *Chavous* noted:

> In the determination of whether to stay discovery while pending dispositive motions are decided, the trial court "inevitably must balance the harm produced by a delay in discovery against the possibility that [a dispositive] motion will be granted and entirely eliminate the need for such discovery."[7]

This seems right and to the extent the Motion for Judgment on the Pleadings is decided soon, the prejudice will be lessened. But what if the State files a series of motions it characterizes as "dispositive?"

The Motion for Judgment on the Pleadings, while it includes inaccurate and extraneous statements of counsel regarding factual matters, is legally grounded entirely on the extremely dubious contention that PsychRights lacks standing under Alaska's liberal standing requirements. This seems clearly rejected under *Trustees for Alaska v. State of Alaska*[8] and its progeny.

However, PsychRights can not safely ignore the unsupported assertions of counsel contained in the Motion for Judgment on the pleadings, and thus under the authority cited

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[7] *Id.*
[8] 736 P.2d 324 (Alaska 1987).

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by the State, as set forth above, it is necessary to discuss the merits and the evidence PsychRights seeks in discovery.

II. The Merits

In this action, PsychRights seeks declaratory and injunctive relief that Alaskan children and youth have the right to prevent defendants from authorizing the administration of or paying for the administration of psychotropic drugs to them 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.[9]

The State's defense is revealed in its Motion for Judgment on the Pleadings, and consists of the complete abdication of responsibility:

> [The defendants] have no meaningful ability to remedy the conduct alleged or administer the relief requested".[10]

Without getting far into the legal analysis here, the State's position is untenable. At a minimum, once the State has taken custody of a child or youth, the United States Supreme Court has held if the State,

[9] *See*, ¶1 of Amended Complaint and §A of PsychRights' Prayer for Relief.
[10] Motion for Judgment on the Pleadings, page 20.

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> fails to provide for his basic human needs-e.g., food, clothing, shelter, medical care, and reasonable safety-it transgresses the substantive limits on state action set by the Eighth Amendment and the Due Process Clause.[11]

Thus, the State may not divest itself of at least these Constitutional responsibilities by what is uniformly a process whereby parents (and the courts) are provided false information about the psychotropic drugs and parents regularly coerced into giving consent.

In its Motion for Judgment on the Pleadings the State goes on to state:

> Insofar as plaintiff disagrees with the practice of pediatric psychiatry and the culture of pharmaceutical marketing and prescribing practices related to psychotropic medication, those matters are not within the Department's meaningful control.[12]

Here, the State admits court intervention is required to protect the children and youth of whom it has taken custody. If the State is incapable of protecting the children and youth in its custody from harmful psychiatric drugging, this Court must step in and do so. It is their right. Of course, this depends on PsychRights proving the current "culture of pharmaceutical marketing" and pediatric psychopharmacology is indeed harming the children and youth of whom the state has seized custody. PsychRights is refraining from loading up this opposition to the State's Motion to Stay Discovery with the piles of evidence on this, but has no doubt it will establish this. In fact, the State does not truly dispute this[13] and PsychRights is not seeking discovery from the State on this issue.

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[11] *DeShaney v. Winnebago County Department of Social Services*, 489 U.S. 189, 200, 109 S.Ct. 998, 1005 (1989).

[12] Motion for Judgment on the Pleadings, page 20.

[13] In its Answer, the state responds that it "is without sufficient information to admit or deny the substance" of PsychRights' allegations regarding the lack of scientific support for the bulk of pediatric psychopharmacology, the great harm it causes, and the far better results achieved if non pharmacological approaches. It is the State's responsibility to

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However, there are issues raised in the State's Motion for Judgment on the Pleadings for which PsychRights does seek discovery from the State. The first is to rebut the unsupported and untrue assertion made by the State in its Motion for Judgment on the Pleadings that the State has nothing to do with authorizing and administering psychotropic drugs to children and youth whom it has taken away from their parent(s).[14] The second is to supply the lack of specificity regarding the State's inappropriate payment for and administration of psychotropic drugs to Alaskan children and youth.[15]

III. Discovery Plan

PsychRights has a very focused discovery plan designed to develop evidence in a logical order and minimize the burden on both sides.[16] The first step is to obtain information on the State's computerized records to enable PsychRights to fashion a focused discovery request to extract relevant information. The second step is to obtain evidence regarding how pediatric psychopharmacology is actually practiced on Alaskan children and youth in State custody and through Medicaid. This involves information from both the State and other parties, such as psychiatrists. In addition PsychRights intends to seek negative data about the drugs that have heretofore been hidden by pharmaceutical

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know. Moreover, PsychRights specifically provided the scientific analysis, including references even prior to bringing suit. *See*, Exhibit G. to Amended Complaint.

[14] Motion for Judgment on the Pleadings, p. 5 ("In short, the administration of psychotropic medication to children in Alaska is a decision left to the parent or legal guardian of the child, or to the superior court.").

[15] Motion for Judgment on the Pleadings, pp 8-9, 18.

[16] For example, PsychRights was originally going to notice a Civil Rule 30(b)(6) deposition covering a large number of topics, but has been working to refine its discovery so as to minimize the burden on all concerned.

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companies as well as the improper promotion of pediatric psychopharmacology by pharmaceutical companies.

IV. Currently Requested Discovery

Attached hereto as Exhibits A & B, respectively, are the Notice of Deposition for Mr. David Campana and PsychRights' First Requests for Production.[17] The only items sought are (1) information about the State's computerized records so that PsychRights can fashion requests for production informed by knowledge of what data is available and how it is organized, and (2) the records of seven specific individuals who are or have been in the custody of the State and who have authorized and directed the State to provide such information.[18]

A. The David Campana Deposition

On January 29, 2009, PsychRights e-mailed the State as follows:

> Can we meet informally with David Campana in the near future to formulate a request for production of computerized Medicaid records rather than take his deposition. What I'd like to do is meet with him with our computer person to formulate the request for production. I am not asking that you waive any rights to object to a request for production.[19]

The State responded that it would prefer to conduct a formal deposition[20] and the parties agreed to conduct the deposition on February 26, 2009.[21] However, two days before the scheduled deposition, the State e-mailed:

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[17] The First Requests for Production includes identifying information which has been redacted from the copy attached hereto.
[18] *See*, Exhibit B, pages 8-14.
[19] Exhibit C, page 2.
[20] Exhibit C, page 1.
[21] *See*, Exhibit D.

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> In preparing for Dave Campana's upcoming deposition, Stacie and I have taken a more extensive look at the complaint and we have concerns about engaging in discovery at this point. As a result of our review we are preparing a dispositive motion that we hope to file in the next two weeks. Therefore we would request that you agree to postpone Dave's deposition until after the court has ruled on our motion. If you are unable to agree to that postponement, we'll file an expedited motion to quash the deposition on similar grounds. We apologize for the late notice but we need to know by COB today if you can agree to this plan.[22]

PsychRights replied:

> I will agree to postpone it for two weeks or maybe a bit more, but I don't think I can agree to anything that open-ended.[23]

The State responded:

> Good enough Jim, we understand that concern. Thanks for your understanding and courtesy on this point and we will be in touch. Procedurally, will you be issuing a notice that cancels Thursday's deposition?[24]

PsychRights responded:

> I will serve you with a re-notice of deposition for say three weeks out, which when we get closer we will presumably have another discussion about.[25]

The State responded to this as follows:

> That's fine, with the understanding that we're not agreeing to a date certain at this point and re-notice will be subject to further discussions and/or motion practice as we get closer to the time. So I believe we're on the same page with how to proceed.[26]

Instead of further discussion, the State filed the instant Motion to Stay Discovery.

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[22] Exhibit E, page 2.
[23] Exhibit E, page 1.
[24] *Id.*
[25] *Id.*
[26] *Id.*

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As mentioned above, the primary purpose of the Campana Deposition is simply to learn about the State's computerized Medicaid records in order to fashion requests for production pertaining thereto. This should be easy for the State to do, especially since it has already assembled this information in connection with *Alaska v. Eli Lilly & Co.*, 3AN 06-05630 CI.[27]

B. First Requests for Production

(1) Descriptions of Computerized Records

Mr. Campana's deposition was noticed under the concept that conducting it would serve as a template for obtaining information about the other relevant computerized records of the State. However, due to the State's delaying the deposition for an extended period of time, PsychRights determined it had to at least get the ball rolling on acquiring the information on all of the State's computer systems relevant to the authorization and administration of psychotropic drugs to children and youth in order to fashion specific requests for production of relevant computerized records. Thus, on March 3, 2009, PsychRights served its First Requests for Production, requesting information on the structure of the computerized records for not only the Medicaid database, but those by the other agencies involved, to wit: the Office of Children's Services, the Division of Juvenile Justice, the Alaska Psychiatric Institute and the Division of Behavioral health. These requests for production asked for the following information:

1. Software utilized,
2. Manuals,
3. File format,

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[27] Exhibit F.

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4. File structure,
5. The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
6. Examples of all report types.[28]

Again, the purpose of these requests is to enable PsychRights to fashion focused requests for production of relevant computerized records. It is PsychRights' expectation that this will obviate the need for broad requests for production of individual paper case files. However, to the extent PsychRights is left with insufficient time to first obtain the information on the data structure of the computerized records, then obtain the relevant computerized records, and then obtain focused and/or randomly generated case files, it may be forced to serve requests for production of all the case files.

While at first blush it seems there is plenty of time, by all indications the State is going to object every step of the way and time will be used up at each step. If PsychRights is left without sufficient time to go through the steps that will allow it to fashion focused discovery requests, it will be forced to seek broader discovery.

(2) Seven Specific Case Files

The only other discovery requested to date are the case files of seven Alaskan youth who are or have been in State custody and who have, to the extent of their authority, authorized and directed the State to provide PsychRights with the requested information.[29]

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[28] Exhibit B, pages 4-6.

[29] *See*, Exhibit B, pages 7-14. Again, the identifying information has been redacted because it does not appear there is any reason why it should be included in this public filing and it is not believed the identity of the specific persons involved is relevant to the Court's consideration.

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If the State has objections to providing these records, it should make such objections known now so they can be considered in an orderly manner.

V. Contemplated Discovery

A. Psychiatrists, the Public and the State Have Been Duped Into Giving Children and Youth Ineffective and Dangerous Drugs

One of the key questions in this case is why psychiatrists are prescribing and custodians are authorizing the administration of extremely improvident and harmful psychiatric drugs to children and youth. The answer is that the pharmaceutical companies have been very effectively illegally promoting their use, especially the neuroleptics, such as Risperdal, Seroquel, Zyprexa, Abilify and Geodon.

Grace E. Jackson, MD, who has been qualified as an expert witness in a number of PsychRights' adult forced psychiatric drugging cases,[30] testified in May of 2008, about how psychiatrists are being misled by the drug companies into improvident prescribing.

> So essentially what happened in the 1990s is that the journals, more than ever before in history, became a tool of marketing, a marketing arm for the drug companies. And drug companies shifted in terms of previous research in the United States.
>
> Most of the research had previously been funded by the government and conducted in academic centers. In the 1990s, that was pretty much over, and most of the funding is now coming from the pharmaceutical industry. So that's really in a nutshell what happened in the 1990s when I was training.
>
> Now, where are we now? What that means is that the journals that most doctors are relying upon for their continuing information continued to be dominated by pharmaceutical industry funded studies and by papers which

[30] *See*, e.g., Exhibit L, page 3 (Transcript page 111, lines 12-18).

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> are being written, if not entirely by the drug companies, then by authors who have part of their finances paid for by the drug companies.[31]

In a 2007 article, Pediatric Bipolar Disorder: An Object Study in the Creation of an Illness,[32] the Scottish psychopharmacology expert, David Healy, MD, describes, among other things, how academics have become marketing arms of the pharmaceutical companies instead of objective researchers. This has recently been further buttressed through documents obtained in discovery and recently made public from various lawsuits.

(1) Risperdal/Joseph Biederman, MD/Harvard's Mass General Hospital and the Johnson & Johnson Cetner for Pediatric Psychopathology

On November 25, 2008, the New York Times ran a story titled, Research Center Tied to Drug Company,[33] about Joseph Biederman, MD, and his undisclosed payments by Johnson & Johnson to produce "academic" research in support of prescribing Risperdal to children and youth as young as four.[34] The article describes the vast influence Dr. Biederman has had in the explosion of prescribing the dangerous neuroleptics,[35]

> Dr. Biederman's work helped to fuel a 40-fold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder and a rapid rise in the use of powerful, risky and expensive antipsychotic medicines in children. Although many of his studies are small and often financed by drug makers, Dr. Biederman has had a vast influence on the field largely because of his position at one of the most prestigious medical institutions in the world.

In his recent deposition Dr. Biederman testified as follows:

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[31] Exhibit L, page 5 (Transcript page 119).
[32] Exhibit H.
[33] Exhibit I.
[34] Exhibit K, p.2, 4.
[35] This class of drugs is also often referred to by the misnomer, "antipsychotic." *See*, e.g., *Sutherland v. Estate of Ritter*, 959 So. 2d 1004, 1006 n.3 (Miss. 2007)

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Q. And do you agree that you are one of the most forceful advocates of the aggressive [psychiatric drug] treatment of preschoolers? . . .

A. I am.[36]

Later in his deposition, Dr. Biederman admitted that he promoted the use of Risperdal in children as young as pre-schoolers (ages four to six[37]), even though no one knows what Risperdal does to the brain and there are no long term studies.[38]

One of the recently unsealed documents includes an e-mail exchange about the Johnson & Johnson Center for Pediatric Psychopathology (J&J Center), in which Dr. Biederman, the Center's leader is recognized as "the pioneer in the area of [Child & Adolescent] Bipolar Disorders,"[39] and that

> He approached Janssen multiple times to propose the creation of a Janssen-MGH center for [Child & Adolescent] Bipolar disorders. The rationale of this center is to generate and disseminate data supporting the use of risperidone in this patient population.[40]

Johnson & Johnson funded the center and the 2002 Annual Report states:

> The mission of the Center is to create a common ground for a strategic collaboration between Johnson & Johnson (J&J) and the Pediatric Psychopharmacology Research Program an[d] at the Massachusetts General Hospital (MGH). . . . An essential feature of the Center is . . . it will move forward the commercial goals of J&J. . . .
>
> Equally important . . . is the demonstration of the validity of [child psychiatric] disorders. . . . Without such data, many clinicians question the wisdom of aggressively treating children with medication, especially those

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[36] Exhibit K, p. 4 from February 27, 2009, deposition transcript of Joseph Biederman
[37] Exhibit K, p. 2.
[38] Exhibit K, p. 5.
[39] In his deposition, Dr. Biederman agreed that he was one of the leaders and that he is considered a "world-renowned child psychiatrist." Exhibit K, p. 3.
[40] Exhibit J, emphasis added.

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like the neuroleptics, which expose children to potentially serious adverse events.". . .

We will generate and publish data on the efficacy and safety of medications for . . . child psychopathology. This work is an essential precursor to the . . . widespread use of medications given that most must be used off-label.. . .

Many children with psychopathology never receive medical treatment due to controversies in the media and debates among professionals about the validity of psychiatric diagnoses in children.[41] . . .

To have an impact on clinical practice, research results from the Center must be disseminated through scientific publications, presentations and national and international meetings and continuing education programs. Our program of dissemination is as follows: . . .[42]

In 2002, we made progress in the following areas: . . .

- We disseminated the results of our work [at] national and international meetings.
- We prepared initial manuscripts for publication. . . .
- We developed and maintained a schedule of regular communication with J&J staff to facilitate collaborative efforts.
- We initiated Yearly Meetings of Experts in Bipolar Disorder[43]

To address the controversy about pediatric bipolar disorder, we initiated a multi-year conference series which seeks to establish a forum for researchers and clinicians to improve dialogue and foster collaborative studies about children who present with extreme temper tantrums and dysregulated mood.[44]

Then Dr. Biederman states that the Center's plans for the future include establishing the efficacy of Risperdal for (the controversial diagnosis of[45]) pediatric Bipolar Disorder (BPD) and Obsessive Compulsive Disorder (OCD).[46]

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[41] Exhibit S, p. 3-4, emphasis added.
[42] Exhibit S, p. 6.
[43] Exhibit S, p. 7.
[44] Exhbit S, p. 16.
[45] *See*, Exhibit S, p. 4.

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The 2003 Business Plan for the J&J Center shows Dr. Biederman's plans to use the J&J Center as a front to (1) "re-analyze" the safety database,[47] and (2) deal with the problem that Risperdal is not approved for any indication for pediatric use.[48] The 2003 Business Plan presentation also discusses the opportunities for partnerships with advocacy groups, which means funding of groups such as the National Alliance for the Mentally Ill to promote its use in children and youth.[49]

These documents show in more detail what Dr. Jackson testified to, and Dr. Healy wrote about, as set forth above, how "Key Opinion Leaders" are being paid handsomely to prostitute their academic positions to promote the commercial interests of their drug company sponsors.

Dr. Biederman's egregious conduct in this regard recently prompted United States Senator Grassly, just a few days ago, on March 20, 2009, to write to the presidents of Harvard University and Massachusetts General Hospital (MGH), which house the J&J Center, about their organizations being used to produce and disseminate what appears to be fraudulent information in support of prescribing Risperdal to children and youth.[50]

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[46] Exhibit S, page 18.
[47] Exhibit T, page 3
[48] Exhibit T, page 4, 5.
[49] Exhibit T, page 3, 4. Dr. Healy also mentions these parent pressure groups in his article about the creation of pediatric bipolar disorder. Exhibit H, p. 1
[50] Exhibit M.

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(2) Eli Lilly and Zyprexa

Eli Lilly & Co (Lilly) recently plead guilty to the illegal marketing of Zyprexa to the elderly and agreed to pay $1.4 Billion in criminal and civil fines.[51] While Lilly may have been able to negotiate away pleading guilty to the off-label promotion of Zyprexa to children and youth, Dr. Healy noted that Lilly had identified the potential for marketing Zyprexa to the children and youth market as early as 1997.[52]

At the January 17, 2007, hearing in *In Re: Zyprexa Litigation* (*Zyprexa MDL*),[53] the following testimony was presented about the illegal off-label marketing of Zyprexa revealed by previously secret documents:

> [T]he documents document the fact that Eli Lilly knew that the -- that Zyprexa causes diabetes. They knew it from a group of doctors that they hired who told them you have to come clean. That was in 2000. And instead of warning doctors who are widely prescribing the drug, Eli Lilly set about in an aggressive marketing campaign to primary doctors. Little children are being given this drug. Little children are being exposed to horrific diseases that end their lives shorter.[54]

(3) Astra-Zeneca and Seroquel

In Re: Seroquel Products Liability Litigation (*Seroquel MDL*)[55] is a consolidation of many products liability lawsuits against the manufacturer of Seroquel, AstraZeneca, for, among other things, (a) AstraZeneca's concealment of Seroquel's propensity to cause diabetes and other related life threatening and deadly conditions, (b) illegal off-label

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[51] *See*, Exhibit G.
[52] Exhibit H, n 39.
[53] MDL 04-1596, United States District Court for the Eastern District of New York.
[54] Exhibit W, page 3.
[55] Multi-District Litigation (MDL) Case #: 6:06-md-01769-ACC-DAB, United States District Court, Middle District of Florida

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marketing, and (c) violation of state consumer protection laws, including AS 40.50.471, *et seq*.[56]

As is apparently typical in these cases,[57] a global protective order was entered under which over 30 million pages of material was produced in discovery,[58] with various mechanisms for their becoming unsealed.[59] On December 12, 2008, the plaintiffs challenged the confidentiality designation of over 60 of these documents, which under §12 of the protective order caused them to automatically lose confidentiality protection unless AstraZeneca filed a motion to maintain confidentiality within 30 days.[60] AstraZeneca filed such a motion on January 12, 2009,[61] and a hearing on the motion set for February 26, 2008.[62]

On February 9, 2009, PsychRights e-mailed the lead plaintiffs' attorney, Camp Bailey, indicating it anticipated having a subpoena issued to take Mr. Bailey's deposition and obtain (a) certain specified documents, (b) information on other negative effects, (c) unpublished studies, including those involving children and youth, and (d) documents

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[56] Master Complaint, Docket No. 42. ¶86(a) is the allegation regarding the Alaska consumer protection violation count, which, along with the rest of the public docket in the *Seroquel MDL* case is available on PACER, the United States Court System's electronic access system, and of which this Court can take public notice.
[57] Without comparing them word for word, the protective order in the *Seroquel MDL* appears to be substantially identical to the one in the *Zyprexa MDL*.
[58] *In Re: Seroquel MDL*, Docket No. 1222, p. 5.
[59] *In Re: Seroquel MDL*, Docket No. 478.
[60] *In Re: Seroquel MDL*, Docket No. 478.
[61] *In Re: Seroquel MDL*, Docket No. 1222.
[62] *See*, Exhibit R, page 1.

regarding the promotion of Seroquel for pediatric use.[63] Under ¶14 of the protective order, upon being served with such a subpoena Mr. Bailey is required to notify AstraZeneca, cooperate with AztraZeneca, and give them a reasonable opportunity to object, prior to producing the documents.[64]

The parties agreed to the release of many of the documents before the February 26, 2009, hearing and on February 27, 2009, a number of documents were unsealed, including a July, 2008, Clinical Overview on Weight Gain in Pediatric Patients on Seroquel.[65] It seems as a result of this study, on December 18, 2008, in a letter that was also unsealed on February 27, 2009, the Food and Drug Administration directed AstraZeneca to advise doctors through the labeling that the safety and effectiveness of Seroquel has not been established for pediatric patients and is not approved for patients under the age of 18 years.[66] As far as PsychRights has been able to determine, at this point, this warning has yet to be conveyed to doctors through the directed changes to the label.

The unsealed documents include e-mails regarding AstraZeneca's suppression of unfavorable studies while promoting favorable data:

> There has been a precedent set regarding "cherry picking" of data. This would be the recent Velligan presentations of cognitive function data from Trial 15 (one of the buried trials). Thus far, I am not aware of any repercussions regarding interest in the unreported data.
>
> That does not mean that we should continue to advocate this practice. There is growing pressure from outside the industry to provide access to all data

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[63] Exhibit R.
[64] *In Re: Seroquel MDL*, Docket No. 478.
[65] Exhibit O.
[66] Exhibit N, page 2.

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> resulting from clinical trials conducted by industry. Thus far, we have buried Trials 15, 31, 56, and are now considering COSTAR.
>
> The larger issue is how do we face the outside world when they begin to criticize us for suppressing data.[67]

On March 18, 2009, the Washington Post reported as follows about "Study 15:"

> The results of Study 15 were never published or shared with doctors, even as less rigorous studies that came up with positive results for Seroquel were published and used in marketing campaigns aimed at physicians and in television ads aimed at consumers. The results of Study 15 were provided only to the Food and Drug Administration -- and the agency has strenuously maintained that it does not have the authority to place such studies in the public domain. . . .
>
> The saga of Study 15 has become a case study in how drug companies can control the publicly available research about their products, along with other practices that recently have prompted hand-wringing at universities and scientific journals, remonstrations by medical groups about conflicts of interest, and threats of exposure by trial lawyers and congressional watchdogs.[68]

It appears Study 15 may have been unsealed on March 13, 2009, and PsychRights is attempting to get it reviewed. However, it also appears with other documents of interest to PsychRights produced in the *In Re: Seroquel MDL* are still being kept secret, including (1) Study 144, Study 125 and its draft manuscript, Study 165, Study 127, (2) the Investigational New Drug Application (IND) to the FDA, and (3) marketing call notes.[69]

B. The Necessity of Determining the Bases Upon Which Current Pediatric Psychopharmacology is Practiced.

It is necessary for PsychRights to be able to depose at least a few child psychiatrists, and perhaps other physicians and other people prescribing psychotropic drugs to Alaskan

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[67] *See*, Exhibit P, p. 2. That Trial 15 is still buried is revealed
[68] Exhibit Q.
[69] Exhibit R, pages 4 & 5.

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children and youth, to have them disclose upon what they are relying in doing so. In addition, since it is illegal for the State to use Medicaid to pay for medications unless they are prescribed for FDA approved indications or included in three specified compendia,[70] and nearly all prescriptions of psychotropic medications to children and youth are off label,[71] it is essential that these prescribers identify where in such compendia such prescribing is included. It is expected that, especially with respect to the neuroleptics and the anti-seizure medications re-branded as "mood stabilizers," they are prescribing these drugs based on off-label marketing by the pharmaceutical companies masquerading as science. Even with respect to the stimulants, such as Ritalin, which have been approved for children and youth, the truth is there is a lack of data supporting long-term efficacy or safety,[72] and it is necessary for PsychRights to learn upon what these prescribers are relying for these drugs as well in order to demonstrate to this Court such prescribing practices are not in Alaskan children and youth's best interests.

Starting in mid-February, PsychRights started trying to coordinate deposition schedules for some psychiatrists with the State's schedule, wanting to give everyone at

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[70] *Ex Rel Franklin v Parke Davis*, 147 F.Supp.2d 39 (DMass2001).
[71] Exhibit S, page 3 ("[N]early all psychiatric medication use in children is off label").
[72] *See*, ¶s 154, 156-165 of the Amended Complaint herein; APA Working Group on Psychoactive Medications for Children and Adolescents. (2006); and Report of the Working Group on Psychoactive Medications for Children and Adolescents. Psychopharmacological, psychosocial, and combined interventions for childhood disorders: Evidence-base, contextual factors, and future directions, Washington, DC: American Psychological Association; National Institute of Mental Health Multimodal Treatment Study of ADHD Follow-up: 24-Month Outcomes of Treatment Strategies for Attention-Deficit/Hyperactivity Disorder, MTA Cooperative Group, *American Academy of Pediatrics*, 113;754-761 (2004)

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least a month to prepare.[73] To the extent discovery is stayed for any length of time, the luxury of being able to give the psychiatrists so much notice and accommodate the State's schedule will be diminished.

Most importantly, it is anticipated that this discovery will result in grounds for one or more preliminary injunctions because of the extreme harm being inflicted on Alaskan children and youth by these practices. No further delay should be countenanced. It is also anticipated that this discovery will result in grounds for at least a partial summary judgment for declaratory relief.[74]

C. The Necessity of Developing the True Involvement of the State.

In its Motion for Judgment on the Pleadings the State asserts the administration of psychiatric drugs to children and youth in its custody "is left to the parent or legal guardian of the child, or to the superior court."[75] This is disingenuous at best[76] and PsychRights intends to conduct focused discovery to show the State's true involvement. It is PsychRights understanding, the "consents" are virtually always obtained because one or

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[73] Exhibit D, p.1.

[74] The State has essentially admitted it is not protecting the children and youth in its care and this discovery will provide the detail for the declaratory judgment aspect. The more difficult task will be to fashion the injunctive relief if the State continues to be unwilling to voluntarily take the appropriate steps. It is PsychRights hope that if such preliminary relief is obtained, the State and PsychRights will be able to fashion a program that will only authorize the administration of psychotropic medications to Alaskan children and youth in state custody or through Medicaid in appropriate circumstances and under appropriate conditions.

[75] Motion for Judgment on the Pleadings, p. 5.

[76] It is also patently untrue because under AS 47.10.084, if parental rights have been terminated and there is no guardian, which is often the case, these residual parental rights accrue to the State.

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more of the defendants seek such consent (or court order) and that parents are often subjected to extreme pressure to agree to the psychiatric drugging of their children. Thus, another aspect of PsychRights' discovery plan is to have the defendants disclose the sources and information it is

(a) relying upon in deciding to seek, and

(b) providing in obtaining,

parental consent and court orders.

Assuming PsychRights obtains the computerized records it intends to seek, PsychRights is contemplating generating a random sample of case files for review to get an objective view of the actual process. Because of the expectation that the State will interpose every objection it can to each and every one of PsychRights' discovery requests, there is likely to be a series of motions related thereto, which will be the occasion for further delay which could seriously jeopardize the entire discovery plan.

For example, even with respect to obtaining information about the file structures of the State's computerized records in order to be able to fashion a discovery request to obtain the actual computerized records, the State first refused to informally provide the information, then it agreed to a deposition date, and then at the last minute it moved for the instant stay. This has been going on since January.[77]

As set forth above, there is an extant request for production of seven case files, <u>for which authorizations have been given</u> and, based on the State's past behavior one can

[77] *See*, Exhibit C., page 2.

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expect it will even object to providing that information, necessitating a motion to compel. For example, on January 20, 2009, the State raised the issue of state confidentiality laws in connection with getting a qualified protective order in place under federal law and PsychRights asked it to identify such laws.[78] The State has thus far failed to do so, but can be expected to interpose it when it has to do so. Presumably the State will do so in response to PsychRights First Requests for Production, served March 3, 2009, and this should not be further delayed.

Just as discovery of what prescribers are relying upon in giving psychotropic drugs to Alaskan children and youth is likely to generate evidence for one or more preliminary injunctions and partial summary judgments, the discovery sought from the State is likely to do the same. Stopping Alaskan children and youth from being subjected to these improvidently administered and harmful drugs should not be delayed through a stay of discovery.

In addition, as set forth above, in *Chavous*, which the State cited, the court held a trial court ordinarily should not stay discovery which is necessary to gather facts in order to defend against a motion to dismiss and that discovery should precede consideration of dispositive motions when the facts sought to be discovered are relevant to consideration of the particular motion at hand. In its Motion for Judgment on the Pleadings the State asserts it plays no role in the psychiatric drugging of children and youth in its custody and through Medicaid. The State bringing this issue into the Motion for Judgment on the

[78] Exhibit U.

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Pleadings, even though it was not supported by any competent evidence, means PsychRights must be allowed to conduct discovery on the issue before this Court may properly consider it.

D. The Necessity of Obtaining Pharmaceutical Company Off-Label Marketing Information

In addition to deposing some psychiatrists and other prescribers regarding the off-label marketing to which they have been subjected by the drug companies, PsychRights intends to seek such materials directly from the pharmaceutical companies and/or from parties having access to discovery depositories concerning these matters. It seems likely that the pharmaceutical companies will object and to the extent that deponents can not be served in Alaska, a commission/letter rogatory for an out of state subpoena must be obtained pursuant to Civil Rule 28(b) and then procedures pursued in another state to have a subpoena issued and enforced. This very well might consume a considerable amount of time -- even to the point of still being unresolved as of the date trial is scheduled. There is no reason for such delay. It certainly isn't a burden on the State, which is the basis for its Motion for Stay. This information is very important to acquire for the Court to get the whole picture about what is transpiring with respect to the administration of psychotropic drugs to Alaskan children and youth.

E. The Necessity of Acquiring Suppressed Data

PsychRights believes it can demonstrate, based on publicly available information, that the current practice of psychopharmacology is ineffective and counterproductive, is doing great harm, and non-pharmacological psychosocial approaches should be used

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instead in most cases,[79] but to the extent this Court might find this insufficient, PsychRights is entitled to seek suppressed studies and evidence related to the off-label marketing of psychotropic drugs for pediatric use. Moreover, this information could be very important in fashioning the form of the injunction sought herein. It is likely the pharmaceutical companies will object to this discovery, and whether or not the discovery should be had, and if so, to what extent this information should be kept secret by this Court, will take some time. As with the evidence sought from the drug companies with respect to the off-label marketing to Alaskan prescribers, this very well might consume a considerable amount of time -- even to the point of still being unresolved as of the date trial is scheduled. There is no reason for such delay with its concomitant extreme harm to the children and youth of Alaska in State custody, nor the disadvantaged children and youth of Alaska who are being subjected to these drugs through Medicaid payments.

VI. Overview

Psychiatrists ought to be able to rely on the information they receive through medical journals and continuing medical education.[80] The State ought to be able to trust that psychiatrists recommending the administration of psychiatric drugs are basing these recommendations on reliable information. Unfortunately, neither of these things which ought to be true are true. It is essential for PsychRights to establish the extent of the administration of psychiatric drugs to Alaskan children and youth in State custody and

[79] *See*, e.g., the CriticalThinkRx Curriculum, including references, that can be accessed from http://criticalthinkrx.org/.

[80] They should be skeptical, however, about "information" provided by drug companies.

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through Medicaid. It is essential that PsychRights establish upon what the psychiatrists are relying in prescribing psychiatric drugs to Alaskan children and youth in State custody and through Medicaid in order for this Court to determine whether current practice sufficiently protects Alaska's children and youth in state custody and whether or not Medicaid is making illegal payments for psychiatric medication to Alaskan children and youth.

The trial in this case is set to begin on February 1, 2010. At first blush, this seems a fair way off, but pretrial deadlines are now looming. The deadline for preliminary witness lists and identification of retained experts is August 31, 2008, just five months from now. The other deadlines follow-on quickly. These deadlines are simply coming up too fast for any delay of any length.

Moreover, by inserting into its Motion for Judgment on the Pleadings, however improperly, that the State plays no role in the authorization of these drugs to children and youth of whom the State has seized custody, the State has set up the situation where discovery with respect to this situation may be necessary in order to determine the motion.[81] Thus, discovery must be allowed to proceed without further delay.

PsychRights has a very focused discovery plan designed to produce the necessary evidence. This discovery plan depends on the discovery occurring in a certain order and to the extent that discovery is delayed for any length of time, the ability to conduct the discovery with minimal burden on the parties is jeopardized.

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[81] PsychRights believes the Motion for Judgment on the Pleadings is so devoid of merit that this Court should have no difficulty in denying it without consideration of the unsupported assertions of the State that it plays no role in the administration of psychiatric drugs to children and youth in State custody.

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Most importantly, Alaskan children and youth are being greatly harmed by the State's admitted inability to properly care for and protect them from the improvident, psychiatric drugging and this should cease as soon as possible. Discovery should not be further delayed and prevent this.

VII. CONCLUSION

For the foregoing reasons, PsychRights respectfully urges this Court to deny the State's Motion to Stay Discovery

DATED: March 24, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein, ABA # 7811100

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
AT ANCHORGE

Law Project for Psychiatric Rights, Inc., Plaintiff(s)	)	**RE-NOTICE OF TAKING DEPOSITION DAVID CAMPANA**
vs.	)	
State of Alaska, et al., Defendant(s)	)	

Case No. 3AN 08-10115 CI

TO:

Elizabeth M. Bakalar/Stacie L. Kraly
Attorney General's Office
P.O. Box 110300
Juneau, AK 99811-0300

PLEASE TAKE NOTICE that on behalf of Law Project for Psychiatric Rights, Plaintiff, the deposition of David Campana has been changed to 1:00 PM on the 26th day of February, 2009, at the offices of the Law Project for Psychiatric Rights, 406 G Street, Suite 206, Anchorage, Alaska 99501, before a court reporter. The designation of materials to be produced is attached and you are invited to attend.

DATED: February 17, 2009.

Law Project for Psychiatric Rights Inc.

By: _____
James B. Gottstein, Esq.
ABA # 7811100

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Attachment to David Campana Subpoena Duces Tecum

All documentation of computerized records relating to payment (or reimbursement) by Medicaid for psychotropic drugs prescribed to children and youth who have or had claims for payment (or reimbursement) for psychotropic drugs from January 1, 1999, to date, including but not limited to:

(1) Manuals,
(2) File format,
(3) File structure,
(4) The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
(5) Examples of all report types.

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

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

Plaintiff,

vs.

STATE OF ALASKA, *et al.*,

Defendants,

Case No. 3AN 08-10115CI

FIRST REQUESTS FOR PRODUCTION

COMES NOW the Plaintiff, Law Project for Psychiatric Rights (PsychRights®), and, pursuant to Rules 26 and 34 of the Alaska Rules of Civil Procedure, requests defendants State of Alaska *et al.*, to produce and permit PsychRights to inspect and copy each document requested as follows:

You must serve written responses to these requests for production within thirty (30) days of service hereof. The responses must state, with respect to each item or category, that the document has been produced as requested, unless the request is objected to, in which event the reasons for objection shall be specifically stated. If objection is made to part of an item or category, the part shall be specified.

In the event that any document called for by these requests is to be withheld for any reason, please identify that document as follows: title, addressor, addressee, indicated or blind copies, date, subject matter, number of pages, attachments or appendices, all persons

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to whom distributed, shown or explained, present custodian, and the basis for withholding the document.

In the event that any document called for by these requests has been destroyed for any reason, please identify that document as follows: date of destruction, manner of destruction, reason for destruction, person authorizing destruction, and person destroying the document.

The requests apply to all documents in your possession, custody or control, including documents in the possession of or subject to the custody or control of your agents or attorneys. Unless otherwise specified, the documents called for by these document requests are documents in your possession, custody or control that were applicable, effective, prepared, written, generated, sent, dated, or received at any time since January 1, 1999.

"Documents" as used herein means all original writings and other forms of recording or documentation of any nature whatsoever, and all non-identical copies thereof, in your possession, custody or control, regardless of where located, and includes, but is not limited to, computer stored or computer generated information, legal documents, agreements, records, communications, reports, studies, summaries, regulations, indices, memoranda, calendar or diary entries, handwritten notes, working papers, agendas, bulletins, notices, announcements, instructions, charts, manuals, brochures, policies, schedules, telegrams, teletypes, films, videotapes, photographs, microfilm or microfiche, all papers, books, journals, ledgers, statements, memoranda, reports, invoices, work sheets, work papers, notes, transcription of notes, letters, correspondence, abstracts, checks,

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diagrams, plans, blueprints, specifications, pictures, drawings, graphic representations, lists, logs, publications, advertisements, instructions, minutes, orders, purchase orders, messages, resumes, contracts, cables, recordings, audio tapes, magnetic tapes, visual tapes, transcription tapes or recordings or any portion thereof or summaries thereof, on which any handwriting, typing, printing, photostatic, or other form of communications are recorded or reproduced, as well as all notations on the foregoing; all originals, all file copies and all other copies of any of the foregoing; and all drafts and notes (whether typed, handwritten or otherwise) made or prepared in connection with such documents, whether used or not, pertaining, describing, referring or relating, directly or indirectly, in whole or in part, to the subject matter of each request, and which are in the possession, custody, or control of defendant, State of Alaska, its subsidiaries, officers, directors, employees, agents, representatives, predecessors, attorneys, or others acting on behalf of it defendants.

THIS REQUEST FOR PRODUCTION SHALL BE DEEMED TO BE CONTINUING IN NATURE SO AS TO REQUIRE SEASONAL, SUPPLEMENTAL RESPONSES IF YOU, YOUR AGENTS, REPRESENTATIVES OR ATTORNEYS OBTAIN FURTHER INFORMATION AS TO THE EXISTENCE OF ADDITIONAL DOCUMENTS BETWEEN THE TIME YOUR RESPONSES ARE FILED AND SERVED AND THE TIME OF TRIAL.

Please produce the following at the Law Project for Psychiatric Rights, 406 G Street, Suite 206, Anchorage, Alaska 99501, or designate the location where PsychRights may inspect and copy such documents, on or before thirty days from service of this request:

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REQUEST FOR PRODUCTION NO. 1. Any and all documentation of computerized records pertaining children and/or youth who have had contact with the Office of Children's Services (OCS) from January 1, 1999, to date, including but not limited to:

1. Software utilized,
2. Manuals,
3. File format,
4. File structure,
5. The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
6. Examples of all report types.

RESPONSE

REQUEST FOR PRODUCTION NO. 2. Any and all documentation of computerized records pertaining children and/or youth who have had contact with the Division of Juvenile Justice (DJJ) from January 1, 1999, to date, including but not limited to:

1. Software utilized,
2. Manuals,
3. File format,
4. File structure,
5. The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
6. Examples of all report types.

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RESPONSE

REQUEST FOR PRODUCTION NO. 3. Any and all documentation of computerized records pertaining children and/or youth who have had contact with the Alaska Psychiatric Institute (API) from January 1, 1999, to date, including but not limited to:

1. Software utilized,
2. Manuals,
3. File format,
4. File structure,
5. The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
6. Examples of all report types.

RESPONSE

REQUEST FOR PRODUCTION NO. 4. Any and all documentation of computerized records pertaining children and/or youth kept by the Division of Behavioral Health (DBH) from January 1, 1999, to date, including but not limited to:

1. Software utilized,

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2. Manuals,
3. File format,
4. File structure,
5. The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
6. Examples of all report types.

RESPONSE

REQUEST FOR PRODUCTION NO. 5. Any and all documentation of computerized records relating to payment (or reimbursement) by the Division of Healthcare Services (HCS) for psychotropic drugs prescribed to children and/or youth who have or had claims for payment (or reimbursement) for psychotropic drugs from January 1, 1999, to date, including but not limited to:

1. Software utilized,
2. Manuals,
3. File format,
4. File structure,
5. The identity and meaning (including codes and/or lookup tables, etc.) of all fields contained in such computerized records, and
6. Examples of all report types.

RESPONSE

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REQUEST FOR PRODUCTION NO. 6. Any and all documents in the care, custody, or control of DHSS, OCS, DJJ, API, DBH & HCS, pertaining to the following individuals, all of whom have executed Authorizations for Release of Information:[1]

1. [redacted]
2. [redacted]
3. [redacted]
4. [redacted]
5. [redacted]
6. [redacted]
7. [redacted]

RESPONSE

DATED: March 2, 2008.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

[1] See, Attachment A.

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PsychRights®
Law Project for
Psychiatric Rights, Inc.

AUTHORIZATION FOR RELEASE OF INFORMATION

To: All Treating Medical Personnel and their Employers, Alaska Department of Health and Social Services, Alaska Office of Children's Services, Alaska Division of Juvenile Justice, Alaska Psychiatric Institute, Alaska Division of Behavioral Health and Alaska Division of Health Care Services.

I, [redacted] to the extent of my author[redacted]eby authorize and direct you to:

(1) communicate with the Law Project for Psychiatric Rights (PsychRights®),
(2) answer all of PsychRights' questions, and
(3) provide copies of all documents and other materials requested by PsychRights pertaining to me.

The purpose of this consent is to enable PsychRights to acquire information in connection with its prosecution of *Law Project for Psychiatric Rights v. State of Alaska et al.*, 3AN 08-10115CI, Alaska Superior Court, Third Judicial District, State of Alaska. This authorization encompasses all information that is relevant or may lead to relevant information in the lawsuit as determined by PsychRights, including, but not limited to:

(i) medical and mental health treatment, including the administration of psychotropic medication,
(ii) diagnoses and indications,
(iii) medical necessity,
(iv) informed consent,
(v) monitoring for negative effects of treatment,
(vi) communications with individuals and agencies,
(vii) consideration of psychosocial interventions, and
(viii) monitoring the level and type(s) of improvement or deterioration in behavior, life skills, family, school, and social relationships, sports, and the ability to cope with life's demands.

I understand that:

(a) The records are protected under federal confidentiality regulations issued under the Health Insurance Portability and Accountability Act (HIPAA) and cannot be disclosed without written consent unless otherwise provided for in the regulations.
(b) The released records may contain sensitive information.
(c) PsychRights is not a covered entity under HIPAA and the information being disclosed may be subject to redisclosure, including use in the court case, and may otherwise no longer be protected under the regulations.
(d) I may revoke this consent at any time by notifying PsychRights.
(e) This consent expires at the earlier of _____, or the conclusion of the lawsuit if the blank is left empty.

A copy hereof, shall be effective.

Executed this 12 day of February, 2009.

[redacted]

[print name]

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http://psychrights.org

PsychRights®
Law Project for
Psychiatric Rights, Inc.

AUTHORIZATION FOR RELEASE OF INFORMATION

To: All Treating Medical Personnel and their Employers, Alaska Department of Health and Social Services, Alaska Office of Children's Services, Alaska Division of Juvenile Justice, Alaska Psychiatric Institute, Alaska Division of Behavioral Health and Alaska Division of Health Care Services.

[redacted], to the extent of my authority, hereby authorize and direct you to:

(1) communicate with the Law Project for Psychiatric Rights (PsychRights®),
(2) answer all of PsychRights' questions, and
(3) provide copies of all documents and other materials requested by PsychRights pertaining to me.

The purpose of this consent is to enable PsychRights to acquire information in connection with its prosecution of *Law Project for Psychiatric Rights v. State of Alaska et al.*, 3AN 08-10115CI, Alaska Superior Court, Third Judicial District, State of Alaska. This authorization encompasses all information that is relevant or may lead to relevant information in the lawsuit as determined by PsychRights, including, but not limited to:

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(ii) diagnoses and indications,
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(iv) informed consent,
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(vii) consideration of psychosocial interventions, and
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(c) PsychRights is not a covered entity under HIPAA and the information being disclosed may be subject to redisclosure, including use in the court case, and may otherwise no longer be protected under the regulations.
(d) I may revoke this consent at any time by notifying PsychRights.
(e) This consent expires at the earlier of _____, or the conclusion of the lawsuit if the blank is left empty.

A copy hereof, shall be effective.

Executed this 15th day of February [redacted]

[redacted]
[print name]

3605 Arctic Blvd, Suite 2363 Anchorage, Alaska 99501 ~ (907) 274-7686 Phone ~ (907) 274-9493 Fax
http://psychrights.org

PsychRights®
Law Project for
Psychiatric Rights, Inc.

AUTHORIZATION FOR RELEASE OF INFORMATION

To: All Treating Medical Personnel and their Employers, Alaska Department of Health and Social Services, Alaska Office of Children's Services, Alaska Division of Juvenile Justice, Alaska Psychiatric Institute, Alaska Division of Behavioral Health and Alaska Division of Health Care Services.

I, [redacted], to the extent of my authority, hereby authorize and direct you to:

(1) communicate with the Law Project for Psychiatric Rights (PsychRights®),
(2) answer all of PsychRights' questions, and
(3) provide copies of all documents and other materials requested by PsychRights pertaining to me.

The purpose of this consent is to enable PsychRights to acquire information in connection with its prosecution of *Law Project for Psychiatric Rights v. State of Alaska et al.*, 3AN 08-10115CI, Alaska Superior Court, Third Judicial District, State of Alaska. This authorization encompasses all information that is relevant or may lead to relevant information in the lawsuit as determined by PsychRights, including, but not limited to:

(i) medical and mental health treatment, including the administration of psychotropic medication,
(ii) diagnoses and indications,
(iii) medical necessity,
(iv) informed consent,
(v) monitoring for negative effects of treatment,
(vi) communications with individuals and agencies,
(vii) consideration of psychosocial interventions, and
(viii) monitoring the level and type(s) of improvement or deterioration in behavior, life skills, family, school, and social relationships, sports, and the ability to cope with life's demands.

I understand that:

(a) The records are protected under federal confidentiality regulations issued under the Health Insurance Portability and Accountability Act (HIPAA) and cannot be disclosed without written consent unless otherwise provided for in the regulations.
(b) The released records may contain sensitive information.
(c) PsychRights is not a covered entity under HIPAA and the information being disclosed may be subject to redisclosure, including use in the court case, and may otherwise no longer be protected under the regulations.
(d) I may revoke this consent at any time by notifying PsychRights.
(e) This consent expires at the earlier of _____, or the conclusion of the lawsuit if the blank is left empty.

A copy hereof, shall be effective.

Executed this 15 day of Febuary, 2009.

[redacted]
[print name]

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[redacted]
[print name]

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Executed this 15th day of February, 2009.

[redacted]
[print name]

3611 C Street, Suite 266, Anchorage, Alaska 99501 ~ (907) 274-7686 Phone ~ (907) 274-8433 Fax
http://psychrights.org

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[redacted]
[print name]

406 G Street, Suite 206, Anchorage, Alaska 99501 ~ (907) 274-7686 Phone ~ (907) 274-3493 Fax
http://psychrights.org

Subject: Re: Medicaid Database
From: Jim Gottstein <jim.gottstein@psychrights.org>
Date: Mon, 02 Feb 2009 12:28:26 -0900
To: "Bakalar, Elizabeth M (LAW)" <libby.bakalar@alaska.gov>
CC: "Kraly, Stacie L (LAW)" <stacie.kraly@alaska.gov>, Jim Gottstein <jim.gottstein@psychrights.org>

Hi Libby,

Bakalar, Elizabeth M (LAW) wrote:

> Hi Jim,
>
> We'd prefer to do any meetings with Dave through a formal deposition. If you have some particular data query in mind that you're thinking of, you can run it by us and we'll talk to Dave. But this is a complex suit of significant proportion/impact with potentially lots of discovery, and we want to make sure all our dots are connected properly (i.e. discovery is formalized and done via Civil Rules). So let's just do this as a deposition on the record.

That's fine.

> On that topic, and in response to your other email, we will accept deposition subpoenas for defendants/employees

Thanks. I assume I can serve them to the Anchorage office.

> , but first can you let us know (a) whom you want deposed;

I sent you a draft of a Rule 30(b)(6) notice, so other than Mr. Campana, who I think we all agree is the person to depose about Medicaid records, for at least the first round, you will be designating the persons to testify about the identified topics.

> (b) the time frame in which you want to depose them, being mindful that many of the principals will be jammed up with legislative business during the session—we can then check on availability of those you want deposed, and you can notice the depos and we can get them scheduled as fast as possible.

I'd like to depose Mr. Campana as soon as possible, at least within the next couple of weeks. I will also need to coordinate with my database person. It seems like we ought to be able to work up a schedule for the others that will work for both of us. I'll probably just set a date for the 30(b)(6) depositions for maybe three weeks out and then we can make adjustments to accommodate the various witnesses' schedules.

> I got your voice mail but I am swamped today—if there's anything else you need that's not addressed here, please feel free to try me again.

Thanks for getting back to me.

> Best,
> Libby
>
> Libby Bakalar
> Assistant Attorney General
> Office of the Attorney General
> P.O. Box 110300
> Juneau, Alaska 99801-0300
> (907) 465-4135 (direct)

(907) 465-3600 (main)
(907) 465-2539 (fax)

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Thursday, January 29, 2009 12:46 PM
To: Bakalar, Elizabeth M (LAW); Kraly, Stacie L (LAW)
Subject: Medicaid Database

Hi Libby and Stacie,

Can we meet informally with David Campana in the near future to formulate a request for production of computerized Medicaid records rather than take his deposition. What I'd like to do is meet with him with our computer person to formulate the request for production. I am not asking that you waive any rights to object to a request for production.

--

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
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--

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

Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501
USA

Subject: RE: Depositions
From: "Bakalar, Elizabeth M (LAW)" <libby.bakalar@alaska.gov>
Date: Tue, 17 Feb 2009 09:32:04 -0900
To: Jim Gottstein <jim.gottstein@psychrights.org>
CC: "Kraly, Stacie L (LAW)" <stacie.kraly@alaska.gov>

1 p.m. should work. Not sure what you mean by manuals and descriptions—if you can be more specific I can let you know if it's something publicly available online or if it will need to come out at the depo.

Libby Bakalar
Assistant Attorney General
Office of the Attorney General
P.O. Box 110300
Juneau, Alaska 99801-0300
(907) 465-4135 (direct)
(907) 465-3600 (main)
(907) 465-2539 (fax)

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, February 17, 2009 9:13 AM
To: Bakalar, Elizabeth M (LAW)
Cc: Kraly, Stacie L (LAW); Matt Joy; Lisa Smith
Subject: Re: Depositions

Hi Libby,

I'm sorry I missed that you proposed the afternoon. I will re-notice the deposition. Does 1:00 work? Is there any way we can get the manuals and file descriptions, etc., enough ahead of time to make the deposition more efficient?

Thanks for the other names.

I'm also planning on taking the depositions of at least some of the psychiatrists. I've started to try and coordinate with their schedules, advising them I was thinking it would be a month or so out. When I hear back (or not) I will contact you to coordinate with you as well.

Bakalar, Elizabeth M (LAW) wrote:
Hi Jim,

I observed that you noticed Dave Campana's deposition for 10 a.m. on 2/26, but as we stated in this earlier email below, he is not available until the afternoon of that day, so the morning won't work. As already indicated we can do the afternoon though. Also, I have the additional information that you requested re: appropriate people to depose re: other databases and records as follows:

1. API: Belinda Hopkins and Steve Schneider
2. DJJ: Dave Salmon
3. OCS: Stevan "Tim" Huffman

All of these folks' mailing addresses are available online on the state website http://www.state.ak.us/local/whtpage1.html. So far no one has any major leave planned that we're aware of.

Thanks,
Libby

Libby Bakalar
Assistant Attorney General
Office of the Attorney General
P.O. Box 110300
Juneau, Alaska 99801-0300
(907) 465-4135 (direct)
(907) 465-3600 (main)
(907) 465-2539 (fax)

From: Bakalar, Elizabeth M (LAW)
Sent: Wednesday, February 11, 2009 8:54 AM
To: 'Jim Gottstein'
Cc: Kraly, Stacie L (LAW)
Subject: Dave Campana's Deposition

Hi Jim,

We are working on figuring out the best date for Dave's deposition. The dates that would work best on our end are the afternoons of Feb 26 and/or 27th. Feb. 19 would be the third choice. We'd prefer to do the depo at your office. Stacie will be there in person, in Anchorage, and I will be telephonic.

Thanks,
Libby

Libby Bakalar
Assistant Attorney General
Office of the Attorney General
P.O. Box 110300
Juneau, Alaska 99801-0300
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jim.gottstein[[at]]psychrights.org
http://psychrights.org/

PsychRights®
Law Project for Psychiatric Rights

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing

Subject: RE: Discovery in Psych Rights
From: "Bakalar, Elizabeth M (LAW)" <libby.bakalar@alaska.gov>
Date: Tue, 24 Feb 2009 16:51:10 -0900
To: Jim Gottstein <jim.gottstein@psychrights.org>
CC: "Kraly, Stacie L (LAW)" <stacie.kraly@alaska.gov>

That's fine, with the understanding that we're not agreeing to a date certain at this point and re-notice will be subject to further discussions and/or motion practice as we get closer to the time. So I believe we're on the same page with how to proceed.

Libby Bakalar
Assistant Attorney General
Office of the Attorney General
P.O. Box 110300
Juneau, Alaska 99801-0300
(907) 465-4135 (direct)
(907) 465-3600 (main)
(907) 465-2539 (fax)

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, February 24, 2009 4:17 PM
To: Bakalar, Elizabeth M (LAW)
Cc: Kraly, Stacie L (LAW); Lisa Smith
Subject: Re: Discovery in Psych Rights

Hi Libby,

I will serve you with a re-notice of deposition for say three weeks out, which when we get closer we will presumably have another discussion about.

Bakalar, Elizabeth M (LAW) wrote:
Good enough Jim, we understand that concern. Thanks for your understanding and courtesy on this point and we will be in touch. Procedurally, will you be issuing a notice that cancels Thursday's deposition?

Libby Bakalar
Assistant Attorney General
Office of the Attorney General
P.O. Box 110300
Juneau, Alaska 99801-0300
(907) 465-4135 (direct)
(907) 465-3600 (main)
(907) 465-2539 (fax)

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, February 24, 2009 3:51 PM
To: Bakalar, Elizabeth M (LAW)
Cc: Kraly, Stacie L (LAW); Lisa Smith
Subject: Re: Discovery in Psych Rights

Hi Libby,

I will agree to postpone it for two weeks or maybe a bit more, but I don't think I can agree to anything that open-ended.

Bakalar, Elizabeth M (LAW) wrote:
Jim,

In preparing for Dave Campana's upcoming deposition, Stacie and I have taken a more extensive look at the complaint and we have concerns about engaging in discovery at this point. As a result of our review we are preparing a dispositive motion that we hope to file in the next two weeks. Therefore we would request that you agree to postpone Dave's deposition until after the court has ruled on our motion. If you are unable to agree to that postponement, we'll file an expedited motion to quash the deposition on similar grounds. We apologize for the late notice but we need to know by COB today if you can agree to this plan.

Libby

Libby Bakalar
Assistant Attorney General
Office of the Attorney General
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--

James B. (Jim) Gottstein, Esq.

RICHARDSON PATRICK WESTBROOK & BRICKMAN, LLC

Christiaan Marcum
843.727.6522 Direct Dial No.
843.216.6509 Direct Fax No.
cmarcum@rpwb.com

September 5, 2007

VIA FIRST CLASS MAIL AND EMAIL
Eric Rothschild, Esquire
Pepper Hamilton LLP
3000 Two Logan Square
Eighteenth and Arch Streets
Philadelphia, PA 19103-2799

Re: State of Alaska v. Eli Lilly and Company
Case No.: 3AN-06-5630CIV

Dear Eric:

Please find enclosed a list of available data fields from the Medicaid claims database, bates numbered **ZYP-AK-03354** to **ZYP-AK-03360**.

With kindest regards, I remain,

Sincerely yours,

Christiaan Marcum

cc: Matthew L. Garretson, Esq.
Joseph W. Steele, Esq.
Eric T. Sanders, Esq.
David Suggs, Esq.

EXHIBIT F
PAGE 1 OF 8

```
MACRO CPHIST
FILE CPHIST
H-ICN                      1   7   P HEADING ('CCN')
H-JULIAN                   1   2   P HEADING ('JULIAN')
H-INVOICE-TYPE             8   2   N HEADING ('INV' 'TYP')
H-CLAIM-CDE               10   3   N
H-CLAIM-TYP               10   2   N HEADING ('CLM' 'TYP')
H-CLAIM-TYP-MOD           12   1   N HEADING ('C' 'T' 'M')
H-PROV-NO                 13   7   A HEADING ('PROV' 'NO')
H-PROV-NO2                13   2   A
H-PROV-NO6                13   6   A HEADING ('BILLING' 'PROV')
H-PROV-NO6-7              18   2   A
H-SVC-PROV-NO             20   7   A HEADING ('SVC' 'PROV' 'NO')
H-SVC-PROV-NO3            20   3   A
H-SVC-PROV-NO1            20   1   A
H-SVC-PROV-NO6            21   6   A
H-RECIP-NO                27   6   P  0 HEADING ('RECIP' 'NUMBER')
H-NDC-PROCEDURE           33  11   A HEADING ('NDC/' 'PROC')
H-NDC-1-8                 33   8   A
H-NDC-LABELER-CODE        33   5   A
H-NDC                     33  11   A HEADING ('NDC' 'CODE')
H-PROCEDURE               33  11   A HEADING 'PROCEDURE'
H-PROC-CODE               33  11   A
H-PROC-3                  33   3   A
H-PROC                    33   5   A HEADING ('PROC' 'CODE')
H-PROC-6                  38   1   A
H-PROC-MOD                33   7   A
H-PROC-MODIFIER           38   2   A HEADING ('PROC' 'MOD')
H-HCPC-MODIFIER           38   2   A HEADING ('PROC' 'MOD')
H-TREAT-PLACE             40   1   A HEADING ('PLACE OF' 'SERVICE')
H-ADMIT-HOUR              41   2   A
H-MOTHA-BABY-IND          43   1   A
H-TOS                     44   1   A HEADING ('TYPE' 'OF' 'SERV')
H-UNITS-VISITS-QUANT      45   5   P 3 HEADING ('UNITS')
H-UNITS-NODECIMAL         45   5   P
H-FROM-DATE               50   4   P HEADING ('FROM' 'DATE')
H-THRU-DATE               54   4   P HEADING ('THRU' 'DATE')
H-BILLING-DATE            58   4   P
H-DATE-ENTERED            62   4   P
H-STATUS-DATE             66   4   P   HEADING ('STATUS' 'DATE')
H-PAYMENT-DATE            70   4   P   HEADING ('PAYMENT' 'DATE')
H-BILLED-CHARGES          74   5   P 2 HEADING ('BILLED' 'CHARGES')
H-TOT-DOC-CHARGE          79   5   P 2 HEADING ('TOT' 'DOC' 'CHARGE')
H-LINE-TPL-AMT            84   4   P 2 HEADING ('LINE' 'TPL' 'AMOUNT')
H-TOT-TPL-AMT             88   4   P 2 HEADING ('TPL' 'AMOUNT')
H-CO-PAY-AMT              92   4   P 2 HEADING ('CO-PAY' 'AMOUNT')
H-ALLOWED-AMT             96   5   P 2 HEADING ('ALLOWED' 'AMOUNT')
H-PAYMENT                101   5   P 2 HEADING ('PAID' 'AMT')
H-PA-NUMBER              106   5   P HEADING ('PRIOR' 'AUTH' 'NUMBER')
H-ACCID-IND              111   1   A
H-STICKER-IND            112   1   A
H-ATTACHMENT-IND1        113   2   A
H-ATTACHMENT-IND2        115   2   A
H-ATTACHMENT-IND3        117   2   A
H-ATTACHMENT-IND4        119   2   A
H-ATTACHMENT-IND5        121   2   A
H-EMPLOY-IND             123   1   A
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EXHIBIT F
PAGE 2 OF 8

ZYP-AK-03354

001441

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H-EPSDT-IND                    124   1   A
H-FAM-PLAN-IND                 125   1   A
H-LOCKIN-IND                   126   1   A
H-PRIOR-AUTH-IND               127   1   A
H-PROV-REV-IND                 128   1   A
H-RECIP-REV-IND                129   1   A
H-TPL-IND                      130   1   A HEADING ('TPL' 'IND')
H-ATTACH-ICN                   131   7   P
H-MED-REC-NO                   138  11   A HEADING ('MED' 'REC' 'NO')
H-DIAG                         149   5   A HEADING 'DIAG'
H-SEC-DIAG                     154   5   A HEADING ('SEC' 'DIAG')
H-ADJ-REASON                   159   2   A
H-COLLOCATION                  161  10   N
H-CC-COMPONENT                 161   2   N
H-COLLOCATE-CODE               163   8   N HEADING ('COLLOCATION' 'CODE')
H-FORMER-ICN                   171   7   P HEADING ('FORMER' 'CCN')
H-FORMER-PAYMENT-DATE          178   4   P HEADING ('PRIOR' 'PAYMENT' 'DATE')
H-FORMER-REMIT-ID              182   4   P
H-FORMER-CHECK-NUM             186   5   P HEADING ('FORMER' 'WARRANT #')
H-OPER-CDE                     191   3   A
H-RECIP-CNTL                   194   6   P  0 HEADING ('RECIP' 'CNTL')
H-ELIG-PROGRAM-CODE            200   2   A
H-ELIG-CODE                    203   2   N HEADING ('ELIG' 'CODE')
H-ELIG-SUBTYPE                 205   2   A HEADING ('SUB' 'TYPE')
H-ELIG-CASH-GRANT              207   1   A
H-PROV-TYPE                    208   2   A HEADING ('PROV' 'TYPE')
H-PROV-SPEC                    210   3   A HEADING ('PROV' 'SPEC')
H-MAX-TIME                     213   4   A
H-DRG-CODE                     217   3   A
H-MDC-CODE                     220   2   A
H-REMIT-ID                     222   4   P
H-CHECK-NUM                    226   5   P HEADING ('CHECK' 'WARRANT #')
H-COS                          231   2   A +
                               HEADING ('CATEGORY' 'OF' 'SERVICE')
H-STATUS                       233   1   N HEADING ('S' 'T' 'A')
H-LINE-NOS                     234   2   N
H-SIG-IND                      236   1   A
H-UB82-BILL-TYPE               237   3   A HEADING ('TYPE' 'OF' 'BILL')
H-BT-FACILITY                  237   1   A
H-BT-BILL-CLASS                238   1   A
H-BT-FREQUENCY                 239   1   A
*
H-ERRORS                       240   3   A OCCURS 10 INDEX ERRIDX
 H-EACH-ERROR      H-ERRORS          2   P
 H-EACH-ERROR-FLAG H-ERRORS +2       1   A
*
H-EACH-ERROR1                  240   2   P HEADING ('ERR' 'CDE' '#1')
H-EACH-ERROR-FLAG1             242   1   A HEADING ('ERR' 'FLG' '#1')
H-EACH-ERROR2                  243   2   P HEADING ('ERR' 'CDE' '#2')
H-EACH-ERROR-FLAG2             245   1   A HEADING ('ERR' 'FLG' '#2')
H-EACH-ERROR3                  246   2   P HEADING ('ERR' 'CDE' '#3')
H-EACH-ERROR-FLAG3             248   1   A HEADING ('ERR' 'FLG' '#3')
H-EACH-ERROR4                  249   2   P HEADING ('ERR' 'CDE' '#4')
H-EACH-ERROR-FLAG4             251   1   A HEADING ('ERR' 'FLG' '#4')
H-EACH-ERROR5                  252   2   P HEADING ('ERR' 'CDE' '#5')
H-EACH-ERROR-FLAG5             254   1   A HEADING ('ERR' 'FLG' '#5')
H-EACH-ERROR6                  255   2   P
```

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H-EACH-ERROR-FLAG6          257   1   A
H-EACH-ERROR7               258   2   P
H-EACH-ERROR-FLAG7          260   1   A
H-EACH-ERROR8               261   2   P
H-EACH-ERROR-FLAG8          263   1   A
H-EACH-ERROR9               264   2   P
H-EACH-ERROR-FLAG9          266   1   A
H-EACH-ERROR10              267   2   P
H-EACH-ERROR-FLAG10         269   1   A
*
H-HIST-ERR                  270   3   A OCCURS 10 INDEX HSTIOX
 H-EACH-HIST-ERR       H-HIST-ERR      2   P
 H-EACH-HIST-ERR-FLAG  H-HIST-ERR +2   1   A
*
H-EACH-HIST-ERR1            270   2   P HEADING ('HIST' 'ERR1')
H-EACH-HIST-ERR-FLAG1       272   1   A HEADING ('HIST' 'FLG1')
H-EACH-HIST-ERR2            273   2   P HEADING ('HIST' 'ERR2')
H-EACH-HIST-ERR-FLAG2       275   1   A HEADING ('HIST' 'FLG2')
H-EACH-HIST-ERR3            276   2   P HEADING ('HIST' 'ERR3')
H-EACH-HIST-ERR-FLAG3       278   1   A HEADING ('HIST' 'FLG3')
H-EACH-HIST-ERR4            279   2   P HEADING ('HIST' 'ERR4')
H-EACH-HIST-ERR-FLAG4       281   1   A
H-EACH-HIST-ERR5            282   2   P HEADING ('HIST' 'ERR5')
H-EACH-HIST-ERR-FLAG5       284   1   A
H-EACH-HIST-ERR6            285   2   P
H-EACH-HIST-ERR-FLAG6       287   1   A
H-EACH-HIST-ERR7            288   2   P
H-EACH-HIST-ERR-FLAG7       290   1   A
H-EACH-HIST-ERR8            291   2   P
H-EACH-HIST-ERR-FLAG8       293   1   A
H-EACH-HIST-ERR9            294   2   P
H-EACH-HIST-ERR-FLAG9       296   1   A
H-EACH-HIST-ERR10           297   2   P
H-EACH-HIST-ERR-FLAG10      299   1   A
H-EACH-OVER-EOB1            300   2   P HEADING ('EOB' 'CDE' '#1')
H-EACH-OVER-EOB-FLAG1       302   1   A HEADING ('EOB' 'FLG' '#1')
H-EACH-OVER-EOB2            303   2   P HEADING ('EOB' 'CDE' '#2')
H-EACH-OVER-EOB-FLAG2       305   1   A HEADING ('EOB' 'FLG' '#2')
H-EACH-OVER-EOB3            306   2   P HEADING ('EOB' 'CDE' '#3')
H-EACH-OVER-EOB-FLAG3       308   1   A HEADING ('EOB' 'FLG' '#3')
H-EACH-OVER-EOB4            309   2   P HEADING ('EOB' 'CDE' '#4')
H-EACH-OVER-EOB-FLAG4       311   1   A HEADING ('EOB' 'FLG' '#4')
H-EACH-OVER-EOB5            312   2   P HEADING ('EOB' 'CDE' '#5')
H-EACH-OVER-EOB-FLAG5       314   1   A HEADING ('EOB' 'FLG' '#5')
H-EACH-OVER-EOB6            315   2   P
H-EACH-OVER-EOB-FLAG6       317   1   A
H-EACH-OVER-EOB7            318   2   P
H-EACH-OVER-EOB-FLAG7       320   1   A
H-EACH-OVER-EOB8            321   2   P
H-EACH-OVER-EOB-FLAG8       323   1   A
H-EACH-OVER-EOB9            324   2   P
H-EACH-OVER-EOB-FLAG9       326   1   A
H-EACH-OVER-EOB10           327   2   P
H-EACH-OVER-EOB-FLAG10      329   1   A
H-CUTBACK-DAYS-UNITS        330   5   P 3
H-CUTBACK-AMT               335   4   P 2
H-RESUBMITTAL-NUM1          339   7   P HEADING ('RTD #')
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```
H-RESUBMITTAL-NUM2          346   7   P
H-RESUBMITTAL-NUM3          353   7   P
H-TPL-STATUS                360   1   A
H-PRICING-LEVEL             361   1   A
H-PRICING-PCT               362   2   P
H-LOCKIN-PROVIDER           364   7   A
H-OLDEST-DOC-DATE           371   4   P
H-LATEST-DOC-DATE           375   4   P
H-EMG-LTC-IND               379   1   A  HEADING ('EMERG' 'IND')
H-SPEC-PROG-IND             380   2   A
H-NPI                       382  10   A
H-SURG-IND                  392   1   A
H-FFP-TYPE                  393   1   A
*
H-TT-DEDUCTIBLE             414   5   P 2
H-TT-COINSURANCE            419   5   P 2
H-TT-MEDICARE-BILLED        424   5   P 2
H-TT-MEDICAID-BILLED        429   5   P 2
H-TT-MEDICARE-PAID-AMT      434   5   P 2
H-TT-MCARE-PAY-DATE         439   4   P
H-TT-BLOOD-DED              443   4   P  HEADING ('BLOOD' 'DEDUCTIBLE')
H-TT-ASSIGNMENT-IND         447   1   A
H-TT-INST-TYPE              448   1   A
H-TT-ATTEND-PHYS            449   7   A
H-TT-ADMIT-PHYS             456   7   A
H-TT-PAT-STATUS             463   2   A
H-TT-DSCHG-DATE             465   4   P
H-TT-TIME-OF-DEATH          469   2   N
H-TT-ADMIT-DATE             474   4   P
H-TT-ADMIT-SOURCE           478   1   A
H-TT-ADMIT-HOUR             479   2   A
H-TT-NATURE-ADMISN          481   1   A HEADING ('NATURE' 'OF' 'ADMIT')
H-TT-COV-DAYS               482   2   P
H-TT-NON-COV-DAYS           484   2   P
*
H-TT-OCCURRENCE-DATA        486   6   A  OCCURS 5  INDEX TTOIDX
H-TT-OCC-CODE          H-TT-OCCURRENCE-DATA          2   A
H-TT-OCC-DATE          H-TT-OCCURRENCE-DATA     +2   4   P
*
H-TT-OCC-SPAN-CODE          516   2   A
H-TT-OCC-SPAN-FROM          518   4   P
H-TT-OCC-SPAN-THRU          522   4   P
H-TT-COND-CODE1             526   2   A
H-TT-COND-CODE2             528   2   A
H-TT-COND-CODE3             530   2   A
H-TT-COND-CODE4             532   2   A
H-TT-COND-CODE5             534   2   A
*
H-TT-VALUE-CODES            536   6   A  OCCURS  8 INDEX VCDIDX
H-TT-VAL-CODE          H-TT-VALUE-CODES              2   A
H-TT-VAL-AMT           H-TT-VALUE-CODES         +2   4   P 2
*
H-TT-BLOOD-FURNISHED        584   2   A
H-TT-BLOOD-REPLACED         586   2   A
H-TT-BLOOD-NOT-REPL         588   2   A
*
H-TT-REVENUE-CODE-DATA      590  24   A  OCCURS 46 INDEX INDXB
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H-TT-PROC-CODE          H-TT-REVENUE-CODE-DATA          5   A
H-TT-REV-CODE           H-TT-REVENUE-CODE-DATA          3   A
H-TT-FILLER             H-TT-REVENUE-CODE-DATA    +3    2   A
H-TT-PROC-MODIFIER      H-TT-REVENUE-CODE-DATA    +5    2   A
H-TT-REV-UNITS          H-TT-REVENUE-CODE-DATA    +7    2   P
H-TT-REV-AMT            H-TT-REVENUE-CODE-DATA    +9    5   P 2
H-TT-REV-NON-COVD-AMT   H-TT-REVENUE-CODE-DATA    +14   5   P 2
H-TT-PROC-ALWD-AMT      H-TT-REVENUE-CODE-DATA    +19   5   P 2
*
H-TT-SURG-PROC1          1694   5   A  HEADING ('SURG' 'PROC')
H-TT-SURG-DATE1          1699   4   P
H-TT-SURG-PROC2          1703   5   A
H-TT-SURG-DATE2          1708   4   P
H-TT-LTC-PATIENT-LIABILITY  1712  4  P
H-TT-SPEC-PROG-IND       1716   1   A
*
H-HO-ATTEN-PHYS           414   7   A   HEADING ('ATTENDING' 'PHYSICIAN')
H-HO-ADMIT-PHYS           421   7   A
H-HO-PAT-STAT             428   2   A   HEADING ('PAT' 'STAT')
H-HO-DSCHG-DATE           430   4   P   HEADING ('DISCHARGE' 'DATE')
H-HO-TIME-OF-DEATH        434   2   N
H-HO-ADMIT-DATE           437   4   P   HEADING ('ADMIT' 'DATE')
H-HO-ADMIT-SOURCE         441   1   A   HEADING ('REFERRAL' 'SOURCE')
H-HO-ADMIT-NATURE         442   1   A   HEADING ('NATURE' 'OF ADMIT')
H-HO-COV-DAYS-9           443   2   P 0 HEADING ('COV' 'DAYS')
H-HO-NON-COV-DAYS         445   2   P 0 HEADING ('NON' 'COV' 'DAYS')
*
H-HO-OCCURRENCE-DATA      447   6   A    OCCURS 5  INDEX HOCIDX
H-HO-OCC-CODE          H-HO-OCCURRENCE-DATA      2  A
H-HO-OCC-DATE          H-HO-OCCURRENCE-DATA +2   4  P
*
H-HO-OCC-SPAN-CODE        447   2   A
H-HO-OCC-SPAN-FROM        479   4   P
H-HO-OCC-SPAN-THRU        483   4   P
H-HO-COND-CODE1           487   2   A
H-HO-COND-CODE2           489   2   A
H-HO-COND-CODE3           491   2   A
H-HO-COND-CODE4           493   2   A
H-HO-COND-CODE5           495   2   A
*
H-HO-VALUE-CODES          497   6   A  OCCURS 8 INDEX HOVIDX
H-HO-VAL-CODE       H-HO-VALUE-CODES        2  A
H-HO-VAL-AMT        H-HO-VALUE-CODES   +2   4  P
*
H-HO-BLOOD-FURN           545   2   A
H-HO-BLOOD-REPL           547   2   A
H-HO-BLOOD-NOT-REPL       549   2   A
*
H-HO-REV-DATA              551  23   A  OCCURS 46 INDEX INDXA
H-HO-PROC-CODE          H-HO-REV-DATA          5   A  +
                        HEADING ('PROC' 'CODE')
H-HO-REV-CODE           H-HO-REV-DATA          3   A  +
                        HEADING ('REV' 'CODE')
H-HO-REV-CODE2          H-HO-REV-DATA          2   A
H-HO-FILLER             H-HO-REV-DATA     +3   2   N
H-HO-REV-UNITS-9        H-HO-REV-DATA     +5   2   P  +
                        HEADING ('REV' 'UNITS')
```

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```
H-HO-REV-AMT              H-HO-REV-DATA      +7   5   P 2  +
                          HEADING ('REV' 'AMOUNT')
H-HO-REV-NON-COVD-AMT     H-HO-REV-DATA      +12  5   P 2  +
                          HEADING ('REV' 'NON COVD' 'AMOUNT')
H-HO-PROC-ALWD-AMT        H-HO-REV-DATA      +17  5   P 2
H-HO-FILLER2              H-HO-REV-DATA      +22  1   A
*
H-HO-SURG-PROC1           1609   5   A  HEADING ('SURG' 'PROC' 'CODE')
H-HO-SURG-DATE1           1614   4   P
H-HO-SURG-PROC2           1618   5   A  HEADING ('SURG' 'PROC' 'CODE2')
H-HO-SURG-DATE2           1623   4   P
H-HO-LTC-PATIENT-LIABILITY 1627  4   P 2
H-HO-LTC-LOC              1631   2   A
H-HO-PER-DIEM             1633   4   P 2
H-HO-LTC-HOME-LEAVE-DAYS  1637   2   N
H-HO-LTC-PAE-DATE         1639   4   P
*
H-TT-PR-DEDUCTIBLE         414   5   P 2 HEADING ('DEDUCTIBLE')
H-TT-PR-COINSURANCE        419   5   P 2 HEADING ('COINSURANCE')
H-TT-PR-MEDICARE-BILLED    424   5   P 2
H-TT-PR-MEDICAID-BILLED    429   5   P 2 HEADING ('MEDICAID' 'BILLED' +
                                         'AMOUNT')
H-TT-PR-MEDICARE-PAID-AMT  434   5   P 2
H-TT-PR-MCARE-PAY-DATE     439   4   P
H-TT-PR-BLOOD-DED          443   4   P
H-TT-PR-REFER-PROV         447   7   A
H-TT-PR-TREAT-PLACE        454   1   A
H-TT-PR-LAB-IND            455   1   A
H-TT-PR-ASSIGNMENT-IND     456   1   A
H-TT-PR-INST-TYPE          457   1   A
H-TT-PR-MCARE-ALLOWED-AMT  458   8   N 2
*
H-PR-REFER-PROV            414   7   A  HEADING ('REFER' 'PROV')
H-PR-LAB-IND               421   1   A
H-PR-DME-CERT-DATE         422   4   P
*
H-TR-REFER-PROV            414   7   A
H-TR-EMER-IND              421   1   A
H-TR-DIAG-IND              422   1   A
H-TR-CONTROL-NO            423   6   A
*
H-DA-TOOTH                 414   2   A  HEADING ('T' 'O' 'O' 'T' 'H')
H-DA-SURF-1                416   1   A  HEADING ('S' 'U' 'R' 'F' '1')
H-DA-SURF-2                417   1   A  HEADING ('S' 'U' 'R' 'F' '2')
H-DA-SURF-3                418   1   A  HEADING ('S' 'U' 'R' 'F' '3')
H-DA-SURF-4                419   1   A  HEADING ('S' 'U' 'R' 'F' '4')
H-DA-SURF-5                420   1   A  HEADING ('S' 'U' 'R' 'F' '5')
H-DA-EMERGENCY-IND         421   1   A
*
H-PH-PRESC-PHYS            414   7   A HEADING ('PRESCR' 'PHYS')
H-PH-RX-NO                 421   10  A HEADING ('RX' '#')
H-PH-REFILL-CODE           431   1   A HEADING ('REFILL' 'CODE')
H-PH-DRUG-PRICE            432   5   P 2 HEADING ('DRUG' 'PRICE')
H-PH-DAYS-SUPPLY           437   2   P   HEADING ('DAY' 'SUP')
H-PH-COMPOUND-CODE         439   1   A
*
H-EPSDT-SVC-CODE           414   1   A
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MEND

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Department of Justice

FOR IMMEDIATE RELEASE
Thursday, January 15, 2009
WWW.USDOJ.GOV

CIV
(202) 514-2007
TDD (202) 514-1888

Eli Lilly and Company Agrees to Pay $1.415 Billion to Resolve Allegations of Off-label Promotion of Zyprexa

$515 Million Criminal Fine Is Largest Individual Corporate Criminal Fine in History; Civil Settlement up to $800 Million

American pharmaceutical giant Eli Lilly and Company today agreed to plead guilty and pay $1.415 billion for promoting its drug Zyprexa for uses not approved by the Food and Drug Administration (FDA), the Department of Justice announced today. This resolution includes a criminal fine of $515 million, the largest ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind. Eli Lilly will also pay up to $800 million in a civil settlement with the federal government and the states.

Eli Lilly agreed to enter a global resolution with the United States to resolve criminal and civil allegations that it promoted its antipsychotic drug Zyprexa for uses not approved by the FDA, the Department said. Such unapproved uses are also known as "off-label" uses because they are not included in the drug's FDA approved product label.

Assistant Attorney General for the Civil Division Gregory G. Katsas and acting U.S. Attorney for the Eastern District of Pennsylvania Laurie Magid today announced the filing of a criminal information against Eli Lilly for promoting Zyprexa for uses not approved by the FDA. Eli Lilly, headquartered in Indianapolis, is charged in the information with promoting Zyprexa for such off-label or unapproved uses as treatment for dementia, including Alzheimer's dementia, in elderly people.

The company has signed a plea agreement admitting its guilt to a misdemeanor criminal charge. Eli Lilly also signed a civil settlement to resolve civil claims that by marketing Zyprexa for unapproved uses, it caused false claims for payment to be submitted to federal insurance programs such as Medicaid, TRICARE and the Federal Employee Health Benefits Program, none of which provided coverage for such off-label uses.

The plea agreement provides that Eli Lilly will pay a criminal fine of $515 million and forfeit assets of $100 million. The civil settlement agreement provides that Eli Lilly will pay up to an additional $800 million to the federal government and the states to resolve civil allegations originally brought in four separate lawsuits under the *qui tam* provisions of the federal False Claims Act. The federal share of the civil settlement amount is $438 million. Under the terms of the civil settlement, Eli Lilly will pay up to $361 million to those states that opt to participate in the agreement.

Under the Food, Drug, and Cosmetic Act (FDCA), a company must specify the intended uses of a product in its new drug application to the FDA. Before approving a drug, the FDA must determine that the drug is safe and effective for the use proposed by the company. Once approved, the drug may not be marketed or promoted for off-label uses.

The FDA originally approved Zyprexa, also known by the chemical name olanzapine, in Sept. 1996 for the treatment of manifestations of psychotic disorders. In March 2000, FDA approved Zyprexa for the short-term treatment of acute manic episodes associated with Bipolar I Disorder. In Nov. 2000, FDA approved Zyprexa for the short term treatment of schizophrenia in place of the management of the manifestations of psychotic disorders. Also in Nov. 2000, FDA approved Zyprexa for maintaining treatment response in schizophrenic patients who had been stable for approximately eight weeks and were then followed for a period of up to eight months. Zyprexa has never been approved for the treatment of dementia or Alzheimer's dementia.

The criminal information, filed in the Eastern District of Pennsylvania, alleges that from Sept. 1999 through at least Nov. 2003, Eli Lilly promoted Zyprexa for the treatment of agitation, aggression, hostility, dementia, Alzheimer's dementia, depression and generalized sleep disorder. The information alleges that Eli Lilly's management created marketing materials promoting Zyprexa for off-label uses, trained its sales force to disregard the law and directed its sales personnel to promote Zyprexa for off-label uses.

The information alleges that beginning in 1999, Eli Lilly expended significant resources to promote Zyprexa in nursing homes and assisted-living facilities, primarily through its long-term care sales force. Eli Lilly sought to convince doctors to prescribe Zyprexa to treat patients with disorders such as dementia, Alzheimer's dementia, depression, anxiety, and sleep problems, and behavioral symptoms such as agitation, aggression, and hostility.

The information further alleges that the FDA never approved Zyprexa for the treatment of dementia, Alzheimer's dementia, psychosis associated with Alzheimer's disease, or the cognitive deficits associated with dementia.

The information also alleges that building on its unlawful promotion and success in the long-term care market, Eli Lilly executives decided to market Zyprexa to primary-care physicians. In Oct. 2000, Eli Lilly began this off-label marketing campaign targeting primary care physicians, even though the company knew that there was virtually no approved use for Zyprexa in the primary-care market. Eli Lilly trained its primary-care physician sales representatives to promote Zyprexa by focusing on symptoms, rather than Zyprexa's FDA approved indications.

The *qui tam* lawsuits alleged that between Sept. 1999 and the end of 2005, Eli Lilly promoted Zyprexa for use in patients of all ages and for the treatment of anxiety, irritability, depression, nausea, Alzheimer's and other mood disorders. The *qui tam* lawsuits also alleged that the company funded continuing medical education programs, through millions of dollars in grants, to promote off-label uses of its drugs, in violation of the FDA's requirements.

"Off-label promotion of pharmaceutical drugs is a serious crime because it undermines the FDA's role in protecting the American public by determining that a drug is safe and effective for a particular use before it is marketed," said Gregory G. Katsas, Assistant Attorney General for the Civil Division. "This settlement demonstrates the Department's ongoing diligence in prosecuting cases involving violations of the Food, Drug, and Cosmetic Act, and recovering taxpayer dollars used to pay for drugs sold as a result of off-label marketing campaigns."

"When pharmaceutical companies ignore the government's process for protecting the public, they undermine the integrity of the doctor-patient relationship and place innocent people in harm's way," said acting U.S. Attorney for the Eastern District of Pennsylvania, Laurie Magid. "Off-label marketing created unnecessary risks for patients. People have an absolute right to their doctor's medical expertise, and to know that their health care provider's judgment has not be clouded by misinformation from a company trying to build its bottom line."

The global resolution includes the following agreements:

- A plea agreement signed by Eli Lilly admitting guilt to the criminal charge of misbranding. Specifically, Eli Lilly admits that between Sept. 1999 and March 31, 2001, the company promoted Zyprexa in elderly populations as treatment for dementia, including Alzheimer's dementia. Eli Lilly has agreed to pay a $515 million criminal fine and to forfeit an additional $100 million in assets.
- A civil settlement between Eli Lilly, the United States and various States, in which Eli Lilly will pay up to $800 million to the federal government and the states to resolve False Claims Act claims and related state claims by Medicaid and other federal programs and agencies including TRICARE, the Federal Employees Health Benefits Program, Department of Veterans Affairs, Bureau of Prisons and the Public Health Service Entities. The federal government will receive $438,171,544 from the civil settlement. The state Medicaid programs and the District of Columbia will share up to $361,828,456 of the civil settlement, depending on the number of states that participate in the settlement.
- The *qui tam* relators will receive $78,870,877 from the federal share of the settlement amount.
- A Corporate Integrity Agreement (CIA) between Eli Lilly and the Office of Inspector General of the Department of Health and Human Services. The five-year CIA requires, among other things, that a Board of Directors committee annually review the company's compliance program and certify its effectiveness; that certain managers annually certify that their departments or functional areas are compliant; that Eli Lilly send doctors a letter notifying them about the global settlement; and that the company post on its website

information about payments to doctors, such as honoraria, travel or lodging. Eli Lilly is subject to exclusion from Federal health care programs, including Medicare and Medicaid, for a material breach of the CIA and subject to monetary penalties for less significant breaches.

"OIG's Corporate Integrity Agreement will increase the transparency of Eli Lilly's interactions with physicians and strengthen Eli Lilly's accountability for its compliance with the law," said Department of Health and Human Services Inspector General Daniel R. Levinson. "This historic resolution demonstrates the Government's commitment to improve the integrity of drug promotion activities."

In addition to the $1.415 billion criminal and civil settlement announced today, Eli Lilly previously agreed to pay $62 million to settle consumer protection lawsuits brought by 33 states. The state consumer protection settlements were announced on Oct. 7, 2008.

"Today's announcement of the filing of a criminal charge and the unprecedented terms of this settlement demonstrates the government's increasing efforts aimed at pharmaceutical companies that choose to put profits ahead of the public's health," said Special Agent-in-Charge Kim Rice of FDA's Office of Criminal Investigations. "The FDA will continue to devote resources to criminal investigations targeting pharmaceutical companies that disregard the safeguards of the drug approval process and recklessly promote drugs for uses for which they have not been proven to be safe and effective."

"The illegal scheme used by Eli Lilly significantly impacted the integrity of TRICARE, the Department of Defense's healthcare system," said Ed Bradley, Special Agent-in-Charge, Defense Criminal Investigative Service. "This illegal activity increases patients' costs, threatens their safety and negatively affects the delivery of healthcare services to the over nine million military members, retirees and their families who rely on this system. Today's charges and settlement demonstrate the ongoing commitment of the Defense Criminal Investigative Service and its partners in law enforcement to investigate and prosecute those that abuse the government's healthcare programs at the expense of the taxpayers and patients."

"This case should serve as still another warning to all those who break the law in order to improve their profits," said Patrick Doyle, Special Agent-in-Charge of the Office of Inspector General for the Department of Health and Human Services in Philadelphia. "OIG, working with our law enforcement partners, will pursue and bring to justice those who would steal from vulnerable beneficiaries and the taxpayers."

The civil settlement resolves four *qui tam* actions filed in the Eastern District of Pennsylvania: *United States ex rel. Rudolf, et al., v. Eli Lilly and Company,* Civil Action No. 03-943 (E.D. Pa.)*; United States ex rel. Faltaous v. Eli Lilly and Company,* Civil Action No. 06-2909 (E.D. Pa.)*; United States ex rel. Woodward v. Dr. George B. Jerusalem, et al.,* Civil Action No. 06-5526 (E.D. Pa.)*;* and *United States ex rel. Vicente v. Eli Lilly and Company,* Civil Action No. 07-1791 (E.D. Pa.). All of those cases were filed by former Eli Lilly sales representatives.

The criminal case is being prosecuted by the U.S. Attorney's Office for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the Justice Department's Civil Division. The civil settlement was reached by the U.S. Attorney's Office and the Commercial Litigation Branch of the Justice Department's Civil Division.

This matter was investigated by the FDA's Office of Criminal Investigations, the Defense Criminal Investigative Service and the Department of Health and Human Services Office of Inspector General.

Assistance was provided by representatives of FDA's Office of Chief Counsel and the National Association of Medicaid Fraud Control Units.

The Corporate Integrity Agreement was negotiated by the Office of Inspector General of the Department of Health and Human Services.

Eli Lilly's guilty plea and sentence is not final until accepted by the U.S. District Court.

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Pediatric bipolar disorder: An object of study in the creation of an illness

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Abstract. In the past decade bipolar disorder in children has been diagnosed with rapidly increasing frequency in North America, despite a century of psychiatric consensus that manic-depressive illness rarely had its onset before adolescence. This emergence has happened against a background of vigorous pharmaceutical company marketing of bipolar disorder in adults. In the absence of a license demonstrating efficacy for their compound for bipolar disorder in children, however, companies cannot actively market pediatric bipolar disorder. This paper explores some mechanisms that play a part in spreading the recognition of a disorder in populations for which pharmaceutical companies do not have a license. These include the role of academic experts, parent pressure groups, measurement technologies and the availability of possible remedies even if not licensed.

Keywords: Bipolar disorder, mood-stabilizers, mood-watching, disease mongering, off-label prescribing

1. Introduction

The diagnosis of bipolar disorder is rapidly increasing in frequency in North America. It seems commonly assumed that pharmaceutical companies must have engineered this.[1] However, no company has a license for treating bipolar disorder in children and hence no company can advertise their drug for use in children in either academic or lay outlets. As such this disease cannot be mongered as readily as social anxiety disorder, panic disorder or other such entities.

This paper seeks to explore the capacities of companies to create a culture that legitimizes practices that would otherwise appear extra-ordinary. The article aims at offering a historically accurate narrative that shares many background themes in common with developments in other medical disorders, but which has in its foreground a comparatively small number of actors whose roles may merit further research. The narrative illustrates how company strategies in one domain can resonate in another, in this case the pediatric domain. To bring this point out, we first describe the marketing of adult bipolar disorder.

2. The marketing of adult bipolar disorder

Just as other corporations do, pharmaceutical companies attempt to establish what marketing departments refer to as the unmet needs of their market [2]. One mechanism is to use focus groups; in the case

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[1] It seems to the authors that this assumption is common and it seems unlikely that this increase in diagnosis would be happening in the absence of possible treatments clinicians could give.

of psychotropic drugs, focus groups consist of academic psychiatrists, also termed opinion leaders. In this process, academics have three roles. As repositories of psychiatric knowledge they help companies understand what the average clinician might perceive as a development. As opinion leaders they help deliver the company message to non-academic clinicians. As academics, they lend their names to the authorship lines of journal articles and presentations at professional meetings reporting the results of company studies or discussing clinical topics of strategic interest to marketing departments [20].

From work like this with opinion leaders in the early 1990s, a series of unmet mental health needs clustering around the concept of bipolar disorder were identified. The field was prepared to believe that bipolar disorder could affect up to 5% of the population; that it was an unacknowledged and under-researched disorder; that antidepressants might not be good for this disorder; that treatment might be better focused on the use of a "mood stabilizer"; and that everybody stood to gain by encouraging patients to self monitor.

Early market research was linked to the introduction of Depakote. In the form of sodium valproate, this anticonvulsant had been available and shown to be helpful in manic-depressive illness from the mid-1960s. Abbott Laboratories reformulated it as semi-sodium valproate,[2] which it was claimed formed a more stable solution than sodium valproate. This trivial distinction was sufficient to enable the company to gain a patent on the new compound, which as Depakote was introduced in 1995 for the treatment of mania. Depakote was approved by the Food and Drugs Administration on the basis of trials that showed this very sedative agent could produce beneficial effects in acute manic states [37]. Any sedative agent can produce clinical trial benefits in acute manic states but no company had chosen to do this up till then, as manic states were comparatively rare and were adequately controlled by available treatments.

Depakote was advertised as a "mood stabilizer". Had it been advertised as prophylactic for manic-depressive disorder, FDA would have had to rule the advertisement illegal, as a prophylactic effect for valproate had not been demonstrated to the standards required for licensing. The term mood stabilizer in contrast was a term that had no precise clinical or neuroscientific meaning [15]. As such it was not open to legal sanction. It was a new brand.[3]

Depakote was referred to exclusively as a mood stabilizer rather than an anticonvulsant, even though there still have not been any studies that prove it to be prophylactic for manic-depressive illness. This branding played a major role in leading to increased sales of the compound compared for instance to sodium valproate, which had better evidence for efficacy but was never referred to as a mood stabilizer. Although the term still has no precise clinical or neuroscientific meaning, mood stabilizers have become the rage, with a range of other agents passing themselves off as mood stabilizers. Before 1995 there were almost no articles in the medical literature on mood-stabilizers but now there are over a hundred a year [21]. Both clinicians and patients seem happy to endorse this rebranding of sedatives despite a continuing lack of evidence that these drugs will achieve their stated aim.

But in addition to branding a new class of psychotropic drugs, the 1990s saw the rebranding of an old illness. Manic-depressive illness became bipolar disorder. While the term bipolar disorder had been introduced in DSM-III in 1980, as late as 1990 the leading book on this disease was called Manic-Depressive Disease [16]. It is rare to hear the term manic-depressive illness now. This combination of a brand new disease and brand new drug class is historically unprecedented within psychiatry.

[2]United States Patent 4,988,731. Date of Patent Jan. 29th 1991; United States Patent 5,212,326. Date of Patent May 18th 1993.

[3]While the term mood-stabilizer is not a trade-marked term, this use of the word brand here is deliberate. While the drugs are products, the identification of these previously existing products under one advertising rubric such as mood-stabilizer or SSRI appears to conform to the notion of a brand.

Lilly, Janssen and Astra-Zeneca, the makers of the antipsychotic drugs, olanzapine (Zyprexa), risperidone (Risperdal) and quetiapine (Seroquel), respectively sought indications in this area and the steps they have taken to market their compounds as mood stabilizers illustrate how companies go about making markets. We will outline six such steps.

First, each company has produced patient literature and website material aimed at telling people more about bipolar disorder, often without mentioning medication; this is a feature of what has been termed disease mongering [32]. In the case of Zyprexa, patient leaflets and booklets – routed in Britain through a patient group, the Manic-Depressive Fellowship – aim at telling patients what they need to do to stay well. Among the claims are "that bipolar disorder is a life long illness needing life long treatment; that symptoms come and go but the illness stays; that people feel better because the medication is working; that almost everyone who stops taking the medication will get ill again and that the more episodes you have the more difficult they are to treat".[4]

A similar message is found in a self-help guide for people with bipolar disorder sponsored by Janssen Pharmaceuticals which under a heading 'the right medicine at the right time' states: "Medicines are crucially important in the treatment of bipolar disorders. Studies over the past 20 years have shown without a shadow of doubt that people who have received the appropriate drugs are better off in the long term than those who receive no medicine" [8].

If studies had shown this, there would be a number of drugs licensed for the prophylaxis of bipolar disorder when in fact until recently lithium was the only drug that had demonstrable evidence for prophylactic efficacy but even this had not received a license from the FDA. More to the point all studies of life expectancy on antipsychotics show a doubling of mortality rates on treatment compared to the non-treated state and this doubling increases again for every extra antipsychotic drug that the patient takes [25]. Patients taking these drugs show a reduction of life expectancy of up to 20 years compared to population norms [6].

Furthermore, to date when all placebo-controlled studies of Depakote, Zyprexa and Risperdal in the prophylaxis of bipolar disorder are combined they show a doubling of the risk of suicidal acts on active treatment compared to placebo [21,38]. In addition, valproate and other anticonvulsants are among the most teratogenic in medicine [10].

These claims about the benefits of treatment therefore appear misleading. No company could make such public statements without the regulators intervening. But by using patient groups or academics, companies can palm off the legal liability for such claims [20].

A second aspect of the marketing of the drugs uses celebrities such as writers, poets, playwrights, artists and composers who have supposedly been bipolar. Lists circulate featuring most of the major artists of the 19th and 20th Century intimating they have been bipolar, when in fact very few if any had a diagnosis of manic-depressive illness.

A third aspect of the marketing has involved the use of mood diaries. These break up the day into hourly segments and ask people to rate their moods on a scale that might go from $+5$ to -5. For example, on the Lilly sponsored mood diary,[5] one would rate a $+2$ if one was very productive, doing things to excess such as phone calls, writing, having tea, smoking, being charming and talkative. For a score of $+1$ your self-esteem would be good, you are optimistic, sociable and articulate, make good decisions and get work done. Minus 1 involves slight withdrawal from social situations, less concentration than

[4]Staying Well... with bipolar disorder. Relapse Prevention Booklet. Produced in Association with the Manic-Depressive Fellowship of Great Britain, Sponsored by Eli Lilly and Company (2004), page 17.

[5]Mood diary produced in consultation with the Manic-Depressive Fellowship of Great Britain, Sponsored by Eli Lilly & Company (2004). Other companies have similarly sponsored mood diaries.

usual and perhaps slight agitation. Minus 2 involves feelings of panic and anxiety with poor concentration and memory and some comfort in routine activities. Most normal people during the course of the week will probably cycle between at least +2 and −2, which is almost precisely the point behind this mood-watching. Most normal people will show a variation in their moods that might be construed as an incipient bipolar disorder.

On IsItReallyDepression.com,[6] Astra-Zeneca, the makers of Seroquel (quetiapine), provide a mood questionnaire which asks whether there has been a period when you were more irritable than usual, more self-confident than usual, got less sleep than usual and found you didn't really miss it, were more talkative than usual, had thoughts race through your mind, had more energy than usual, were more active than usual, were more social or outgoing than usual, or had more libido than usual.

These are all functions that show some variation in everyone. Answering Yes to 7 of these, leads to two further questions one of which is whether you have ever had more than one of these at any one time and the second of which is whether you have ended up in any trouble as a result of this. If you answer yes to these two questions you may meet criteria for bipolar disorder and are advised to seek a review by a mental health professional. Whether or not you meet criteria, if concerned, it is suggested you might want to seek a mental health review.

This measurement induced mood watching has an historical parallel in the behavior of weight watching that came with the introduction of weighing scales [19]. This new behavior coincided with the emergence of eating disorders in the 1870s. There was subsequently an increase in frequency in eating disorders in the 1920s that paralleled a much wider availability of weighing scales and the emergence of norms for weight that had a rather immediate impact on our ideas of what is beautiful and healthy. In the 1960s there was a further increase in the frequency of eating disorders and again this paralleled the development of smaller bathroom scales and their migration into the home. While there are undoubtedly other social factors involved in eating disorders, it is a moot point as to whether eating disorders could have become epidemic without the development of this measurement technology.

There is an informational reductionism with mood diaries that is perhaps even more potent that the biological reductionism to which critics of psychiatry often point. Measuring is not inherently a problem and figures may provide potent reinforcement to behaviors, but the abstraction that is measurement can lead to an oversight for context and other dimensions of an individual's functioning or situation that are not open to measurement or that are simply not being measured. If these oversights involve significant domains of personal functioning, we are arguably being pseudoscientific rather than modestly scientific in measuring what we can.

A fourth aspect of the current marketing of all medical disorders involves the marketing of risk. This is true for the marketing of depression and bipolar disorder as well disorders like osteoporosis, hypertension and others. In the case of osteoporosis, companies will typically present pictures of a top model looking her best in her mid-20s and juxtapose that image with a computer generated image of how the same person might look during her 60s or 70s with osteoporosis. On the one hand a beautiful woman, on the other a shrunken crone. The message is 'one can never be too safe'. If one wants to retain beauty and vitality it is best to monitor for osteoporosis from an early age and even treat prophylactically. In the case of bipolar disorder the risks of suicide, alcoholism, divorce, and career failure are marketed.

All of the above come together in a fifth strategy in North America – direct to consumer advertising. A now famous advertisement produced by Lilly, the makers of Zyprexa (olanzapine) begins with a vibrant woman dancing late into the night. A background voice says, "Your doctor never sees you like

[6] Accessed April 27th 2006.

this". The advert cuts to a shrunken and glum figure, and the voiceover now says, "This is who your doctor sees". Cutting again to the woman, in active shopping mode, clutching bags with the latest brand names, we hear: "That is why so many people being treated for bipolar disorder are being treated for depression and aren't getting any better – because depression is only half the story". We see the woman depressed, looking at bills that have arrived in the post before switching to seeing her again energetically painting her apartment. "That fast talking, energetic, quick tempered, up-all-night you", says the voiceover, "probably never shows up in the doctor's office".

Viewers are encouraged to log onto bipolarawareness.com, which takes them to a "Bipolar Help Center", sponsored by Lilly Pharmaceuticals. This contains a "mood disorder questionnaire".[7] In the television advert, we see our heroine logging onto bipolarawareness.com and finding this questionnaire. The voice encourages the viewer to follow her example: "Take the test you can take to your doctor, it can change your life. Getting a correct diagnosis is the first step in helping your doctor to help you".

No drugs are mentioned. The advert markets bipolar disorder. Whether this is a genuine attempt to alert people who may be suffering from a debilitating disease, or an example of disease mongering, it will reach beyond those suffering from a clearcut mood disorder to others who as a consequence will be more likely to see aspects of their personal experiences in a way that will lead to medical consultations and will shape the outcome of those consultations. "Mood-watching" like this risks transforming variations from an emotional even keel into indicators of latent or actual bipolar disorder. This advert appeared in 2002 shortly after Zyprexa had received a license for treating mania, when the company was running trials to establish olanzapine as a "mood stabilizer".

The sixth strategy involves the co-option of academia and is of particular relevance to the pediatric bipolar domain. The American Psychiatric Association meeting in San Francisco in 2003 offers a good symbol of what happened. Satellite symposia linked to the main APA meeting, as of 2000, could cost a company up to $250,000. The price of entry is too high for treatment modalities like psychotherapy. There can be up to 40 such satellites per meeting. Companies usually bring hundreds of delegates to their satellite. The satellites are ordinarily distributed across topics like depression, schizophrenia, OCD, social phobia, anxiety, dementia and ADHD. At the 2003 meeting, an unprecedented 35% of the satellites were for just one disorder – bipolar disorder.[8] These symposia have to have lecturers and a Chair,[9] and 57 senior figures in American psychiatry were involved in presenting material on bipolar disorder at these satellites, not counting other speakers on the main meeting program. One of these satellite symposia, a first ever at a major meeting, was on juvenile bipolar disorder.

The upshot of this marketing has been to alter dramatically the landscape of mental disorders. Until recently manic depressive illness was a rare disorder in the United States and Canada involving 10 per million new cases per year or 3300 new cases per year. This was a disorder that was 8 times less common than schizophrenia. In contrast bipolar disorder is now marketed as affecting 5% of the United States and Canada – that is 16.5 million North Americans, which would make it is as common as depression and 10 times more common than schizophrenia. Clinicians are being encouraged to detect and treat it. They are educated to suspect that many cases of depression, anxiety or schizophrenia may be bipolar disorder and that treatment should be adjusted accordingly [23]. And, where recently no clinicians would have accepted this disorder began before adolescence, many it seems are now prepared to accept that it can be detected in preschoolers.

[7] http://www.bipolarhelpcenter.com/resources/mdq.jsp.

[8] American Psychiatric Association (2003). Meeting Program.

[9] All of which comes with a fee, unlike symposia on the main program.

3. Bipolar disorder in children

The emergence of bipolar disorder in children needs to be reviewed against the background outlined above. Until very recently manic-depressive illness was not thought to start before the teenage years and even an adolescent onset was atypically early. The clearest indicator of change came with the publication of *The Bipolar Child* by Papolos and Papolos [35]. This sold 70,000 hardback copies in half a year. Published in January 2000, by May it was in a 10th printing. Other books followed, claiming that we were facing an epidemic of bipolar disorders in children [24] and that children needed to be treated aggressively with drugs from a young age if they were to have any hope of a normal life [12]. Newspapers throughout the United States reported increasingly on cases of bipolar children, as outlined below.

A series of books aimed at children with pastel colored scenes in fairy tale style also appeared. In *My Bipolar Roller Coaster Feelings Book* [23], a young boy called Robert tells us he has bipolar disorder. As Robert defines it doctors say you are bipolar if your feelings go to the top and bottom of the world, in roller coaster fashion. When Robert is happy he apparently hugs everybody, he starts giggling and feels like doing backflips. His parents call it bouncing off the walls. His doctor, Doctor Janet, calls it silly, giddy and goofy.

Aside from giddiness, Robert has three other features that seem to make the diagnosis of pediatric bipolar disorder. One is temper tantrums. He is shown going into the grocery store with his Mum and asking for candy. When she refuses, he gets mad and throws the bag of candy at her. His mum calls this rage and he is described as feeling bad afterwards.

Second, when he goes to bed at night Robert has nightmares. His brain goes like a movie in fast forward and he seemingly can't stop it. And third, he can be cranky. Everything irritates him – from the seams in his socks, to his sister's voice, and the smell of food cooking. This can go on to depression when he is sad and lonely, and he just wants to curl up in his bed and pull the blanket over his head. He feels as though it's the end of the world and no one cares about him. His doctor has told him that at times like this he needs to tell his parents or his doctor and he needs to get help.

Dr. Janet gives Robert medication. His view on this is that while he doesn't like having bipolar disorder, he can't change that. He also doesn't like having to take all those pills but, the bad nightmares have gone away and they help him have more good days. His father says a lot of kids have something wrong with their bodies, like asthma and diabetes and they have to take medicine and be careful, and so from this point of view he's just like many other children.

His parents have told him that his bipolar disorder is just a part of who he is, not all of who he is. That they love him and always will. Finally his doctor indicates that it's only been a little while since doctors knew that children could have bipolar disorder, and that they are working hard to help these children feel better.

In another book, *Brandon and the Bipolar Bear*, we are introduced to Brandon, who has features in common with Robert that the unwary might fail to realize indicate bipolar disorder [1]. When we are introduced to Brandon, he has just woken up from a nightmare. Second, when requested to do things that he doesn't want to do he flies into a rage. And third, he can be silly and giddy.

His mother takes both Brandon and his bear to Dr. Samuel for help, where Brandon is told that he has bipolar disorder. Dr. Samuel explains that the way we feel is controlled by chemicals in our brain. In people with bipolar disorder these chemicals can't do their job right so their feelings get jumbled inside. You might feel wonderfully happy, horribly angry, very excited, terribly sad or extremely irritated, all in the same day. This can be scary and confusing – so confusing that it can make living seem too hard.

When Brandon responds that he thinks he got bipolar disorder because he is bad, Dr. Samuel responds that many children have bipolar disorder, and they come to the doctor for help. Neither they nor Brandon are bad – it's a case of having an illness that makes you feel bad.

Brandon moves on to asking how he got bipolar disorder if he didn't get it from being bad, to which Dr. Samuel responds by asking him how he got his green eyes and brown hair. Brandon and his mother respond that these came from his parents. And Dr. Samuel tells them it's the same with bipolar disorder. That it can be inherited. That someone else in the family may have it also.

The final exchange involves Brandon asking whether he will ever feel better. Dr. Samuel response is upbeat – there are now good medicines to help people with bipolar disorder, and that Brandon can start by taking one right away. Brandon is asked to promise that he will take his medicine when told by his mother.

Brandon and the Bipolar Bear comes with an associated coloring book, in which Brandon's Dad makes it clear that a lot of kids have things wrong with their bodies, like asthma and diabetes, and they have to take medicine and be careful too.

Janice Papolos, co-author of *The Bipolar Child*, in a review on the back cover of Brandon and the Bipolar Bear says: 'children will follow (and relate to) Brandon's experience with rapid mood swings, irritability, his sense of always being uncomfortable and his sadness that he can't control himself and no-one can fix him. The comforting explanation that Dr. Samuel gives him makes Brandon feel not alone, not bad, but hopeful that the medicine will make him feel better. We were so moved by the power of this little book and we feel better that we can now highly recommend a book for children aged 4 through 11'.

The book *The Bipolar Child* arrived at Sheri Lee Norris' home in Hurst, Texas, in February 2000. When it did Karen Brooks, a reporter in the Dallas Star-Telegram describes Norris as tearing open the package with a familiar mix of emotions. Hope, skepticism, fear, guilt, shame, love. But as she reads in the book about violent rages, animal abuse, inability to feel pain, self-abuse and erratic sleeping patterns, Norris is reported as feeling relief for the first time in over a year. Now she finally knew what was wrong with her daughter... Within days, Heather Norris, then 2, became the youngest child in Tarrant County with a diagnosis of bipolar disorder [5].

Brooks goes on to note that families with mentally ill children are plagued with insurance woes, a lack of treatment options and weak support systems but that parents of the very young face additional challenges. It is particularly hard to get the proper diagnosis and treatment because there has been scant research into childhood mental illness and drug treatments to combat them. Routine childcare is difficult to find, because day-care centers, worried about the effect on other children, won't accept mentally ill children or will remove them when they are aggressive. Few baby sitters have the expertise or the desire to handle difficult children, leaving parents with little choice but to quit work or work from home.

Having outlined these difficulties, Brooks also notes that the lack of public awareness of childhood mental illness means that parents are judged when their children behave badly. They are accused of being poor parents, of failing to discipline their children properly, or even of sexual or physical abuse or neglect. The sense of hopelessness is aggravated when they hear about mentally ill adults; this leaves them wondering whether the battles they and their children are fighting will go on forever.

In a few short paragraphs here Brooks outlines the once and future dynamics of disease from ancient to modern times – the reflection on parents or family, the concerns for the future, the hope for an intervention. But she also covers a set of modern and specifically American dynamics. Heather Norris's problems began with temper tantrums at 18 months old. Sheri-Lee Norris had a visit from the Child Protective Services. Someone had turned her in because Heather behaved abnormally. Sheri-Lee was furious and felt betrayed. She brought Heather to pediatricians, play therapists and psychiatrists, where

Heather was diagnosed with ADHD and given Ritalin. This made everything worse. Faced with all this, a psychiatrist did not make the diagnosis of bipolar disorder because the family had no history of it. But Sheri-Lee began asking relatives and discovered that mental illness was, indeed, in her family's history. She presented that information along with a copy of *The Bipolar Child* to her psychiatrist, and Heather got a diagnosis of bipolar disorder immediately.

Heather Norris' story is not unusual. The mania for diagnosing bipolar disorders in children hit the front cover of *Time* in August 2002, which featured 9-year-old Ian Palmer and a cover title Young and Bipolar [26], with a strapline, why are so many kids being diagnosed with the disorder, once known as manic-depression? The Time article and other articles report surveys that show 20% of adolescents nationwide have some form of diagnosable mental disorder. Ian Palmer, we are told, just like Heather Norris, had begun treatment early – at the age of 3 – but failed to respond to either Prozac or stimulants, and was now on anticonvulsants.

While Heather Norris was in 2000 the youngest child in Tarrant County to be diagnosed as bipolar, Papolos and Papolos in *The Bipolar Child* indicate that many of the mothers they interviewed for their book remembered their baby's excessive activity *in utero*, and the authors seem happy to draw continuities between this and later bipolar disorder. The excessive activity amounts to hard kicking, rolling and tumbling and then later keeping the ward awake with screaming when born. Or in some instances being told by the sonographer and obstetrician that it was difficult to get a picture of the baby's face or to sample the amniotic fluid because of constant, unpredictable activity [35]. It is not unusual to meet clinicians who take such reports seriously.

Anyone searching the Internet for information on bipolar disorder in children are now likely to land at BPChildren.com, run by Tracy Anglada and other co-authors of the books mentioned above. Or at the Juvenile Bipolar Research Foundation (JBRF), linked to the Papoloses and *The Bipolar Child*. Or at a third site, bpkids.org, linked to a Child and Adolescent Bipolar Foundation, which is supported by unrestricted educational grants from major pharmaceutical companies.

In common with the mood-watching questionnaires in the adult field, all three sites offer mood-watching questionnaires for children. The Juvenile Bipolar Research Foundation has a 65-item Child Bipolar Questionnaire, which also featured in the *Time* magazine piece above; on this scale most normal children would score at least modestly.[10]

The growing newsworthiness of childhood bipolar disorder also hit the editorial columns of the American Journal of Psychiatry in 2002 [40]. But where one might have expected academia to act as a brake on this new enthusiasm, its role has been in fact quite the opposite.

4. The academic voice

As outlined above until very recently manic-depressive illness was not thought to start before the teenage years. The standard view stemmed from Theodore Ziehen, who in the early years of the 20th century established, against opposition, that it was possible for the illness to start in adolescence [3]. This was the received wisdom for 100 years.

As of 2006, European articles on the issue of pre-pubertal bipolar disorder continued to express agnosticism as to whether there was such an entity [28]. The view was that patterns of overactivity could be seen in patients with learning disabilities/mental retardation, or for example in Asberger's syndrome, but it was not clear that these should be regarded as indicative of manic-depressive disease.

[10] www.jbrf.org/cbq/cbq_survey.cfm. Accessed December 1st 2005.

Geller and colleagues in St. Louis framed the first set of criteria for possible bipolar disorder in children in 1996 as part of an NIMH funded study [13]. Using these criteria the first studies reporting in 2002 suggested that essentially very little was known about the condition. There were children who might meet the criteria, but these had a very severe condition that in other circumstances have been likely to be diagnosed as childhood schizophrenia or else they displayed patterns of overactivity against a background of mental retardation [14].

The course of this study and the entire debate had however been derailed by the time the Geller study reported. In 1996, a paper from an influential group, based at Massachusetts' General Hospital, working primarily on ADHD, suggested there were patients who might appear to have ADHD who in fact had mania or bipolar disorder [4,11]. This study had used lay raters, did not interview the children about themselves, did not use prepubertal age specific mania items, and used an instrument designed for studying the epidemiology of ADHD. Nevertheless the message stuck. Cases of bipolar disorder were being misdiagnosed as ADHD. Given the many children diagnosed with ADHD who do not respond to stimulants, and who are already in the treatment system, this was a potent message for clinicians casting round for some other option.

A further study by Lewinsohn and colleagues in 2000 added fuel to the fire [29]. Even though this study primarily involved adolescents and pointed toward ill-defined overactivity rather than proper bipolar disorder, the message that came out was that there was a greater frequency of bipolar disorder in minors that had been previously suspected.

These developments led in 2001 to an NIMH roundtable meeting on prepubertal bipolar disorder [34] to discuss the issues further. But by then any meeting or publication, even one skeptical in tone, was likely to add fuel to the fire. Simply talking about pediatric bipolar disorder endorsed it. The Juvenile Bipolar Research Foundation website around this time noted that bipolar disorder in children simply does not look like bipolar disorder in adults, in that children's moods swing several times a day – they do not show the several weeks or months of elevated mood found in adults. They baldly state that "The DSM needs to be updated to reflect what the illness looks like in childhood".[11]

The Child and Adolescent Bipolar Foundation convened a meeting and treatment guideline process in July 2003 that was supported by unrestricted educational grants from Abbott Astra-Zeneca, Eli Lilly, Forrest, Janssen, Novartis and Pfizer. This assumed the widespread existence of pediatric bipolar disorder and the need to map out treatment algorithms involving cocktails of multiple drugs [27].

There are many ambiguities here. First is the willingness it seems of all parties to set aside all evidence from adult manic-depressive illness which involves mood states that persist for weeks or months and argue that children's moods may oscillate rapidly, up to several times per day, while still holding the position that this disorder is in some way continuous with the adult illness and therefore by extrapolation should be treated with the drugs used for adults.

Another ambiguity that the framers of the American position fail to advert to is a problem with DSM-IV. Advocates of pediatric bipolar disorder repeatedly point to problems with DSM-IV that hold them back from making diagnoses. But in fact, DSM-IV is more permissive than the rest of world in requiring a diagnosis of bipolar disorder following a manic episode – in practice any sustained episode of overactivity. The International Classification of Disease in contrast allows several manic episodes to be diagnosed without a commitment to the diagnosis of bipolar disorder. The rest of the world believes it simply does not know enough even about the relatively well understood adult illness to achieve diagnostic consistency worldwide. DSM-IV in fact therefore makes it easier to diagnose bipolar disorder

[11] www.jbrf.org/juv_bipolar/faq.html. Accessed December 1st 2005.

than any other classification system, but therapeutic enthusiasts want an even further loosening of these already lax criteria.

Finally, we appear to have entered a world of operational criteria by proxy. Clinicians making these diagnoses are not making diagnoses based on publicly visible signs in the patients in front of them, or publicly demonstrable on diagnostic tests, as is traditional in medicine. Nor are they making the diagnoses based on what their patients say, as has been standard in adult psychiatry, but rather these are diagnoses made on the basis of what third parties, such as parents or teachers, say without apparently any method to assess the range of influences that might trigger parents or teachers to say such things – the range of influences brought out vividly by Karen Brooks in her Star-Telegram articles.

When clinicians raise just this point [17], the response has been aggressive. "Mood need not be elevated, irritable etc. for a week to fulfill criteria... A period of 4 days suffices for hypomania. This is... itself an arbitrary figure under scrutiny... Dr. Harris is incorrect... that the prevalence of adult bipolar disorder is only 1–2%. When all variants are considered the disease is likely to be present in more than 6% of the adult pop. There are still those who will not accept that children commonly suffer from bipolar illness regardless of how weighty the evidence. One cannot help but wonder whether there are not political and economic reasons for this stubborn refusal to allow the outmoded way of thought articulated by Dr. Harris to die a peaceful death. It is a disservice to our patients to do otherwise" [9].

Where one might have thought some of the more distinguished institutions would bring a skeptical note to bear on this, they appear instead to be fueling the fire. Massachusetts's General Hospital (MGH) have run trials of the antipsychotics risperidone and olanzapine on children with a mean age of 4 years old [30,31]. A mean age of 4 all but guarantees three and possibly two year olds have been recruited to these studies.

MGH in fact recruited juvenile subjects for these trials by running its own DTC adverts featuring clinicians and parents alerting parents to the fact that difficult and aggressive behavior in children aged 4 and up might stem from bipolar disorder. Given that it is all but impossible for a short term trial of sedative agents in pediatric states characterized by overactivity not to show some rating scale changes that can be regarded as beneficial, the research can only cement the apparent reality of juvenile bipolar disorder into place.

As a result where it is still rare for clinicians elsewhere in the world to make the diagnosis of manic-depressive illness before patients reach their mid to late teens, drugs like olanzapine and risperidone are now in extensive and increasing use for children including preschoolers in America with relatively little questioning of this development [7].

Studies run by academics that apparently display some benefits for a compound have possibly become even more attractive to pharmaceutical companies than submitting the data to the FDA in order to seek a license for the treatment of children. Companies can rely on clinicians to follow a lead given by academics speaking on meeting platforms or in published articles. The first satellite symposium on juvenile bipolar disorder at a major mainstream meeting, the American Psychiatric Association meeting in 2003 featured the distinguished clinical faculty of MGH. The symposium was supported by an unrestricted educational grant. None of the speakers will have been asked to say anything other than what they would have said in any event. The power of companies does not lie in dictating what a speaker will say but in providing platforms for particular views. If significant numbers of clinicians in the audience are persuaded by what distinguished experts say, companies may not need to submit data to FDA and risk having lawyers or others pry through their archives to see what the actual results of studies look like. As an additional benefit, academics come a lot cheaper than putting a sales force in the field.

It would seem only a matter of time before this American trend spreads to the rest of the world. In a set of guidelines on bipolar disorder issued in 2006, Britain's National Institute of Health and Clinical Excellence (NICE), which is widely regarded as being completely independent of the pharmaceutical industry, has a section on children and adolescents [33]. The guideline contains this section because if there are treatment studies on a topic, NICE has to perforce consider them; it cannot make the point that hitherto unanimous clinical opinion has held that bipolar disorders do not start in childhood. But simply by considering the treatment for bipolar disorders in childhood, NICE effectively brings it into existence, illustrating in the process the ability of companies to capture guidelines (Healy D., submitted). And again, the need for a company to seek an indication for treatment in children recedes if influential guidelines tacitly endorse such treatment.

5. Munchausen's syndrome new variant?

As outlined above, a number of forces appear to have swept aside traditional academic skepticism with the result that an increasing number of children and infants are being put on cocktails of potent drugs without any evidence of benefit.

One of the features of the story is how a comparatively few players have been able to effect an extraordinary change. There the academics noted above and a handful of others. One was Robert Post who was among the first to propose that anticonvulsants might be useful for adult manic-depressive disease, who when the frequency of the disorder began to increase rather than decrease as usually happens when treatments work, promoted the idea that the reason we were failing was because we had failed to catch affected individuals early enough. No age was too early.

> One would encourage major efforts at earlier recognition and treatment of this potentially incapacitating and lethal recurrent central nervous system disorder. It would be hoped that instituting such early, effective, and sustained prophylactic intervention would not only lessen illness-related morbidity over this interval, but also change the course of illness toward a better trajectory and more favorable prognosis [36].

Another group consists of evangelical parents and clinicians, who bring to the process of proselytizing about bipolar disorder a real fervor. Some of these parents and clinicians readily contemplate the possibility of making a diagnosis *in utero*. When those challenging such viewpoints are subject to opprobrium, one has to ask what has happened to the academic voices that should be questioning what is happening here.

Finally there is the role of companies who make available the psychoactive drugs without which the diagnoses would not be made, unrestricted educational grants, and access to academic platforms. This has clearly facilitated the process outlined above. While companies cannot market directly to children, it is now clear that documents from 1997 show that at least one company was aware of the commercial opportunities offered by juvenile bipolar disorder [39].

If the process outlined here was one that could reasonably be expected to lead to benefits it could regarded as therapeutic. But given that there is no evidence for benefit and abundant prima facie evidence that giving the drugs in question to vulnerable subjects in such quantities cannot but produce consequent difficulties for many of these minors, one has to wonder whether we are not witnessing instead a variation on Munchausen's syndrome, where some significant other wants the individual to be ill and these significant others derive some gain from these proxy illnesses.

The contrast between the developing situation and the historical record is striking. The records of all admissions to the asylum in North Wales from North West Wales for the years from 1875 to 1924 show that close to 3,500 individuals were admitted, from a population base of slightly more than a quarter of a million per annum (12,500,000 person years). Of these, only 123 individuals were admitted for manic-depressive disease. The youngest admission for manic-depression was aged 17. The youngest age of onset may have been EJ, who was first admitted in 1921 at the age of 26, but whose admission record notes that she "has had several slight attacks in the last 12 years, since 13 years of age". All told there were 12 individuals in 50 years with a clear onset of illness under the age of 20 [18]. But it would seem almost inevitable that there will be a greater frequency of hospital admissions for juveniles in future diagnosed with bipolar disorder. This is not what ordinarily happens when medical treatments work.

Competing interests

J. Le Noury has no competing interests.

In the past 10 years D. Healy has had consultancies with, been a principal investigator or clinical trialist for, been a chairman or speaker at international symposia for or been in receipt of support to attend meetings from Astra-Zeneca, Boots/Knoll Pharmaceuticals, Eli Lilly, Janssen-Cilag, Lorex-Synthelabo, Lundbeck, Organon, Pharmacia & Upjohn, Pierre-Fabre, Pfizer, Rhone-Poulenc Rorer, Roche, Sanofi, SmithKline Beecham, Solvay. In the past two years, he has had lecture fees and support to attend meetings from Astra-Zeneca and Lundbeck.

In the past ten years D. Healy has been an expert witness for the plaintiff in 15 legal actions involving SSRIs and has been consulted on a number of attempted suicide, suicide and suicide-homicide cases following antidepressant medication, in most of which he has offered the view that the treatment was not involved. He has been an expert witness for the NHS in a series of therapy (LSD/ECT) related cases, and in one patent case.

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Research Center Tied to Drug Company

By GARDINER HARRIS

When a Congressional investigation revealed in June that he had earned far more money from drug makers than he had reported to his university, Dr. Joseph Biederman, a world-renowned child psychiatrist, said that his "interests are solely in the advancement of medical treatment through rigorous and objective study."

But e-mails and internal documents from Johnson & Johnson made public in a court filing reveal that Dr. Biederman pushed the company to fund a research center at Massachusetts General Hospital whose goal was "to move forward the commercial goals of J&J," the documents state. The documents also show that Johnson & Johnson wrote a draft summary of a study that Dr. Biederman, of Harvard University, was said to author.

Dr. Biederman's work helped to fuel a 40-fold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder and a rapid rise in the use of powerful, risky and expensive antipsychotic medicines in children. Although many of his studies are small and often financed by drug makers, Dr. Biederman has had a vast influence on the field largely because of his position at one of the most prestigious medical institutions in the world.

Johnson & Johnson manufactures Risperdal, also known as risperidone, a popular antipsychotic medicine. More than a quarter of Risperdal's use is in children and adolescents.

Last week, a panel of federal drug experts said that medicines like Risperdal are being used far too cavalierly in children and that federal drug regulators must do more to warn doctors of their substantial risks. Other popular antipsychotic medicines, also referred to as neuroleptics, are Zyprexa, made by Eli Lilly; Seroquel, made by AstraZeneca; Geodon, made by Pfizer; and Abilify, made by Bristol-Myers Squibb.

Thousands of parents have sued Johnson & Johnson, AstraZeneca and Eli Lilly, claiming that their children were injured after taking the medicines, whose risks the companies minimized, the parents claim. As part of the suits, plaintiffs' attorneys have demanded millions of documents from the companies. Nearly all of those documents have been provided under judicial seals, but a select few that mentioned Dr. Biederman became public after plaintiffs attorneys sought a judge's order to require Dr. Biederman to be interviewed by plaintiff attorneys under oath.

In a motion filed two weeks ago, attorneys for the families argued that they should be allowed to interview Dr. Biederman under oath because his work has been crucial to the widespread acceptance of pediatric uses of antipsychotic medicines. To support this contention, the lawyers included more than two dozen documents, including e-mails from Johnson & Johnson that mentioned Dr. Biederman. That interview request has yet to be ruled upon.

The documents offer an unusual glimpse into the delicate relationship that drug makers have with influential doctors. In one November 1999 e-mail, John Bruins, a Johnson & Johnson marketing executive, begs his supervisors to approve a $3,000 check to Dr. Biederman in payment for a lecture he gave at the University of Connecticut.

“Dr. Biederman is not someone to jerk around,” Mr. Bruins wrote. “He is a very proud national figure in child psych and has a very short fuse.”

Mr. Bruins wrote that Dr. Biederman was furious after Johnson & Johnson rejected a request that Dr. Biederman had made to receive a $280,000 research grant. “I have never seen someone so angry,” Mr. Bruins wrote. “Since that time, our business became non-existant (sic) within his area of control.”

Mr. Bruins concluded that, unless Dr. Biederman received a check soon, “I am truly afraid of the consequences.”

A series of documents described the goals behind establishing the Johnson & Johnson Center for the study of pediatric psychopathology, for which Dr. Biederman still serves as chief.

A 2002 annual report for the center stated that its research must satisfy three criteria: improve psychiatric care for children, have high standards and “move forward the commercial goals of J&J,” according to court documents.

“We strongly believe that the center’s systematic scientific inquiry will enhance the clinical and research foundation of child psychiatry and lead to the safer, more appropriate and more widespread use of medications in children,” the report stated. “Without such data, many clinicians question the wisdom of aggressively treating children with medications, especially those like neuroleptics, which expose children to potentially serious adverse events.”

A February 2002 e-mail from Georges Gharabawi, a Johnson & Johnson executive, stated that Dr. Biederman approached the company “multiple times to propose the creation” of the center. “The rationale of this center is to generate and disseminate data supporting the use of risperidone in” children and adolescents, the e-mail stated.

Johnson & Johnson gave the center $700,000 in 2002 alone, documents show.

A June 2002 e-mail from Dr. Gahan Pandina, a Johnson & Johnson executive, to Dr. Biederman included a brief abstract of a study of Risperdal in children suffering disruptive behavior disorder. The study was intended to be presented at the 2002 annual meeting of the American Academy of Child & Adolescent Psychiatry, the e-mail stated.

“We have generated a review abstract, but I must review this longer abstract before passing this along,” Dr. Pandina wrote. One problem with the study, Dr. Pandina wrote, is that the children given placebos and those given Risperdal both improved significantly, “so, if you could, please give some thought to how to handle this issue if it occurs.”

The draft abstract that Dr. Pandina included in the e-mail, however, stated that only the children given Risperdal improved, while those given placebos did not. Dr. Pandina asked Dr. Biederman to sign a form listing himself as author so the company could present the study to the conference, according to the e-mail.

"I will review this morning," Dr. Biederman responded, according to the documents. "I will be happy to sign the forms if you could kindly send them to me." The documents do not make clear whether Dr. Biederman approved the final summary of the brief abstract in similar form or asked to read the longer report on the study.

Drug makers have long hired professional writers to compose scientific papers and then recruited well-known doctors to list themselves as authors. The practice, known as ghostwriting, has come under intense criticism recently, and medical societies, schools and journals have condemned it.

In June, a Congressional investigation revealed that Dr. Biederman had failed to report to Harvard at least $1.4 million in outside income from Johnson & Johnson and other makers of antipsychotic medicines.

In one example, Dr. Biederman reported no income from Johnson & Johnson for 2001 in a disclosure report filed with the university. When asked by Senator Charles E. Grassley, a Republican of Iowa, to check again, Dr. Biederman said he received $3,500. But Johnson & Johnson told Mr. Grassley that it paid Dr. Biederman $58,169 in 2001.

On Monday, David J. Cameron, a Harvard spokesman, said the university was still reviewing Mr. Grassley's allegations against Dr. Biederman. He added that they had not seen the drug company documents in question and that the university is not directly involved in the child psychiatry center at Massachusetts General Hospital.

Calls to Dr. Biederman were not returned. Johnson & Johnson did not immediately comment or make executives available for comment.

From: Cote, Christine [JANUS]
Sent: Tuesday, February 05, 2002 12:55 PM
To: Gharabawi, Georges [JANUS]; Vergis, Janet [JANUS]; Parish, Irene [JANUS]
Cc: Mahmoud, Ramy [JANUS]; Pandina, Gahan [JANUS]; Kovacs, Clare [JANUS]; Deloria, Carmen [JANUS]; Kalmeijer, Ronald [JANUS]
Subject: RE: Janssen-MGH Child and Adolescent Bipolar Center - Dr Joe Biederman

I am able to do the 14th March and will block out the day ,,I am leaving for a big trip on the 28th so unless it was early am and local I would not be able to do 28th

Dr. Christine Cote
V.P. Medical Affairs
Janssen Pharmaceutica, Inc.
Tel: 609-730-3677
Fax: 609-730-3406

-----Original Message-----
From: Gharabawi, Georges [JANUS]
Sent: Tuesday, February 05, 2002 7:42 AM
To: Vergis, Janet [JANUS]; Cote, Christine [JANUS]
Cc: Mahmoud, Ramy [JANUS]; Pandina, Gahan [JANUS]; Kovacs, Clare [JANUS]; Deloria, Carmen [JANUS]; Kalmeijer, Ronald [JANUS]
Subject: Janssen-MGH Child and Adolescent Bipolar Center - Dr Joe Biederman

Subject
Invitation to a meeting with Prof Biederman and his team at Janssen on March 14 or March 28, 2002 (date pending your approval) to agree on the main deliverables from the Janssen/MGH Center for Child and Adolescent Bipolar Disorders and prioritize the different activities - Your attendance of the 1st hour is needed.

Background
Dr Biederman is the pioneer in the area of C&A Bipolar Disorders. He approached Janssen multiple times to propose the creation of a Janssen-MGH center for C&A Bipolar disorders. The rationale of this center is to generate and disseminate data supporting the use of risperidone in this patient population. I met with Dr Biederman in August 2001 and discussed with him the feasibility of this center and agreed that, should Janssen decide to support it, the main focus will be on 2 topics: 1) Diagnostics, including the creation of a screening/diagnostic tool to train clinicians (Pediatricians and General Psychiatrists) on how to diagnose C&A BPD, use of genetics and Neuro-imaging techniques to recognize C&A BPD and the different variants of the disorders and 2) Therapeutics, including short and long-term outcomes of the management of C&A BPD with risperidone including the long-term prophylactic effect on drug abuse. Following a number of internal discussions within the Brand team and with Janet, it was decided to 1) explore the feasibility of involving other J&J companies that would be interested in participating in the center and share the financial support and 2) fund the center pending the submission of a 5-year plan of deliverables including retrospective analyses and prospective exploratory research.

Current status
* In a number of meetings with McNeil and OMP, it was agreed that there was a need for all J&J companies to act as partners and share this research, data generation and dissemination opportunity. Further, it was agreed that the 3 teams should meet and elaborate a plan that would ultimately include research initiatives on combination therapies.
* A Risperdal Reanalyses, Research and Publication grid was produced by Dr biederman's team. The grid includes proposed deliverables over the upcoming 5 years starting from 2002. It is planned to produce similar grids for the J&J sister companies over the next 3-6 months.
* The Risperdal Brand team agreed to fund the center for the year 2002. 500KUS$ were paid and assigned to the

year 2002.

Next Steps
We recently organized a meeting with Dr Biederman including the marketing group from McNeil in order to discuss the next steps. We invited Dr Biederman and his group to an HOV at Janssen Titusville. This meeting will involve, in addition to Dr Biederman's research team, the Risperdal, REDACTED teams with the objective of elaborating a full research plan for the years 2002-2007 including a reanalyses and publications plan.

Proposed agenda
- Opening address (J&J)
- Background on Child and Adolescent Bipolar Disorders- A clinical and research perspective (Dr Joe Biederman)
- Breakout session:
- Epidemiology and genetics of C&S BPD
- Diagnosis: Reanalyses, validation and publication of screening tools
- Neuro-imaging plans, publication plan
- Reanalyses of the existing Risperdal data, publication plan
- Prospective short and long-term studies

Christine and Janet, Your presence, at least at the first part of the meeting is highly desirable and would allow us to continue positioning Janssen as a major partner in the area of C & A psychopharmacology. Further, following your approval of the proposed date, we will extend the invitation to S. Spielberg but will eet with him first.

Sincerely

Georges

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SUPERIOR COURT OF NEW JERSEY
LAW DIVISION - MIDDLESEX COUNTY

In re: Risperdal/Seroquel/Zyprexa Litigation Case Code 274

Alma Avila, as next friend of Amber N. Avila, an individual case

v.

Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P., a/k/a Janssen, L.P., et al.

Civil Action
Docket Number
L-6661-06

Video Deposition of Joseph Biederman, M.D.
Friday, February 27, 2009
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Also Present:
George Döbrentey, Videographer
on behalf of Hogan & Hartson

INDEX

Q. Are these the side effects associated with Risperdal?
A. Yes.

Q. The next point -- And, by the way, the use of Risperdal in the pediatric population was off-label at this time, wasn't it?
A. Yes.
Q And what does that mean?
A. Off-label means that the medicine is used by physicians that is not specifically approved by the FDA for that use.
Q So it means a drug is being used for something that the FDA hasn't approved it for. Right?
A. Yes.
Q. Okay. And so you were proposing to do research on off-label uses of Risperdal Right?
A. I was proposing to do research on the efficacy and safety of risperidone relative to other

medicines.
Q. In an off-label population. Right?
A. The use in children at that time was off-label and two years ago has been approved.
MR. TRAMMELL: Objection, nonresponsive.

Q. One of the things you wanted to study was the efficacy of Risperdal in preschoolers. Right?
A. Yes.
Q. And how old are preschool kids?
A. Could you repeat the question?
Q. How old are preschool kids?
A. Four to six.
Q. And what age range was Risperdal approved for at that time?

A. It was approved, to my recollection, for individuals older than 18.

Q. So what you're saying is there's evidence that is accumulating that kids or that pediatric bipolar disorder onsets in these preschool kids, who I assume are three and four years old?
A Usually four to six.
Q Okay. So pediatric bipolar disorder onsets in four- to six-year-old kids coupled with the fact that the drugs are widely used, despite that, there's not a lot of data on efficacy. Right?
MR. PECK: Object to form. It's a compound question.
A. On efficacy and safety, yes.
Q. And so basically what you mean is, what you're trying to say is that we have kids suffering

from this disease or it's possible that they're suffering from this disease in the preschool years, the drug is used a lot in these kids, we ought to have some data to instruct doctors about whether it's safe and effective to be doing this?
A. Yes.

Q Who makes Wellbutrin?
A. Bupropion was initially made by Glaxo or Wellcome, Burroughs Wellcome, and then when they merged I don't know who owns Wellbutrin. I think GlaxoSmithKline, I think.

Q. Did Janssen fund any studies that you did to study other companies' drugs?

Q. And the purpose of the scientific process is what?
A. You are in a study, you are testing, you are addressing a question, you are testing a hypothesis. You subject the data to statistical analysis to examine whether the findings are chance or not likely to be chance, and you draw conclusions based on your findings.
Q. It is a search for the greatest truth that can be obtained. Correct?
A. It is a method to investigate.
Q. And the method to investigate that you use requires that you be very precise. Correct?
A. As precise as the field allows.
Q. And you are a very precise individual, are you not?
A. I am.
Q. You are a very deliberate individual, are you not?
A. I am not sure what you mean by that.
Q. Well, what you do is a result of your intentional conduct?
A. Well, what I do is I ask questions that I have about how to improve the life of the people under my care. So all my research is based on

trying to understand the diseases that the children that are under my care are afflicted and how to better approach them therapeutically, with medicines and with psychosocial treatments.
Q. Now, you've already told us that you consider yourself a world-renowned scientist. Correct?
A. It is not what I consider myself. It is what others consider myself.
Q So you're familiar with your reputation across the world. Correct?
A. I am familiar with my reputation.
Q. And your reputation is that you are a specialist in the field of bipolar disease in children?
A. I am a specialist in pediatric psychopharmacology.
Q. Which includes bipolar mania?
A. It is one of many conditions that afflict children.
Q. Well, I thought you indicated to me yesterday -- and correct me if I'm wrong -- that your two subspecialties within the field of psychopathology are bipolar mania and ADHD.
A. I indicated that that's the predominance

of my scientific work, not the only work that I do or the only type of research that I do.
Q. When the Grassley committee hearing or the Grassley investigation was initiated, you were the subject of newspaper comments, were you not?
A. I was.
Q. And I have today a copy of a page from The New York Times, November 25, 2008. Was that approximately when this issue came to the public's eye? Approximately.
A. November 2008, I think The New York Times published e-mails that you released to the press from some attempt to quash the subpoena. This is what I think happened in the paper in 2008. There was an article, there are articles before that, but the 2008 I believe is related to e-mails that you released to the press.
Q. You think I released something to the press?
A. Obviously somebody released.
Q. Well, you said "you" and you looked at me. Do you think I released it?
A. I am using the "you" generically.
Q. Okay. So the "you" could be anybody in the world. Right?

A. No, could be somebody related to this case.
Q. Well, who?
A. I don't know. It's not -- I have no access to that information.
Q. Well, the purpose for this is that in this document, and I only have one copy but I will represent to you that I'm going to read it accurately, it says "Dr. Joseph Biederman, a world-renowned child psychiatrist." And that's how people see you, do they not?
A. Yes.
Q. Would you consider yourself the leading psychiatrist in the world for the treatment of bipolar mania or bipolar disease in children?
A. One of the leaders.
Q. One of the leaders?
A. (Witness nodded.)
Q. Are you a football fan?
A. Fair-weather.
Q. Fair-weather. We had a football coach in Texas named Bum Phillips. You ever hear of Bum Phillips?
A. No.
Q. His son Wade Phillips is actually the

opposite." That research is not forthcoming.
So the people, the mostly vocal critics are people that have not done any critical body of research disputing the findings. They're only saying I don't like it, which in science is not the same. You're not having the same interlocutors by saying I don't like that. You can say it about a hamburger or a hotdog but not in science. In science in order for you to say that this is not true, you need to show equal amount of work that shows the opposite result, and that's the dispute. Today pediatric bipolar illness is accepted by the practicing community.
MR. FIBICH: Object to that as being nonresponsive.
BY MR. FIBICH:
Q. Do you disagree with this statement: The diagnosis of pediatric bipolar disease is controversial?
A. I disagree. The controversy is about how to best define, what are the best ingredients. That's the controversy, not that a group of children that are very sick with high levels of morbidity and disability exist. That controversy is over. The controversy today is about how to best define it.

That's the controversy.
MR. FIBICH: Mark this as the next exhibit. And we're skipping one but I'll come back to it.
MR. BURNEY: So I'm sorry. The number on this is 19 or 20? You said the next exhibit but we're skipping one.
MR. FIBICH: Hold on.
THE WITNESS: This is 18.
MR. FIBICH: This is going to be 20.
MR. BURNEY: This is going to be 20? Okay.
(Biederman Deposition Exhibit 20 marked for identification.)
BY MR. FIBICH:
Q. Let me show you what I've marked as Exhibit 20, Dr. Biederman.
A. Mm-hmm.
Q. And this is an article out of The Washington Post, February 2005. Do you see that?
A. Mm-hmm.
Q. And if you would turn to page 3 and under the heading Very Disturbed Children, read the comments that are attributed to you, sir.
A. Mm-hmm.

Q. Did you talk to The Washington Post?
A. I don't remember who I talked to, but apparently I talked to this person.
Q. The comments that are contained in the first two paragraphs are comments of yours and you were quoted accurately. Correct?
A. This is not a quote, this is an interpretation of what I said.
Q. Is it a correct interpretation of what you said?
A. I said the same as I said to you. I did not compare myself to Galileo. I said that Earth was once flat. The reporter is not quoting me here. It is her interpretation. She could have said that I am comparing myself to God. This is her interpretation of what I said. I said that Earth was once flat. This is what I said.
Q. Well, why didn't you compare yourself to God?
A. Because I am not God. I am saying that the interpretation of my statement is her interpretation.
Q. Is her interpretation of your statement an accurate statement?
A. I said that Earth was once flat. I did

not compare myself to Galileo.
Q. Sir, I'm asking you, what she says is "Joseph Biederman, a professor of psychiatry at Harvard and one of the most forceful advocates of the aggressive treatment of preschoolers, thinks bipolar disorder has been severely underdiagnosed in children." Is that a correct statement?
A. That is correct. That's a quote.
Q. Okay, that's a quote. And the next statement is "He likens the criticism he has encountered to the outrage that greeted Galileo's challenge to the notion that the Earth was flat." Is her interpretation of what you said accurate? Yes or no.
A. Yes, it was accurate.
Q. And do you agree that you are one of the most forceful advocates of the aggressive treatment of preschoolers?
A. It is her statement about me.
Q. I didn't ask you if it was her statement about you. I'm asking you if you agree that you are one of the most forceful advocates of the aggressive treatment of preschoolers.
A. I am.
Q. Doctor, what is the purpose of publishing

that you do not consider the research you do to be what is termed clinical research?
A. No, it is clinical research.
Q. You what?
A. It is clinical research.
Q. Okay. There seemed to be some misunderstanding about that.
Now, before we go any further, I'd asked you if you generally understood what was in the label for Risperdal.
A. Yes.
Q. And are you aware that the label contains a statement that the mechanism of action for Risperdal is unknown?
A. Correct.
Q. And what does that mean?
A. It means that the exact way that the risperidone and other medications work in the brain is not fully elucidated.
Q. Well, I'm not interested in other medications. I'm just interested in Risperdal with respect to that question. Okay?
A. Yes, yes.
Q. What it means is we don't know really how it works. Right?

A. Fully. We have some ideas. For example, the prolactin problem that we talked yesterday is due to the effect of risperidone on a particular type of receptors in the dopamine system that are called dopamine 2 receptors. So other mechanisms are not fully known.
Q. Well, basically we know that Risperdal affects the chemistry in the brain. Correct?
A. The hypothesis, the reason that risperidone, Clozaril and others are called atypical neuroleptics is because they exert influences at least in two brain systems. One is dopamine and the other one is serotonin.
Q. And do children's brains develop over time?
A. Children's brain and adults' brain develop over time.
Q. And are there any studies on the long-term effect of giving children Risperdal for any period of time, the safety of that?
A. There are studies today of a few years, not more than a few years' follow-up. When a drug is, say, brought to market there is a requirement that there is at least one or two years of follow-up, so I believe that risperidone has some

type of follow-up data.
Q. You believe so? You don't know so?
A. I do not know for sure. As I told you, I did not participate in the study so I do not know. But that's a standard requirement of the FDA.
Q. And of course if the drug is being used off-label, then the FDA would not have required that type of study. Correct?
A. Physicians use all the time medicines available to them to help their patients off-label. It's a legal activity; it's done all the time; and many of the discoveries in medicine, in psychiatry and other fields occurred through using medications off-label. So off-label is not a bad practice necessarily. Only means that the pharmaceutical company has not yet conducted the clinical study. In the case of risperidone, as you know, the pivotal studies were conducted.
MR. FIBICH: Object to that as being nonresponsive.
BY MR. FIBICH:
Q. What I was asking you was, were there any long-term studies of the effect of Risperdal on children? And you said --
A. To my knowledge we, in our research, we

followed the children that responded to risperidone, our small sample, for a year. So we had some small data on long-term effects.
Q. You have anecdotal evidence from your practice. Correct?
A. No, it's -- Yes, I have anecdotal evidence, but we followed in the studies of risperidone that we conducted, we followed those children that responded and were willing to be followed, we followed them for a year and we collected data.
Q. And my question is the long-term effect. Are you aware of any published data that established the safety of Risperdal on children for a long period of time?
A. The risperidone -- I am not aware, but there is no data on adults either, on long-term effects.
Q. I didn't understand what you said.
A. There is not only absence of long-term data in pediatrics, but there is neither long-term data in adults.
Q. So this is a drug that we don't know how it works and you propose giving it to certain children under the age of six. Correct?

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

IN THE MATTER OF:

Plaintiff,

vs.

WB: WILLIAM BIGLEY

Defendant.

Case No. 3AN-08-00493 PR CI

[redacted]

VOLUME II

TRANSCRIPT OF MOTION HEARING

BEFORE THE HONORABLE SHARON GLEASON
Superior Court Judge

Anchorage, Alaska
May 14, 2008
10:17 A.M.

APPEARANCES:

FOR THE STATE: Timothy M. Twomey, Esq.
Assistant Attorney General
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501

FOR THE DEFENDANT: James B. Gottstein, Esq.
Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501

3AN6308-79
10:17:01
THE COURT: Okay. We are back on record in a case involving Mr. Bigley, who is present here in the courtroom. And we have Mr. Twomey and Mr. Gottstein.
And I received paperwork from you, Mr. Gottstein, yesterday. And in it, it indicated you had not yet received the chart. Has that been remedied, or what is the status there?
MR. GOTTSTEIN: Your Honor, I received -- it was there when I got back from my supreme court oral argument, so yesterday.
THE COURT: All right. And I see a rather lengthy witness list. And I am concerned about the timeframe. So -- and it looks like three are simply to have available for cross examination of the materials you submitted, which I have reviewed; is that correct?
MR. GOTTSTEIN: Yes, Your Honor. I really only have three witnesses I plan to call.
THE COURT: Dr. Jackson, Dr. Hopson, and Camry Altaffer (phonetic)?
MR. GOTTSTEIN: Altaffer.
THE COURT: Altaffer. All right.
Mr. Twomey, are you ready to proceed?

MR. TWOMEY: Yes, Your Honor.
THE COURT: All right. And who would you seek to call first, Mr. Gottstein?
MR. GOTTSTEIN: Dr. Jackson. And her number is area code 910/208-3278.
THE COURT: All right. Thank you.
So did I indicate until noon today we could go, or did I -- is that what I had indicated? Or did I make any indication?
I have to go to an event at noon or there about. So we'll see where we are time-wise. I know it's an important issue for your client, Mr. Gottstein. If we need to find more time in the next couple of days, we can do so. So let's see what progress we can make up until noon.
MR. GOTTSTEIN: You indicated noon.
THE COURT: I did. All right. That was my recollection, but I didn't see it in the log notes. All right.
We are a little late getting started, which was not really my fault, but my reality, anyway.
MR. GOTTSTEIN: Your Honor, I gave the clerk exhibits for this morning.
THE COURT: I have them right here. A through F; is that correct?

MR. GOTTSTEIN: Yes, ma'am. And I gave them to Mr. Twomey.
THE COURT: Mr. Twomey, you have a copy, as well?
MR. TWOMEY: Yes. I received them this morning, Your Honor.
THE COURT: Do I have Grace Jackson on the phone?
THE WITNESS: Yes.
THE COURT: All right. Good morning, Ms. Jackson. My name is Judge Gleason. We have you on a speakerphone here in a courtroom in Anchorage, Alaska.
You have been called as a witness on behalf of the respondent, William Bigley. It is a matter here where I have the lawyer from the state and Mr. Gottstein present.
I am going to be recording your testimony here in just a moment. I will administer an oath to you. But any questions first?
THE WITNESS: No.
THE COURT: All right. If you'd raise your right hand, please.
(Oath administered.)
THE COURT: If you would then please state

and spell your full name.
THE WITNESS: Grace Elizabeth Jackson. That's G-R-A-C-E, Elizabeth, E-L-I-Z-A-B-E-T-H, Jackson, J-A-C-K-S-O-N.
THE COURT: All right. Thank you.
Go ahead, please, Mr. Gottstein.

DR. GRACE JACKSON

called on behalf of the respondent, testified telephonically as follows on:

DIRECT EXAMINATION

BY MR. GOTTSTEIN
Q Thank you, Dr. Jackson. First off, did you send me a copy of your curriculum vitae?
A Yes, I did.
Q And it's 11 pages?
A I believe that is correct, yes.
MR. GOTTSTEIN: I'd move to -- it's Exhibit A. I would move to admit.
THE COURT: Any objection there?
MR. TWOMEY: No, Your Honor.
THE COURT: All right. A will be admitted.
(Exhibit A admitted.)
MR. GOTTSTEIN: Should I give this to the clerk at this point?
THE COURT: That's fine. You can hold on to

it, and we'll get it later, if that's easier for you.
BY MR. GOTTSTEIN
Q Okay. And if I might just take care of the other part of it, too. Did you also send me essentially an analysis of the neuroleptics, neurotoxicity of -- oops, I didn't number it -- 19 pages.
A Yes, that's correct.
Q And is that your work?
A Yes, that is my work.
Q And this analysis is true to the best of your knowledge?
A That's correct.
MR. GOTTSTEIN: I would move to admit that, Your Honor.
THE COURT: That is Exhibit E?
MR. GOTTSTEIN: E.
THE COURT: All right. Any objection to E, Mr. Twomey?
MR. TWOMEY: No, Your Honor.
THE COURT: All right. E will be admitted.
(Exhibit E admitted.)
BY MR. GOTTSTEIN
Q Thank you, Dr. Jackson. Could you briefly describe to the court your experience, training --

training, education and experience?
A Certainly. I attended medical school at the University of Colorado between 1992 and 1996.
Following that, I entered and successfully completed residency in psychiatry, which was performed actually within the U.S. Navy. And that residency was performed -- well, the internship was in 1996 through '97, the residency 1997 through 2000.
Subsequent to completing that residency program, I served as an active duty psychiatrist in the U.S. military. I actually transitioned out of the military in the spring of 2002, and I have been actually in self-employed status since 2002 working at a variety of different positions in order to have some flexibility for research, lecturing, writing, and clinical work, and also forensic consultation.
Q Could you describe -- so have you published papers?
A Yes. I have published papers in peer-review journals. I have contributed chapters to other books which have been edited by other mental health professionals, both in this country and overseas.
And I am also the author of my own book, which I published in the year 2005.
Q And what was the name of that book?

A That book is called Rethinking Psychiatric Drugs, a Guide for Informed Consent.
Q And have you testified as an expert -- testified or consulted as an expert in psychopharmacology cases?
A Yes. I have served as a consultant in a number of cases involving psychiatric rights similar to this case.
Also involving disputes over the use of medications versus alternative treatments in regards to child treatments. I've served as a consultant to families or their doctors in other states in order to assist in the preparation of different treatment plans.
And I've also been involved as an expert witness in consulting on product liability cases.
Q Were you qualified as an expert in psychiatric and psychopharmacology in what's known as the Myers case in Alaska here in 2003?
A Yes, I was.
Q And did Dr. Moser testify I think something like that you -- that you knew more about the actions of these drugs on the brain than any clinician he knew in the United States?
MR. TWOMEY: Objection, hearsay, Your Honor.

THE WITNESS: I'm sorry. I'm getting a lot of beeps on my phone. Can you hear me all right?
THE COURT: Yes.
But, Mr. Gottstein, your response to the hearsay objection?
MR. GOTTSTEIN: It's actually in the testimony that was filed, I believe.
THE COURT: Well, then the testimony speaks for itself.
MR. GOTTSTEIN: Okay.
THE COURT: So you can go forward.
MR. GOTTSTEIN: I would move Dr. Jackson as an expert in psychiatry and psychopharmacology.
THE COURT: Any objection there, Mr. Twomey, or voir dire?
MR. TWOMEY: No, Your Honor.
THE COURT: All right. Then I will find the doctor so qualified in those two fields.
Go ahead, please, Mr. Gottstein.
BY MR. GOTTSTEIN
Q Dr. Jackson, in preparation for this case, have you reviewed the -- what's known as the -- well, the affidavit of Robert Whitaker?
A Yes, I have.
Q And what is your opinion on that affidavit?

A I believed it was very truthful. I thought it was a very accurate presentation of the history of this specific class of medications which we are discussing in this case, the antipsychotic medications.

And also a very succinct but accurate description of some of the problems that have emerged, not only in the conduct of the research, but also in terms of the actual lived experience of patients. So I felt it was a very accurate and very clear presentation of the information as I understand it myself.

Q Now, would it be fair to say that this information is not generally shared by most clinicians in the United States?

A Oh, I think that would be a very fair -- very fair statement.

Q And why would you say that is?

A Well, I think we have a short time here. It's really a broad subject. But quite succinctly what has happened is that the educational process throughout medicine, not just psychiatry, and also the continuing medical education process, even when physicians have completed the first steps of their training, have actually presented a very biased

depiction of the history, or actually omitting the history of many medications.

So a lot of this is a reflection of the educational process, both in the first stages of medical school and residency, and then what is occurring in the medical literature even now.

Q Let me stop you right there just for a minute. So were you trained in this way?

A Yeah. I was -- absolutely. I was trained in the traditional sense that basically serious -- especially severe -- quote, severe mental illness or mental illnesses are diseases of the brain which require chemical treatments, i.e., medication treatments, and that in most cases, these medications must be used on a very chronic or even permanent basis.

Q And did something happen to cause you to change your mind or question that information?

A Lots of things happened. Probably one of the most important things is that I was fortunate enough to be trained -- or be training in a location that exposed me to some additional information.

In other words, some of the history, and also some of the alternative work which could be done that might be effective. So that was one part, is I did

begin to have an exposure to a different perspective.

But the most -- probably the most important thing for me was the lived reality of my patients, just opening my eyes and really paying attention to see whether or not people were improving.

Q I'm sorry; I missed that a little bit. Could you go into that a little bit further, what you found?

A Sure. Well, what really happened is that internship -- I should probably just back up and say that I regard -- in retrospect, I look at the educational process as really an indoctrination.

And I think it's rather unique or heroic when people can begin to examine things more critically. And I was just lucky enough to have an exposure to some individuals who allowed me to do that.

But more specifically, I began to see that in clinic after clinic, whatever setting I was moving through, I was seeing the patients were in fact not improving, that in most cases, in fact, patients were getting sicker and sicker.

And there are two ways to react to that. One could either blame that on the underlying illness and say that we just don't have treatments yet that are effective, or one could even begin to pay attention and ask a broader question or more pointed question,

gee, is it possible that there's something about the way we are approaching these phenomena that is in fact getting in the way of recovery?

And once I began to ask that question, I basically had a 180-degree turnabout in terms of how I had to practice ethically and according to science.

Q And did that result in a -- I think you kind of testified to this -- in a change in direction more towards researching this issue?

A Oh, absolutely. Well, basically, it resulted in two things. It resulted in a great deal of conflict between myself and most conventional settings. It's why I'm an independent practitioner and not a person enjoying an academic appointment or an appointment in a facility.

So it really made -- I had to make a firm decision, was I going to be truthful to science or was I going to go after a $200,000 a year job with nice perks and the respect of my colleagues?

So it was very clear to me that in order to honor the dictum first do no harm, I had to really stay truthful to the science. And that's really what necessitated my breakaway. So that's why I'm really an independent person who does my own research and tried to just help where -- you know, where the help

is actually needed or asked for.
Q Thank you. And so then, just to kind of fill in then this, it's Exhibit C, your neurotoxicity analysis, that would be some of your, you know, more recent work, is that correct, or current state of your research into this issue?
A Yeah. Fairly current.
I am trying to finish a second book this year. And what has really happened over the past two years is that I try to do clinical work to keep myself current with that.
But I also step aside. And probably every single day, I am working on the most current research in the field in order to, you know, lecture and to also write this second book.
What really happened about four years ago is I began to appreciate the fact that most physicians -- and this isn't just a criticism of psychiatry, by any means. But most of us ignore something which is called target organ toxicity. We don't pay attention to how the treatments we're using might actually be adversely affecting the very target we are trying to fix or help improve or repair.
So in my case, about two years ago, I started to just begin focusing on the most current research

that looked at the brain-damaging effects of different kinds of interventions. And that is really what I've been focusing on.
So the document that you have there is a reflection of some of that research. I should say that it's not completely up to date, because some of the research I've been doing more recently even demonstrates that these drugs are more toxic than what I have written in this report.
Q Okay. Thank you. I want to get to that -- get to that also a little bit more. But I'm also -- are there other reasons why clinicians are not really understanding this -- this state of affairs?
A Sure. Well, I think there are so many things that happened.
I'll just take my example. I went to medical school in 1992, graduated in '96, and did my residency until 2000. This was a very pivotal time in what was occurring within the mental health field and also within the United States culturally. And if I just picked, like, maybe four key things.
One is the government decided to name this decade the decade of the brain. In doing so, it sort of attached a governmental license or the (indiscernible) of sanctioning regarding these

phenomena as brain diseases.
The second thing that happened was the birth of something called evidence-based medicine. This was -- actually sort of became official through the Journal of the American Medical Association and other major journals to really elevate an importance, not the actual day-to-day observations that a doctor would be making and not the actual science of what causes illness, but clinical trials that are aimed at just improving or changing symptoms.
The third thing that happened was something that is called direct consumer advertising in 1997, which again was trying to market these drugs and make them more popular or appealing to the public.
And the fourth big thing that has really changed is something called the preemption doctrine. And also, the Daubert litigation.
Daubert was a supreme court decision in 1993 that has really made it quite difficult for toxic tort litigation to occur, so that the implications of that for doctors -- and they don't realize this. It's very much behind the scenes -- is that the pharmaceutical industry began publishing as many papers that they could as fast as possible in the journals in order to meet the Daubert standard of something called weight

of evidence or preponderance of the evidence.
So essentially what happened in the 1990s is that the journals, more than ever before in history, became a tool of marketing, a marketing arm for the drug companies. And drug companies shifted in terms of previous research in the United States.
Most of the research had previously been funded by the government and conducted in academic centers. In the 1990s, that was pretty much over, and most of the funding is now coming from the pharmaceutical industry. So that's really in a nutshell what happened in the 1990s when I was training.
Now, where are we now? What that means is that the journals that most doctors are relying upon for their continuing information continued to be dominated by pharmaceutical industry funded studies and by papers which are being written, if not entirely by the drug companies, then by authors who have part of their finances paid for by the drug companies.
And while I don't believe that it's necessarily going to buy us the information in an article, I think trials have to be funded by someone. Unfortunately what has happened is that there have been too many episodes of the suppressed information,

so that doctors cannot get the whole truth.
Q Well, I want to follow up on that. What do you mean by suppressed information?
A Well, one of the things that has happened repeatedly, and again, most doctors don't realize this, is that the pharmaceutical industry has not been forthcoming in terms of surrendering all of the information to the Food and Drug Administration that they were by law I believe, or at least under ethics, required to do.

For instance, in January of this year, the New England Journal of Medicine published a very important article that had been done. Actually, one of the key authors was a former reviewer at the Food and Drug Administration, who is now back in private practice, or somewhere.

And he and his co-authors had actually had access and reviewed the clinical trial database on the antidepressant medications. And they found that 31 percent of the trials were never published. So 31 percent of that information was never reported in the journals so that doctors could see it.

Okay. Well, you might say who cares. The point of it is that within that 31 percent, had they been published, the overall risk benefit understanding

of this category of medications would have been changed. Instead of favoring these drug treatments, it would have altered the whole face of the journals, and potentially the use of these medications would have become more limited.

Because that 31 percent of the information was showing that the medications were, A, not terribly effective or not more effective than placebo at all, and, B, it really began to reveal the full scope of the hazard. So by not publishing all this information, there is a false view of efficacy and safety.

I should say the same thing has happened with Vioxx. The same thing has happened with the cholesterol-lowering drugs. This is an epidemic right now, which is a real crisis in the integrity of medicine. It's not just psychiatry.

Q Does the same thing happen with respect to the neuroleptics?
A Absolutely, the same thing has happened with respect to the neuroleptics. I think you're a perfect example of someone who has tried to work to bring some of this hidden material to the forefront, because I still think there are concerns among professionals, and I hope among the public, that the Food and Drug

Administration still may not have seen all of the actual data that has been generated in the actual trials. So it is a continuing problem and a continuing concern.

And yes, I believe that most people -- I'll give you an example. When I was working in the VA clinic a couple summers ago in Oregon, I attended a dinner lecture where a speaker for a specific antipsychotic medication slipped out some information that I thought was extremely important. He said that the FDA and the public still has not seen information on Abilify, Aripiprazole, another antipsychotic.

And he alluded to the fact that there was a severe problem with cardiac toxicity, but he would not go any further. He was speaking on behalf of another company. But he said that it would be possible to contact him and perhaps he could share that information.

Well, my point is, why are the rest of the doctors not getting this information that Abilify is eight times more toxic to the heart than the other antipsychotics? I sort of filed that away in the background of my head and said, boy, you know, I'd like to have this information.

But the point is, doctors are not getting the

information. And that's a real problem both for them and it's a problem for their patients.
Q Is it fair to say that you've really devoted your life to -- or your work at this point to ferreting out this sort of information and making it available?
A Right. As best I can. And you know, it's -- it's really sort of a Catch 22. I would love to have the respect of my peers. I would love to be at Harvard teaching. You know, I would love to be an academic able to teach medical students.

But unfortunately, the system is so skewed still in the direction of the pharmaceutical companies and their products that I can't, you know, even get a foot in the door.

So yes, I am full-time researcher trying to do my best to understand this material accurately, and fairly, and objectively, and then to actually act responsibly in response to that knowledge.
Q So in reviewing this information, is it important to carefully look at the data and analyze what's actually presented?
A It's extremely important to look at the methodology. I don't think -- unless a person is actually working at the Food and Drug Administration

or one of the actual clinical trial researchers, you know, actually producing the data that you would actually -- that a person like myself would have access to the raw data.

But what I can analyze and ask questions about is to go to people who have either performed these studies, or when I read the published studies, which is usually what I have access to, to really use good critical thinking in terms of analyzing the methods that have been used.

And you might -- I'm not sure if we're going to have time to discuss methodology, but this is one of the key things that any physician really has to pay attention to.

It's not just the fact that there might be 10 or 20 studies that say a particular medication is either good, bad, or indifferent. It's actually important to -- you know, before even looking at that conclusion, to address how the study was performed so that one can make a well-informed and an appropriate judgment as to whether or not the conclusion should even be considered.

Q And so without going too much into it, could you describe a couple of methodological concerns that you have with respect to the second generation of

neuroleptic studies of which Risperdal is a member?

A Certainly. One of the things that has happened is that the database or the research (indiscernible), which is actually used to approve medications in this country, psychiatric medications, and then used to continue to argue in their favor, especially in product liability litigation or in a lot of cases. That data set is very limited in terms of generalizability.

What most people don't realize is that when a drug is being approved, the people performing the research want to pick the healthiest or the least sick or the least damaged patients, so that they can try and produce good outcomes. So that is one of the main concerns that all of us doctors have about clinical trials is that we recognize the fact that the generalizability is limited.

What do I mean by that? Well, they usually want to pick people who don't have additional illnesses, such as diabetes, heart disease, lung problems, liver disease.

Well, that's going to rule out a large number of people who are actually existing in the real world, because once they've been on many of these medications, they are guaranteed to have some of these

problems.

Number two is they eliminate the use of additional drugs, meaning additional medication. Well, that eliminates another huge portion of the United States population, because most of the people who are being seen in mental health settings are actually receiving more than one, and in some cases, you know, as many as 10 or even 20 medications for various conditions.

So it makes it very difficult to extrapolate to the real-world setting the information that they get or they find in a clinical trial.

Another problem is the length of a clinical trial. A clinical trial usually is cut off at six weeks. That's it. And the drug companies understand and actually choose the six-week cut off for a very good reason. They know that generally speaking, they can't continue to produce favorable results after six weeks.

And then another big problem with these methodologies is the fact that they really are enrolling people who have previously been receiving medications.

So what does that mean and why does that alter or bias the results? Well, one of the problems

in the antipsychotic medication literature, as in the antidepressant literature, is the fact that patients are brought into the study and they have previously been taking a medication, in some cases right up to the day that they enter the study.

And then the first seven to ten days in most of these trials involve taking the patients off of those previous or pre-existing medications. So seven to ten days, the person is abruptly cut off from their previous drug.

Now the real stage of the trial begins. So that first seven- to ten-day window is something that is called a washout. And sometimes what they'll do is they'll give everybody a sugar pill in those first seven to ten days and call it a placebo washout.

Now, the use of the term washout has two meanings. Washout meaning whatever other drugs the person may have been taking before, those are supposed to wash out of the system. And the second part -- and the second meaning of washout is that if someone begins to improve too much in those seven to ten days, they are removed from the study.

Q So may I interrupt you?

A Sure.

Q Are you saying that when people are withdrawn

from the drugs they were taking previously and they improve when they get taken off the drugs, then they are eliminated from the study?

A That's right. They take them out of the study. Because they only want to have people remaining in the study who are going to continue to look -- you know, either continue to look bad on the placebo if they continue to stay -- if they are randomized to the placebo part of the trial.

Or if they are then switched back on to an active medication, something chemically active instead of a sugar pill, their withdrawal symptoms, having been cut off of a previous drug, will hopefully respond to having another drug that was similar to the previous drug, you know, put back into their system.

So you understand completely, they remove people -- and this is important in terms of this case. Because for instance, in the Zyprexa trials, a full 20 percent of the people improved so much in the first seven to ten days when they were taken off their previous drugs that they kicked all those people out of the trial.

If they had retained them in the trial, they could not have gotten results that made Zyprexa look like it was any better than a sugar pill. It would

have biased the results in favor of the sugar pill.

Q So now, did you -- did you analyze the studies that the FDA used in --

THE COURT: And I am going to cut off here and say what would be helpful to me, Mr. Gottstein, is as I understand it, API is proposing Risperdal here, correct?

MR. GOTTSTEIN: Yes.

THE COURT: And so if we focused exclusively on that, I think given our time constraint and the proposal, I think that would be the most helpful for me.

MR. GOTTSTEIN: Well, Your Honor, one of the problems is that we didn't know until Monday that -- you know, that it was Risperdal.

THE COURT: But now that we do, if we could focus on that, I think that would help.

BY MR. GOTTSTEIN

Q Well, are all these -- are all these things that you mentioned also applicable to the Risperdal studies?

A As far as I know. And I have no reason to believe from what I've read in the literature -- I haven't had time to read the FDA review on Risperidone as I have done with olanzapine. But based on the

trials that I have seen in the regular journals, I have no reason to believe that anything other than this procedure has been used repeatedly.

In other words, the placebo washout and actually switching people or removing people who improve too much, it's sort of a standard protocol that you have a certain score in terms of symptoms. And if people don't meet that cutoff, in other words, they begin to improve too quickly, they don't get to stay in the study.

So I have no reason to believe that Risperidone was any different than Zyprexa in terms of this method of eliminating people who -- and you know, favoring or biasing the result of the study.

Q In the interest of moving forward, is it fair to say there are other methodological problems with these studies?

A Oh, absolutely. What many of these studies will do is to allow certain concomitant treatments. In other words, certain additional medicines during the study so that you can't really be sure that the results they are claiming are the result of the actual interventional drug. For instance, Risperdal instead of a benzodiazepine or an antihistamine.

Another thing is the way that the data

themselves get reported. And one of the things that is frequently done is to use something called LOCF, or last observation carried forward. So what that means is if you were to enter a study for instance, and they started you on Risperdal, and you start to have a severe side effect, let's say Parkinsonian symptoms, and you dropped out of the study at two weeks, but the study is supposed to end at six weeks, they will carry forward your score to the six-week mark.

Now, this will sometimes -- people will actually drop out when they have a higher score and they'll carry that forward, as well. But the use of LOCF statistics, especially when they carry forward people who are dropping out on placebo, those are people who are dropping out because they are in withdrawal. They have been cut off from a previous drug.

And so they carry forward an end result, which is not a reflection of the underlying illness, let's say, but a reflection of this introductory bias, the placebo washout.

So the fact they report all of these LOCF data, meaning the fact that they are just carrying forward the results or the statistics from people who drop out of the study early, biases the results in

favor of the drug, when in fact it's not an accurate reflection of what's really going on in the study.

And that happens quite often, and that certainly happened in the Risperdal/Risperidone literature.

Q So just to kind of finish up this part, would it just generally be fair to say that it would be pretty difficult for a practicing psychiatrist in clinical practice to have this information that you are providing to the court?

A Oh, it would be almost impossible. It's -- it would be something you would really have to devote your study to.

And actually, you know, not only would it be difficult for the ordinary doctor to know this is going on, but he or she would read what is published in the regular journals and see that the results are promising, like 70 to 80 percent response rates, meaning a good response with patient satisfaction, et cetera.

And then he or she would be in the real-world setting, and maybe be lucky see 30 or 40 percent of the patients able to even tolerate the drug. So it not only is something that would be hard for doctors to know, but what they're actually being exposed to is

so far removed from reality that they are very unlikely to understand what is going on in the real world.

Q Okay. So what is going on in the real world? What is the impact of drug -- well, specifically Risperdal on patients?

A Well, the real effects in the real world are -- are really in two categories. And as a doctor, you know, I am sort of thinking in terms of safety first. I sort of think of, boy, what do I really have to look out for here if somebody comes into my office and they are receiving this medication or I am asked to begin it?

So one of the things that, you know, we are really talking about is safety. Are people dying on these drugs? Do people die from taking Risperidone? Yes. People are actually experiencing shorter life spans.

Initially it was felt that the life spans for people on medications like Risperidone were perhaps shortened maybe ten or 15 years. And I think that's even been elevated in the most recent government studies to more like 20- or 25-year shorter life spans. So instead of a male -- and we're usually talking about, you know, males with mental illness,

would probably be living, you know, if they were lucky, 72, 74 years of age for men in the United States these days. And we are really talking about something which drops the lifespan down into the 60s.

So at the worst what is going on is that we are actually contributing to morbidity, actually shortening people's life spans. And that's -- and that is either through an acute event like a stroke or a heart attack or something called a pulmonary embolism, or we are talking about more chronic illnesses that eventually take their tolls, things like diabetes and heart failure.

So at the very worst, what is going on in the United States is an epidemic of early suffering or mortality that was not present before these medications were being used, you know, by such a prevalence -- in such high numbers.

The second thing that is going on is that we are arguably worsening the long-term prognosis of people, and in directions that were not previously seen or talked about. And I think my affidavit speaks to this. And also Mr. Whitaker's affidavit speaks to the history and the actual historical outcomes when individuals were being offered something other than just the medication or the priority on medication.

And so that is the other big thing in terms of what's going on.

What's going on is that people are suffering in great numbers, and that people are dying early, and that people are having what might have previously been a transient, that is a limited episode, converted into a chronic and more disabling form of experience.

Q Is -- are these drugs brain damaging?

A Well, I try and not sound like I am, you know, really off -- off my rocker. Because people probably wouldn't like it if I actually used a term for what's happening.

But I sort of say we have unfortunately contributed to a population of CBI patients, meaning chemically brain injured.

I was in the military, so I am very used to TBI patients, traumatic brain injury from, you know, concussions and explosions and what's going on in Iraq and Afghanistan.

But what is the elephant in the room that people aren't addressing in psychiatry and neurology is this population of CBI, chemically brain injured.

So yes, I actually would say that what we have created, and I think Mr. Bigley is an example of this, is that we are creating dementia on a very large

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

March 20, 2009

Via Electronic Transmission

Dr. Drew Gilpin Faust
President
Harvard University
Massachusetts Hall
Cambridge, MA 02138

Dr. Peter L. Slavin
President
Massachusetts General Hospital (Partners Healthcare)
55 Fruit Street
Boston, MA 02114

Dear Drs. Faust and Slavin:

The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under these programs. As Ranking Member of the Committee, I have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars appropriated for these programs. The actions taken by thought leaders, like those at Harvard Medical School, often have a profound impact upon taxpayer funded programs like Medicare and Medicaid and the way that patients are treated and funds expended.

I have also taken an interest in the almost $24 billion annually appropriated to the National Institutes of Health (NIH) to fund grants at various institutions such as yours. As you know, institutions are required to manage a grantee's conflicts of interest.[1] But I continue to learn that this task is sometimes made difficult because physicians do not consistently report all the payments received from drug companies. To encourage transparency, Senator Kohl and I introduced the Physician Payments Sunshine Act (Act). This Act will require drug companies to report publicly any payments that they make to doctors, within certain parameters.

Recently, I was provided a number of documents, including slides, that became available during ongoing litigation.[2] A number of the documents reviewed by my staff relate to, among other matters: Dr. Joseph Biederman of Harvard University (Harvard) and Massachusetts General Hospital (MGH/Partners), (collectively, the Institutions); and to the Johnson & Johnson Center for Pediatric Psychopathology Research (Center). As part of the litigation, Dr. Biederman produced several slide sets, and my staff have pulled several slides from these various presentations. I am not certain if these slides sets were

[1] Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. 50 (1995).
[2] Alma Avila, as Next Friend of Amber N. Avila, an Individual Case vs. Johnson & Johnson, et al., Docket No.: MID- L-6661-06
(In Re Risperdal/Seroquel/Zyprexa; Superior Court of Middlesex County, New Jersey).

United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

created by Dr. Biederman, and I am not certain if he has ever presented these slides publicly. However I do know that they were produced by Dr. Biederman.

The slides raise potential concerns about, among other matters, Dr. Biederman and the Center. My main concern is whether or not the attached slides suggest a predisposition to specific findings and conclusions prior to the studies being commenced. My other concern is whether or not NIH was aware that Dr. Biederman was performing research sponsored by J&J on psychiatric disorders when it awarded him a grant to collaborate with other doctors to study those same psychiatric disorders. I am also wondering if the physicians Dr. Biederman was collaborating with under the NIH grant were notified of Dr. Biederman's corporate sponsored research.

Accordingly, this letter seeks, among other things, your guidance as to whether or not the materials discussed in this letter are in compliance with all applicable rules followed by the Institutions. In addition, I would like to better understand the role played by the Institutions when proposals are drafted by professors, and whether those policies and procedures were followed with regard to the materials attached to this letter.

I. Attachment A

Slides in Attachment A, highlight several "Key Projects for 2005," and state:

- Concerta for the treatment of ADHD NOS in adolescents
  - Extend to adolescents positive findings with Concerta in ADHD NOS in adults

- Randomized Clinical Trial of Risperidone vs. Placebo in children younger than 10 years of age with bipolar disorder
  - Will complement registration efforts of studies with older youth
  - Will provide Janssen with critical competitive data on safety and efficacy of risperidone in children (80% of referrals)

Please explain:

1) Why do these slides suggest an expectation of positive outcomes for the drugs prior to the commencement of the clinical trials?

II. Attachments B and C

Slides set forth in Attachment B seem to explain what MGH would provide Johnson & Johnson in return for the funding. As part of the "deliverables," the slide reads:

- Research posters at major national and international meetings
- Research publications in peer reviewed journals
- Programs and symposia at major national and international meetings
- Help J&J develop state of the art, data based CME [continuing medical education] programs and educational materials

Several of the deliverables set forth in this slide are typical deliverables when performing scientific research, with the exception of the statement that the Center will in some way be helping J&J to create "state of the art, data based" CME programs. Accordingly please explain the following:

1) According to protocols and policies of Harvard/MGH, is it appropriate that a portion of the deliverables include the development of "state of the art data based CME programs and educational materials" for a particular pharmaceutical sponsor, in this case J&J? Please explain.

The slides in Attachment C describe, among other things the "Benefits" of the J&J Center. One slide reads:

- Supports research on the disorders that J&J products treats:
  - Concerta
  - Risperdal
  - Reminyl
  - Topamax

Another slide in Attachment C says the following:

- Provides rationale to treat chronically and aggressively highly morbid child psychiatric disorders

And yet another slide reads:

- Provides ongoing consultation for protocol development of new J&J products or new uses for existing compounds
  - Concerta for adult ADHD NOS
  - Reminyl for ADHD

1) Please explain why the slides set forth above suggest that the study being proposed could find new uses for J&J products?

III. Attachments D and E

The slides in Attachment D highlight several additional issues. The first is entitled "Key Projects for 2004" and says:

- Comparative effectiveness and tolerability of Risperidone vs. competitors in the management of pediatric bipolar disorder: acutely and chronically

  - Will clarify the competitive advantages of risperidone vs. other atypical neuroleptics

Another slide in Attachment D reads, in pertinent part:

- Effectiveness and safety of Risperdone in pre-schoolers

- Will support the safety and effectiveness of risperidone in this age group

The slides in Attachment E titled "Planned Investigator Initiated Studies" seem to complement those in Attachment D and say:

- Randomized Clinical Trial of Risperidone vs. Placebo in children younger than 10 years of age with bipolar disorder
  - Will complement registration efforts of studies with older youth
  - Will provide Janssen with critical competitive data on safety and efficacy of risperidone in children (80% of referrals)

Accordingly, please respond to the questions below regarding Attachments D and E.

1) Please explain how these slides could suggest that a study, which had not yet commenced "will support the safety and effectiveness of…." any particular drug and "complement" other efforts?

2) Is it possible that the study proposed in Attachment D would not support the safety and effectiveness of risperidone in pre-schoolers and if this is the case, why would the slide not so state?

Again, Dr. Faust and Dr. Slavin, I am having difficulty putting the Attachments to this letter in proper context. Indeed, I reached out to a physician researcher for an independent review of the slides attached to this letter. In response to my inquiry, the physician researcher said that it appeared that the slides discussed in this letter were nothing more than marketing tools, as opposed to discussions of independent scientific research.

IV. The Janssen Study

We also learned that these slides did result in funds being paid to Dr. Biederman and that he eventually published a Janssen supported study that found a 30% reduction in ADHD symptoms in 29% of study subjects when taking risperidone. This study was published in 2008 and its finding seem to correlate with the slides that were apparently produced years earlier and attached to this letter.[3] More specifically, Dr. Biederman's study concluded, "treatment with risperidone is associated with tangible but generally modest improvement of symptoms of ADHD in children with bipolar disorder." Even more troubling, the published study lists support from Janssen, the Stanley Medical Research Institute, and the NIH. In fact, the NIH funding for this study raises still more concerns in that federal dollars may have been used to support research when the results may have been "predicted" before the study began.

[3] Biederman, Joseph et al "Risperidone treatment for ADHD in children and adolescents with bipolar disorder" *Neuropsychiatr Dis Treat*, Feb 2008, 4(1): pp 203-207. Published online Feb 2008.

V. Attachment F and Possible Conflict of Interest

There is yet another aspect of documents reviewed in this matter that is concerning me. It is my understanding that Dr. Biederman was seminal in the creation of the Center and that he received almost half a million dollars [Attachment F] from the NIH to run the annual Collaborative Pediatric Bipolar Disorder Conference (2003: $95,015, 2004: $96,631; 2005: $99,209; 2006: $101,865; 2007: $101,567). It appears that running the Center on bipolar disorder, while also running a conference for the NIH on bipolar disorder could be perceived as a conflict. Therefore, I would appreciate your views on this. I also want to advise you that the NIH told me that MGH never informed them of this possible conflict.

VI. Attachments G and H

In addition to materials regarding the Center and Dr. Biederman, I also received materials produced for ongoing litigation by J&J. It seems, based upon a review of J&J internal communications, that the collaboration between the Center and J&J was driven more by business and marketing as opposed to pure science and research. For instance, in Attachment G there are J&J slides titled "2003 Business Plan." In one slide J&J notes that it will "leverage" the MGH Center to raise awareness of bipolar disorder in kids because "use of psychotropic medications in [children and adolescents] remains controversial." Another slide identified as Attachment H was presented by a J&J employee and was titled "A New Initiative! J&J Pediatric Research Center at Mass General Hospital." The relevant slide states that the initial discussions with MGH to create the Center involved participation "with marketing." So I ask, is it typical in your experiences to include the marketing division of a sponsor company during discussions of possible collaboration with your institution?

VII. Attachment J

Another document provided to me is entitled, "PHARMA SALARY SUMMARY" is identified as Attachment J. This document appears to be a summary of payments made to Dr. Biederman over a 3 year period. Accordingly, please respond to the following questions:

1) Explain the payments made and the services provided.

2) Address whether or not these payments were reported to you by Dr. Biederman.

3) Address whether or not if these payments were reported by you to me in previous correspondence.

4) Regarding Attachment J, please explain if Dr. Biederman received compensation from these companies as detailed in the attachment. If yes, provide an annual summary from each company.

VIII. Protocol Violations

Based upon a review of still other documents produced, I see that MGH's Institutional Review Board (IRB) found "a serious breach of the protocol and procedures and provisions" in Dr. Biederman's study of risperidone and olanzapine in preschool children. Based upon the materials in my possession [Attachment I], when this issue was brought to Dr. Biederman's attention in 2004, the human research committee at MGH reported that this was the sixth protocol violation for the study. If a study is supported with federal funds, then such violations should have been reported to the Office for Human Research Protection (OHRP) at the Department of Health and Human Services. Additionally, when the study was apparently published in 2005, the article listed support from the Stanley Medical Research Institute and the National Institute of Mental Health.[4] However, OHRP informed me that it was never notified of any protocol violations for this study.

Accordingly, please respond to the following questions and requests for documents. For each response, first repeat the question followed by the appropriate answer.

1) Why did Harvard/MGH not inform the NIH about Dr. Biederman's collaboration with J&J when it applied for the NIH bipolar disorder grant?

2) Several documents that Dr. Biederman supplied to the court make note of a "JB rent fund." What is the "JB rent fund" and to whom did the money go?

3) Why did MGH not inform OHRP about the IRB protocol violations in Dr. Biederman's study?

4) For that particular study, please explain each IRB protocol violation and how those violations were resolved.

5) Did representatives of MGH discuss collaborating on the Center with marketing people from J&J, as Attachment H states?

6) Were the slides detailed in the attachments to this letter created by Dr. Biederman? If not, who created them?

7) Please explain if these slides were ever presented to an audience. If so, who saw these presentations?

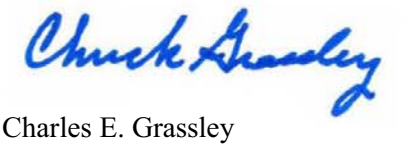
Thank you again for your continued cooperation and assistance in this matter. As you know, in cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

---

[4] Biederman, Joseph, et al "Open-Label, 8-week Trial of Olanzapine and Risperidone for the Treatment of Bipolar Disorder in Preschool-Age Children," *Biol Psychiatry*, 2005, 58: pp 589-594.

I look forward to hearing from you by no later than April 17, 2009. All documents responsive to this request should be sent electronically in PDF format to Brian_Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Paul Thacker at (202) 224-4515.

Sincerely,



Charles E. Grassley
Ranking Member

cc: Raynard Kington, M.D., PhD.
Acting Director
National Institutes of Health

Attachments

Attachment A

Johnson & Johnson Center for Pediatric Psychopathology Research

Director: Joseph Biederman, M.D.

Co- Director: Steve Faraone, Ph.D.

Data Management Director: Eric Mick, Sc.D

Business Administrator: Kate Balcke, MA

Administrative Coordinator: Megan Aleardi

Massachusetts General Hospital
Harvard Medical School

Key Projects for 2005

Planned IITs

- Concerta for the treatment of ADHD NOS in adolescents
  - Extend to adolescents positive findings with Concerta in ADHD NOS in adults

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- Randomized Clinical Trial of Risperidone vs. Placebo in children younger than 10 years of age with bipolar disorder
  - Will complement registration efforts of studies with older youth
  - Will provide Janssen with critical competitive data on safety and efficacy of risperidone in children (80% of referrals)

Attachment B

Deliverables

Johnson & Johnson Center for Pediatric Psychopathology Research

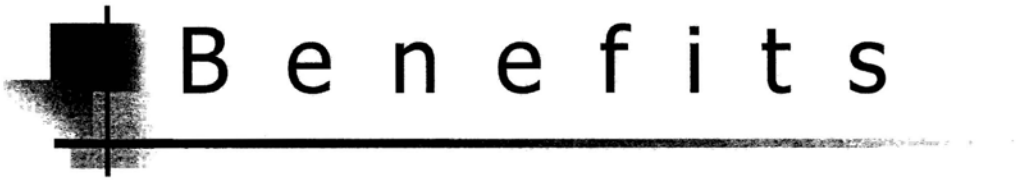
Massachusetts General Hospital

- Research posters at major national and international meetings
- Research publications in peer reviewed journals
- Programs and symposia at major national and international meetings
- Help J&J develop state of the art, data based CME programs and educational material

Deliverables

- Manuscripts
  - ADHD Follow-ups
  - Smoking as Gateway Drug
  - Ris for pediatric bpd
  - Ris for preschoolers
  - Age, gender; anxiety; cohort analyses
  - Driving
  - Lab workplace
  - PET
- Abstracts
  - APA
  - Biol Psych
  - CINP
  - ECNP Stanley
  - Bipolar Conf
  - Special issue

Attachment C


Benefits

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- **Gains access to many millions of dollars in data that have already been collected through NIH and other grants**
- **Gains access to world class experts in a variety of fields**
  - **Pediatric and Adults Psychopathology**
  - **Clinical Trials**
  - **Genetics**
  - **Neuroimaging**
  - **Biostatistics and Epidemiology**
  - **Neuropsychology**
  - **Driving Simulation**

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- **Supports research on the disorders that J&J products treat**
  - Concerta
  - Risperdal
  - Reminyl
  - Topamax

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- Documents the morbidity and disability associated with ADHD, pediatric bipolar disorder and related psychiatric and cognitive comorbidities
- Provides rationale to treat chronically and aggressively highly morbid child psychiatric disorders

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- Puts J&J at the forefront of pediatric psychiatry research
- Provides ongoing consultation for protocol development of new J&J products or new uses for existing compound
  - Concerta for adult ADHD NOS
  - Reminyl for ADHD
- Facilitates pilot and proof of concept studies

Attachment D

Key Projects for 2004

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- Comparative effectiveness and tolerability of Risperidone vs competitors in the management of pediatric bipolar disorder: acutely and chronically
  - Will help clarify the competitive advantages of risperidone vs. other atypical neuroleptics

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- Risperidone in the treatment of pediatric ADHD when comorbid with bipolar disorder
  - Will complement prior work on risperidone for DBD

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- Effectiveness and safety of Risperidone in pre-schoolers
  - Will support the safety and effectiveness of risperidone in this age group
- Pharmacogenetics of Risperidone
  - Will search for markers of response and adverse effects in pediatric bipolar disorder

Attachment E

Planned Investigator Initiated Studies

Planned IITs

- Concerta for the treatment of ADHD NOS in adolescents
  - Extend to adolescents positive findings with Concerta in ADHD NOS in adults

Planned IITs

- PET studies of Concerta in ADHD
  - Further clarification of Concerta's unique pharmacological and therapeutic profile

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- Randomized Clinical Trial of Risperidone vs. Placebo in children younger than 10 years of age with bipolar disorder
  - Will complement registration efforts of studies with older youth
  - Will provide Janssen with critical competitive data on safety and efficacy of risperidone in children (80% of referrals)

Attachment F

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

FEB 13 2009

The Honorable Charles E. Grassley
United States Senate
Washington, D.C. 20510

Dear Senator Grassley:

I am writing in response to your letter of December 19, 2008, regarding Drs. Joseph Biederman and Timothy Wilens of Harvard University (Harvard) and Massachusetts General Hospital (MGH). Specifically, you asked if Harvard and/or MGH notified the National Institutes of Health (NIH) about any potential conflicts of interest regarding NIH grant U13 MH 064077, titled *Collaborative Pediatric Bipolar Disorder Conference*.

MGH, the grantee institution responsible for reporting financial conflicts of interest to NIH under the regulation at 42 CFR Part 50, Subpart F, *Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought*, has not notified the NIH of any potential conflicts of interest concerning the above-referenced grant for which Dr. Biederman served as Principal Investigator.

Subsequent to your letter, MGH informed the NIH of the results of its financial conflict of interest review for those NIH grants under which Drs. Biederman, Wilens, and/or Spencer had a role in the design, conduct, or reporting of the research. The NIH is in the process of following up with MGH regarding its review, including, specifically, its review of U13 MH 064077.

I hope this information is helpful. If you need any additional information, please contact Marc Smolonsky, NIH Associate Director for Legislative Policy and Analysis, at (301) 496-3471.

Sincerely yours,

Raynard S. Kington, M.D., Ph.D.
Acting Director

			assess how gene variants will predict adult outcome. In our preliminary work, we have begun to address each of the Specific Aims that are the focus of the proposed work. We view the proposed extension of our work as an essential step for several reasons. First, although there have been seven follow-up studies of ADHD children and only two (our included) used DSM-III-R criteria. Moreover, unlike most prior follow-up studies, the proposed work can comprehensively address psychiatric comobidity in ADHD because we did not use comorbid conditions to exclude cases at baseline and we assessed for a wide range of comorbid conditions at each assessment. Only a few prior studies assessed intelligence, achievement and school functioning, none have thoroughly examined attentional-executive neuropsychological functions and only one examined psychosocial and family functioning. In contrast, our study has taken a multidimensional approach to measurement; we have assessed these domains of functioning at baseline and each follow-up assessment. Because the treatment interventions used in our sample are not being controlled, we will be able to document to naturalistic course of treatment use. Also, we are the only long-term study to collect clinical and molecular genetic data on all first degree relatives and to follow the siblings of ADHD and control subjects into adulthood. For these reasons, we expect the proposed work to clarify the course and outcome of ADHD.	
2003	1U13MH064077-01A1	Collaborative Pediatric Bipolar Disorder Conference	DESCRIPTION (provided by applicant): We are proposing a multi-year conference grant which seeks to establish a forum for researchers to pursue collaborative studies of pediatric bipolar disorder. This application was conceived in response to a recent roundtable discussion convened by the NIMH's Director, Dr. Steve Hyman, in collaboration with the Developmental Psychopathology and Prevention Research Branch and the Child and Adolescent Treatment and Preventive Intervention Research Branch. Despite controversy, the notion that pediatric bipolar disorder is exceedingly rare has been challenged by case reports and emerging research findings that suggest that this disorder may not be rare but, rather, that it is difficult to diagnose. It is also quite clear that, despite debate over nosological issues, many clinicians recognize that a sizable number of children suffer from a severe form of psychopathology associated with extreme irritability, violence, and incapacitation that is highly suggestive of bipolar disorder. Since a sizable clinical population currently exists for which relatively little systematic information is available, efforts that increase the pace and utility of research are desperately needed. Thus, an appropriate mechanism designed to facilitate regular communication among investigators and clinicians is needed as a first step to build collaborative research and guide clinical efforts that will foster a more efficient and streamlined approach to the understanding and treatment of this perplexing disorder. The main aim of the proposed conference grant is to overcome the hurdles to collaboration by establishing yearly conferences among investigators studying pediatric bipolar disorder. Subgoals of these conferences are: (1) to define the boundaries of the bipolar spectrum phenotype and determine if children who technically meet criteria for bipolar disorder actually have this disorder or are affected with another condition.; (2) to standardize data collection methods across different centers to facilitate pooling of diagnostic data and validation of the disorder; (3) to facilitate joint submissions of large collaborative projects that will enable the study of a broad spectrum of scientific questions including genetic, imaging and therapeutic protocols; and (4) to create a mechanism for pooling samples so that potential findings from one group may be cross-validated on	$95,015

			pooled data from other groups. Although scientific projects studying pediatric bipolar disorder are likely to be funded in the coming years, these efforts will likely take many years to unfold. This scientific void and ongoing diagnostic and therapeutic uncertainties calls for immediate action to foster contact and dialogue among interested parties in the clinical and scientific community. While the field faces a dearth of information, more and more children and families are being referred to clinics for evaluation and treatment. Thus, steps that increase the identification of children with bipolar spectrum disorder and the development of initial therapeutic approaches to help them is of high clinical, scientific and public health importance. While the proposed conference does not intend to solve all outstanding problems associated with pediatric bipolar disorder, it will provide a forum to begin formulating a solution.	
2004	5R01HD036317-07	Adult Outcome of Attention Deficit Hyperactivity Disorder	same as 2R01HD036317-06	$541,514
2004	5U13MH064077-02	Collaborative Pediatric Bipolar Disorder Conference	same as 1U13MH064077-01A1	$96,631
2005	5R01HD036317-08	Adult Outcome of Attention Deficit Hyperactivity Disorde	same as 2R01HD036317-06	$559,193
2005	5U13MH064077-03	Collaborative Pediatric Bipolar Disorder Conference	same as 1U13MH064077-01A1	$99,209
2006	5R01HD036317-09	Adult Outcome of Attention Deficit Hyperactivity Disorde	same as 2R01HD036317-06	$566,125
2006	5U13MH064077-04	Collaborative Pediatric Bipolar Disorder Conference	same as 1U13MH064077-01A1	$101,865.
2007	1R03MH079954-01	Course of psychopathology in female youth: Analysis with extant longitudinal data	DESCRIPTION (provided by applicant): Although attention-deficit/hyperactivity disorder (ADHD) is more prevalent in boys than girls, little doubt exists that ADHD is also an important cause of psychiatric disability in girls. Despite this, the scientific literature on females with ADHD is scarce, and mostly cross-sectional. Thus, large-scale studies examining the course and outcome of psychopathology in ADHD in girls are sorely needed. Such information can inform patients, families, teachers and clinicians and facilitate prevention and intervention efforts for females with ADHD, an understudied population. We propose a data analysis project that utilizes an existing longitudinal database to address these questions. The overall goal of this application is to use longitudinal measurements, a multigenerational perspective and an extensive assessment of multiple domains of functioning to investigate the developmental course and outcome of psychopathology in female youth with and without ADHD. Our specific aims are to: 1) examine the risk for psychopathology associated with ADHD across development; 2) describe the clinical characteristics of psychopathology in a sample of ADHD girls; 3) estimate the effect of antecedent risk factors on psychopathology in a sample of ADHD girls; and 4) to estimate the effect of psychopathology on subsequent functional outcomes in a sample of ADHD girls. The psychopathological conditions to be examined	$87,500

Attachment G

Child and Adolescent & Other New Business

2003 Business Plan

July 29, 2002

Strategic Initiatives

Use of psychotropic medications in C&A remains controversial	*Limited education and awareness of appropriate use of APSs*	*Physician misperception of RIS safety profile*	*Lack of indication*
Raise awareness regarding prevalence, economic and emotional burden	***Develop educational platform***	***Establish Risperdal as having a favorable risk-benefit ratio***	***Partner with JJPRD to facilitate development plans***
• Partner with advocacy to drive caregiver education • Generate and disseminate data supporting clinical rationale and utility of APS in C&A • Leverage CAPRI initiative with NIMH • Leverage J&J-MGH Pediatric Psychopathology Center to drive awareness	• Partner with McNeil to drive and leverage educational program • Targeted medical education to pediatricians and neurologists • Leverage J&J-MGH Pediatric Psychopathology Center to drive educational needs	• Neutralize safety and tolerability concerns • Leverage current datasets • Develop EMRP plan addressing datagaps: ADHD, bipolar disorder, autism, acute agitation, Tourette's • Maximize RUPP autism publication	• Work to expedite enrollment in ongoing Schizophrenia trial • Assist in development of adolescent bipolar trial • Expedite transfer and analysis of RUPP database • Work with JJPRD and Pediatric Development Group to expedite receipt of written request

Use of psychotropic medications in children is controversial

- Raise awareness regarding prevalence, economic, and emotional burden of untreated C&A mental illnesses and the long-term implications

Key Tactic: C&A Mental Health Summit

Description

One day national summit which addresses current issues in mental illnesses in children and adolescents

Audience

Advocacy, KOLs, AACAP, NIMH

Subject to legal and regulatory review

2003 Business PLan

Limited education and awareness of appropriate use of APS

- Develop educational platform to establish the role of APSs in the treatment of C&A mental illness

Key Tactic#1: "Branded" educational initiative

Description

Multi- medium, comprehensive branded educational campaign on the role of APS in the treatment of C&A mental health: Centers of excellence, Regional CME symposia, monographs

Audience

National and regional key opinion leaders, community based physicians

Key Tactic#2: Academic collaboration (MGH and CAPRI)

Lack of indication

- Partner with JJPRD and J&J Pediatric Institute to facilitate current development plans
  - RUPP (autism)
  - Schizophrenia
  - Bipolar Disorder
  - Exclusivity

Subject to legal and regulatory review

Risperdal C&A 2003 PME's

Description	2002 PME ($K)	Proposed 2003 PME ($K)	2003 PME (%)
Medical Marketing/Education	**3,890**	**3,300**	**51.6%**
CME Branded Initiative		1,800	
PsychLink/Teletopics		450	
Symposia (2)		350	
Publications		500	
National Ad Board		200	
Advisory Boards (RAB/HOV)	**1,800**	**1,900**	**29.7%**
Public Relations	**325**	**500**	**7.8%**
C&A Summit		400	
Other		100	
Grants	**160**	**300**	**4.6%**
Other	**225**	**400**	**6.3%**
Total PME	**$6,400**	**$6,400**	**100%**

Subject to legal and regulatory review

2003 Business PLan

Attachment H

J&J Pediatric Research Ctr. at MGH

Background *(continued)*

- With marketing, held initial discussions with MGH to discuss collaboration re: specific extramural research with risperidone
- Discussed the concept of a J&J center at MGH, reviewing specific scientific questions related to key business areas
- Discussed partnerships with J&J sister companies (OMP, McNeil) to coordinate support of MGH collaboration
- Designed a model methodology for collaboration, with specific scientific deliverables and timelines for delivery

Attachment I

INVESTIGATOR REPORT OF MAJOR PROTOCOL VIOLATION

This form is to be used to report **major** protocol violations. Protocol violations are deviations from the IRB-approved protocol that are not approved by the IRB prior to initiation or implementation. A **major protocol violation** is a violation that may impact subject safety, affect the integrity of the study data, and/or affect the willingness of the subject to participate in the study. Refer to PHRC guidance document Protocol Violations, Deviations, and Exceptions for more information and for examples of major and minor violations, see http://healthcare.partners.org/phsirb/prodevex.htm.

1. PROTOCOL INFORMATION

Protocol #:	**2001-P-000422**
Principal Investigator:	**Joseph Biederman, MD**
Title of Study:	**Open-Label Comparative Study of Risperidone Versus Olanzapine for Mania in Preschool Children 4 to 6 Years of Age with Bipolar Spectrum Disorder**

2. SUBJECT INFORMATION

Subject(s) ID #	Subject Initials	Date of Violation	Date of Discovery
3601102	**MATMCD**	**03/07/02**	**03/12/04**

3. DESCRIPTION OF THE VIOLATION

Briefly describe the protocol violation.

Subject MATMCD missed visits 4 through 6 during the acute phase of the study and subsequently all the necessary tasks (ie questionnaires, vitals) were not completed. Additionally, six weeks instead of the usual four lapsed between the week 3 and week 7 visits. At week 8, the subjects olanazpine dose was increased beyond the protocol specifications. For the purpose of stabilizing the subject, the dose was increased to 10 mg/QD when the maximum dose per protocol is 7.5 mg/QD. At month 1 of extension, the dose was again increased to 12.5 mg/QD. Each increase was well tolerated and was initiated for the purpose of stabilizing the subject.

4. CORRECTIVE ACTION

For guidance on appropriate corrective action, see http://www.partners.org/phsqi/ Contact the Quality Improvement/Human Subject Protection Program if additional guidance is needed.

☐	None to date
☒	Note-to-file was prepared
☐	Subject was consented/re-consented
☐	Other, describe below

NOTE: Major violations should be reported to the sponsor in accordance with the reporting requirements in the sponsor's protocol.

5. PREVENTIVE MEASURES

Describe below preventive measures developed/implemented to prevent similar violations from occurring in the future.

In no way was the subject's safety jeopardized as the treating clinician was in constant contact with the family and made adjustments to the dosing regimen based on reports from the subject's primary reporter. Study coordinators have been asked to stress the

importance of subjects' coming into the office for each weekly appointment. Furthermore, study coordinators will contact subjects before each visit in order to remind them of their appointments. The treating clinician and study staff will be instructed to follow the protocol strictly.

6. CHANGES TO THE PROTOCOL DOCUMENTS AND/OR CONSENT FORM

☒ No	☐ Yes	If Yes, submit amendment form and revised documents, as applicable

7. SIGNATURE OF PRINCIPAL INVESTIGATOR (required)

Signature of Principal Investigator	Date

MASSACHUSETTS GENERAL HOSPITAL

HARVARD MEDICAL SCHOOL

15 Parkman Street, WACC 725
Mail Zone WAC 725
Boston, Massachusetts 02114-3139
Tel: 617 726-1731, Fax: 617 724-1540
E-mail: jbiederman@partners.org

Joseph Biederman, M.D.
Chief, Clinical and Research
Program in Pediatric Psychopharmacology
and Adult ADHD
Massachusetts General Hospital
Professor of Psychiatry
Harvard Medical School

DATE: April 9, 2004
TO: Human Research Committee

RE: Response to IRB review of Violation: "Open-Label Study of Risperidone Versus Olanzapine for Mania in Preschool Children 4 to 6 years of age with Bipolar Spectrum Disorder"

Dear Committee Members:

Enclosed please find a response to your review of a violation that will be brought to a full committee.

Sincerely,

Joseph Biederman, MD

INVESTIGATOR RESPONSE TO IRB QUESTIONS/CONCERNS

PROTOCOL#: 2001-P-000422

1. PRINCIPAL/OVERALL INVESTIGATOR:

(cannot be resident or research fellow-except for bem/onc studies)

Name: **Joseph Biederman, MD**
First Name, Middle Initial, Last Name, Degree(s)

Institution: ☐ BWH ☐ DFCI ☒ MGH Employee ID#: 231-03-91

Dept/Service: **Psychiatry** Div/Unit: **Pediatric Psychopharmacology Unit**

Address: **185 Alewife Brook Parkway, Suite 2000, Cambridge MA 02138**

Telephone: **617-503-1063** Beeper: **35417** FAX: **617-503-1092**

E-Mail/Internet Address: **jbiederman@partners.org**

2. STUDY TITLE

Open-Label Comparative Study of Risperidone Versus Olanzapine for Mania in Preschool Children 4 to 6 Years of Age with Bipolar Spectrum Disorder

3. IRB Review Date: Please indicate date of IRB Review

4/1/04

4. Submission Reviewed: Indicate what was reviewed; e.g., 8/8/96 Amendment

Major Violation

5. RESPOND POINT BY POINT TO IRB QUESTIONS/CONCERNS:

I am fully aware that this breach will be brought to the attention of the full Partners Healthcare Human Research Committee as it represents a major violation. While this serious violation should never have occurred and is not justified, the HRC should be aware of the circumstances in which the violation occurred.

The main points are:
1) The clinician raised the dose above the protocol limit in an attempt to stabilize a very sick child who was experiencing severe psychopathology.
2) The dose used was above that approved in the protocol but within the range of what is used clinically. The correct procedure would have been to terminate the child and continue treatment at the higher clinically indicated dose.
3) The child experienced no adverse outcome.

To avoid the recurrence of this unfortunate and unacceptable event, the following steps were taken:
1) A stern notification was sent to all research clinicians in my program via email alerting them of this violation and stating the utmost seriousness of the event and the absolute need to fully comply with all aspects of an IRB approved research protocol and its dosing

requirements.
2) A formal meeting was held on 4-6-04, with the clinical staff of our research program to review this critical issue and formalize procedural changes moving forward.
3) Research staff was informed that in the case that an urgent or otherwise compelling clinical situation were to arise that appeared to warrant an exception to the approved protocol, the clinician will contact the PI immediately to review the situation and if the clinical circumstances are judged to warrant a potential protocol deviation, the PI will contact Harry Demonaco, Dr. Jonathan Alpert, or Dr. Elizabeth Hohmann at the IRB to review the situation and seek appropriate authorization to move forward with a protocol exception per PHRC guidelines . Without such authorization, no changes will occur.
4) If changes are still deemed necessary and the proposed exception is not authorized, the subject will be dropped from the protocol and treated clinically.

I hope that these procedures will avoid future inappropriate violation as the one that occurred. Please feel free to contact me with additional suggestions and recommendations if you feel that these procedures are inadequate and I will be happy to implement them immediately.

Principal/Overall Investigator Signature (required)

4/8/04
Date

Human Research Committee
Massachusetts General Hospital
Lawrence House
10 North Grove Street
Boston, MA 02114
(617) 726-3494

Violation/Deviation: Notification of IRB REVIEW
Protocol #: 2001-P-000422/40; MGH

Date: 04/05/2004

To: Joseph Biederman, MD
Psychiatry
Warren 705

From: Ronda Cox Goldman
MGH Research Management
LRH 3

Title of Protocol:	Open-Label Comparative Study of Risperidone Versus Olanzapine for Mania in Preschool Children 4 to 6 Years of Age with Bipolar Spectrum Disorder
IRB V/D #:	6
IRB Review Type:	Expedited
IRB Review Date:	04/01/2004
IRB Review Action:	Requires Modification

This Violation/Deviation has been reviewed by the MGH IRB, Assurance # FWA00003136. During the review of this Violation/Deviation, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

Please read this memo carefully and respond in a point-by-point manner to the issues raised below within 60 days of the review date.

This is a serious breach of the Protocol procedures and provisions. The maximum dose of olanzepine allowed during the study participation is 7.5mg. The dose escalation to 12.5mg in the context of non-compliance on the part of the parents to study procedures seems inappropriate based on study requirements. Although the distinction between clinical care and clinical research is blurred in this subject popualtion, the absolute requirements of the Protocol should have required subject discontinuation from the study and clinical management. Continued participation in this subject is a serious violation of study procedures.

Human Research Committee
Massachusetts General Hospital
Lawrence House
10 North Grove Street
Boston, MA 02114
(617) 726-3494

This breach will be brought to the attentionof the full Partners Healthcare Research Committee as it represents a major violation. Any additional information concerning this subjects' participation should be forwarded as soon as possible. This is the sixth violation of Protocol procedures noted in the study file. One other violation involved the addition of prohibited concomitant medications. The investigator is asked to provide additional details concerning procedural changes that will ensure that clinicians follow mandated study procedures. This subject should be considered discontinued from further study participation and managed clinically as deemed appropriate by caregivers.

Direct any questions, correspondence and forms to Ronda Cox Goldman, (617) 724-2130.

c: Stephanie Dunkel, BA

FAX COVER SHEET

To: Joseph Birnbaum MD / Stephanie Dankel From: Ronda Cox Goldman

Fax #: 617 583-1060 Tele #: 617-724-2130

Fax #: 617-724-1919

Date: 4-5-04

Message:

Number of Pages: 3

Human Research Committee
Massachusetts General Hospital
Lawrence House
10 North Grove Street
Boston, MA 02114
(617) 726-3494

Violation/Deviation: Notification of IRB Approval/Activation

Protocol #: 2001-P-000422/41; MGH

Date: 05/10/2004

To: Joseph Biederman, MD
Psychiatry
Warren 705

From: Ronda Cox Goldman
MGH Research Management
LRH 3

Title of Protocol:	Open-Label Comparative Study of Risperidone Versus Olanzapine for Mania in Preschool Children 4 to 6 Years of Age with Bipolar Spectrum Disorder
Sponsor:	Private Grant
IRB Review Type:	Full
IRB Approval Date:	04/27/2004
Approval Effective Date:	05/10/2004
IRB Expiration Date:	01/06/2005

This Violation/Deviation has been reviewed and approved by the MGH IRB, Assurance # FWA00003136. During the review of this Violation/Deviation, the IRB specifically considered (i) the risks and anticipated benefits, if any, to subjects; (ii) the selection of subjects; (iii) the procedures for securing and documenting informed consent; (iv) the safety of subjects; and (v) the privacy of subjects and confidentiality of the data.

Please note that if an IRB member had a conflict of interest with regard to the review of this project, that member left the room during the discussion and the vote on this project.

NOTES: Subject MATMCD missed visits 4 through 6 during the acute phase of the study and none of the study procedures were completed. In addition, the time between weeks 3 and 7 visits was six weeks rather than four weeks. At week 8 the subject's dose was increased to 10 mg/QD and the protocol states the maximum is 7.5 mg/QD. At month one of the extension phase of the study the dose was increased to 12.5 mg/QD. Each increase was well tolerated.

The investigator responded to HRC concerns and the full HRC reviewed the violation.

As Principal Investigator you are responsible for the following:

1. Submission in writing of any and all changes to this project (e.g., protocol, recruitment materials, consent form, etc.) to the IRB for review and approval prior to initiation of the change(s), except where necessary to eliminate apparent immediate hazards to the subject(s). Changes made to eliminate apparent immediate hazards to subjects must be reported to the IRB within 24 hours.

Human Research Committee
Massachusetts General Hospital
Lawrence House
10 North Grove Street
Boston, MA 02114
(617) 726-3494

2. Submission in writing of any and all adverse event(s) that occur during the course of this project that are both serious and unexpected within 10 working/14 calendar days of notification of event.
3. Submission in writing of any and all unanticipated problems involving risks to subjects or others.
4. Use of only IRB approved copies of the consent form(s), questionnaire(s), letter(s), advertisement(s), etc. in your research. Do not use expired consent forms.
5. Informing all physicians listed on the project of changes, adverse events, and unanticipated problems.

The IRB can and will terminate projects that are not in compliance with these requirements. Direct questions, correspondence and forms (e.g., continuing reviews, amendments, adverse events, safety reports) to Ronda Cox Goldman, (617) 724-2130.

c: Stephanie Dunkel, BA, Psychiatry, 185 Alewife

Attachment J

PHARMA SALARY SUMMARY

	2005	2006	2007
JB concerta (MCNEIL)	$ 14,888	$ 16,411	$ -
Lillt Ctr (ELI LILLY)	$ 30,034	$ 27,697	$ 13,143
J&J Ctr	$ 7,919	$ 7,266	$ 3,976

DETAILS

	Biederman, Joseph Oct-06	$	1,490.49
	Biederman, Joseph Sep-06	$	1,490.43
	Biederman, Joseph Aug-06	$	1,473.11
	Biederman, Joseph Jul-06	$	1,490.58
	Biederman, Joseph Jun-06	$	1,490.58
	Biederman, Joseph May-06	$	1,490.58
	Biederman, Joseph Apr-06	$	1,490.58
	Biederman, Joseph Mar-06	$	1,490.58
	Biederman, Joseph Feb-06	$	1,490.58
	Biederman, Joseph Jan-06	$	1,490.58
JB CONCERTA 2006		$	14,888.09
	Biederman, Joseph Dec-05	$	1,490.58
	Biederman, Joseph Nov-05	$	1,490.58
	Biederman, Joseph Sep-05	$	1,490.58

	Biederman, Joseph Aug-05	$	1,490.58
	Biederman, Joseph Jul-05	$	1,490.58
	Biederman, Joseph Jun-05	$	1,490.58
	Biederman, Joseph May-05	$	1,490.58
	Biederman, Joseph Apr-05	$	1,490.58
	Biederman, Joseph Mar-05	$	1,490.58
	Biederman, Joseph Feb-05	$	1,490.55
	Biederman, Joseph Jan-05	$	1,505.34
JB CONCERTA 2005		$	16,411.11
	Biederman, Joseph Jun-07	$	2,070.77
	Biederman, Joseph May-07	$	2,070.77
	Biederman, Joseph Apr-07	$	2,070.77
	Biederman, Joseph Mar-07	$	2,310.40
	Biederman, Joseph Feb-07	$	2,310.40
	Biederman, Joseph Jan-07	$	2,310.40
Lilly crtr 2007		$	13,143.51
	[redacted]		

	2005	2006
JB concerta (MCNEIL)	$ 14,888	$ 16,411
Lillt Ctr (ELI LILLY)	$ 30,034	$ 27,697
J&J Ctr	$ 7,919	$ 7,266

	Biederman, Joseph Dec-06	$ 2,310.40
	Biederman, Joseph Nov-06	$ 2,310.40
	Biederman, Joseph Oct-06	$ 2,310.40
	Biederman, Joseph Sep-06	$ 2,310.23
	Biederman, Joseph Aug-06	$ 2,283.49
	Biederman, Joseph Jul-06	$ 2,310.36
	Biederman, Joseph Jun-06	$ 2,310.36
	Biederman, Joseph May-06	$ 2,310.36
	Biederman, Joseph Apr-06	$ 2,310.36
	Biederman, Joseph Mar-06	$ 2,310.36
	Biederman, Joseph Feb-06	$ 2,310.36
	Biederman, Joseph Jan-06	$ 2,310.36
Lilly crtr 2006		$ 27,697.44
	Biederman, Joseph Dec-05	$ 2,310.36
	Biederman, Joseph Nov-05	$ 2,310.36
	Biederman, Joseph Oct-05	$ 2,310.36

	[redacted]	$	2,310.36
	Biederman, Joseph Aug-05	$	2,310.36
	[redacted]	$	2,310.36
	Biederman, Joseph Jun-05	$	2,310.36
	[redacted]	$	2,310.36
	Biederman, Joseph Apr-05	$	2,310.36
	[redacted]	$	2,310.36
	Biederman, Joseph Feb-05	$	4,620.71
	[redacted]	$	2,310.36
Lilly crtr 2005 J&J		$	30,034.67
	Biederman, Joseph Jun-07	$	661.18
	[redacted]	$	661.18
	Biederman, Joseph Apr-07	$	661.18
	[redacted]	$	661.18
	Biederman, Joseph Feb-07	$	661.18
	[redacted]	$	661.18

J&J crtr 2007		$	3,967.08
	[redacted]		
	Biederman, Joseph Dec-06	$	661.18
	[redacted]	$	661.18
	Biederman, Joseph Oct-06	$	661.18
	[redacted]	$	661.29
	Biederman, Joseph Aug-06	$	653.57
	[redacted]	$	661.39
	Biederman, Joseph Jun-06	$	661.39
	[redacted]	$	-
	Biederman, Joseph Apr-06	$	661.39
	[redacted]	$	661.39
	Biederman, Joseph Feb-06	$	661.39
	[redacted]	$	661.39
J&J crtr 2006		$	7,266.74
	[redacted]		
	Biederman, Joseph Dec-05	$	661.39
	[redacted]	$	661.39

	Biederman, Joseph Oct-05	$	661.39
	Biederman, Joseph Sep-05	$	661.39
	Biederman, Joseph Aug-05	$	661.39
	Biederman, Joseph Jul-05	$	661.39
	Biederman, Joseph Jun-05	$	661.39
	Biederman, Joseph May-05	$	661.39
	Biederman, Joseph Apr-05	$	661.39
	Biederman, Joseph Mar-05	$	661.39
	Biederman, Joseph Feb-05	$	661.14
	Biederman, Joseph Jan-05	$	644.92
J&J crtr 2005		$	7,919.96

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-639 S-048

AstraZeneca Pharmaceuticals LP
Attention: Kathryn Bradley
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Bradley:

We acknowledge receipt of your supplemental new drug application dated and received December 4, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Seroquel (quetiapine fumarate) tablets.

This "Changes Being Effected" supplemental new drug application provides for revised labeling to include new safety information for both adult and pediatric patients.

We have no objection to your submission of the new safety information pertaining to the clinical trials as a CBE supplement. However, the Division is requesting that you reformat the information for better integration in the overall label prior to your intended implementation on January 4, 2009. Specifically:

1. Place the pediatric safety information in the relevant sections of labeling with the adult data rather than separately in sections 5.19 and 8.4. For example, the proposed pediatric data in the section 8.4 subtitled "Changes in Thyroid Function Tests" should be placed at the end of section 5.10 (Warnings and Precautions: Hypothyroidism). The same principle applies to other pediatric safety information that already has adult data included prominently.
2. The weight gain signal is significant for both adult and pediatric populations and should be elevated to the Warnings and Precautions section rather than the vital signs section (the latter section could refer back to the information in Warnings and Precautions section) with inclusion of data for both populations. In fact, the data for weight change, glucose changes, and lipid changes from the clinical trials, both adult and pediatric, need to be elevated to the Warnings/Precautions section of labeling. Please see the format used in the currently distributed label for another antipsychotic drug, i.e., Zyprexa, for the correct format for this information.
3. The safety data for Increases in Blood Pressure is an unexpected signal and there is currently no similar adverse event signal for the adult population. Because of this unexpected and clinically significant signal that may be specific to the pediatric population, this safety data should be included in a separate section in Warnings and Precautions. Please offer your rationale for this unusual finding.

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4. For each section describing pediatric safety signals, the following statement should be included "Safety and effectiveness of SEROQUEL have not been established in pediatric patients and SEROQUEL is not approved for patients under the age of 18 years".
5. Please replace your proposed Hyperprolactinemia statement with the standard language now used for more recently approved atypical antipsychotic agents, e.g., Invega. Any actual clinical trials data regarding prolactin elevation should, of course, be data for quetiapine, including the pediatric data.
6. All pediatric safety data and the other changes we are requesting for Seroquel should be included in revised labeling for Seroquel XR as well.

The above requested changes should be implemented immediately, and they should be submitted as an amendment to your pending supplemental application to the Seroquel NDA and as an original supplemental application to the Seroquel XR NDA, 22-047, within 30 days from the date of this letter, or notify FDA that you do not believe these changes are warranted, and submit a statement detailing the reasons. If you wish to have our prior comment on your alternative proposal in response to these requests, we would be happy to provide such comment.

Please note that your proposed labeling language in the above referenced CBE is under continuing review by the Agency. Please also note that the Division is currently reviewing your metabolic data submission and the pediatric efficacy supplements submitted under this NDA (S-045 and S-046). We will be providing further labeling comments, if any, and will take final action on these submissions when reviews are completed.

If you have any questions, call Kimberly Updegraff, M.S., Regulatory Project Manager, at 301-796-2201.

Sincerely,

{See appended electronic signature page}

Thomas Laughren, M.D.
Director
Division of Psychiatry Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Thomas Laughren
12/18/2008 04:06:08 PM

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AstraZeneca

Clinical Overview

Drug Name Quetiapine fumarate

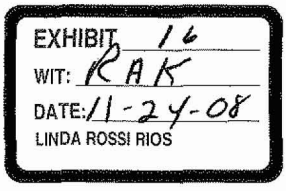
Date July 2008

SEROQUEL™ (quetiapine fumarate)
Clinical Overview on Weight Gain in pediatric patients

Authors:

Leigh Jefferies M.D.
Global Safety Physician
Patient Safety, Wilmington, DE

Eva S.K. Alam, M.S., Pharm.D., RPh
Safety Surveillance Team Leader
Patient Safety, Wilmington, DE



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LIST OF TABLES

1. PRODUCT DEVELOPMENT RATIONALE

1.1 Introduction

The Core Data Sheets for SEROQUEL is to be amended following an internal safety evaluation and review meeting on 09 July 2008. The purpose of this document is to summarize the key information on which the decision to amend the CDS was based, to document the Core Data Sheet amendment and to support changes to local Prescribing Information.

1.1.1 SEROQUEL and SEROQUEL XR

SEROQUEL and SEROQUEL XR are atypical antipsychotic agents, presented as tablets containing quetiapine fumarate, which exhibits affinity for brain serotonin (5HT2) and dopamine D1 and D2 receptors. In addition, SEROQUEL/SEROQUEL XR also have high affinity at histaminergic and adrenergic α1 receptors, with a lower affinity at adrenergic α2 receptors, but no appreciable affinity at cholinergic, muscarinic or benzodiazepine receptors.

SEROQUEL was first approved for marketing in the United Kingdom (UK) on 31 July 1997 and was first launched in the UK on 22 September 1997. By 31 March 2008, SEROQUEL has been approved in 89 countries for schizophrenia, 86 countries for bipolar mania, (with Mexico being the first country to approve bipolar mania on 29 May 2003), 26 countries for bipolar depression, (with Czech Republic being the first country to approve bipolar depression on 27 September 2006), and in one country for bipolar maintenance (USA being the first country to approve bipolar maintenance on 14 May 2008). SEROQUEL is presented as tablets delivering a dose of 25 mg, 50 mg, 100 mg, 150 mg, 200 mg, 300 mg, or 400 mg of quetiapine free-base. SEROQUEL is not approved for children or adolescents below 18 years of age.

SEROQUEL XR was first approved for marketing in the United States (US) for acute schizophrenia on 18 May 2007 and for maintenance of schizophrenia on 15 November 2007. By 31 March 2008, SEROQUEL XR has been approved in 30 countries for schizophrenia (including 14 countries in the Mutual Recognition Procedure), 7 countries for bipolar mania (with Slovakia being the first country to approve bipolar mania on 28 June 2007), and in one country for bipolar depression (Mexico being the first country to approve bipolar depression in October 2007). SEROQUEL XR is presented as tablets delivering a dose of 50 mg, 200 mg, 300 mg, or 400 mg of quetiapine free-base. SEROQUEL XR is not approved for children or adolescents below 18 years of age.

1.2 Proposed label change

The following text will be added to Section 4.8 *Undesirable effects* of the SEROQUEL CDS under a subheading of *Children and adolescents.*

Children and adolescents

The same ADRs described above for adults apply to children and adolescents. The following table summarizes ADRs that occur in a higher frequency category in children and adolescents patients (10-17 years of age) than in the adult population or ADRs that have not been identified in the adult population.

Weight gain in children and adolescents

In one 6-week, placebo-controlled trial in adolescent patients (13-17 years of age) with schizophrenia, the mean increase in body weight, was 2.0 kg in the quetiapine group and -0.4 kg in the placebo group. Twenty one percent of quetiapine-treated patients and 7% of placebo-treated patients gained ≥ 7 % of their body weight.

In one 3-week, placebo-controlled trial in children and adolescent patients (10-17 years of age) with bipolar mania, the mean increase in body weight was 1.7 kg in the quetiapine group and 0.4 kg in the placebo group. Twelve percent of quetiapine-treated patients and 0% of placebo-treated patients gained ≥ 7 % of their body weight.

In the open-label study that enrolled patients from the above two trials, 63% of patients (241/380) completed 26 weeks of therapy with quetiapine. After 26 weeks of treatment, the mean increase in body weight was 4.4 kg. Forty five percent of the patients gained ≥ 7% of their body weight, not adjusted for normal growth. In order to adjust for normal growth over 26 weeks an increase of at least 0.5 standard deviation from baseline in BMI was used as a measure of a clinically significant change; 18.3% of patients on quetiapine met this criterion after 26 weeks of treatment.

Since clinical trials in pediatric patients have been conducted with SEROQUEL and not SEROQUEL XR this change applies only to the SEROQUEL CDS.

2. OVERVIEW OF BIOPHARMACEUTICS

This section is not relevant to this document.

3. OVERVIEW OF CLINICAL PHARMACOLOGY

This section is not relevant to this document.

4. OVERVIEW OF EFFICACY

This section is not relevant to this document.

5. OVERVIEW OF SAFETY

5.1 Data summary and discussion

5.1.1 Pediatric clinical trial data

The data presented below is taken from two acute placebo-controlled studies with SEROQUEL in pediatric patients with schizophrenia or bipolar mania and one longer-term open-label study with SEROQUEL. The patients in the longer-term trial were originally enrolled in one of the two acute placebo-controlled trials. The following is a brief description of these three trials.

- D1441C00112: a 6-week, International, Multicenter, Randomized, Double-blind, Parallel group, Placebo-controlled, Phase IIIb Study of the Efficacy and Safety of Quetiapine Fumarate (SEROQUEL™) Immediate-release Tablets in Daily Doses of 400 mg and 800 mg Compared with Placebo in the Treatment of Adolescents with Schizophrenia

- D1441C00149: a 3-week, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Phase IIIb Study of the Efficacy and Safety of Quetiapine Fumarate (SEROQUEL™) Immediate-release Tablets in Daily Doses of 400 mg and 600 mg Compared with Placebo in the Treatment of Children and Adolescents with Bipolar I Mania

- D1441C00150: a 26-week, International, Multicenter, Open-label Phase IIIb Study of the Safety and Tolerability of Quetiapine Fumarate (SEROQUEL™) Immediate-release Tablets in Daily Doses of 400 mg to 800 mg in Children and Adolescents with Bipolar I Disorder and Adolescents with Schizophrenia

5.1.2 Acute placebo-controlled data

5.1.2.1 D144C00112

Mean increase in body weight

In study D144C00112, mean weights were similar at baseline for the three treatment groups. Mean changes in weight from baseline were higher for quetiapine-treated patients at each time point compared to placebo. At Day 42, the mean changes from baseline were 2.2 kg in the 400 mg/day quetiapine group, 1.8 kg in the 800 mg/day quetiapine group, and –0.4 kg in the placebo group (see Table 1).

Table 1 D144C00112: Mean increase in weight from baseline

Change from Baseline	QTP 400 mg	QTP 800 mg	PLACEBO
Day 42	2.2 kg	1.8 kg	-0.4 kg

Patients with ≥7% weight gain

A higher percentage of quetiapine-treated patients (23.21% in the 400 mg/day and 18.18% in the 800 mg/day) had ≥7% weight gain at Day 42 compared to the placebo-treated patients (6.82%) (see Table 2).

Table 2 D144C00112: Patients with ≥ 7% weight gain (Summary safety population)

Visit	QTP 400 mg N=56 n (%)	QTP 800 mg N = 55 n (%)	PLA N = 44 n (%)
Day 42	13 (23.2)	10 (18.2)	3 (6.8)

5.1.2.2 D144C00149

Mean increase in weight

Mean increases in weight from baseline to Day 21 were higher for quetiapine-treated patients at each time point compared to placebo. These increases from baseline were 1.7 kg in the 400 mg quetiapine-treated group, 1.7 kg in the 600 mg quetiapine-treated group and 0.4 kg in the placebo group. Quetiapine-treated patients experienced higher mean increases in weight compared to placebo at Day 21 (see Table 3).

Table 3 D144C00149: Mean increase in weight from baseline

Change from baseline	QTP 400 mg	QTP 600 mg	PLA
Day 21	1.7 kg	1.7 kg	0.4 kg

Patients with ≥7% weight gain

A higher percentage of quetiapine-treated patients (14.47% in the 400 mg/day and 9.88% in the 600 mg/day) had ≥7% weight gain at Day 21 compared to placebo-treated patients (0%) (see Table 4).

Table 4 D144C00149: Patients with ≥7% weight gain (Summary safety population)

Visit	QTP 400 mg N = 76 n (%)	QTP 600 mg N = 81 n (%)	PLACEBO N = 68 n (%)
Day 21	11 (14.5)	8 (9.9)	0 (0)

5.1.3 Longer-term open-label pediatric data

5.1.3.1 D1441C00150

Study D1441C00150 was an open-label extension study designed to assess the safety and tolerability of quetiapine (flexibly dosed at 400 mg/day to 800 mg/day) in adolescents with schizophrenia (continuing from Study D144C00112) and in children and adolescents with bipolar I disorder (continuing from Study D144C00149). There were a total of 380 patients in the safety analysis set, including 175 with schizophrenia and 205 with mania. Sixty-three percent of patients (241) completed 26 weeks of therapy with quetiapine.

All patients treated with quetiapine 50 mg/day on Day 1 then escalated to 400 mg on Day 5. From Day 5, the target dose of 400 mg/day was maintained or increased by no more than 100 mg/day, up to 800 mg/day or adjusted down to 200 mg/day. Patients were treated for up to 26 weeks.

Mean increase in weight

The mean change in weight for schizophrenia and bipolar I patients (who enrolled) from OL baseline as well as DB baseline to final visit are provided in Table 5.

Table 5 **Study D1441C00150: mean changes from baseline to the final visit (safety population)**

	Acute feeder study treatment								
	Prior Placebo (N=129)			All prior QTP (N=251)			Total (N=380)		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
112 DB Baseline									
Final visit (150 OL BSLN)	62	67.4	16.3	113	64.8	19.2	175	65.7	18.2
Change from 112 DB BSLN	62	4.1	8.5	113	4.8	10.8	175	4.6	10.0
Change from 150 OL Baseline	62	4.3	6.9	113	2.8	10.1	175	3.3	9.1
149 DB Baseline									
Final visit (150 OL BSLN)	64	68.3	21.9	136	64.5	18.4	200	65.8	19.6
Change from 149 DB BSLN	64	5.8	6.4	136	5.1	5.7	200	5.3	5.9
Change from 150 OL Baseline	64	5.5	5.8	135	3.2	4.8	199	4.0	5.2
Total 149 and 112 pooled DB Baseline									
Final visit (150 OL BSLN)	126	67.9	19.3	249	64.7	18.7	375	65.7	19.0
Change from DB BSLN	126	5.0	7.50	249	5.0	8.3	375	5.0	8.1
Change from 150 OL Baseline	126	4.9	6.4	248	3.0	7.6	374	3.7	7.3

In patients who completed 26 weeks of therapy with quetiapine (n=241) in Trial D1441C00150, the mean change in weight from OL baseline was 4.4 kg.

Patients with ≥7% weight gain

In the safety population, 134 patients (35.6%) experienced ≥7% weight gain from OL baseline to final visit (see Table 6).

Table 6 **Study D1441C00150: Patients with ≥ 7% weight gain (Summary safety population)**

	Acute feeder study treatment								
	Prior Placebo (N=129)			Prior All QTP (N=251)			Total (N=380)		
	N	n	(%)	N	n	(%)	N	n	(%)
Pooled data 149 and 112									
From DB Baseline	127	58	45.7	249	119	47.8	376	177	47.1
From 150 OL Baseline	127	50	39.4	249	84	33.7	376	134	35.6
Study 112 (schizophrenia)									
From DB Baseline	62	24	38.7	113	43	38.1	175	67	38.3
From 150 OL Baseline	62	19	30.6	113	32	28.3	175	51	29.1
Study 149 (BP I)									
From DB Baseline	65	34	52.3	136	76	55.9	201	110	54.7
From 150 OL Baseline	65	31	47.7	136	52	38.2	201	83	41.3

Of the patients who completed 26 weeks of treatment with quetiapine, 44.8% (108/241) had a ≥7% increase in weight from OL baseline.

5.1.4 Additional analysis of Pediatric data

5.1.4.1 Z-scores

Since body weight and height should increase in children, data showing an increase in weight with time sometimes may not indicate a problem. One convenient way to express body weight is in terms of body mass index (BMI), since with BMI, the weight is adjusted for height (Correll et al 2006).

A better measure of weight change in children and adolescents is to convert the mean weight and BMI to a Z-score taking into consideration the age and gender of the subject. Z-scores are able to show how different a child's weight or BMI is from the average children of the same height (Reyes et al 2006).

One of the criteria proposed to show significant weight gain in children and adolescents is a greater than or equal to an increase in BMI Z-score of 0.5 over any duration of time (Correll et al 2006). This increase represents a change of 0.5 standard deviation from baseline.

BMI Z-scores

The mean BMI Z-scores (for patients who enrolled in study D1441C00150) from the DB baseline for schizophrenia to the final visit and end of treatment are higher for the prior placebo group compared to the prior quetiapine group (see Table 7).

Table 7 Study D1441C00150: Mean values of BMI Z score at baseline, end of treatment and final visit (safety population)

	Acute feeder study treatment								
	Prior Placebo (N=129)			All prior QTP (N=251)			Total (N=380)		
	n	Mean	SD	n	Mean	SD	n	Mean	SD
112 DB Baseline	62	**0.3**	1.2	113	**-0.1**	1.4	175	**0.0**	1.3
Week 26	41	0.4	1.1	86	0.1	1.22	127	0.2	1.2
Final Visit	62	**0.5**	1.0	113	**0.2**	1.3	175	**0.3**	1.2
149 DB Baseline	67	**1.0**[a]	1.0	138	**0.9**[a]	1.1	205	**0.9**[a]	1.0
Week 26	37	1.2	1.0	77	1.2	1.0	114	1.2	1.0
Final Visit	63	**1.2**	1.0	135	**1.0**	1.0	198	**1.1**	1.0
DB Total Baseline	129	**0.6**	1.2	251	**0.4**	1.3	380	**0.5**	1.3
Week 26	78	0.8	1.1	163	0.6	1.2	241	0.7	1.2
Final Visit	125	**0.9**	1.0	248	**0.7**	1.2	373	**0.7**	1.2

[a] The mean BMI Z score at baseline is much higher for the 149 population

Table 8 below shows patients who had a ≥ 0.5 shift in BMI Z-score during trial D1441C00150 from both DB baseline and OL baseline and by indication. Of all patients who completed 26 weeks of treatment with quetiapine, 18.3% (44/241) had a shift of ≥ 0.5 BMI Z-score.

Table 8 **Patients with ≥ 0.5 shift in BMI Z score in Study D1441C00150 by indication**

Occurrence	Schizophrenia to OL 150		BP to OL 150		OL 150
Time/baseline	DB All Quetiapine	DB Placebo	DB All Quetiapine	DB Placebo	OL All - Quetiapine
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	N/N (%)
End of Treatment/DB	24/113 (21.2)[a]	17/62 (27.4)[a]	29/135 (21.5)[c]	12/63 (19)[c]	82/373 (22)
End of Treatment/OL	16/113 (14.2)[b]	15/62 (24)[b]	11/133 (8.3)[b]	12/63 (19)[b]	54/371 (14.6)[b]

[a] From double blind baseline of study 112 to end of study 150; [b] From OL baseline of study 150 to end of study 150; [c] From double blind baseline of study 149 to end of study 150

Patients with ≥0.5 shift in standardized BMI Z-score in Study D1441C00150 by age group

A similar percentage of patients ≤12 years of age (who enrolled in study D1441C00150) treated with prior placebo (28% at EOT) had ≥0.5 shift in standardized BMI Z-score compared with prior quetiapine-treated patients (25% at EOT) from the DB baseline (see Table 9).

A higher percentage of patients ≤12 years of age (who enrolled in study D1441C00150) treated with prior placebo (24% at EOT) had ≥0.5 shift in standardized BMI Z-score compared with prior quetiapine-treated patients (8.6% at EOT) from the OL baseline (see Table 9).

A similar percentage of pediatric patients 13-18 years of age (who enrolled in study D1441C00150) treated with prior placebo (22% at EOT) had ≥0.5 shift in standardized BMI Z-score compared to prior quetiapine-treated patients (20.1% at EOT) from the DB baseline (see Table 9).

A higher percentage of pediatric patients 13-18 years of age (who enrolled in study D1441C00150) treated with prior placebo (21% at EOT) had ≥0.5 shift in standardized BMI Z-score compared to prior quetiapine-treated patients (11.7% at EOT) from the OL baseline (see Table 9).

Table 9 **Patients with ≥0.5 shift in BMI Z score in Study D1441C00150 by age group***

Occurrence	≤ 12 years OL 150		13 to 17 years OL 150		OL 150
Time/baseline	DB All Quetiapine	DB Placebo	DB All Quetiapine	DB Placebo	OL All - Quetiapine
	n/N (%)	n/N (%)	n/N (%)	n/N (%)	n/N (%)
End of Treatment/DB	15/59 (25)	7/25 (28)	38/189 (20.1)	22/100 (22)	82/373 (22)
End of Treatment/OL	5/58 (8.6)	6/25 (24)	22/188 (11.7)	21/100 (21)	54/371 (14.6)

* Study 112 was a six week placebo controlled trial in adolescent patients (13-17 years) and study 149 was a three week trial in children and adolescent patients (10-17 years)

5.1.4.2 Overall summary of pediatric clinical trial data

In trial D1441C00112, the mean increase in body weight was 2 kg in the quetiapine group and -0.4 kg in the placebo group. Twenty-one percent of quetiapine patients and 7% of placebo patients had gained ≥7% of their body weight.

In trial D144C00149, the mean increase in body weight was 1.7 kg in the quetiapine group and 0.4 kg in the placebo group. Twelve percent of quetiapine patients and 0% of placebo patients had gained ≥7% of their body weight.

In trial D1441C00150, where 63% of patients (241/380) completed 26 weeks of therapy with quetiapine, the mean increase in body weight was 4.4 kg. Forty-five percent of the patients had ≥7% increase in body weight, not adjusted for normal growth. In order to adjust for normal growth over 26 weeks, an increase of at least 0.5 standard deviation from baseline in BMI was used as a measure of a clinically significant change; 18.3% of patients on quetiapine met this criterion after 26 weeks of treatment.

6. BENEFITS AND RISKS CONCLUSIONS

The purpose of this application is to update the SEROQUEL Core Data Sheet and local Prescribing information with current findings in relation to weight gain in patients treated with quetiapine. AstraZeneca believes that these data do not alter the overall safety and tolerability profile of SEROQUEL and SEROQUEL XR and that the benefit/risk profile of SEROQUEL and SEROQUEL XR remains positive.

7. REFERENCES

Correll et al 2006
Correll CU, Carlson HE. Endocrine and metabolic adverse effects of psychotropic medications in children and adolescents. J. Am. Acad. Child. Adolesc. Psychiatry. 2006; 45 (7):771-791.

Reyes et al 2006
Reyes M, Croonenberghs J, Augustyns I, Eerdekens M. Long-term use of risperidone in children with disruptive behavior disorders and subaverage intelligence: efficacy, safety and tolerability. J. Child. Adolescent. Psychopharmacol. 2006; 16(3): 260-272.

According to his/her respective qualification the undersigned expert declares hereby to have performed the duties set out in the Article 12 and in accordance with Annex I Part I 1.4 of Directive 2001/83/EC, as amended

CLINICAL:

Name of the expert: Leigh Jefferies, MD
Global Safety Physician
Patient Safety

Signature:

Address:
1800 Concord Pike
Wilmington, DE 19850

Date:

According to the Annex I of Directive 2001/83/EC as amended, brief information (curriculum vitae) on the educational, training and occupational experience of the expert is attached.

Unknown

From: Gavin Jim JP
Sent: Wednesday, December 08, 1999 12:32 PM
To: De Vriese Geert
Cc: Holdsworth Debbie D;Tumas John JA;Tugend Georgia GL;Czupryna Michael MJ;Gorman Andrew AP;Wilkie Alison AM;Litherland Steve S;Murray Michael MF;Rak Ihor IW;Owens Judith J;O'Brien Shawn SP;Denerley Paul PM;Goldstein Jeffrey JM
Subject: RE: 2 EPS Abstracts for APA

Attachments: jamapubs.pdf

Thanks for this Geert. If I could add my own thoughts in advance of the GPT tomorrow...Certainly any progress on the (selective) use of data from COSTAR would be particularly appreciated, as I'm currently getting mixed messages on whether we use the EPS data from this trial.

I was interested to hear that we are discussiing the recent JAMA article on the reporting of clinical trials (link attached). This article concerns me as it highlights what appears to be an increasing scepticism among journal editors with regards to certain aspects of company-sponsored publications. Janssen have had their fingers burned in the past in this regard, and are consequently cited every time such an editorial appears, something that presumably irritates the hell out of them. Quite apart from any ethical considerations, if they thought we were publishing positive data vs risperidone from QUEST while results from a second trial were being buried, they'd be onto it in a flash. Selectively using (for example) the EPS data from COSTAR is pushing it too far in my opinion, and might prove extremely damaging in the long run (and you can bet Janssen would push it), and would destroy our current high standing in the publishing community.

jamapubs.pdf (112 KB)

Regards
Jim

From: Owens Judith J
Sent: 08 December 1999 09:24
To: Gavin Jim JP
Subject: FW: 2 EPS Abstracts for APA

FYI

From: De Vriese Geert
Sent: 08 December 1999 08:42
To: Baker Kendra; Tumas John JA
Cc: Scanlon Rose Ann RA; Denerley Paul PM; Owens Judith J
Subject: RE: 2 EPS Abstracts for APA

Kendra,
John,

REDACTED

From: Baker Kendra
Sent: 07 December 1999 22:49
To: Owens Judith J; De Vriese Geert
Cc: Tumas John JA; Scanlon Rose Ann RA; Denerley Paul PM
Subject: FW: 2 EPS Abstracts for APA

PRIVILEGED AND CONFIDENTIAL

EXHIBIT 42
WIT: RAK
DATE: 11-25-08
LINDA ROSSI RIOS

REDACTED

Best regards,
Kendra Baker
Attorney
Legal Department
AstraZeneca
Tel. (302) 886-4233 Fax: (302) 886-8221
Kendra.Baker@astrazeneca.com

From: Scanlon Rose Ann RA
Sent: Tuesday, December 07, 1999 2:33 PM
To: Baker, Kendra
Subject: FW: 2 EPS Abstracts for APA

REDACTED

Rose Ann Scanlon
Assistant General Counsel
AstraZeneca
Telephone: 302 886 4009
Fax: 302 886 8221

From: Denerley Paul PM
Sent: December 07, 1999 10:24 AM
To: Scanlon Rose Ann RA
Subject: FW: 2 EPS Abstracts for APA

From: Tumas John JA
Sent: Monday, December 06, 1999 11:45 PM
To: Owens Judith J; Jones Martin AM - PHMS; Litherland Steve S; Gavin Jim JP
Cc: Holdsworth Debbie D; Tugend Georgia GL; Czupryna Michael MJ; Gorman Andrew AP; Wilkie Alison AM; Murray Michael MF; Rak Ihor IW; O'Brien Shawn SP; Denerley Paul PM; Goldstein Jeffrey JM; Woods Paul PB; Holdsworth Debbie D; De Vriese Geert; Shadwell Pamela PG
Subject: RE: 2 EPS Abstracts for APA

Please allow me to join the fray.

There has been a precedent set regarding "cherry picking" of data. This would be the recent Velligan presentations of cognitive function data from Trial 15 (one of the buried trials). Thus far, I am not aware of any repercussions regarding interest in the unreported data.

That does not mean that we should continue to advocate this practice. There is growing pressure from outside the industry to provide access to all data resulting from clinical trials conducted by industry. Thus far, we have buried Trials 15, 31, 56, and are now considering COSTAR.

The larger issue is how do we face the outside world when they begin to criticize us for suppressing data. One

could say that our competitors indulge in this practice. However, until now, I believe we have been looked upon by the outside world favorably with regard to ethical behavior. We must decide if we wish to continue to enjoy this distinction.

The reporting of the COSTAR results will not be easy. We must find a way to diminish the negative findings. But, in my opinion, we cannot hide them.

Best regards,

John

From: Gavin Jim JP
Sent: Monday, December 06, 1999 1:59 PM
To: Owens Judith J; Jones Martin AM - PHMS; Litherland Steve S
Cc: Holdsworth Debbie D; Tumas John JA; Tugend Georgia GL; Czupryna Michael MJ; Gorman Andrew AP; Wilkie Alison AM; Murray Michael MF; Rak Ihor IW; O'Brien Shawn SP; Denerley Paul PM; Goldstein Jeffrey JM; Woods Paul PB; Holdsworth Debbie D; De Vriese Geert; Shadwell Pamela PG
Subject: RE: 2 EPS Abstracts for APA

Steve's comments are pertinent, as the EPS abstracts (for the APA) and the Scourge of EPS review both emanate from the ECNP symposium, and as such represent a potential transition of COSTAR data from a "closed" mtg to a public forum. Coming in late to the debate, the only directive I have on QUEST/COSTAR (contained in a document compiled by Ihor & Martin in August) suggested using them "as clinically appropriate", but independently.

I believe the newly-formed Commercial Support Team will be considering looking at potential ways of using COSTAR. With regards to the present outputs however, a short-term solution (given the impending APA deadline) is to avoid reference to COSTAR in the proposed APA abstract. Whether or not we discuss it in either the poster or the review subsequently will need to decided by the team, with reference to how we would then need to approach the efficacy story.

Regards
Jim

From: Litherland Steve S
Sent: 06 December 1999 11:51
To: Owens Judith J; Jones Martin AM - PHMS
Cc: Holdsworth Debbie D; Tumas John JA; Tugend Georgia GL; Czupryna Michael MJ; Gorman Andrew AP; Wilkie Alison AM; Gavin Jim JP; Murray Michael MF; Rak Ihor IW; O'Brien Shawn SP; Denerley Paul PM; Goldstein Jeffrey JM; Woods Paul PB; Holdsworth Debbie D; De Vriese Geert
Subject: RE: 2 EPS Abstracts for APA

Martin has drawn our attention to an enduring problem which requires resolution as soon as possible.

- should we publish COSTAR? The disadvantages are obvious, not least that we provide the opposition with potentially damaging data when they calculate p values re the primary efficacy endpoint
- if not, can we extract some information and use this to support our messages? The following is scheduled to appear in Clear Vision (proceedings of the ECNP EPS meeting):

A second study comparing flexible dosing of risperidone (6-10 mg daily) and quetiapine (300-600 mg daily) reported that over 10 weeks significantly more risperidone patients (31.4%) than quetiapine patients (14.1%)In my draft 30.4 and 13.1% ; need to check experienced EPS or akathisia (30.4% and 16.6 15.4 in MR doc%, respectively) ($p<0.001$ for both comparisons) (Data on file).

This was sanctioned for the meeting but when it appears in Clear Vision it will be in the public domain. We can be accused of "cherry picking" and this may fuel demands to see the entire study (Cochrane would be most interested, for example).

- Are we using QUEST promotionally? If so, we could be accused of not telling the complete story

I am concerned that by doing nothing re COSTAR, except to allow details to emerge in dribs and drabs we are not taking control of the situation. An initial step may perhaps be to canvass expert opinion

outside the Company (I know that we have had some feedback but I understand this was conflicting and uncoordinated).

Steve

From: Jones Martin AM - PHMS
Sent: 06 December 1999 10:55
To: Owens Judith J
Cc: Holdsworth Debbie D; Tumas John JA; Tugend Georgia GL; Czupryna Michael MJ; Gorman Andrew AP; Wilkie Alison AM; Gavin Jim JP; Litherland Steve S; Murray Michael MF; Rak Ihor IW; O'Brien Shawn SP; Denerley Paul PM; Goldstein Jeffrey JM
Subject: RE: 2 EPS Abstracts for APA

Judith

I have no real comments on the Juncos abstract, but am concerned about Tandon's.

In Tandon's results section, he refers to a randomised comparative study. This study is COSTAR. I think that we are still not comfortable about communicating the overall results of this study. Whilst this data may have been presented orally in London, I think this abstract would be the first time we have put anything 'down on paper'. Are we sure that this we can present the EPS data in isolation given the nature of the other results ? Will we not create a desire for further information about the study ? Can we not refer to published (non-comparative) data for risperidone, as we must be doing this for olanzapine ? Should we be looking at the ziprasidone data too ? They seem to have dose-response effect as well.

Martin

From: Owens Judith J
Sent: 02 December 1999 17:14
To: Wilkie Alison AM; Gavin Jim JP; Litherland Steve S; Murray Michael MF; Rak Ihor IW; Jones Martin AM - PHMS; O'Brien Shawn SP; Denerley Paul PM; Goldstein Jeffrey JM
Cc: Holdsworth Debbie D; Tumas John JA; Tugend Georgia GL; Czupryna Michael MJ; Gorman Andrew AP
Subject: 2 EPS Abstracts for APA
Importance: High

Dear All
Please find attached, for your review, 2 EPS abstracts that are intended for submission to APA. The abstracts are based on presentations at the AstraZeneca symposium 'CLEAR VISION - A fresh look at EPS' held during this year's ECNP.
Please return any comments you may have by midday (UK time) **Monday 6 December**.
Kind regards
Judith
<<File: Juncos abstract.doc>><<File: Tandon abstract.doc>>

Judith Owens
Ext: 24164
11F34 Mereside

The Washington Post

A Silenced Drug Study Creates An Uproar

By Shankar Vedantam
Washington Post Staff Writer
Wednesday, March 18, 2009; A01

The study would come to be called "cursed," but it started out just as Study 15.

It was a long-term trial of the antipsychotic drug Seroquel. The common wisdom in psychiatric circles was that newer drugs were far better than older drugs, but Study 15's results suggested otherwise.

As a result, newly unearthed documents show, Study 15 suffered the same fate as many industry-sponsored trials that yield data drugmakers don't like: It got buried. It took eight years before a taxpayer-funded study rediscovered what Study 15 had found -- and raised serious concerns about an entire new class of expensive drugs.

Study 15 was silenced in 1997, the same year Seroquel was approved by the Food and Drug Administration to treat schizophrenia. The drug went on to be prescribed to hundreds of thousands of patients around the world and has earned billions for London-based AstraZeneca International -- including nearly $12 billion in the past three years.

The results of Study 15 were never published or shared with doctors, even as less rigorous studies that came up with positive results for Seroquel were published and used in marketing campaigns aimed at physicians and in television ads aimed at consumers. The results of Study 15 were provided only to the Food and Drug Administration -- and the agency has strenuously maintained that it does not have the authority to place such studies in the public domain.

AstraZeneca spokesman Tony Jewell defended the Seroquel research and said the company had disclosed the drug's risks. Since 1997, the drug's labeling has noted that weight gain and diabetes were seen in study patients, although the company says the data are not definitive. The label states that the metabolic disorders may be related to patients' underlying diseases.

The FDA, Jewell added, had access to Study 15 when it declared Seroquel safe and effective. The trial, which compared patients taking Seroquel and an older drug called Haldol, "did not identify any safety concerns," AstraZeneca said in an e-mail. Jewell added, "A large proportion of patients dropped out in both groups, which the company felt made the results difficult to interpret."

The saga of Study 15 has become a case study in how drug companies can control the publicly available research about their products, along with other practices that recently have prompted hand-wringing at universities and scientific journals, remonstrations by medical groups about conflicts of interest, and threats of exposure by trial lawyers and congressional watchdogs.

Even if most doctors are ethical, corporate grants, gifts and underwriting have compromised psychiatry, said an editorial this month in the American Journal of Psychiatry, the flagship journal of the American Psychiatric

Association.

"The public and private resources available for the care of our patients depend upon the public perception of the integrity of our profession as a whole," wrote Robert Freedman, the editor in chief, and others. "The subsidy that each of us has been receiving is part of what has fueled the excesses that are currently under investigation."

Details of Study 15 have emerged through lawsuits now playing out in courtrooms nationwide alleging that Seroquel caused weight gain, hyperglycemia and diabetes in thousands of patients. The Houston-based law firm Blizzard, McCarthy & Nabers, one of several that have filed about 9,210 lawsuits over Seroquel, publicized the documents, which show that the patients taking Seroquel in Study 15 gained an average of 11 pounds in a year -- alarming company scientists and marketing executives. A Washington Post analysis found that about four out of five patients quit taking the drug in less than a year, raising pointed doubts about its effectiveness.

An FDA report in 1997, moreover, said Study 15 did offer useful safety data. Mentioning few details, the FDA said the study showed that patients taking higher doses of the drug gained more weight.

In approving Seroquel, the agency said 23 percent of patients taking the drug in all studies available up to that point experienced significant weight increases, compared with 6 percent of control-group patients taking sugar pills. In 2006, FDA warned AstraZeneca against minimizing metabolic problems in its sales pitches.

In the years since, taxpayer-funded research has found that newer antipsychotic drugs such as Seroquel, which are 10 times as expensive, offer little advantage over older ones. The older drugs cause involuntary muscle movements known as tardive dyskinesia, and the newer ones have been linked to metabolic problems.

Far from dismissing Study 15, internal documents show that company officials were worried because 45 percent of the Seroquel patients had experienced what AstraZeneca physician Lisa Arvanitis termed "clinically significant" weight gain.

In an e-mail dated Aug. 13, 1997, Arvanitis reported that across all patient groups and treatment regimens, regardless of how numbers were crunched, patients taking Seroquel gained weight: "I'm not sure there is yet any type of competitive opportunity no matter how weak."

In a separate note, company strategist Richard Lawrence praised AstraZeneca's efforts to put a "positive spin" on "this cursed study" and said of Arvanitis: "Lisa has done a great 'smoke and mirrors' job!"

Two years after those exchanges, in 1999, the documents show that the company presented different data at an American Psychiatric Association conference and at a European meeting. The conclusion: Seroquel helped psychotic patients lose weight.

The claim was based on a company-sponsored study by a Chicago psychiatrist, who reviewed the records of 65 patients who switched their medication to Seroquel. It found that patients lost an average of nine pounds over 10 months.

Within the company, meanwhile, officials explicitly discussed misleading physicians. The chief of a team charged with getting articles published, John Tumas, defended "cherry-picking" data.

"That does not mean we should continue to advocate" selective use of data, he wrote on Dec. 6, 1999, referring to a trial, called COSTAR, that also produced unfavorable results. But he added, "Thus far, we have buried Trials 15, 31, 56 and are now considering COSTAR."

Although the company pushed the favorable study to physicians, the documents show that AstraZeneca held

the psychiatrist in light regard and had concerns that he had modified study protocols and failed to get informed consent from patients. Company officials wrote that they did not trust the doctor with anything more complicated than chart reviews -- the basis of the 1999 study showing Seroquel helped patients lose weight.

For practicing psychiatrists, Study 15 could have said a lot not just about safety but also effectiveness. Like all antipsychotics, Seroquel does not cure the diseases it has been approved to treat -- schizophrenia and bipolar disorder -- but controls symptoms such as agitation, hallucinations and delusions. When government scientists later decided to test the effectiveness of the class of drugs to which Seroquel belongs, they focused on a simple measure -- how long patients stayed on the drugs. Discontinuation rates, they decided, were the best measure of effectiveness.

Study 15 had three groups of about 90 patients each taking different Seroquel doses, according to an FDA document. Approximately 31 patients were on Haldol. The study showed that Seroquel failed to outperform Haldol in preventing psychotic relapses.

In disputing Study 15's weight-gain data, company officials said they were not reliable because only about 50 patients completed the year-long trial. But even without precise numbers, this suggests a high discontinuation rate among patients taking Seroquel. Even if every single patient taking Haldol dropped out, it appears that at a minimum about 220 patients -- or about 82 percent of patients on Seroquel -- dropped out.

Eight years after Study 15 was buried, an expensive taxpayer-funded study pitted Seroquel and other new drugs against another older antipsychotic drug. The study found that most patients getting the new and supposedly safer drugs stopped taking them because of intolerable side effects. The study also found that the new drugs had few advantages. As with older drugs, the new medications had very high discontinuation rates. The results caused consternation among doctors, who had been kept in the dark about trials such as Study 15.

The federal study also reported the number of Seroquel patients who discontinued the drug within 18 months: 82 percent.

Jeffrey Lieberman, a Columbia University psychiatrist who led the federal study, said doctors missed clues in evaluating antipsychotics such as Seroquel. If a doctor had known about Study 15, he added, "it would raise your eyebrows."

Subject: Prospective Subpoena in PsychRights v. Alaska
From: Jim Gottstein <jim.gottstein@psychrights.org>
Date: Thu, 19 Feb 2009 09:53:52 -0900
To: cbailey@bpblaw.com
CC: ccoutroulis@carltonfields.com, jisani@hunton.com, mcfisk@bloomberg.net, Jim Gottstein <jim.gottstein@psychrights.org>, Kris Hundley <krishundley@gmail.com>, VERACARE <veracare@ahrp.org>, Lisa Demer <LDemer@adn.com>, "Toomey, Sheila" <SToomey@adn.com>

Dear Mr. Bailey,

In *Law Project for Psychiatric Rights v. State of Alaska, et al.*, Case No. 3AN 08-10115 CI, we are seeking declaratory and injunctive relief that Alaskan children and youth have the right not to be administered psychotropic drugs unless and until:

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

and that all children and youth currently receiving such drugs be evaluated and brought into compliance with the above.

We understand you are lead attorney in the *Seroquel Products Liability Litigation* in the US District Court for the Middle District of Florida, MDL No. 1769, and that there is a hearing on February 26th before Magistrate Judge Baker regarding Astra-Zeneca's desire to keep under seal certain information of vital public importance.

It is clear this same information is very relevant in *PsychRights v. Alaska*, because as I am sure you know Seroquel is often prescribed to children and youth in state custody and through Medicaid. Thus, we are very interested in the documents and anticipate having a deposition subpoena issued to you for at least the documents set forth on the (hopefully) attached list if they are not unsealed in the near future. Because *PsychRights v. Alaska* is not limited to the problem of Seroquel causing diabetes and other blood sugar/metabolic problems, we are also interested in other negative effects of Seroquel, unpublished studies, including those involving children and youth, and the promotion of Seroquel for pediatric use.

In accordance with our practice, rather than just serve you with a subpoena without warning, if the documents are going to remain sealed for any length of time, we would like to arrange for a mutually satisfactory date/time/location for the deposition, service of the subpoena, delivery of the documents, etc. We are also open to suggestions of a different person(s) to subpoena. I have reviewed the September 19, 2007, Protective Order, including ¶14, and understand it to be the operative document. If I am mistaken in this, please so advise me and provide the operative document. We anticipate Astra-Zeneca, whose attorney is copied on this, will (unlike Lilly) timely invoke ¶14 of the Protective Order and we will be litigating in *PsychRights v. Alaska* our entitlement to the documents and under what conditions, if any, they will be produced.

One question I have is if Magistrate Judge Baker decides at the February 26th hearing that the documents should be unsealed, is that likely to be subjected to further proceedings before the documents are actually unsealed and available to the public?

Please call at your convenience to discuss this matter, remembering that Alaska is three hours behind Houston (one hour behind the West Coast).

--

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

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

PsychRights®
Law Project for Psychiatric Rights

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

090121ListOfAZDocuments.pdf	**Content-Type:** application/pdf **Content-Encoding:** base64

EXHIBIT A -- DOCUMENTS CHALLENGED BY PLAINTIFFS

DOCUMENTS TO RETAIN CONFIDENTIALITY STATUS UNTIL TRIAL

#	PLAINTIFFS 11/24/08 MOTION & SEALED EXHIBIT #	DESCRIPTION
1	Genl Cause - Generic and Case-Specific Ex. 16	June 26, 2008 NDA 20-639 Submission (1,156 pages)
2	Genl Cause - Generic and Case-Specific Ex. 21; Omnibus MSJ Ex. 42	06/25/2008 letter (3-pages) from FDA to AZ
3	Genl Cause - Generic and Case-Specific Ex. 26	Internal email chain including from L Boornazian to M Deyr dated 04/26/2007
4	Genl Cause - Generic and Case-Specific Ex. 27; Omnibus MSJ Ex. 10	Internal email from Lisa Arvanitis dated 8/13/1997
5	Genl Cause - Generic and Case-Specific Ex. 41	Internal email chain including from Richard Owen to Matthew Lowe dated 3/18/05
6	Genl Cause - Generic and Case-Specific Ex. 51	Internal email chain including from David Duff to Kim Gilchrist, et al re Gianfrancesco work dated 5/23/03
7	Genl Cause - Generic and Case-Specific Ex. 52	A Comprehensive Retrospective Study of Associations Between Diabetes and Treatment with Risperidone, Olanzapine, Quetiapine, and Conventional Antipsychotics by HECON Associates, Inc.
8	Genl Cause - Generic and Case-Specific Ex. 58	08/18/00 email from Geller including attached Safety Position Paper
9	Genl Cause - Generic and Case-Specific Ex. 59	Portions of Dep of Wayne Geller (pp. 426-431) re: submission to Dutch health authority
10	Genl Cause - Generic and Case-Specific Ex. 60	Email from Dorothee Wientjens to Wayne Geller
11	Genl Cause - Generic and Case-Specific Ex. 64	Email from Connie Ou to Ronald Leong re Re-Challenge of Seroquel dated 2/4/03
12	Omnibus MSJ Ex. 1	Feb 2005 letter from French afssaps
13	Omnibus MSJ Ex. 2	03/09/2000 Seroquel Commercial Support Team - Technical Document (TD004)
14	Omnibus MSJ Ex. 3	03/06/2000 Seroquel Commercial Support Team - Technical Document (TD 005)
15	Omnibus MSJ Ex. 4	Internal email chain including M. Murray, M. Jones, J.Tumas, J.Goldstein dated 03/23/00
16	Omnibus MSJ Ex. 5	Excerpts of Kevin Birkett dep transcript 4/24/08
17	Omnibus MSJ Ex. 6	Sales Story Flow document
18	Omnibus MSJ Ex. 7	Wayne Macfadden dep transcript excerpts
19	Omnibus MSJ Ex. 8	Draft of article by Joyce Small re: Quetiapine
20	Omnibus MSJ Ex. 11	Martin Brecher dep transcript excerpts
21	Omnibus MSJ Ex. 12	Barry Arnold dep transcript excerpts
22	Omnibus MSJ Ex. 13	Internal memo from Richard Lawrence re: Study 15
23	Omnibus MSJ Exs. 14 (multiple documents)	Various internal emails which include: Internal email from Nick Hough re Small Review dated 5/10/99; 5/11/99 email from John Tumas to Michael Murray, et al; emails including Jim Gavin, John Tumas re: EPS data
24	Omnibus MSJ Ex. 17	Internal email from Don Beamish re: Reinstein
25	Omnibus MSJ Ex. 18	Discussion Document dated 6/22/00

#	PLAINTIFFS 11/24/08 MOTION & SEALED EXHIBIT #	DESCRIPTION
26	Omnibus MSJ Ex. 19	Wayne Geller dep transcript excerpts
27	Omnibus MSJ Ex. 20	Discussion Document
28	Omnibus MSJ Ex. 21	Safety Position Paper
29	Omnibus MSJ Ex. 22	09/18/2000 email thread from Geller re: glucose metabolism disorders and attaching Safety Position Paper
30	Omnibus MSJ Ex. 23	10/03/2000 email thread from D. Wientjens to Geller re Quetiapine and glucose metabolism disorders
31	Omnibus MSJ Ex. 24	Vikram Dev dep transcript excerpts
32	Omnibus MSJ Ex. 25	CBG Medicines Evaluation Board re: 1/2001response to MEB request to amend the SmPC
33	Omnibus MSJ Ex. 26	08/00 Response to FDA request
34	Omnibus MSJ Ex. 27	Internal email chain including Wayne Geller and Melissa Partridge re Metabolic issues dated 12/05/01
35	Omnibus MSJ Ex. 30	Objection Handler on Atypical antipsychotics and glucose dysregulation
36	Omnibus MSJ Ex. 32	Internal voicemail re: Weight and Diabetes Sell Sheet dated 08/15/05
37	Omnibus MSJ Ex. 37	10/15/2003 AZ letter to FDA re NDA 20-639, response to FDA request for labeling change
38	Omnibus MSJ Ex. 39	SERM Minutes 06/08/07
39	Omnibus MSJ Ex. 40	06/22/2007 AZ letter to FDA re NDA 20-639 and NDA 22-047, Supplement-Changes Being Effectuated
40	Haller SJ Motion Ex. 9-10	Speaker/Attendance Info
41	McA SJ Motion Ex. 14	Accounts Payable Info
42	Unger SJ Motion Ex. 15	Accounts Payable Info
43	Burns SJ Motion Ex. 17	Excerpts of Pharmaceutical Sales Specialist Deposition
44	Curley SJ Motion Ex. 12	Excerpts of Pharmaceutical Sales Specialist Deposition
45	Supp. Mem. on General Cause re: Rak	Rak Dep Transcript (includes numerous company documents as dep exhibits and testimony regarding same)
46	From Various Motion Responses	Various Expert Declarations, Expert Reports, and Expert Dep Excerpts, as well as Prescriber Dep Excerpts, which discuss confidential documents that were attached as exhibits to plaintiffs' responses
TRADE SECRET AND CONFIDENTIAL DOCUMENTS TO RETAIN CONFIDENTIALITY STATUS THROUGH TRIAL		
1	Genl Cause - Generic and Case-Specific Ex. 19	04/01/2008 CSR for study 144 (1,922 pages)
2	Genl Cause - Generic and Case-Specific Ex. 15	06/12/2006 CSR for study 125 (4,582 pages)
3	Genl Cause - Generic and Case-Specific Ex. 28	03/08/1996 IND for Seroquel (5,224 pages)
4	Genl Cause - Generic and Case-Specific Ex. 29	11/30/2006 CSR for study 165 (1,800 pages)
5	Genl Cause - Generic and Case-Specific Ex. 32	06/19/2007 CSR for study 127 (6,434 pages)
6	Genl Cause - Generic and Case-Specific Ex. 57	Draft Manuscript for Study 125 by Newcomer, J, et al.
7	Haller SJ Motion Ex. 9-10	Call Notes
8	McA SJ Motion Ex. 10-13	Call Notes
9	Unger SJ Motion Ex. 12-14	Call Notes
10	Whittington SJ Motion Ex. 5-7	Call Notes

#	PLAINTIFFS 11/24/08 MOTION & SEALED EXHIBIT #	DESCRIPTION
11	Guinn SJ Motion Ex. 10, 12, 13	Call Notes
12	Burns SJ Motion Ex. 16	Call Notes
13	Curley SJ Motion Ex. 9-11	Call Notes

Annual Report 2002: The Johnson and Johnson Center for Pediatric Psychopathology at the Massachusetts General Hospital

Director: Joseph Biederman, MD
Co-Director: Stephen V. Faraone, PhD

Executive Summary

Overview

The mission of the Center is to create a common ground for a strategic collaboration between Johnson & Johnson (J&J) and the Pediatric Psychopharmacology Research Program an at the Massachusetts General Hospital (MGH). The Center provides an infrastructure for MGH researchers to collaborate with J&J researchers on comprehensive studies of pediatric psychopathology, including diagnostic, therapeutic, and neurobiologic studies. The formation of the Center has created a forum for multidisciplinary collaborative research in a number of key areas, with an initial focus on pediatric mood and disruptive behavior disorders.

An essential feature of the Center is its ability to conduct research satisfying three criteria: a) it will lead to findings that improve the psychiatric care of children; b) it will meet high levels of scientific quality and c) it will move forward the commercial goals of J&J. We strongly believe that the Center's systematic scientific inquiry will enhance the clinical and research foundation of child psychiatry and lead to the safer, more appropriate and more widespread use of medications in children. Considering that nearly all psychiatric medication use in children is off label, studies of safety and efficacy in children are essential for clinicians, parents and patients to feel comfortable using these medications in children. The Center is poised to test the effectiveness and safety of RISPERDAL, REDACTED and new products as the emerge from the pipeline.

Equally important to effective use of medications is the demonstration of the validity of disorders. Because parents, patients and clinicians are exposed to a media that frequently questions the validity of childhood disorders, genetic and brain imaging studies are needed to show the validity of these disorders as brain disorders that respond to medication. Epidemiologic studies are needed to show that childhood disorders are frequently chronic and severely debilitating. Without such data, many clinicians question the wisdom of aggressively treating children with medications, especially those like neuroleptics, which expose children to potentially serious adverse events. Epidemiologic studies also show the continuity of childhood and adult disorders. This provides an additional measure of validation for the childhood disorder and in some cases validates the disorder as a disorder of adulthood as we have seen for adult attention deficit hyperactivity disorder (ADHD).

Through the funding provided by J&J, we are creating a team of investigators focusing on the following issues.

Assessing the Efficacy and Safety of Medications for Child Psychopathology

We will generate and publish data on the efficacy and safety of medications for improving currently available treatment options for child psychopathology. This work is an essential precursor to the safe, appropriate and widespread use of medications given that most must be used off-label. Specific goals of this area of work include:

- Assessing the full range of symptoms treated by RISPERDAL by analyzing data from Janssen's study of RISPERDAL among conduct disordered/mentally retarded youth. This will allow us to extend Janssen's prior findings indicating efficacy for conduct disorder to mania, anxiety and other classes of psychopathology.
- Using MGH open-label studies to assess the differential effectiveness and safety of RISPERDAL and ZYPREXA in the treatment of pediatric bipolar disorder (BPD). For example, we have already shown that ZYPREXA leads to twice the weight gain as RISPERDAL.

- Using MGH open-label studies to demonstrate how combination pharmacotherapy can be used to treat complex cases. Examples include using RISPERDAL and CONCERTA to treat ADHD with BPD, REDACTED
- REDACTED
- [redacted]
- [redacted]
- [redacted]

Resolving Complex and Controversial Diagnostic Issues

Many children with psychopathology never receive medical treatment due to controversies in the media and debates among professionals about the validity of psychiatric diagnoses in children. Additional under-treatment occurs due to lack of mental health screening in primary care clinics The Center seeks to address complex and controversial diagnostic issues through empirical research. This domain of work includes validating diagnostic methods, validating tools for screening and treatment monitoring and, if needed, creating new measures which will allow physicians to confidently screen for and diagnoses child psychopathology. Center investigators are now examining diagnostic and measurement issues for three disorders that have been particularly controversial: pediatric BPD, adult ADHD and pediatric psychosis. Specific goals of this area of work include:

- Analyzing databases at MGH to characterize pediatric BPD, adult ADHD and pediatric psychosis. This will help clinicians understand the nature of these disorders, which will facilitate their ability to diagnoses them in their practices.
- Developing and assessing the validity of screening tests for complex disorders such as comorbid ADHD, psychosis and pediatric BPD. Once appropriately validated, the use of these screening tests will alert physicians about disorders that exist which RISPERDAL and CONCERTA might treat. Currently, many children with psychosis and BPD and many ADHD adults are not identified as such so are not treated outside of specialty academic centers.
- Implementing training programs for screening tools in continuing medical education programs targeting pediatricians and general psychiatrists.
- Analyzing baseline data from Janssen funded studies to validate affective disorder sub-type in the conduct disorder subpopulation. Further validation of this group will alert physicians to the existence of a large group of children who might benefit from treatment with RISPERDAL.
- Analyzing data bases at MGH to clarify the continuity between childhood and adult disorders. Showing how pediatric mania evolves into what some have called mixed or atypical mania in adulthood, will provide further support for the chronic use of

RISPERDAL from childhood through adulthood. Such data will teach clinicians about how to identify these symptoms in adults.

- Using the classic criteria of Robins and Guze (1970) to validate diagnostic criteria for pediatric BPD, childhood psychosis and adult ADHD using studies of course, outcome, genetics, cognition and neuroimaging as described in the following sections.
- Using neuropsychological measures to accurately identify executive brain dysfunction and differentiate it from ADHD. Because executive brain dysfunction is seen in many ADHD children, there is some debate about whether it is a separate syndrome or another manifestation of ADHD. By clarifying this issue, we will demonstrate the need for clinicians to assess for executive brain dysfunction and consider potential medical treatments for this condition in their ADHD patients.
- REDACTED

Assessing the Severity and Chronicity of Child Psychopathology

We will study the natural course of pediatric psychopathology, the long-term incidence of the various dysfunctions and the long-term effects of pharmacologic and other interventions. This work validates childhood disorders by demonstrating how it evolves in adult manifestations of the same disorders. It shows clinicians that aggressive treatment is warranted because these disorders lead to substantial disability. By clarifying the chronicity of disorders, it further documents the necessity for the chronic treatment of some disorders by debunking myths which present childhood psychopathology as a normal phase of development. For example, in the past, ADHD was viewed as a remitting disorder and treatment was usually stopped during adolescence. Today, due to longitudinal studies the American Academy of Pediatrics now recommends treating ADHD as a chronic illness. Specific goals of this area of work include:

- Assessing the severity and chronicity of pediatric BPD using the same methods we have used for longitudinal studies of ADHD (Biederman et al., 1998b; Biederman et al., 2000).
- Characterizing the chronic, debilitating course of BPD to help people understand need for aggressive treatments such as RISPERDAL.
- Evaluating the effectiveness of medical and psychosocial treatments on long term outcomes in pediatric BPD using a naturalistic design.
- Evaluating the effect of RISPERDAL treatment on functioning in pediatric BPD in database studies and prospective short and long term studies.
- Assessing the disability associated with adult ADHD to help us understand the future of child ADHD and the need for chronic treatment. We are addressing this through a large longitudinal family study of ADHD and are also developing a day-long laboratory protocol to quantify the "real world" impairments associated with ADHD such as impaired driving skills and difficulty concentrating on work requiring sustained attention.

Clarifying the Biological Basis of Childhood Psychopathology

One of the main obstacles to the medical treatment of childhood disorders is the myth that they simply reflect problems of family and culture rather than dysfunctions of the brain. We will help dispel these myths using genetic and neuroimaging studies. These studies further validate childhood disorders as medical conditions and thereby give physicians more confidence in the use of medical treatments. By clarifying the causes of childhood disorders, these studies also lay

the ground work for the development of more efficacious treatments or the use of current treatments in a more effective manner. Specific goals of this area of work include:

Genetics

- Identifying genes that increase the susceptibility to child psychopathology with an initial emphasis on ADHD and BPD.
- Validating diagnostic criteria and assessing the validity of comorbidity using designs from genetic epidemiology.
- Creating a platform for collaboration between MGH and the J&J pharmacogenetics department by working with J&J to collect, DNA, safety data and efficacy data. The goal of this work is to discover genes which predict therapeutic response or adverse events during treatment with J&J medications.
- Collecting pharmacogenetic data in MGH studies of RISPERDAL, REDACTED REDACTED
- Studying children having a bipolar parent to develop rules for identifying pre-clinical cases. By accurately identifying children at risk for psychopathology, we will be able to develop early intervention and prevention treatment programs.

Neuroimaging

- Using magnetic resonance imaging to identify structural and functional patterns in the brain that characterize psychopathological subgroups, particularly controversial diagnoses such as pediatric BPD and adult ADHD.
- Initiating a prospective study of the efficacy and safety of RISPERDAL in pediatric BPD, including neuroimaging on a subset of patients.
- Using magnetic resonance spectroscopy to examine changes in NAA/CA, Choline, and other brain metabolites in response to RISPERDAL treatment.
- Using structural and functional magnetic resonance imaging in medication naïve patients to demonstrate that brain changes are associated with childhood disorders, not their treatment.

Disseminating Research Results and Educating Clinicians

To have an impact on clinical practice, research results from the Center must be disseminated through scientific publications, presentations and national and international meetings and continuing education programs. Our program of dissemination is as follows:

- Presenting findings and national meetings of the American Psychiatric Association, the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, the American Psychological Association, Biological Psychiatry, NCDEU and the American College of Neuropsychopharmacology.
- Presenting findings at international meetings of the World Psychiatric Association, the World Congress of Psychiatric Genetics, the European College of Neuropsychopharmacology (ECNP) and the Collegium Internationale Neuro-Psychopharmacologicum (CINP).
- Developing and implementing a BPD continuing education program to teach pediatricians and psychiatrists how to screen for, diagnose and treat BPD

- Present continuing medical education programs at national and international professional meetings:
- Convening a yearly international conference for investigators studying pediatric BPD (this is possible through funding from Janssen and a grant from the National Institute of Mental Health to Dr. Biederman).
- Convening a yearly international conference for investigators studying the genetics of ADHD (this is possible through funding from the National Institute of Mental Health to Dr. Faraone).
- Preparing manuscripts for publication in psychiatric, pediatric and psychological journals.

Details of Center Activities in 2002

In 2002, we made progress in the following areas:

- At MGH, we identified a multidisciplinary team of psychiatrists, psychologists, psychiatric clinical nurse specialists, epidemiologists, and behavioral geneticists to participate in the Center
- We initiated several research projects
- We initiated data analyses of archival J&J and MGH data sets.
- We disseminated the results of our work and national and international meetings.
- We prepared initial manuscripts for publication.
- We supported junior faculty efforts to develop expertise in pediatric BPD.
- We developed and maintained a schedule of regular communication with J&J staff to facilitate collaborative efforts.
- We Initiated Yearly Meetings of Experts in Bipolar Disorder.

Creation of a Multidisciplinary Team

Table 1 lists the MGH investigators participating in the Center. These participants are each faculty members in the Harvard Medical School Department of Psychiatry at MGH. As Table 1 shows, they have experience using a wide range of methods and measurement tools. A comprehensive description of all the prior work in these areas of measurement is beyond the scope of this report, but an examination of the biographical sketches of the investigators (see Appendix A) shows the extent of their prior empirical work, most of which has used the methods and assessment measures to be used in the proposed Center.

Table 1: MGH Participants in Center Research

EXPERTISE	INVESTIGATOR
Psychosocial Treatment Outcome Designs	Stephen Faraone, PhD Ross Green, Ph.D Dina Hirschfeld, Ph.D.
Psychopharmacological Treatment Outcome Designs	Joseph Biederman, MD Tom Spencer, MD Tim Wilens, MD
Epidemiological Designs	Stephen Faraone PhD Eric Mick, Sc.D.
Molecular and Statistical Genetics	Stephen Faraone, PhD James Gusella, PhD Paul Van Eerdewegh, PhD
Psychiatric Assessment, Diagnosis and Treatment-Outcome	Joseph Biederman, MD Tom Spencer, MD Tim Wilens, MD Janet Wozniak, MD
Psychological and Psychosocial Assessment	Stephen Faraone, Ph.D. Ross Green, Ph.D Dina Hirschfeld, Ph.D.
Neuropsychological Assessment	Larry Seidman, PhD Alysa Doyle, Ph.D
Neuroimaging	Larry Seidman, PhD
Statistical Analysis Analysis	Stephen Faraone PhD Eric Mick, Sc.D.
Data Base Programming; Computer Hardware; Networking; Data Quality and Security	Eric Mick, Sc.D.
Biostatistics	Stephen Faraone PhD Eric Mick, Sc.D.

Through this multidisciplinary faculty, the Center has access to the systematic assessments needed for screening, study recruitment and study implementation. Table 2 shows the domains of assessment expertise available to the Center. Most studies need structured interviews for psychiatric diagnostic assessments. Treatment protocols also require measurement in domains of functioning at baseline that might be predictive of subsequent treatment response as well as measures of psychopathology and functioning that will be sensitive to the clinically meaningful changes that will occur with treatment. The Center maintain assessment tools that allow for the assessment of functioning in multiple domains: psychiatric, psychosocial, neuropsychological, quality of life, and the utilization of health services.

Table 2: Measurement Domains Available to the Center

	Type of Study		
	Diagnostic Studies	Treatment Studies	Etiology Studies
Psychiatric Symptoms			✓
Structured Diagnostic Psychiatric Interview	✓	✓	✓
Substance Use Assessments		✓	✓
Clinical Rating Scales	✓	✓	✓
Social Functioning	✓	✓	✓
Family Environment Scale		✓	✓
Expressed Emotion		✓	✓
Family Burden		✓	
Neuropsychological Functioning			
Health Services Utilization	✓	✓	

Because much of the under-treatment of psychiatric disorders in children is due to concerns about the accuracy and validity of diagnostic measures, the ability to validate measures of childhood psychopathology is an essential component of the Center. The availability and use of good measurement technologies leads to improved acceptance of research results by the FDA, physicians, patients, their parents and the general public.

Center investigators have completed many methodological studies that validate the use of these assessment tools in pediatric populations. Examples include:

- Showing that parent-based diagnoses of ADHD are predictive of teacher-based diagnoses (Biederman et al., 1993b; Biederman et al., 1990a). This work has facilitated drug development for ADHD, when teacher reports are lacking. This makes adolescent studies feasible and also provides reassurance to clinicians when they must diagnose children without information from teachers.
- Using clinical trials data to show that parent reports are sufficient for detecting efficacy in studies of long-acting medications for ADHD (Biederman et al., submit). This work provides reassurance to clinicians when they must titrate medications without feedback from teachers
- Demonstrating that structured interview diagnoses of child psychopathology show high reliability and diagnostic efficiency (Faraone et al., 1995). This type of work clarifies the objective nature of diagnosis, which helps clinicians understand the value of applying them in pediatric settings.
- Supporting the validtity of adult ADHD diagnoses by showing that parental ADHD does not bias reports of ADHD in children (Faraone et al., in press), that symptom reports by ADHD adults are not influenced by the presence of ADHD in their children (Faraone et al., 1997) and that adult relatives of ADHD children have high rates of ADHD and that family study methods show adult ADHD to be a valid diagnosis (Faraone et al., 2000a). By demonstrating the validity of adult ADHD diagnoses, this and other work has led to a more widespread acceptance of the diagnosis, including acceptance by the FDA, which previously doubted its validity but has now given Lilly an adult ADHD indication for STRATTERA.
- Creating a method for assessing medication efficacy in a naturalistic setting by applying structured assessments to medical records (Biederman et al., 1999). This provides a simple method for assessing efficacy. As we have shown for the RISPERDAL treatment of bipolar disorder (Biederman et al., 1999), this method provides a quick assessment of whether a currently available medication is worth pursuing in a clinical trial.
- Using multiple definitions of remission to assess course and outcome (Biederman et al., 2000) and creating an assessment and analysis scheme for defining normalized functioning in children (Biederman et al., 1998b) we have been able to quantify the chronicity and severity of disorders and, thus, the need for chronic, aggressive medical treatment.
- Demonstrating the validity of the Social Adjustment Scale for Children and Adolescents (Biederman et al., 1993a) provides a useful tool for assessing the efficacy of medications in this "real world" domain of dysfunction affected by many psychiatric disorders.
- Creating new designs to clarify psychiatric comorbidity using the family study method has validated comorbid conditions and strengthened the rational for treating them (Faraone et al., 1999).

- Showing that exclusive reliance on youth self-reports may identify a mild form of depression associated with limited morbidity and disability compared with that identified by parental reports (Braaten et al., 2001) and showing that the potential distortion of indirect interviews by depressed mothers may be stronger in community than in clinical settings and does not account for the increased risk for MD in referred adolescents with ADHD (Mick et al., 2000) This work will lead to better methods of identifying depression in children.
- Documenting substantial stability of Child Behavior Checklist (CBCL) scales over time for ADHD patients to support the informativeness of the CBCL as a useful measure of longitudinal course in clinical samples of youth with ADHD (Biederman et al., 2001b). This work provides further evidence that the CBCL is a useful tool for screening and monitoring the progression of disorders.
- Developing new methodologic approaches for prevention protocols (Faraone et al., 2002). This work will, in the long-term, lead to psychopharmacologic protocols aimed at the primary prevention of childhood psychiatric disorders

The Center also includes substantial expertise in data management and analysis, which allows it to provide methodological, statistical and data base management assistance to participating investigators. To facilitate study efficiency and data sharing the Center has implemented a common data analytic infrastructure. This infrastructure has enabled the design of shared databases for analytic efforts of data collected across various studies.

Eric Mick, ScD heads the Center's data management efforts. As an epidemiologist, he is highly experienced in the collection, editing and management of large complex data sets from psychiatric studies, including longitudinal and family studies. He and our data base developer, Ellie Remskar, are responsible for setting-up and maintaining the central data management system. To achieve the goals of central data management, he plans for the software and hardware needs of the central system and supervises the day to day work of the central data management staff. He also assures the integrity of data management for each Center project.

Stephen Faraone, Ph.D. heads the Center's data management efforts by coordinating group of two junior faculty and three masters level statisticians well versed in a variety of statistical techniques. This resource is available to participating investigators (i.e., developing and established scientists), clinicians planning to become investigators and students (including graduate students, interns, residents and fellows). The data analysis efforts at the Center also include the development of new methods to deal with new issues that arise in the Center's research program. Prior examples of methods development include:

- The use of analytic mathematics and simulations to choose among methods for analyzing autocorrelated binary data (Faraone and Dorfman, 1987);
- The development of a method to assess inter-observer agreement in the presence of autocorrelation (Faraone and Dorfman, 1988);
- Creation of a method to render radioreceptor assay results comparable between different neuroleptic medications (Young et al., 1989).
- The use of simulations to choose among methods of morbidity risk estimation (Faraone et al., 1994) and to assess the statistical power of linkage studies (Chen et al., 1992).
- The use of multidimensional scaling to clarify diagnostic confusability and reliability (Faraone et al., 1996).
- The use of mathematical genetic considerations to choose phenotypes for genetic analysis (Faraone et al., 2000b).

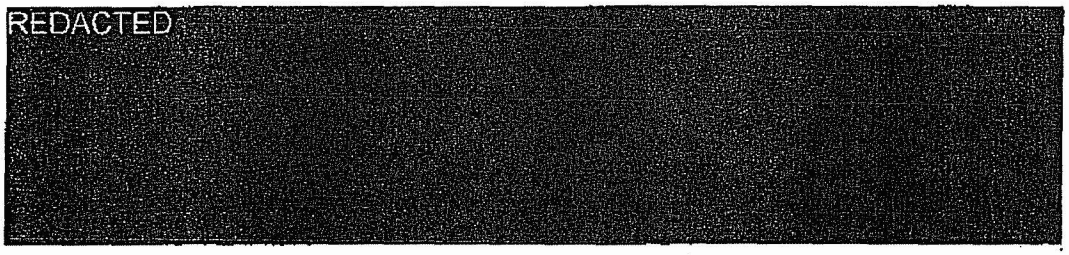
- The use of latent class methods to measure diagnostic accuracy in the absence of a gold standard (Faraone and Tsuang, 1994).
- An analytic demonstration of the effects of fixed-dose, clinical-dose and reduced-dose treatment designs on outcome measures (Faraone et al., 1992).
- The development of a receiver operating characteristic (ROC) based method to optimize the validity of psychiatric diagnoses (Faraone et al., 1993).
- The development of an ROC based method to comprehensively describe differences in efficacy between drug and placebo or between two drugs (Faraone et al., 2000c).
- Comprehensive reviews of ascertainment and statistical methods in psychiatric genetics (Faraone and Santangelo, 1992; Faraone et al., 1999; Faraone and Tsuang, 1995).

Data Collection Efforts Initiated in 2002

Treatment Studies

We will add descriptions of these.

Comparative Effectiveness and Tolerability of RISPERDAL with SEROQUEL, GEODON, ZYPREXIA



RISPERDAL and CONCERTA for ADHD in Children and Adults with Bipolar Disorder

MR spectroscopy study of children before and after RISPERDAL

Development of driving simulator for adults with ADHD

Sleep apnea and ADHD in adults

Treatment of Psychiatric Comorbidity in Bipolar Disorder.

Bipolar youth frequently present with one or more of the following comorbid disorders: ADHD, oppositional defiant disorder, pervasive developmental disorder, anxiety, and major depression. These disorders complicate treatment planning for two reasons. First, little is known about how to sequence the treatments for co-occurring conditions. In addition, the standard treatments for some comorbid conditions (e.g. stimulants for ADHD, SSRIs for depression) may exacerbate mania. Our plan is to develop open label trials targeted at these comorbid conditions to get an early signal regarding the effectiveness of these therapies. Those that look promising will be further developed by pursuing external funding for large scale clinical trials. We have currently initiated the following studies of comorbidity:

- Open-label study of RISPERDAL for pediatric BPD. This study serves as an ascertainment source for cases of BPD with ADHD, which can then be enrolled in a

study assessing the effectiveness of CONCERTA for ADHD in RISPERDAL treated BPD children.

- REDACTED

Pharmacokinetics and Drug-Drug Interactions.

Because many of the medications we are studying have not been used extensively in pediatric populations, it is essential that we collect pharmacokinetic data. Moreover, some of our protocols use more than one compound. Thus, a key component of our program is to evaluate potential drug-drug interactions associated with combined treatments using appropriate pharmacokinetic and pharmacodynamic protocols. Current pharmacokinetic studies are as follows:

- Pharmacokinetics of RISPERDAL in Pediatric ADHD
- REDACTED
- Pharmacokinetics of RISPERDAL and CONCERTA in Children with BPD and ADHD

Olanzapine plus Topiramate.

Topiramate has been used to offset weight gain associated with atypical neuroleptics in clinical practice but has not been systematically evaluated. Thus, the objective of this study is to evaluate the safety and effectiveness of added topiramate to minimize iatrogenic weight gain approaches to the treatment of BPD in children and adolescents.

Initial Treatment Studies of Bipolar Depression.

Since depression is a highly morbid state of bipolar disorder and since antidepressants can exacerbate manic symptoms, the evaluation of safe and efficacious treatments for bipolar depression remains uncertain. To this end, we initiated a clinical trial comparing the effectiveness of buproprion and paroxetine for the treatment of bipolar children with active symptoms of depression. These are potentially useful options to evaluate in this population since they have each been shown to have a low manicogenic risk in adults.

Epidemiologic and Genetic Studies of Pediatric Psychopathology.

Genotyping Efforts and Genetic Databank Development

We have been collecting blood samples from each member of the nuclear family of children with bipolar disorder. This blood is stored so that DNA may be extracted in the future in order to conduct linkage, association or pharmacogenetic analyses.

Phenotypic characterization of velo-cardio-facial (VFC) Syndrome

Since VCF has been associated with bipolar disorder in some studies, we are collecting digital photographs of children with bipolar disorder in order to test the hypothesis that hemizygous deletion of chromosome 22q11 may result in bipolar affective disorder. This finding may eventually lead towards the identification of candidate genes for early onset bipolar disorder.

Studies of Temperamental Risk Factors for Pediatric Bipolar Disorder.

Another major research interest of our group has been the study of temperament as a risk factor for subsequent psychopathology in at-risk children. We currently have a large program which has shown that behavioral inhibition is an early onset precursor of subsequent anxiety disorders

(Biederman et al., 2001a; Biederman et al., 1993c; Biederman et al., 1990b). If the new Center is funded, we plan to create a research program aimed at identifying temperamental risk factors for pediatric bipolar disorder. In particular, we intend to follow-up on some intriguing leads from our pilot studies, which suggest that behavioral disinhibition may be a very early onset risk factor for pediatric bipolar disorder.

Longitudinal Family Study of Pediatric Bipolar Disorder.

Longitudinal studies of pediatric bipolar disorder hold the promise of settling controversies that have plagued the field. If bipolar disorder is a valid diagnosis in children, signs of the disorder should remain evident at follow-up assessments. Equally important will be determining the course of comorbidity in pediatric bipolar disorder to see if they have a course and outcome that parallels that which has been seen for the comorbid disorder when it occurs in the absence of bipolar disorder. Dr. Wozniak collected 110 families ascertained via pediatric bipolar patients through her NIMH Career Development Award. With J&J funding, we have been able to initiate a follow-up study of this sample.

Follow-Up of Preschoolers with Bipolar Disorder.

In light of extensive media attention devoted to a recent pharmacoepidemiological analysis which asserted that large number of preschool children are inappropriately treated with pharmacotherapy and since children with bipolar disorder frequently present to clinics at very young ages with a very severe clinical picture, we are following preschoolers (age<6 years) who meet criteria for bipolar disorder to systematically evaluate the longitudinal course of this disorder in this age group.

Children at High Risk for Bipolar Disorder

We will add descriptions of this.

Neuropsychology and Neuroimaging of Pediatric Psychopathology

Magnetic Resonance Imaging of BPD+ADHD Adults

We will add descriptions of this.

MR Spectroscopy of BPD children before and after treatment with RISPERDAL

Analyses of Archival Data Sets

Data Sets Available Through MGH

Clinic Data

For the past decade we have systematically collected data on consecutive admissions to our pediatric psychopharmacology clinic. As a result, we have extensive clinical data (e.g., structured interviews, rating scales, psychometric tests) on more than 2000 patients not selected for a specific disorder. We also have the capability of completing systematic chart reviews using the methodology developed by Biederman et al. (Biederman et al., 1998a; Biederman et al., 1999). Ongoing analyses of these data are as follows:

- Clinical Features of Pediatric BPD
- Gender and Psychiatric Comorbidity in Adult ADHD
- Clinical Features of Children with Psychosis

Longitudinal Family Study of ADHD

Over the past twenty years, Drs. Biederman and Faraone have, with funding from NIMH, been following families of 140 ADHD boys, 140 ADHD girls and more than 200 gender and age matched control families from childhood to adulthood. Baseline and follow-up studies (which have also included family members) have provided a wealth of data about the course, outcome, clinical correlates and familial aggregation of ADHD. These data sets have allowed for the following analyses:

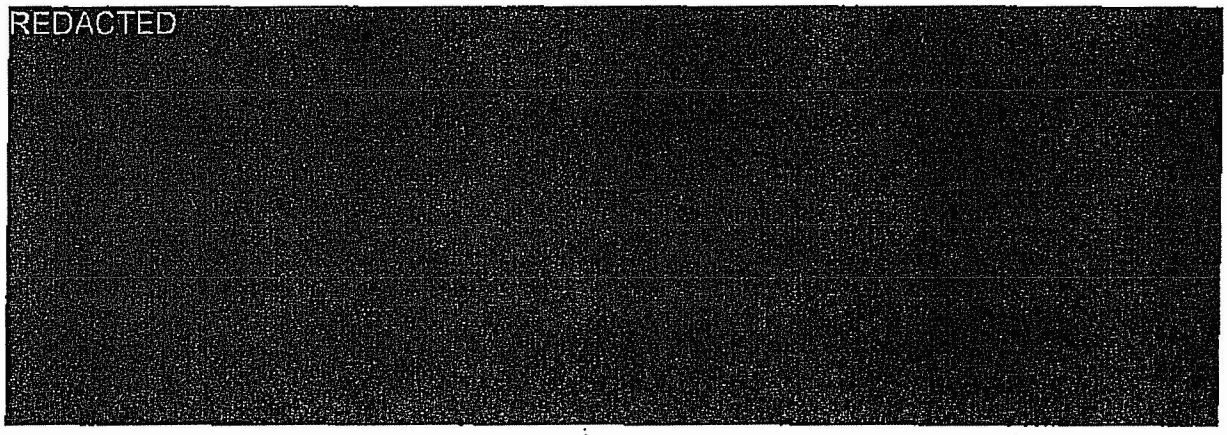
- Comorbid Anxiety Disorders Among Children with BPD
- Exposure to Parental Bipolar Disorder as a Risk Factor.
- Follow-up Study of ADHD children with BPD

Data Sets Available Through J&J

Double-Blind Trial of RISPERDAL in Children with Conduct Disorder and Mental Retardation

This data set contains the results of Janssen's clinical trial of RISPERDAL for conduct disorder and mental retardation. It also includes outcome ratings on a wide variety of symptoms, which makes it useful for assessing the efficacy of RISPERDAL for other conditions in this population and for assessing psychometric features of the measures. Analyses completed to date are:

- Efficacy of RISPERDAL for manic symptoms
- Replication of Factor Analysis of BPD Symptoms



Other Data Sets

Bipolar Genetic Linkage Data.

We have access to the NIMH bipolar disorder genetic linkage data set, which is a public resource available through the NIMH Genetics Initiative Program. We are using this data set for the following:

- Linkage analysis of the age at onset of manic symptoms

- Factor analysis of manic symptoms
- Published Data

We have found meta-analysis to be very useful for clarifying issues in pediatric psychopathology. We have already applied this methodology to studying the DRD4 gene in ADHD (Faraone et al., 2001), the efficacy of ADHD medications (Faraone and Biederman, 2002; Faraone et al., 2002) and to studying the effects of stimulant medications on substance abuse in ADHD (Wilens et al., in press). We are currently using meta-analysis of published data as follows:

- Meta-analysis of multiple studies using CBCL to validate profiles
- Meta-analysis of the DAT gene in ADHD (through collaboration with the ADHD Genetics Network, S. Faraone (PI)).
- Meta-analysis of the DRD5 gene in ADHD (through collaboration with the ADHD Genetics Network, S. Faraone (PI)).

Support of Junior Faculty to Develop Expertise in Pediatric Psychopathology Research

Perhaps the most enduring impact of our Center will be the work of trainees and junior investigators whom we have attracted to the study of pediatric psychopathology. By doing so, we will create a new generation of investigators committed to studying the causes of and treatments for childhood psychopathology.

Table 3 describes the young investigators supported by our research program. The table shows that we have been creating a team of new investigators who have a wide range of expertise including psychopharmacology, psychosocial treatment, substance abuse, neuroimaging and pharmacology. Although each of these new investigators has a specific expertise, our approach to training requires that they study pediatric bipolar disorder within the broader context of childhood psychopathology. For example, we have not set up a bipolar disorder specialty clinic. Instead, clinicians are taught to diagnose bipolar disorder and all comorbid psychopathology. This makes it easier to recognize comorbidity and to devise research protocols aimed at understanding its causes or devising methods for its treatment.

Table 3: Young Investigators Being Trained in the MGH Pediatric Psychopharmacology Research Program

Investigator	Speciality	Projects
Janet Wozniak, MD	Pediatric BPD	Clinical trials and longitudinal family study of BPD.
Ross Greene, PhD	Psychosocial Treatment	Clinical Trials of Psychosocial Therapies for Children with Bipolar Disorder.
Louise Cohen, PharmD	Pharmacokinetics	Developmental Pharmacokinetics of Psychotropic Drugs
Dina Hirshfeld, PhD	Anxiety Disorders	Temperament as a Risk Factor for Psychopathology
REDACTED		
Eric Mick, ScD	Methodology	Methods Development and Applications
Aude Henin, Ph.D.	Children at Risk	Children at Risk for Bipolar Disorder
Alysa Doyle, Ph.D.	Neuropsychology	Cognition and Genetics of ADHD
Dan Geller, MD	Obsessive Compulsive Disorder	Treatment and Epidemiologic Studies of OCD
Eve Valera, Ph.D	Neuroimaging	Structural and Functional MRI of ADHD

Our training program also encourages cross-fertilization among disciplines, a process that is facilitated by the fact that the Center Director, Dr. Biederman, is a psychiatrist, his Co-Director, Dr. Faraone, is a psychologist and the Scientific Coordinator, Dr. Mick, is an epidemiologist. On a practical, training level, cross-fertilization means that junior investigators must learn about

concepts and methods outside their main area of inquiry. Moreover, they must incorporate these into their research protocols.

Communication With J&J Staff to Facilitate Collaborative Efforts
We will add descriptions of this.

Initiation of Yearly Meetings of Experts in Bipolar Disorder

To address the controversy about pediatric bipolar disorder, we initiated a multi-year conference series which seeks to establish a forum for researchers and clinicians to improve dialogue and foster collaborative studies about children who present with extreme temper tantrums and dysregulated mood. Preceding roundtables on pediatric bipolar disorder had stressed the pressing need to advance the scientific knowledge of this severe mental disorder and had recognized the paralyzing effects of the ongoing controversy surrounding pediatric bipolar disorder and bipolar spectrum disorders. This controversy led to a vicious circle of diagnostic skepticism, void of scientific information, and therapeutic nihilism with its detrimental impact on patients and their families.

Fostering dialogue among scientists and clinicians is a key step to better defining the clinical and scientific questions and fostering necessary collaborative research critical to building a scientific foundation for the understanding and treatment of pediatric bipolar disorder. When collaborations are considered, they frequently face hurdles that cannot be easily surmounted. For example, clinical traditions at different centers often clash regarding diagnostic conceptualizations as well as over which clinical and research strategies are best suited to answering important research questions. Thus, the main goal of the conference series on pediatric bipolar disorder is to build consensus through a network of clinicians and investigators who are studying or are planning to study pediatric bipolar disorder. Sub-goals of these conferences are:

- To define the boundaries of the bipolar spectrum phenotype and determine if children who technically meet criteria for bipolar disorder actually have this disorder or are affected with another condition.
- To standardize data collection methods across different centers to facilitate pooling of diagnostic data.
- To facilitate joint submissions of large collaborative projects that will enable the study of a broad spectrum of scientific questions including genetic, imaging and therapeutic protocols.
- To create a mechanism for pooling samples so that potential findings from one group may be cross-validated on pooled data from remaining groups

The first meeting was held in March, 2002, through an unrestricted educational grant by Janssen Pharmaceuticals. The proceedings of the first meeting will be published in Biological Psychiatry (See www.mgh.harvard.edu/depts/pediatricpsych/bipolar_2002.htm to view the slide presentations). A list of the presentations follows:

- Phenotypes of Inpatient Children with Mania: Gabrielle Carlson, MD
- Convergence between Structured Interviews and Clinician Assessments of BPD: Janet Wozniak, M.D.
- High Risk Studies of Children at Risk for BPD: Kiki Chang, PhD.
- Dysphoric Conduct Disorder: The overlap between conduct disorder and BPD: Joseph Biederman, MD
- Proposed Cross Natural Study of Diagnosis of Pediatric Mania: Richard Harrington, MD

- Genetics of Pediatric Bipolar Disorder and Its Comorbidities: Steven Faraone, Ph.D.
- Magnetic Resonance Imaging Studies of Pediatric BPD: Jean Frazier, MD
- Combination Pharmacotherapy in Children and Adolescents with Bipolar Disorders: Robert Kovatch, MD
- Temperament and Mood DisordersóBehavioral Disinhibition: Dina Hirshfeld-Becker, Ph.D.
- Parent Advocacy Perspective: Martha Hellander
- Multifamily Psychoeducation Groups for Pediatric Bipolar Disorder: Mary Fristad, MD
- Defining Clinical Phenotypes of Juvenile Bipolar Disorder: Ellen Leibenluft, MD
- Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD): Andrew Nierenberg, MD
- Children and Adolescents with Bipolar Disorder: Methodological Issues: Boris Birmaher, MD
- Methodological Issues in Pediatric BPD: Eric Mick, Sc.D.
- Retrospective, unblinded chart review of pediatric BPD. Luis Rohde, MD
- BPD Among ADHD Children. Philip Hazell, MD

Plans for the Future

Table 4 presents our original timeline for research at the J&J Center for Psychopathology Research at MGH.

Table 4: Project Timeline for the J&J Center for Psychopathology Research at MGH						
	Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
Treatment Research						
Efficacy of RISPERDAL for Pediatric BPD	X	XP	XP			
Pediatric BPD RISPERDAL PK Study		XP	XP			
Meridia for weight gain in Risp treated patients		XP	XP			
REDACTED						
PK study of stimulants and RISPERDAL		XP	XP			
Efficacy of adding Wellbutrin or Paxil for depression to RISPERDAL treated BPD patients		XP	XP			
PK study of Wellbutrin/Paxil and RISPERDAL		XP	XP			
Cabergolinefor hyperprolactinemia in Risp treated patients		XP	XP			
Efficacy of galantamine for executive dysfunction in BPD			XP	XP		
Efficacy of RISPERDAL for BPD in PDD Children				XP	XP	
Efficacy of RISPERDAL for BPD in OCD Children				XP	XP	
Efficacy of Multimodal treatment of BPD using risperdone and cognitive behavior therapy				XX	XP	XP
Long term follow-up of Efficacy Studies to assess psychosocial outcome, cognitive outcome, symptomatic outcomes and substance use outcomes				XP	XP	XP
Etiologic Research						
Structural MRI of BPD adults with and without ADHD		XX	XP			
Structural MRI of BPD children with and without ADHD	XX			XX	XP	
Pharmacogenetic studies of BPD trials	XX	XX	XP	XP	XP	
Velo-Cardio Facial Syndrome and BPD			XX	XP		
Candidate gene studies of Pediatric BPD			XX	XP	XP	XP
Longitudinal Research						
Validation of affective-type conduct disorder with family study	XX	XX	XX	XP	XP	XP
Follow-up of BPD Children		XX	XX	XP	XP	XP
Follow-up of children at risk for BPD		XX	XX	XP	XP	XP
Analysis of Existing Data						
Efficacy of RISPERDAL for affective-type conduct disorder in Janssen clinical trial	XP	XP				
Use MGH follow-up and family study data to define and validate antisocial and non-antisocial subtypes of BPD	XP	XP				
Use MGH follow-up data to define risk factors and developmental trajectories of BPD			XP			
Use MGH follow-up and family study data to define CBCL screening rules for pediatricians			XP			
Use MGH follow-up and family study data to define executive dysfunction measure for galantamine study		XP				
Educational Initiatives						
Yearly Pediatric BPD Conference	X	X	X	X	X	X
Development of BPD CME Program	X	XX				
Implementation of BPD CME Program	X		XX	XX	XX	XX
BPD Programs at national and international professional meetings: NCDEU, AACAP, Biological Psychiatry, ACNP, APA, AAP, ECNP, CINP, WPA		XX	XX	XX	XX	XX

Appendix A: Biographical Sketches of MGH Investigators

APPENDIX B: Presentations at National and International Meetings in 2002 By MGH Pediatric Psychopharmacology Research Program

APPENDIX C: Preparation of Manuscripts for Publication in 2002 By MGH Pediatric Psychopharmacology Research Program

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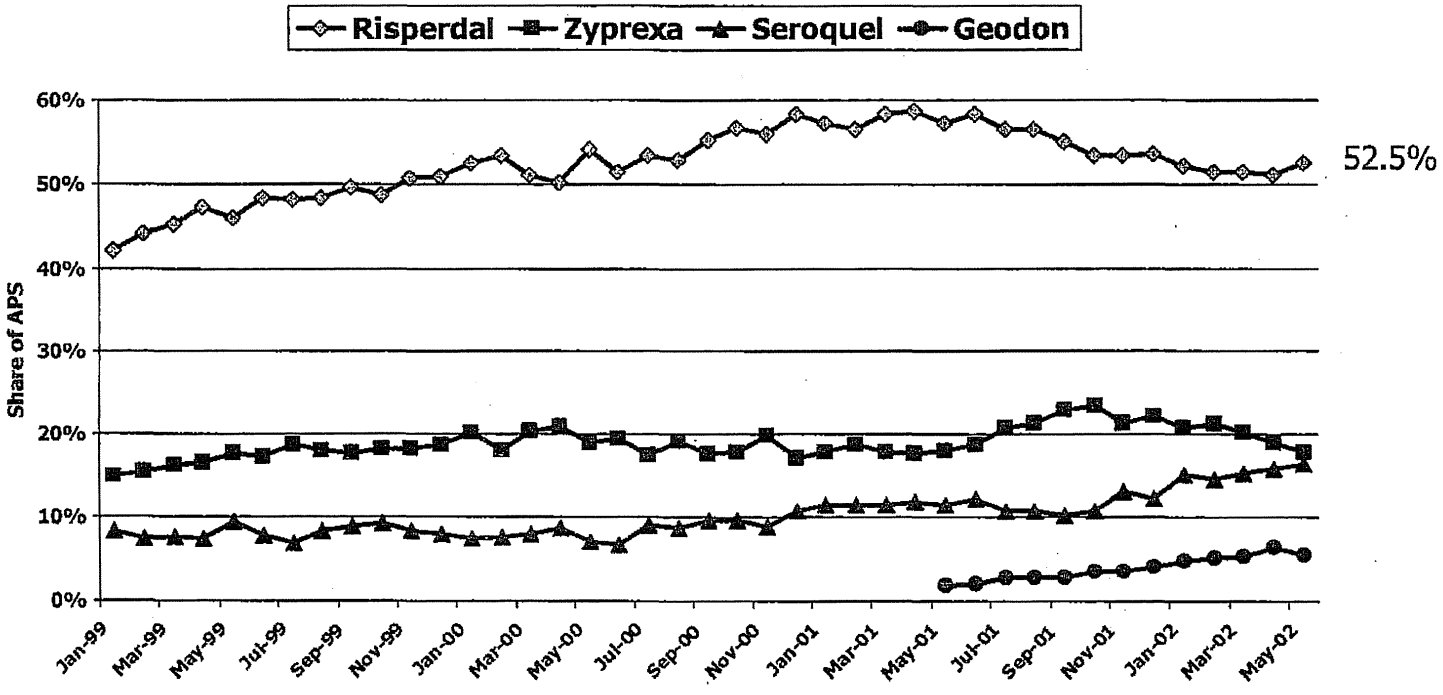
Child and Adolescent & Other New Business

2003 Business Plan

July 29, 2002

Antipsychotic Share in Child & Adolescent Market



Subject to legal and regulatory review

Source: IMS Health, NDTI
Child and adolescent defined as ages 0-17.

2003 Business PLan

Lessons Learned

Lessons Learned

- C&A market is becoming increasingly competitive: increased comfort with newer agents
- Prolactin, EPS, TD and weight gain continue to be important issues (especially long-term implications)
- Competitors are driving negative safety and tolerability perceptions for Risperdal (e.g., prolactin)
- C&A market growth has flattened
- Advocacy is seeking to define a public position regarding C&A use of antipsychotics

Implications

- Generation and dissemination of current and future data is essential
- Dissemination of re-analyses of safety databases is critical
- Stigma and lack of education regarding appropriate use of APS in C&A must be addressed
- Opportunities exist for partnerships with advocacy

Subject to legal and regulatory review

2003 Business PLan

SWOT Analysis

STRENGTHS

- **APS market leader in C & A market**
- **Perceived efficacy advantage:**
  - **trust and experience with product**
- **Most data (Relative to Other APS)**
- Low dose availability/oral Solution
- KOL support
- Early onset of action

WEAKNESSES

- **Safety perceptions (Prolactin, EPS, TD, Weight Gain)**
- **Lack of awareness of appropriate dosing**
- Lack of promotional platform/indication
- Lack of sedation relative to other APS

OPPORTUNITIES

- **External data sources (e.g., RUPP)**
- **Clinical partnerships (e.g., Mass General)**
- **Under serviced market/unsatisfied market**
- Zyprexa safety profile (e.g., metabolic)
- JNJ "pediatric" synergy (MCC, OMP, Alza)
- Better diagnosis (DSM - V, consensus guidelines)
- Advocacy is seeking partnership
- Quicksolv

THREATS

- **Further delay of labeling/exclusivity**
- **Negative PR regarding use of APS in C&A**
- **Increased focus of competition on C&A market**
- Perceived legal liability by prescribers
- Sensitivity regarding use of APS in C&A
- Emerging clinical data with other APS
- Migration to other classes of drugs

Subject to legal and regulatory review

2003 Business PLan

Key Issues

- Use of psychotropic medications in child and adolescents remains controversial
- Limited education and awareness of appropriate use of APS
- Physician misperception of Risperdal safety profile: driven primarily by increasingly competitive market
- Lack of indication

Subject: RE: Qualified Protective Order
From: "Bakalar, Elizabeth M (LAW)" <libby.bakalar@alaska.gov>
Date: Tue, 20 Jan 2009 16:58:14 -0900
To: Jim Gottstein <jim.gottstein@psychrights.org>
CC: "Kraly, Stacie L (LAW)" <stacie.kraly@alaska.gov>

Hi Jim,

With all due respect and fully appreciating the need for expedience, we can't really respond to any of the below absent actual and specific discovery requests propounded to us per the Civil Rules. Once we receive those we'll be happy to assist you in meeting their demands to the best of our ability. You are correct that Dave Campana is the state pharmacist. Likewise we'll deal with any deposition noticed to him and/or others in due course.

Libby

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From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, January 20, 2009 4:01 PM
To: Bakalar, Elizabeth M (LAW)
Cc: Kraly, Stacie L (LAW); Amanda Metivier; Jim Gottstein
Subject: Re: Qualified Protective Order

Hi Libby,

If you have specific state confidentiality law you believe applies that can be included let me know.

I disagree it is premature to enter such an order. Discovery will also be obtained from non-parties and I need to at least have sought to obtain a Qualified Protective Order before conducting such discovery.

I have (hopefully) attached a draft of a Rule 30(b)(6) deposition notice. There may be some changes to it before I issue the subpoena, but it seems like we can talk about sequence and timing. The first thing I will need are the electronic files pertaining children and youth being administered psychiatric drugs, so I would like first depose the people who know about them. I understand David Campana is probably the person to depose about the Medicaid database, but I also need to get the relevant computer records from OCS, DBH, DJJ, and API. I am happy to work with the AGO informally to the extent we can. Thus, for example, I have (hopefully) attached a list of what I believe are the Medicaid Fields. I'd be happy to get together with Mr. Campana and my computer guy to understand the database and get the records we want. I would want to do the same thing with the other agencies' databases.

Of course, my great preference is to reach some kind of settlement, but in the absence of any movement on that front, I need to pursue discovery with some dispatch.

Bakalar, Elizabeth M (LAW) wrote:
Jim,

We're not averse to the concept of a protective order and we're not trying to be difficult, but until specific discovery

requests are propounded, we think this is a little general/premature. Once we get down to the nitty gritty of discovery, we're going to be dealing with state confidentiality law—not just HIPAA—and any protective order issued should be tailored to the specific request. Obviously if we're talking about raw data, a protective order is probably not needed. So in short we'd prefer to wait until specific discovery requests come in before we jump the gun on this one.

Libby

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From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Tuesday, January 20, 2009 2:43 PM
To: Bakalar, Elizabeth M (LAW); Kraly, Stacie L (LAW)
Cc: Amanda Metivier; Jim Gottstein
Subject: Qualified Protective Order

Hi Libby and Stacie,

We need to get a "Qualified Protective Order" in place under HIPAA for the conduct of discovery and I have taken the initiative to draft the (hopefully) attached one. My preference is to jointly present one, but if we can't agree on its terms, I will go ahead and move for it.

My anticipated schedule got blown up by the Bill Bigley case, essentially losing three months, so I am feeling pressed to move this case along.

--

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

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PsychRights®
Law Project for Psychiatric Rights

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging. We are further dedicated to exposing the truth about these drugs

and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Extensive information about this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

--

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Subject: Re: Our Pending Litigation
From: Jim Gottstein <jim.gottstein@psychrights.org>
Date: Mon, 09 Feb 2009 12:49:32 -0900
To: "Bakalar, Elizabeth M (LAW)" <libby.bakalar@alaska.gov>
CC: "Kraly, Stacie L (LAW)" <stacie.kraly@alaska.gov>, Jim Gottstein <jim.gottstein@psychrights.org>
BCC: Amanda Metivier <facing_fostercare@yahoo.com>, Vicki Colca <VColca@cs.com>

Hi Libby,

I, too, hope you are not "one of the 'huge wealthy enemies'" referred to in the Huffington Post article. I'm working on configuring our discovery requests and hope to get at least some of them out by the end of this week or early next. I agree we should obtain "concrete facts and figures derived through formal discovery." Analyzing the Medicaid database seems likely to provide the most global picture. I initially proposed we could meet informally in order to formulate the precise request for the Medicaid database, but you want do even that through formal discovery, which is fine.

In addition to the Medicaid Database I understand the Office of Children's Services (OCS) uses "ORCA" and the Division of Behavioral Health (DBH) uses AKAIMS. I don't know what the Alaska Psychiatric Institute (API) and the Division of Juvenile Justice (DJJ) use. We'll just start through the 30(b)(6) deposition, but I am trying to be careful and thorough about putting it together, which is why it hasn't gone out yet.

How about if we set March 19th to start the 30(b)(6) deposition of the state?

Bakalar, Elizabeth M (LAW) wrote:

> We too look forward to working with you, so I truly apologize if it wasn't clear from our January meeting that we were planning to take a hard look at the issues you identified in your agenda. We are doing so as we speak, and just this morning I had a long meeting with DHSS folks to discuss. Settlement (in our opinion) will be helped enormously by concrete facts and figures derived through formal discovery. That way we will have a better idea as to the validity of your allegations, the scope of possible settlement, and the financial impact of any proposals. Our point was simply that there is no need to informally "lobby" the public with respect to issues already being addressed through active litigation. That's our position, but obviously you'll do what you need to do. And no, I was not aware that you were officially scheduled to present at the BTKH meeting. But I sincerely hope that we are not one of the "huge wealthy enemies" referred to in the Huffington Post piece you've attached. We have a common goal of keeping kids in custody safe and healthy. We need to be partners—not combatants—in that endeavor. We are trying to work with you sincerely and in good faith and our point was simply that it's difficult to do so when you're on the sidelines maligning DHSS.
>
> Libby Bakalar
> Assistant Attorney General
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> Juneau, Alaska 99801-0300
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>
> ---
>
> **From:** Jim Gottstein [mailto:jim.gottstein@psychrights.org]
> **Sent:** Friday, February 06, 2009 7:16 PM
> **To:** Bakalar, Elizabeth M (LAW)
> **Cc:** Kraly, Stacie L (LAW); Amanda Metivier; Jim Gottstein
> **Subject:** Re: Our Pending Litigation

Hi Libby,

It is very encouraging to hear the State is working on settlement issues. I wasn't encouraged when we left our meeting a month ago and this is the first indication I have heard the State is working on settlement issues. You ask that I consider limiting public advocacy efforts "during the the time we have specifically identified to work on settling the issues you raised." What time have you specifically identified to work on settling the issues I raised?

When I thought about timing, (a) the Legislature is presumably going to adjourn in mid April, and since (b) the trial is set for February 1, 2010, (c) it was hard to see how we could even get there from here, especially since (d) as far as I am aware, there has been no effort by the Administration to even raise the possibility with the Legislature. If, on the other hand, the Administration has been talking to legislators, I certainly don't see how it can complain about me communicating with it as well. If my e-mail to the Legislature caused the Administration to talk to legislators about the issue, from my perspective that seems good.

My e-mail to all of the legislators was really more of a courtesy, and especially so they could not say they hadn't been informed by me, if, as I hope, absent a settlement, we obtain a court order requiring the State to immediately cease the way it is psychiatrically drugging and paying for the psychiatric drugging of children and youth. Unless requested by legislators for more information, I am not intending to contact them further because I believe, without support from the Administration, it would be a waste of my time, which will be better spent on the litigation. However, as I think you know, I am scheduled to make a presentation to the Alaska Mental Health Trust Authority's Bring the Kids Home workgroup meeting Wednesday afternoon. I am doing that because, as we both know, there will need to be resources devoted to solving the problem and the Trust is potentially part of the solution.

As to PsychRights' general public advocacy efforts, we see that as a key part of the effort. In that regard, you might be interested in the item appearing in the influential Huffington Post blog a couple of days ago at http://www.huffingtonpost.com/dr-peter-breggin/a-hero-protects-americas_b_164020.html . I have also (hopefully) attached the February Nine Star Youth Services Newsletter, "The Teen Beat," which has a couple of articles about the issue starting at page 7.

The State should be ashamed of what it is doing to children and youth, should be immediately taking steps to rectify the situation, and I hope hard questions do start being asked of the Administration and Legislature. In my mind, that would encourage settlement.

I look forward to working with you on these issues.

Bakalar, Elizabeth M (LAW) wrote:
Hi Jim,

It's come to our attention that you've recently contacted the Alaska Legislature regarding our pending litigation (3AN-08-10115). Specifically, you e-mailed members of the Legislature on January 27 to inform them of the alleged "incredible amount of harm the State of Alaska is unnecessarily inflicting" on youth in state custody. We also understand that you have sought to participate in at least one public meeting attended and/or sponsored by

DHSS, possibly for the purpose of addressing issues related to this litigation.

We, along with our clients, attended our January 2009 settlement meeting in good faith. As a result of that meeting we have started to work on many of the issues you identified in the hopes that we could either narrow the scope of this lawsuit or frame future settlement proposals. We understand that you will soon be propounding formal discovery requests, which hopefully will go a long way toward advancing these goals.

So we were a bit surprised and confused by your overtures to the Legislature and others to seek public venues in which to discuss this case. Our clients believe that given our pending litigation, these issues are more appropriately resolved through discovery, settlement, and other established judicial processes.

While no one disputes your right to advocate your position to the public, we ask that you consider limiting these efforts during the time we have specifically identified to work on settling the issues you have raised. It is very difficult and distracting for the Department to engage in settlement discussions while having to simultaneously address and respond to your public advocacy efforts.

Thanks.

Libby Bakalar
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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
----------x
IN RE:
ZYPREXA LITIGATION,

MDL 04 1596
United States Courthouse
Brooklyn, New York
----------x
January 17, 2007
11:00 a.m.

TRANSCRIPT OF HEARING
Before: HON. JACK B. WEINSTEIN, District Judge
APPEARANCES
Attorneys for Plaintiff:
DOUGLAS & LONDON, ESQ.
111 John Street
Suite 1400
New York, N.Y. 10038
BY: MICHAEL A. LONDON, ESQ.

THE MILLER FIRM
The Sherman Building
108 Railroad Avenue
Orange, Virginia 22960
BY: MICHAEL J. MILLER, ESQ.

FRED VON LOHMANN, ESQ.
Attorney for Electronic Frontier Foundation
454 Shotwell Street
San Francisco, Ca 94110

MR. HAYES: Right.
THE COURT: I think it's reasonable to read the letter plus the attachment as indicating December 20th as the date for supplying the exhibits.
MR. McKAY: Your Honor --
THE COURT: Do you want to ask anything?
MR. McKAY: No, your Honor. I think that it's really argumentative. It's the date of the deposition and we agree with that.
THE COURT: Then I'm prepared to release the witness.
MR. HAYES: Yes.
THE COURT: Have a good trip back to Alaska, sir?
THE WITNESS: Thank you, your Honor.
(Witness excused.)
THE COURT: Next witness.
MR. LEHNER: At this time we would call Vera Sharav who is still in the courtroom, I believe.
VERA SHARAV, having been called as a witness, first being duly sworn, was examined and testified as follows:
THE CLERK: Could you please spell your name for the court reporter.
THE WITNESS: Vera Sharav, V-E-R-A S-H-A-R-A-V.
DIRECT EXAMINATION

Gottstein, is that correct?
A It was validated in my mind when they appeared on Sunday in the New York Times front page, then again on Monday on the front page. Then of course the editorial calling for congressional hearings about the content of the documents and that is really my interest. My interest is the content because the documents document the fact that Eli Lilly knew that the -- that Zyprexa causes diabetes. They knew it from a group of doctors that they hired who told them you have to come clean. That was in 2000. And instead of warning doctors who are widely prescribing the drug, Eli Lilly set about in an aggressive marketing campaign to primary doctors. Little children are being given this drug. Little children are being exposed to horrific diseases that end their lives shorter.

Now, I consider that a major crime and to continue to conceal these facts from the public is I think really not in the public interest. This is a safety issue.

MR. LEHNER: I move to strike as being nonresponsive to my last question and I would like to ask the court reporter if he is able to -- I think I remember my last question. I'll repeat my last question. Nonetheless, I'll make a motion to strike the last answer.

THE COURT: Denied.

Q My question was was it Mr. Gottstein who conveyed to you the impression that you formed in your mind that these

IN THE SUPERIOR COURT FOR THE DEFENDANTS OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services, Defendants.	REC'D MAR 30 2009 Case No. 3AN 08-10115 CI

DEFENDANTS' REPLY MEMORANDUM TO PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO STAY DISCOVERY

In Opposition to defendants' Motion to Stay Discovery, Psych Rights submits a 28-page opposition and close to 200 pages of exhibits[1] arguing two main

[1] The first 22-pages of the exhibits relate to the pending discovery requests in this case and are relevant to the instant motion. The remaining pages appear to relate to Psych Rights "discovery plan" which is discussed, *infra*. As argued in this reply, the discovery plan is beyond the scope of this motion and these documents should be stricken or not relied upon by the court. To the extent the Motion to Stay is not granted, or the underlying Motion for Judgment on the Pleadings is denied, then the defendants will

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points: 1) that the burden and expense of discovery does not outweigh the benefit to Alaska youth in bringing this litigation, and 2) that the Motion to Dismiss, which is the basis for the Motion to Stay, lacks merit. Both these arguments fail for the reasons set forth below. Therefore, the Motion to Stay should be granted.

ARGUMENT

1. Discovery Prior To The Court's Decision On The Motion For Judgment On The Pleadings Is Unwarranted And Burdensome

Psych Rights' primary argument is a policy argument that the benefits of this litigation to Alaska youth are paramount to any burden or expense to the defendants in engaging in discovery at this time. This opinion should not trump legal precedent. Even if Psych Rights is correct that the ultimate benefit to children should be considered primary, the rules of civil procedure still require process to be followed. This ends-justify-the-means argument does not work because in order to get to the end, Psych Rights must have a case that can go forward. This argument also fails to recognize a long line of case law, cited to by the defendants in its motion, that supports the position that discovery is not appropriate because the defendants should not be subjected to the time, expense, and burden of discovery unless there are factual issues in dispute related to the dispositive motion.[2]

In *Karen L. v. Defendants*, the Alaska Supreme Court held that in the case where a dispositive motion related to official immunity was raised, the State defendants were entitled to a stay of discovery because "official immunity shelters government officials, not just from liability, but from *suit*, including pre-trial discovery."[3] In *Karen L.*, a mother sued the Department of Health and Social Services alleging

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work with Psych Rights to establish a mutually agreeable discovery plan, or will seek the court's assistance in developing such a plan. In short, the defendants reserve the right to argue as to the merits of this plan and these documents should it be necessary, and its silence here should not be considered as a waiver of those rights.

[2] *See, e.g., Karen L. v. Defendants Dept. of Health and Social Services, Div. of Family and Youth Services*, 953 P.2d 871, 880 (Alaska 1998), *citing* to *Mitchell v Forsyth*, 472 U.S. 511, 5265, 105 St. Ct. 2806, 86 L.Ed.2nd 411 (1985).

[3] *Id.* (emphasis in original)

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negligent and intentional infliction of emotional harm and loss of filial consortium. In that case, the mother clearly had standing to sue, but the defendants moved for summary judgment alleging that their actions were immune from suit. The superior court granted a motion to stay discovery while the motions related to immunity were litigated.

If, in a case such as *Karen L.*, discovery can be stayed because the issue of immunity from suit was before the court, the same analysis should apply where there is an allegation that the plaintiff cannot meet the case and controversy requirement of standing to sue in the first place.[4] The analysis to grant the stay related to protection from pre-trial discovery is equally, if not more, compelling in a case where there is an allegation that the plaintiff lacks standing. In both cases, there exists a threshold bar to proceeding with the actual litigation, which includes barring pre-trial discovery. This is especially true when cases involve governmental entities because the concept of unfettered discovery may impose "an undue burden on public officials and government agencies."[5]

Psych Rights then argues that the federal cases cited by the defendants do not support its Motion to Stay. Citing to *Chavous v. District of Columbia Financial Responsibility and Management Assistance,* [6] Psych Rights argues that discovery should not be stayed when there are factual issues related to the pending substantive motion. While this statement is correct, it does not apply to this case because there is no need for discovery of factual issues related to whether Psych Rights has standing to bring this suit.

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[4] Psych Rights argues that *Karen L.* is inapplicable because the defendants in that case were sued in their personal and not their official capacities. The undersigned does not see in the case where the defendants were sued in their individual capacity; but even if that was the case the distinction is without merit. The issue that is relevant in this case is when there are dispositive issues that preclude the suit in total, pre-trial discovery to develop a factual record is not allowed.

[5] *Williamson v. U.S. Dept. of Agriculture*, 815 F.2d 368 (5th Cir. 1987), *citing Halperin v. Kissinger*, 606 F.2d 1192 (D.C. Cir. 1979), *aff'd* in pertinent part, 452 U.S. 713 (1981). (The court properly stayed discovery pending resolution of threshold governmental immunity issues).

[6] 201 F.R.D. 1, 3, D.D.C. 2001

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Additionally, Psych Rights argues that the defendants have requested a "blanket stay of discovery without a showing that any of the discovery is in any way unwarranted, or even burdensome, let alone that it would not lead to evidence that might be relevant to the Motion for Judgment on the Pleadings." This statement misses the point. If the Motion for Judgment on the Pleadings is granted and the matter is dismissed, then any discovery conducted prior to that point is *per se* unwarranted and burdensome because there is no case upon which to conduct discovery. In fact, if the court finds that Psych Rights does not have standing (the legal argument in the Motion for Judgment on the Pleadings), then a new lawsuit must be filed with proper plaintiffs who can establish the requisite standing to proceed. Newly named plaintiffs would likely change the factual issues and the claims for relief in the complaint - all of which would render discovery conducted at this time not only costly and burdensome, but quite possibly irrelevant. There is no question that discovery is unwarranted and burdensome in this instance when the named plaintiff does not have standing to bring this suit.

It is well settled that when jurisdictional issues are raised that would bar the litigation in whole, it is well within the discretion of the court to stay discovery. Such a decision should be entered here. While there is a core question remaining as to whether Psych Rights has standing to file the litigation that has been filed, the defendants should not be subjected to the cost and burden on discovery. The Motion to Stay should be granted.

2. Psych Rights Has Not Amended Its Complaint To Add Plaintiffs Therefore, The Motion For Judgment On The Pleadings Is Not Unmeritorious

Psych Rights argues that the dispositive motion is "unmeritorious" and the issue could be addressed by simply naming new plaintiffs. While this statement is hypothetically true, as of this date, Psych Rights has not attempted to amend the Complaint to add new plaintiffs. A hypothetical solution to this problem does not render the Motion for Judgment on the Pleadings unmeritorious. As long there is a real question on whether Psych Rights has standing to proceed, discovery should be stayed.

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3. The Defendants Has Not Gone Outside Of The Motion For Judgment On The Pleadings

In an effort to get to discovery, Psych Rights argues that the underlying motion "goes outside the pleadings," which means that discovery must be allowed. In support of this argument, Psych Rights cites to statements made in the Motion for Judgment on the Pleadings to support its contention that the defendants have "gone outside the pleadings." Psych Rights then claims that discovery is warranted because the motion has "gone outside the pleadings." This argument is misplaced. The statements relied upon by Psych Rights to support the argument that the motion "goes outside the pleadings" is contained in the factual background and the conclusion, not the legal argument. They are statements of the existing law or summaries of positions taken in the defendants' answer and affirmative defenses; they are not part of the defendants' legal argument.[7] A summary of the defendants' position in its answer or on the applicable law does not render the motion outside of the pleadings sufficient to defeat the motion to stay.

4. Psych Rights Discovery Plan Is Premature

The remainder of Psych Rights' motion, close to 20-pages, is devoted to outlining the careful and focused discovery plan that Psych Rights has developed to make this process logical, efficient, and less burdensome. The problem with the "plan" is that it is only logical, efficient, and not burdensome *if* Psych Rights can show the requisite adversity to allow this case to go forward. If Psych Rights wants to know about the defendants' computerized records system, then obtain discovery on how pediatric psychopharmacology is practiced on youth in defendants' custody, and then seek information about negative data related to these medications – it must have standing to do so.

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[7] *See* defendants' Answer to the First Amended Complaint, Affirmative Defenses Nos. 2, 9, and 10.

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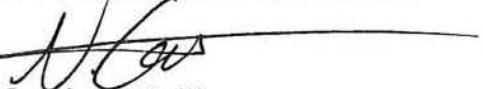
Discovery is the process whereby parties are allowed to develop the factual assumption related to the theory of a case.[8] If a case cannot meet the "case and controversy" test to go forward, there is no need to develop facts as contemplated by the civil rules governing discovery. In the simplest of terms, unless Psych Rights has standing to sue, any factual issues it seeks to develop are not ripe at this time. A logical, efficient, and less burdensome plan should only be implemented after standing has been established.

CONCLUSION

There is no discovery that can be obtained during the pendency of the dispositive motion that will affect the court's decision, thus, discovery is not warranted and is burdensome until standing is established. For the foregoing reasons, the defendants request that the court stay discovery pending the court's decision on the defendants' contemporaneous Motion for Judgment on the Pleadings.

DATED this 27th day of March, 2009.

RICHARD A. SVOBODNY
ACTING ATTORNEY GENERAL

By: 
Nevhiz E. Calik
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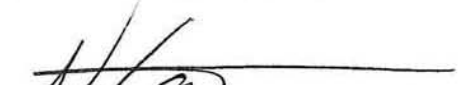
By: 
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[8] Alaska Rules of Civil Procedure 26-36.

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

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation, Plaintiff, vs. STATE OF ALASKA, *et al.*, Defendants.	)

Case No. 3AN 08-10115CI

OPPOSITION TO JUDGMENT ON THE PLEADINGS

Plaintiff, the Law Project for Psychiatric Rights (PsychRights®), opposes the Motion for Judgment on the Pleadings (Motion) filed by defendants State of Alaska, *et al.*, (State). Eliminating extraneous matter, the State's sole ground for the motion is the assertion that PsychRights lacks "citizen-taxpayer," standing because there are better parties to bring this suit. This is false. No one else has or is likely to bring such an action and no one else is in a position to competently assert the legal claims made herein.

I. Standards for Considering Motions for Judgment on the Pleadings

Civil Rule 12(c) provides:

> **(c) Motion for Judgment on the Pleadings**. After the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings. If, on a motion for judgment on the pleadings, matters out-side the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed as provided in Rule 56, and all parties shall be given reasonable opportunity to present all material made pertinent to such a motion by Rule 56. A decision granting a motion for judgment on the pleadings is not a final judgment under Civil Rule 58. When the decision adjudicates all unresolved claims as to all parties, the judge shall direct the appropriate party to file a proposed final judgment. The proposed judgment must be filed within 20 days of service of the decision, on a separate document distinct from any opinion, memorandum or order that the court may issue.

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In *Prentzel v. State, Dept. of Public Safety*,[1] the Alaska Supreme Court held a movant for judgment on the pleadings can prevail only if the "pleadings contain no allegations that would permit recovery if proven." The Alaska Supreme Court in *Prentzel* also made clear that "a party should be permitted to amend if there is no showing that amending would cause injustice," reversing the superior court's denial of such a motion.[2]

In *Hebert v. Honest Bingo*,[3] which was cited by the State, the Alaska Supreme Court reversed the granting of a motion for judgment on the pleadings, saying:

> [A] Rule 12(c) "motion only has utility when all material allegations of fact are admitted in the pleadings and only questions of law remain."

The Court also held"

> When a court considers a motion for judgment on the pleadings, it must "view the facts presented in the pleadings and the inferences to be drawn therefrom in the light most favorable to the nonmoving party."[4]

II. Standing

The only legal ground actually asserted in the State's Motion for Judgment on the Pleadings is the affirmative defense that PsychRights lacks standing. In *Hebert*, the Alaska Supreme Court discussed the special situation posed when a motion for judgment on the pleadings is based solely on an affirmative defense.[5]

> A Rule 12(c) motion based solely upon an affirmative defense poses a special situation because a plaintiff is not permitted to reply to affirmative defenses or new material contained in the defendant's answer absent a court order to the contrary. Accordingly, judgment on the pleadings is inappropriate if the defendant seeks

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[1] 53 P.3d 587, 590, (Alaska 2002).
[2] 53 P.3d at 590-91.
[3] 18 P.3d 43, 46 (Alaska 2001), footnote omitted.
[4] 18 P.3d at 46-47, footnote omitted.
[5] 18 P.3d at 47, footnotes omitted.

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relief based upon any factual matters raised in the answer to which the plaintiff has not had an opportunity to respond: "Thus, when material issues of fact are raised by the answer and defendant seeks judgment on the pleadings on the basis of this matter, his motion cannot be granted."

The seminal case for "citizen-taxpayer" standing in Alaska is *Trustees for Alaska v Alaska Department of Natural Resources*,[6] in which the Alaska Supreme Court laid out the requirements as follows:

> First, the case in question must be one of public significance. . . . Second, the plaintiff must be appropriate in several respects. For example, standing may be denied if there is a plaintiff more directly affected by the challenged conduct in question who has or is likely to bring suit. The same is true if there is no true adversity of interest, such as a sham plaintiff whose intent is to lose the lawsuit and thus create judicial precedent upholding the challenged action. Further, standing may be denied if the plaintiff appears to be incapable, for economic or other reasons, of competently advocating the position it has asserted

A. Citizen-Taxpayer Standing

(1) Pleading Citizen-Taxpayer Standing

The State raises that PsychRights did not include a specific allegation of citizen-taxpayer standing. In *Hebert*, the Court said:[7]

> [J]udgment on the pleadings is appropriate where the defendant raises an affirmative defense that is supported by the undisputed facts. For example, when the statute of limitations is alleged as a bar to the plaintiff's claims, a Rule 12(c) motion may be an appropriate avenue for relief if the statute of limitations defense is apparent on the face of the complaint and no question of fact exists

Assuming *arguendo*, that the Amended Complaint is technically insufficient for failing to include the allegation that PsychRights has citizen-taxpayer standing, PsychRights will be

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[6] 736 P.2d 324, 329-30 (Alaska 1987), footnotes omitted.
[7] *Id.*, footnote omitted.

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moving for leave to amend the Complaint to do so. Allowance of such an amendment appears to be mandatory.[8]

(2) This Case is of Public Significance

The State does not dispute that this case raises issues of public significance.[9] This can not be seriously disputed.

(a) Psychiatric Drugs Are Being Pervasively Prescribed to Children & Youth in State Custody and Through Medicaid In Spite of the Lack of Scientific Support for the Practice

Attached hereto as Exhibit 1 is a copy of the CriticalThinkRx Curriculum, which is funded by the Attorneys General Consumer & Prescriber Education Grant Program, overseen by the Attorney General offices of Florida, New York, Ohio, Oregon, Texas, Vermont and two rotating states (CPGP).[10] The CriticalThinkRx Curriculum was specifically developed to inform non-medically trained professionals working in child welfare and mental health and was the result of systematic literature searches selecting materials based on relevance and accuracy.[11]

Among the CriticalThinkRx findings are:

> "Basic empirical support of efficacy in children is lacking for most individual [psychotropic] medication classes and no studies have established the safety and efficacy of combination treatments in children."[12]

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[8] *Prentzel*, 53 P.3d at 590-91; *Fomby v. Whisenhunt*, 680 P.2d 787, 790 (Alaska 1984).
[9] Motion for Judgment on the Pleadings, page 16.
[10] Exhibit 1, p. 2. The funds available to the CPGP came from the settlement of a lawsuit against the manufacturer of the anticonvulsant Neurontin for the illegal marketing of Neurontin for unapproved ("off-label") use. *Id.*
[11] *Id.*
[12] Exhibit 1, p, 17, CriticalThinkRx Curriculum, citing to Bhatara, V., Feil, M., Hoagwood, K., Vitiello, B., & Zima, B. (2004), National trends in concomitant psychotropic

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In spite of this, the number of children and youth in the United States administered these drugs tripled during the 1990s and is still rising in this decade.[13] Seventy-five per cent of all psychiatric medication use in children is for uses not approved by the Food and Drug Administration (FDA).[14]

> "The bottom line is that the use of psychiatric medications [in children] far exceeds the evidence of safety and effectiveness."[15]

Psychotropic drugs given to children and youth increase behavioral toxicity, causing apathy, agitation, aggression, mania, suicidal ideation and psychosis, leading to additional mental illness diagnoses and more psychiatric drugging.[16]

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medication with stimulants in pediatric visits: Practice versus knowledge. Journal of Attention Disorders, 7(4), 217-226; Jensen, P.S., Bhatara, V.S., Vitiello, B., Hoagwood, K., Feil, M., and Burke, L.B. (1999). Psychoactive medication prescribing practices for U.S. children: Gaps between research and clinical practice. Journal of the Academy of Child and Adolescent Psychiatry, 38(5), 557-565; Martin, A., Sherwin, T., Stubbe, D., Van Hoof, T., Scahill, L., & Leslie, D. (2002). Use of multiple psychotropic drugs by Medicaid-insured and privately insured children. Psychiatric Services, 53(12), 1508; Vitiello, B. (2001). Psychopharmacology for young children: Clinical needs and research opportunities. Pediatrics, 108(4), 983-989

[13] Exhibit 1, page 16, citing to Olfson, M., Blanco, C., Liu, L., Moreno, C., & Laje, G. (2006). National trends in the outpatient treatment of children and adolescents with antipsychotic drugs. Archives of General Psychiatry, 63(6), 679-685; Olfson, M., Marcus, S.C., Weissman, M.M., & Jensen, P.S. (2002). National trends in the use of psychotropic medications by children. Journal of the American Academy of Child and Adolescent Psychiatry, 41(5), 514-21; and Zito, J. M., *et al.*, (2003), Psychotropic practice patterns for youth: A 10-year perspective. Archives of Pediatric & Adolescent Medicine, 157(1), 17-25.

[14] Exhibit 1, page 17, citing to Vitiello, B. (2001). Psychopharmacology for young children: Clinical needs and research opportunities. Pediatrics, 108(4), 983-989; and Zito, J. M., *et al.*, (2003), *supra*.

[15] Robert Farley, The 'atypical' dilemma: Skyrocketing numbers of kids are prescribed powerful antipsychotic drugs. Is it safe? Nobody knows, *St. Petersburg Times*, July 29, 2007, quoting Ronald Brown, Chair, 2006 American Psychological Association Task Force on Psychotropic Drug Use in Children.

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Children in foster care are 16 times more likely to receive psychotropic drugs than their non-foster care counterparts.[17] Children in welfare settings, such as those enrolled in Medicaid, are two and three times more likely to be given psychiatric drugs than children in the general community.[18]

These alarming facts apply to Alaska as the State admits in its Answer.[19] From April 1, 2007, through June 30, 2007, at least the following number of Alaskan children and youth under the age of 18 received the following psychiatric drugs through Medicaid:

- second generation neuroleptics -- 1,033
- first generation neuroleptics -- 15
- stimulants -- 1,578
- supposedly non-stimulant drugs such as Strattera --293
- antidepressants -- 871
- anticonvulsants marketed as "mood stabilizers" -- 723
- noradrenergic agonists, most likely Clonidine to counteract problems caused by the administration of neuroleptics -- 470[20]

In fact, Facing Foster Care in Alaska (FFCA), the statewide group of foster Youth and Alumni in Alaska,[21] held a statewide retreat in November of 2008, and issued its report, "Mental Health Services and Foster Care," (FFCA Report) in which they state:

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[16] Exhibit 1, page 18, citing to Safer, D. J., Zito, J. M., & dosReis, S. (2003). Concomitant psychotropic medication for youths. American Journal of Psychiatry, 160(3), 438-449.
[17] Zito, J. M., *et al.* (2003), supra.
[18] Exhibit 1, page 20, citing to Breland-Noble, A.M., Elbogen, E.B., Farmer, E.M.Z., Dubs, M.S., Wagner, H.R., & Burns, B.J. (2004). Use of psychotropic medications by youths in therapeutic foster care and group homes. Psychiatric Services, 55(6), 706-708; Raghavan, R., Zima, B. T., Andersen, R. M., Leibowitz, A. A., Schuster, M. A., & Landsverk, J. (2005). Psychotropic medication use in a national probability sample of children in the child welfare system. Journal of Child and Adolescent Psychopharmacology.Special Issue on Psychopharmacoepidemiology, 15(1), 97-106.
[19] Paragraphs 229-235 of the Amended Complaint herein and the State's Answer pertaining thereto.
[20] *Id.*

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In their 2008 Policy Agenda, FFCA members called for Decreased use of Psychotropic Medication for Alaska's foster youth. Many of Alaska's youth and alumni complain about being prescribed psychotropic medications after entering the foster care system for symptoms of depression, anxiety, trauma, attachment issues, and misbehavior. The youth and alumni of FFCA feel that these are all normal symptoms of child maltreatment and dealing with all that comes out of being placed in foster care. There has been a national focus on the use of psychotropic medications being over-prescribed for children and youth in foster care. FFCA members have also complained about side-effects caused by these medications resulting in a decreased ability to focus on their education as well as function in everyday society. The youth and alumni of FFCA would like to see that the prescription of psychotropic medications for Alaska's foster children and youth is decreased and reviewed more closely.[22]

Among the comments in the FFCA Report made about children and youth in foster care being given psychiatric drugs are:[23]

- Too young for drugs
- Worse Afterwards
- Makes you Worse
- Lies & deception
- In hell
- Messes with life
- No Choice
- Constant Labeling
- False Accusations
- No advocating What-so-ever
- Guinea pigs
- Other alternatives
- No reason
- Forced
- Over-mediating
- Prolific diagnosis
- Taking away childhood
- Normality-shouldn't we be like this?

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[21] FFCA defines "Youth" as "a young person in foster care" and "Alumni" as "a person who was in foster care at some point during their life." Exhibit 2, p. 7

[22] Exhibit 2, p. 4, emphasis added.

[23] Exhibit 2, p. 3.

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Interestingly, the solutions suggested by the FFCA Youth and Alumni correspond closely to those the scientific evidence set forth in the CriticalThinkRx Curriculum and incorporated into the Amended Complaint herein show are effective.

There is no doubt this case raises issues of public importance.

(3) There is No More Directly Affected Plaintiff Likely to Bring Suit For A Systemic Injunction Against The Improper Psychotropic Drugging of Alaskan Children and Youth In State Custody or Paid For Through Medicaid.

PsychRights satisfies the citizen-taxpayer standing requirement that there be no more directly affected plaintiff likely to bring suit. The State asserts "there is no reason to presume [a minor Medicaid recipient or child in state custody who has been prescribed or is taking psychotropic medication] would not sue."[24] This fundamentally misconstrues the lawsuit by ignoring that individual affected persons may not be able to obtain the relief requested. Individuals can assert the right that they, or their child or ward, not be subjected to such inappropriate psychiatric drugging and perhaps even obtain a declaratory judgment to that effect. However, the most important relief requested is the injunction against the State improperly administering or paying for the administration of psychotropic drugs to any Alaskan children or youth. This was one of the reasons PsychRights brought this action in its own name, and did not name any other plaintiffs.

(b) The State Would Not Be a Proper Plaintiff

The State asserts:

> To the extent [PsychRights] purports to represent the general public interest of children in state custody . . ., representation of the general public interest of children

[24] Motion for Judgment on the Pleadings, pages 17-18.

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> in state custody "rests with the Attorney General for the State of Alaska, the Department, and/or the parents and guardians of individual children in state custody or the children themselves -- not [PsychRights]."[25]

Would that it were so that the Alaska Attorney General was protecting the legal rights of children and youth in State custody and through Medicaid from the improvident, largely ineffective, and harmful administration of psychotropic drugs. Instead, it is defending the indefensible.

Would that it were so that the Department of Health and Social Services was fulfilling its obligations with respect to the improper administration of psychotropic medication to children and youth of whom it has seized custody and paying for through Medicaid.

The State's attention was directed to the CriticalThinkRx Curriculum on June 11, 2008, which was two and one half months before this action was even filed,[26] yet when answering the Amended Complaint on these same facts,[27] responded it was without sufficient information to admit or deny them.[28] Instead, the State asserts it is powerless to stop the harm to children and youth of whom it has seized custody:

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[25] Motion for Judgment on the Pleadings, pages 14-15.
[26] Exhibit G to Amended Complaint.
[27] The vast majority of the allegations in the Amended Complaint regarding (1) the FDA Drug Approval Process, (2) Undue Drug Company Influence Over Prescribing Practices, (3) Pediatric Psychotropic Prescribing, (4) Neuroleptics, (5) Antidepressants, (6) Stimulants, (7) Anticonvulsants Promoted as "Mood Stabilizers," and (8) Evidence-Based, Less Intrusive Alternatives: Psychosocial Interventions, as well as (9) the "CriticalThinkRx Specifications," come from the CriticalThinkRx Curriculum.
[28] Answer, ¶s 38- 84, 86-92, 94-106, 108-110, 113-132, 134-135, 138, 140-143, 145-148, 152, 154-158, 162-163, 166-167, 169-181, 186, 190-199, 201-211.

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> A reading of the Complaint makes obvious that the true subject of plaintiff's grievances is not the Department, but prescribers of psychotropic pharmaceuticals, the pharmaceutical companies which produce and market them, and the overall culture of pediatric psychiatry. The implication that the Department possesses meaningful authority and control over these matters-or is in any realistic position to administer the relief requested even if the court were to order it-is a fiction.[29] . . .
>
> Insofar as plaintiff disagrees with the practice of pediatric psychiatry and the culture of pharmaceutical marketing and prescribing practices related to psychotropic medication, those matters are not within the Department's meaningful control.[30]

As set forth below, it is not only within the State's control to stop the immense harm caused by the administration of psychotropic drugs to children and youth in its custody, it is its obligation to do so. It is clear from the State's abdication of responsibility that this Court must step in to protect these most vulnerable of Alaskan children and youth from the harm being inflicted upon them through the State's abdication of responsibility.

At pages 3-4 of its Motion for Judgment on the Pleadings, citing to AS 47.10.084, AS 47.12.150, and AS 47.30, the State asserts only parents or the courts can authorize the administration of psychotropic medication, going on to say:

> In short, the administration of psychotropic medication to children in Alaska is a decision left to the parent or legal guardian of the child, or to the superior court. None of the named defendants is permitted to prescribe, authorize, or administer psychotropic medication to any child in the state absent consent from that child's parent, legal guardian, a superior court judge, or, in some circumstances, the child himself or herself. The named defendants simply do not administer psychotropic medication to children in custody in the manner portrayed by plaintiffs Complaint. Rather, there exist well-established statutory schemes-none of which is referenced in the Complaint-to seek individual approval to make such decisions.[31]

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[29] Motion for Judgment on the Pleadings, page 2.
[30] Motion for Judgment on the Pleadings, page 20.
[31] Motion for Judgment on the Pleadings, page 5

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First, this is clearly untrue because AS 47.10.084(a) provides that when parental rights have been terminated the State assumes the parents' residual right to give consent.

Second, the State is clearly wrong on the law regarding its responsibility under AS 47.12.150 even if parental rights have not been terminated. In *Matter of A.E.O*,[32] in another context, the Alaska Supreme specifically rejected the State's interpretation that the existence of residual parental rights and responsibilities relieved it of the same responsibilities:

> The term "subject to" in section .084(a) best connotes the idea that the state's responsibility is subordinate to that of the parent, not that it is eliminated because the parents are also responsible.

Frankly, the State's interpretation that AS.47.10.84 divests it of responsibility for the psychiatric drugging of children and youth in its custody doesn't make sense.

As set forth above, *Matter of A.E.O.* rejects the State's interpretation of the language in another context. Accepting the State's interpretation creates a conflict within AS 47.10.084. AS 47.10.084 provides in pertinent part:

> (a) When a child is committed under AS 47.10.080(c)(1) to the department, . . . or committed to the department or to a legally appointed guardian of the person of the child under AS 47.10.080(c)(3), a relationship of legal custody exists. This relationship imposes on the department and its authorized agents or the parents, guardian, or other suitable person the responsibility of physical care and control of the child, . . . the right and duty to protect, nurture, train, and discipline the child, the duty of providing the child with . . . medical care . . .. These obligations are subject to any residual parental rights and responsibilities . . .. When parental rights have been terminated . . . the responsibilities of legal custody include those in (b) and (c) of this section. . . .
>
> (b) When a guardian is appointed for the child, the court shall specify in its order the rights and responsibilities of the guardian. . . . The rights and responsibilities

[32] 816 P.2d 1352, n9 (Alaska 1991).

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> may include, but are not limited to, having the right and responsibility of . . . consenting to major medical treatment . . ..
>
> (c) When there has been transfer of legal custody or appointment of a guardian and parental rights have not been terminated by court decree, the parents shall have residual rights and responsibilities. These residual rights and responsibilities of the parent include, but are not limited to . . . consent to major medical treatment except in cases of emergency or cases falling under AS 25.20.025, . . . except if by court order any residual right and responsibility has been delegated to a guardian under (b) of this section. In this subsection, "major medical treatment" includes the administration of medication used to treat a mental health disorder.[33]

As the Alaska Supreme Court held in *A.E.O.*, the proper way to interpret this is that the "subject to" does not divest the State of its "right and duty to protect, nurture, train, and discipline the child, the duty of providing the child with . . . medical care . . ."

It is also the State's responsibility to provide the proper non-psychopharmacological approaches identified in PsychRights Amended Complaint in compliance with its AS 47.10.084(a) "duty to protect, nurture, train, and discipline" when that is in the child or youth's best interests, instead of immediately reaching for the pill bottle.[34]

In addition to these statutory obligations, the State has the constitutional obligation to protect children in its custody. The United States Supreme Court has held if a state,

> fails to provide for his basic human needs-e.g., food, clothing, shelter, medical care, and reasonable safety-it transgresses the substantive limits on state action set by the Eighth Amendment and the Due Process Clause.[35]

Third, it is PsychRights understanding, the "consents" are virtually always obtained because one or more of the defendants seek such consent (or court order). In seeking such

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[33] Emphasis added.
[34] *See*, AS 47.10.084(a). §A(1) of PsychRights Amended Complaint seeks this relief.
[35] *DeShaney v. Winnebago County Department of Social Services*, 489 U.S. 189, 200, 109 S.Ct. 998, 1005 (1989).

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consents from parents and guardians, and for that matter, court orders, the State provides the parents and guardians with inaccurate information in order to obtain the consents and court orders.[36] In addition, it is PsychRights' understanding parents are often subjected to extreme pressure to agree to the psychiatric drugging of their children.[37] The State's protestations of non-involvement are disingenuous.

It is clearly the State's responsibility to prevent the children and youth in its custody from being harmed by inappropriate psychiatric drugging. It is shameful the State is abdicating its responsibility when it should be working to correct the problem. If, as the State asserts through the Attorney General, that "representation of the general public interest of children in state custody rests with the Attorney General for the State of Alaska," it should not be using the full weight of its office to defending the defendants indefensible position, but instead insisting the State fulfill its statutory, constitutional, and moral duty to the children and youth of Alaska.

In *Trustees for Alaska*, the Alaska Supreme Court rejected the possibility that the United States Attorney General might bring suit as a sufficient basis for finding it was "a plaintiff more directly affected by the challenged conduct in question who has or is likely to bring suit" and thereby divest Trustees for Alaska of standing.[38] Here, it is clear the

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[36] §A(iii) of PsychRights' Prayer for Relief is "the person or entity authorizing administration of the drug(s) is fully informed of the risks and potential benefits." This includes parents giving consent under AS 47.10.084(c).

[37] PsychRights also understands parents are often threatened that they will have no chance of getting their child(ren) back if they don't consent to the psychotropic drugs. These facts are expected to be established through discovery.

[38] 736 P.2d 330.

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State is not likely to be such a plaintiff and if it did file such a suit, it would be acting as exactly the type of sham plaintiff that is not permitted.[39]

(c) No Affected Child or Youth, Parent or Guardian Is Likely to Sue

The State asserts "there is no reason to presume [a minor Medicaid recipient or child in state custody who has been prescribed or is taking psychotropic medication] would not sue."[40] This is a far cry from *Trustees for Alaska's* requirement of "likely to sue" as the grounds for divesting PsychRights of citizen-taxpayer standing.[41] It is also untrue. There is every reason to presume that neither the children or youth themselves, nor parents or guardians parties, would sue.

First, none have. In *Ruckle v. Anchorage School Dist.*,[42] cited by the State, the Alaska Supreme Court affirmed dismissal because a more directly affected plaintiff already had filed suit. In *Trustees for Alaska*,[43] itself, the Alaska Supreme Court, citing to *Carpenter v. Hammond*[44] and *Coghill v. Boucher*,[45] made it very clear that no one else having filed suit is a strong indication that no one else is likely to file suit.

Second, these children and youth, as well as their parents, lack the resources to do so, and are subject to severe retribution if they tried. They are uniformly poor and otherwise disadvantaged. Guardians are perhaps sometimes in a different situation, but

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[39] *Id.*
[40] Motion for Judgment on the Pleadings, pages 17-18.
[41] 736 P.2d at 329.
[42] 85 P.3d 1030, 1035 (Alaska 2004).
[43] 736 P.2d at 330.
[44] 667 P.2d 1204, 1210 (Alaska 1983), as cited in *Trustees for Alaska* 736 P.2d at 330.
[45] 511 P.2d 1297 (Alaska 1973).

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often, the guardian is the State itself. With respect to non-state guardians for adults, PsychRights knows of a case where a guardian was not allowed to object to forced psychiatric drugging of her ward, and another one where the guardian, the wife of the ward, was removed as guardian because she didn't want him forced to take psychiatric drugs. Part of the discovery planned by PsychRights is to flesh out the State's overwhelming influence if not outright coercion of parents and guardians. Guardians are simply not usually in a position to mount such a lawsuit.

It is known that children and youth attempting to assert their rights are punished therefor. The FFCA Report on Mental Health Services evidences, "one member commented that he did know his rights, but if he did refuse medication he would be placed in North Star."[46] It is also known that if parents don't "toe the line" they are told they will have no chance of reunification.

Third, the potential for being subjected to an award of attorney's fees against them, is a powerful disincentive to bringing such a lawsuit.[47]

Fourth, the State is almost certain to assert children and youth in state custody do not have the right to bring such a lawsuit on their own behalf.

(4) PsychRights Satisfies the Adversity Requirement

In *Trustees for Alaska*, the Alaska Supreme Court described the adversity requirement as follows:

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[46] Exhibit 2, p.4.
[47] *See*, discussion of this issue in §II.B., below.

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> [Standing may be denied] if there is no true adversity of interest, such as a sham plaintiff whose intent is to lose the lawsuit and thus create judicial precedent upholding the challenged action

The State does not contest that PsychRights is sufficiently adverse, conceding PsychRights is a "legitimate public advocacy organization."[48]

The Alaskan not-for profit corporation, tax-exempt,[49] public interest law firm of Law Project for Psychiatric Rights was founded in late 2002 to mount a strategic litigation campaign against forced psychiatric drugging and electroshock.[50]

> The impetus was the book *Mad in America: Bad Science, Bad Medicine, and the Enduring Mistreatment of the Mentally Ill*, by Robert Whitaker. PsychRights recognized this as a possible roadmap for demonstrating to the courts that forced psychiatric drugging is not achieving its objectives but is, instead, inflicting massive amounts of harm.[51]

"In 2006, due to what can only be considered an emergency, PsychRights adopted strategic litigation against the enormous and increasing amount of psychiatric drugging of children as a priority."[52] Because it is the adults in their lives rather than they who are making the decisions, children are essentially forced to take psychiatric drugs[53] and thus this lawsuit fits squarely within PsychRights' mission.

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[48] Motion for Judgment on the Pleadings, p. 16.
[49] *See*, Internal Revenue Services Advance Ruling Letter, dated April 1, 2003, and Public Charity Ruling Letter, dated July 11, 2007, which can be downloaded from the Internet at http://psychrights.org/CorpSec/501c3.pdf and http://psychrights.org/about/Finances/IRSPublicCharityLtr073007.pdf, respectively.
[50] J. Gottstein, "Involuntary Commitment and Forced Psychiatric Drugging in the Trial Courts: Rights Violations as a Matter of Course," 25 Alaska L. Rev. 51, 53 (2008).
[51] *Id.*
[52] *Id*, n. 2.
[53] *See*, also Exhibit 2, p. 4 (older youths will be hospitalized and drugged against their will there if they exercise right to refuse the drugs).

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PsychRights has been successful in pursuing its mission. First, it won *Myers v. Alaska Psychiatric Institute*,[54] in which the Alaska Supreme Court held Alaska's forced drugging statute unconstitutional for failing to require the court to find the drugging to be in the person's best interest and there is no less intrusive alternative. Next, it won *Wetherhorn v. Alaska Psychiatric Institute*,[55] in which the Alaska Supreme Court held it was unconstitutional to involuntarily commit someone as gravely disabled unless, the level of incapacity is so substantial that the respondent is incapable of surviving safely in freedom. In the preface of the 2007 pocket section of his five-volume treatise on mental health law, noted scholar Michael Perlin stated the following:

> *Wetherhorn* . . . reflects how seriously that state's Supreme Court takes mental disability law issues. Last year, we characterized its decision in *Myers v. Alaska Psychiatric Institute*, as "the most important State Supreme Court decision" on the question of the right to refuse treatment in, perhaps two decades. This year, again, the same court continues along the same path, in this case looking not only at the "grave disability issue," but also building on its *Myers* decision.

Of course, it takes a litigant to bring a case to the Alaska Supreme Court in order to give the Court an opportunity to rule. Until PsychRights commenced its strategic litigation campaign, it appears the attorneys appointed to represent psychiatric respondents in involuntary commitment and forced drugging cases failed to bring even one appeal.[56]

Most recently, in *Wayne B.*,[57] the Alaska Supreme Court required strict compliance

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[54] 138 P.3d 238 (Alaska 2006).
[55] 156 P.3d 371 (Alaska 2007).
[56] "Involuntary Commitment and Forced Psychiatric Drugging in the Trial Courts," *supra.*, 25 Alaska L. Rev. at 53.
[57] 192 P.3d 989 (Alaska 2008).

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with Civil Rule 53(d)(1)'s transcript requirement, invalidating the longstanding practice of the superior court, in Anchorage at least, of approving the recommendations of probate masters in involuntary commitment and forced drugging cases without having such a transcript.[58]

Currently, PsychRights has two cases on appeal to the Alaska Supreme Court, *W.S.B. v. Alaska Psychiatric Institute*,[59] in which the issue is whether it is permissible for the Superior Court to close the court file to the public when the respondent has elected to have the hearing open to the public as was his right under AS 47.30.735(b)(3) and desires to have the court file open to the public as well, and *William S. Bigley v. Alaska Psychiatric Institute*,[60] in which PsychRights asserts Mr. Bigley is constitutionally entitled to the provision of an available less intrusive alternative to being forced to take psychotropic drugs against his will.[61]

PsychRights has adversity.

(5) PsychRights is Able to Competently Advocate the Position Asserted

Because of the improvident, largely ineffective and counterproductive, and extremely harmful yet pervasive administration of psychiatric drugs by the State of Alaska of children and youth of whom it has seized custody and through Medicaid payments, PsychRights filed this action seeking declaratory and injunctive relief that Alaskan

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[58] The Court did hold where the superior court "actually listens" to the recording the failure to have a transcript is cured. 192 P.3d at 991.
[59] Case No. S-13015.
[60] Case No. S-13116.
[61] Mr. Bigley also raised other issues, such as the denial of due process in having less than one business day's notice to defend against the forced drugging petition there.

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children and youth have the right to prevent defendants from authorizing the administration of or paying for the administration of psychotropic drugs to them 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.[62]

PsychRights is able to competently advocate this position.[63]

Counsel for PsychRights in this action is James B. (Jim) Gottstein, Esq., the founder, President and CEO of PsychRights, where he works *pro bono* to advance PsychRights' mission.[64] Mr. Gottstein has been practicing law in Alaska since 1978, when, in addition to being admitted to the Alaska bar, he was admitted to practice before the United States District Court, District of Alaska and the Ninth Circuit Court of Appeals.[65] Mr. Gottstein was admitted to the United States Supreme Court in 1994.[66]

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[62] *See*, ¶1 of Amended Complaint and §A of PsychRights' Prayer for Relief.
[63] In reviewing the status of the pleadings, PsychRights realized it should add to the relief requested to effectuate ¶22 of the Amended Complaint, to wit that the State be enjoined from paying for outpatient psychiatric drugs for anything other than indications approved by the Food and Drug Administration (FDA) or included in the following compendia: (a) American Hospital Formulary Service Drug Information, (b) United States Pharmacopeia-Drug Information (or its successor publications), or (c) DRUGDEX Information System. A motion to amend the complaint to include this relief will be forthcoming shortly.
[64] 25 Alaska L. Rev at 51.
[65] Exhibit 3, p.1.
[66] *Id.*

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Mr. Gottstein represented the class of people diagnosed with serious mental illness in *Weiss et al v. Alaska*,[67] the lawsuit over the State of Alaska's illegal misappropriation of the one million acre federal land grant in trust first for the necessary expenses of the mental health program, resulting in a settlement in 1994 valued at approximately $1.3 Billion and creation of the Alaska Mental Health Trust Authority.[68]

From 1998 to 2004, Mr. Gottstein was appointed to and served on the Alaska Mental Health Board,[69] which, among other things, is the state agency charged with planning mental health services funded by the State of Alaska.[70] In 2007, Mr. Gottstein was appointed by the Chief Justice of the Supreme Court to the Probate Rules Subcommittee on Involuntary Commitments and the Involuntary Administration of Psychotropic Medication established to recommend court rules to govern these proceedings.[71]

In 2008, Mr. Gottstein published the law review article, Involuntary Commitment and Forced Psychiatric Drugging in the Trial Courts: Rights Violations as a Matter of Course,[72] in which he documented the lack of efficacy, life shortening and threatening, and otherwise extremely harmful nature of the neuroleptics, which is the class of drugs normally forced on adults faced with court proceedings to force them to take psychiatric drugs against their will, and identified a number of ways in which Alaskans' fundamental

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[67] 4FA 82-2208Civ.
[68] *Weiss v. State*, 939 P.2d 380 (Alaska 1997).
[69] Exhibit 3, p. 1.
[70] AS 47.30.666.
[71] Exhibit 4.
[72] 25 Alaska L. Rev. 51.

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liberty rights in being free of psychiatric confinement and unwanted psychiatric drugs are improperly infringed by the courts of Alaska.

Psychiatrists ought to be able to rely on the information they receive through medical journals and continuing medical education.[73] The State ought to be able to trust that psychiatrists recommending the administration of psychiatric drugs are basing these recommendations on reliable information. Unfortunately, neither of these things which ought to be true are true. Thus, one of the key questions in this case is why psychiatrists are prescribing and custodians are authorizing the administration of harmful psychotropic drugs of little or no demonstrated benefit to children and youth. The answer is that the pharmaceutical companies have been very effectively illegally promoting their use. Section V of PsychRights' Opposition to Motion to Stay Discovery describes some of this and rather than repeat it here, PsychRights hereby incorporates it herein as though fully set forth, including exhibits.

As set forth in the discovery plan set forth by PsychRights in its Opposition to Motion to Stay Discovery, establishing through discovery the bases upon which psychotropic drugs are prescribed to Alaskan children and youth in state custody and through Medicaid is an essential part of this litigation. For example, at page 21 of PsychRights' Opposition to Stay of Discovery, it stated:

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[73] They should be skeptical, however, about "information" provided by drug companies.

> Even with respect to the stimulants, such as Ritalin, which have been approved for children and youth, the truth is there is a lack of data supporting long-term efficacy or safety,[74]

In other words, PsychRights has cited studies that show such practice is improvident and it is necessary to establish upon what bases psychiatrists and others prescribers are prescribing stimulants to Alaskan children and youth. PsychRights can conduct this discovery.

Interestingly, in the short time since PsychRights filed its Opposition to Motion to Stay Discovery, the Washington Post ran a story on just this subject:

> New data from a large federal study have reignited a debate over the effectiveness of long-term drug treatment of children with hyperactivity or attention-deficit disorder, and have drawn accusations that some members of the research team have sought to play down evidence that medications do little good beyond 24 months.
>
> The study also indicated that long-term use of the drugs can stunt children's growth.
>
> The latest data paint a very different picture than the study's positive initial results, reported in 1999.
>
> One principal scientist in the study, psychologist William Pelham, said that the most obvious interpretation of the data is that the medications are useful in the short term but ineffective over longer periods but added that his colleagues had repeatedly sought to explain away evidence that challenged

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[74] Citing to ¶s 154, 156-165 of the Amended Complaint herein; APA Working Group on Psychoactive Medications for Children and Adolescents. (2006); and Report of the Working Group on Psychoactive Medications for Children and Adolescents. Psychopharmacological, psychosocial, and combined interventions for childhood disorders: Evidence-base, contextual factors, and future directions, Washington, DC: American Psychological Association; National Institute of Mental Health Multimodal Treatment Study of ADHD Follow-up: 24-Month Outcomes of Treatment Strategies for Attention-Deficit/Hyperactivity Disorder, MTA Cooperative Group, *American Academy of Pediatrics*, 113;754-761 (2004)

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> the long-term usefulness of medication. When their explanations failed to hold up, they reached for new ones, Pelham said.
>
> "The stance the group took in the first paper was so strong that the people are embarrassed to say they were wrong and we led the whole field astray," said Pelham, of the State University of New York at Buffalo. Pelham said the drugs, including Adderall and Concerta, are among the medications most frequently prescribed for American children, adding: "If 5 percent of families in the country are giving a medication to their children, and they don't realize it does not have long-term benefits but might have long-term risks, why should they not be told?"[75]

Indeed, why haven't the psychiatrists and other prescribers been telling people the truth about these drugs?

As set forth above and in the Opposition to Motion to Stay Discovery, the answer is the drug companies have provided the psychiatrists with inaccurate information. PsychRights will develop this in discovery and through presenting the evidence to this Court. It also seems worth noting here that it is virtually inconceivable that any parent or guardian, or any child or youth, not represented by PsychRights would or could effectively pursue this information, which further buttresses the argument in §II.A.(3) that no other plaintiff is likely to adequately pursue the claims in this action.

B. Interest-Injury Standing

The State argues that PsychRights has not claimed interest-injury standing and it is correct about that. PsychRights could move to amend the Complaint to add individual children and youth, their parents, or guardians, or any combination thereof, to achieve such interest-injury standing, but is reluctant to do so. The original Complaint did not include

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[75] Exhibit 5, p. 1.

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such plaintiffs for a number of reasons, which PsychRights carefully considered before filing the Complaint in this action.

First, as set forth above, the most important relief requested is for systemic relief, especially an injunction, to which individual affected parties would appear not entitled. Naming PsychRights as the plaintiff allows the lawsuit to narrowly tailor the requested relief to the deprivation of rights suffered by Alaskan children & youth in State custody and enrolled in Medicaid.

Second, while PsychRights anticipates being the prevailing party, it seems unfair to expose such plaintiffs to the possibility of attorney's fee awards against them. Counsel has experience with the Alaska Attorney General obtaining attorney's fees against people on welfare who unsuccessfully sought to vindicate their rights in court and understands it is the Attorney General Office's policy to always seek fees against non-prevailing parties, even if they can't afford them.

Until 2003, such plaintiffs named in this action could expect to be found public interest litigants and exempt from such an award. In 2003, however, in ch. 86, § 2(b), SLA 2003, codified at AS 09.60.010 (b)-(e), the Legislature abolished the public interest exception from Rule 82 awards against non-prevailing parties. Under AS 09.60.010(c)(2) an award against such plaintiffs is still not allowed for attorney's fees devoted to claims concerning constitutional rights and under (e) relief can be granted for "undue hardship."

This case raises constitutional claims, as well as substantial non-constitutional claims, thus potentially subjecting such individual plaintiffs to an award of attorney's fees

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against them. This would potentially subject the named plaintiffs to an award of attorney's fees.

Even though PsychRights expects to be the prevailing party and even though the undue hardship exemption under AS 09.60.010(e) seems applicable, PsychRights feels it needs to consider the other possibilities and decided this was another reason not to name individual children and youth, their parents or guardians. It just seemed unfair to expose them to the possibility of having to carry another big brick on their already heavy load.

Should this Court decide that PsychRights does not have citizen-taxpayer standing to bring this suit, PsychRights will consider whether to amend the Complaint to add such named plaintiffs or whether to appeal instead. It is a conundrum because any delay in granting the requested relief is doing great harm to Alaskan children and youth. However, as set forth above, PsychRights has citizen-taxpayer standing and no such amendment is necessary.

III. The Motion is Untimely

Finally, Civil Rule 12(c) requires that a motion for judgment on the pleadings be brought "within such time as not to delay the trial" and the State's Motion for Judgment on the Pleadings is untimely, especially when considered in conjunction with its contemporaneously filed Motion to Stay Discovery.

This action was filed September 2, 2008 and the State filed its Answer to the Amended Complaint on or around October 14, 2008. The instant Motion for Judgment on the Pleadings was not filed until on or around March 12, 2009, some six months after this action was commenced and five months after the State's Answer was filed.

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PsychRights commenced efforts to conduct discovery in January, with which the State originally cooperated, but then at the last minute filed its Motion to Stay Discovery contemporaneously with the filing of the instant Motion for Judgment on the Pleadings. In its Motion to Stay Discovery, the State seeks to stay discovery pending determination of the instant Motion for Judgment on the Pleadings.

In support of its Motion for Expedited Consideration of the State's Motion to Stay, the State submitted an affidavit swearing to the following:

> In preparing for Mr. Campana's deposition, counsel began to review the underlying Complaint more extensively and developed concerns about engaging in further discovery at that time.[76]

The trial is set to commence February 1, 2010, and pretrial deadlines are looming. Decision on this motion may potentially take some time. If discovery remains stayed, it will likely delay the trial and prejudice PsychRights. Frankly, in light of the State's concurrent Motion to Stay Discovery, and what seems to PsychRights to be a patently unmeritorious Motion for Judgment on the Pleadings, it is hard to see how it was made for any reason other than to obstruct and delay the conduct of discovery and thereby jeopardize the trial date and/or prejudice PsychRights' ability to present its case.

IV. Conclusion

Because PsychRights has citizen-taxpayer standing, the State's Motion for Judgment on the Pleadings should be **DENIED**. To the extent that there may be some

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[76] Affidavit of Elizabeth Bakalar, dated March 12, 2009.

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technical deficiency in the Amended Complaint, PsychRights should be allowed leave to amend.

DATED: March 31, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

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

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation, Plaintiff, vs. STATE OF ALASKA, *et al.*, Defendants,	)

Case No. 3AN 08-10115CI

EXHIBITS TO
to
OPPOSITION TO MOTION FOR JUDGMENT ON THE PLEADINGS

1. June, 2008, CriticalThinkRx Curriculum, June, 2008.
2. Facing Foster Care in Alaska Report on Mental Health Services, November 2008.
3. Curriculum Vitae of James B. (Jim) Gottstein, Esq., September 12, 2008.
4. Appointment of James B. Gottstein to the Probate Rules Subcommittee on Involuntary Commitments and the Involuntary Administration of Psychotropic Medication, June 28, 2007.
5. Washington Post Article, "Debate Over Drugs For ADHD Reignites Long-Term Benefit For Children at Issue," March 27, 2009.

A Critical Curriculum on Psychotropic Medications

Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
  - **David Cohen, Ph.D.**
- **Research Coordinator:**
  - **Inge Sengelmann, M.S.W.**
- **Professional Consultants:**
  - David O. Antonuccio, Ph.D. (psychology)
  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

Critical Think Rx
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CriticalThinkRx was made possible 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 the prescription drug Neurontin®

Module 1

Why a Critical Skills Curriculum on Psychotropic Medications?

Part A

Curriculum Rationale, Funding and Contents

Curriculum Rationale

Physicians write prescriptions, but other professionals often influence who gets prescribed and why

Training for these professionals is mostly haphazard and often influenced by the pharmaceutical industry

6

Curriculum Objectives

Help practitioners in mental health and child welfare sharpen *critical thinking skills* to deal with complex and evolving issues about psychotropic medication

7

Critical thinking

✓involves assessing beliefs, arguments and claims to arrive at well-reasoned judgments

✓uses standards such as clarity, accuracy, relevance, and completeness

8

Critical thinking

✓asks "who benefits?"

✓is sensitive to the influence of vested interests on information

✓emphasizes the ethical implications of treatment decisions

9

CriticalThinkRx

A prescription for critical thinking about psychotropic medications

10

Curriculum funding

- Received from the *Attorneys General Consumer & Prescriber Education Grant Program* (CPGP)
- CPGP is overseen by the Attorney General offices of Florida, New York, Ohio, Oregon, Texas and Vermont (plus two rotating states)

11

Funding source of CPGP

2003: Attorneys General of 50 states charged Warner Lambert, a subsidiary of Pfizer, Inc., with conducting an unlawful marketing campaign promoting the off-label uses of the anticonvulsant drug Neurontin

12

Neurontin settlements

2004: The company settled for $430 million

—$21 million was earmarked for research and education aimed at health professionals

13

CPGP awards grants

2006: CPGP funded 28 applications in 19 states

- *CriticalThinkRx*, funded at Florida International University, is the only project targeting non-medically trained professionals in child welfare and mental health

14

CPGP aims to improve prescribing practices by educating health professionals about

- ✓the drug development and approval process
- ✓pharmaceutical industry marketing
- ✓knowledge and skills to evaluate drug information critically

15

CPGP requires that

- ✓the curriculum be maintained in the public domain, freely accessible by anyone
- ✓the investigators and their consultants forego funding from the pharmaceutical industry for the duration of their grants

16

Selection of content

Systematic literature searches were conducted in 2006-2007 on databases in medicine, pharmacology, public health, social work, counseling, and psychology

- Materials were selected based on relevance and accuracy

17

Mainstream views

Researchers agree that clinical practice has far outpaced the empirical evidence, yet…

- Mainstream mental health practice subscribes to a "medical" model supporting medication of children with little evidence of safety or efficacy

18

Content bias

CriticalThinkRx offers alternative views based on empirical evidence to stimulate critical thinking and a more balanced evaluation based on ethical codes of practice

19

Content orientation

CriticalThinkRx emphasizes the ethical dictate: **"First, do no harm"**

CriticalThinkRx tries to close gaps between research and practice to maximize opportunities to help clients and avoid harm

20

Curriculum design

Modules designed by experienced researcher/clinician with input from independent consultants in counseling, psychology, psychiatry, social work, and law

21

Principal Investigator

David Cohen, Ph.D., L.C.S.W.

- Professor of Social Work, Florida International University, Miami, and a private practitioner
- Author of numerous publications on psychiatric drugs, medicalization, and law and psychiatry
- His latest books are *Your Drug May Be Your Problem* (2nd rev. ed, 2007) and *Critical New Perspectives on ADHD* (2006)

22

Research Coordinator

Inge Sengelmann, M.S.W.

- M.S.W. with a background in journalism and corporate communication
- Clinician focused on holistic approaches to the treatment of trauma-related mood and behavioral problems

23

Consultant: Counseling

R. Elliott Ingersoll, Ph.D.

- Professor of Counseling, College of Education and Human Services, Cleveland State University
- A licensed psychologist and clinical counselor in Ohio, he has authored books, book chapters, and articles on psychopharmacology, spiritual approaches to counseling, and Integral theory in mental health
- Author, *Psychopharmacology for Helping Professionals: An Integral Exploration* (2006)

24

Consultant: Social Work

Kia J. Bentley, Ph.D., L.C.S.W.

- Professor, Director of the Ph.D. Program, and Associate Dean for Strategic Initiatives in Social Work at Virginia Commonwealth University, where she has taught since 1989
- Author, *The Social Worker & Psychotropic Medication* (3rd ed., 2006) (with Joseph Walsh)
- Editor, *Psychiatric Medication Issues for Social Workers, Counselors and Psychologists* (2003)

25

Consultant: Psychology

- Professor, Department of Psychiatry, University of Nevada School of Medicine
- Fellow, American Psychological Association; Diplomate, clinical psychology, American Board of Professional Psychology
- His articles on the comparative effects of psychotherapy and pharmacotherapy have received extensive national coverage and are models of careful scholarship
- Has received many prestigious awards for his outstanding contributions to clinical science and research

David O. Antonuccio, Ph.D.

26

Consultant: Psychiatry

Stefan P. Kruszewski, M.D.

- Harvard Medical School graduate and board-certified in adolescent psychiatry
- Pensylvannia-based clinician and scientist working with U.S. and international judicial, legislative, and regulatory bodies
- His publications appear in *American Journal of Psychiatry* and *BMJ*

27

Consultant: Law

Robert E. Rosen, J.D., Ph.D.

- Professor of Law, University of Miami, Coral Gables, FL
- Has taught courses in children and the law, professional responsibility, and sociology and the law
- Has served as member of Miami-Dade's Community-Based Care Alliance, and is a reviewer for Foster Care Review
- Holds a J.D. from Harvard Law School, and a Ph.D. in sociology from the University of California at Berkeley
- Former fellow, Harvard's Program in Ethics and the Professions

Use of drug names

Most prescription drugs have a generic and a brand name (e.g., fluoxetine/Prozac)

In this course, charts show both names, but discussions use brand names because they are more familiar to laypersons

29

30

A recent tragic case raises questions about the use of psychiatric medications in young children

31

Case 1: Rebecca Riley

(April 11, 2002 - Dec.13, 2006)

What went wrong?

Concerns raised before death of 4-year-old girl

Teachers, a social worker, a nurse and a therapist had noticed something wasn't right about Rebecca Riley. A

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CBS NEWS

60 MINUTES

What Killed Rebecca Riley?

Katie Couric Reports On The Diagnosis Of Bipolar Disorder In Kids

Sept. 30, 2007

Girl's death stirs debate over psychiatric meds

Parents of 4-year-old accused of intentionally overmedicating daughter

AP Associated Press

Updated: 3:11 p.m. ET March 23, 2007

HULL, Mass. - In the final months of Rebecca Riley's life, a school nurse said the little girl was so weak she was like a "floppy doll."

The preschool principal had to help Rebecca off the bus because the 4-year-old was shaking so badly.

And a pharmacist complained that Rebecca's mother kept coming up with excuses for why her daughter needed more and more medication.

33

Some salient facts

In 2002, then again in 2005-2006, Massachusetts' DSS investigated complaints that the three Riley children might be sexually or physically abused and neglected by their parents

DSS ruled complaints unfounded

34

By 2006, all three Riley children were diagnosed with Bipolar I Disorder and prescribed psychotropic drug cocktails by same child psychiatrist from Tufts Medical Center

- Parents were also diagnosed and mother received Paxil
- As discussed in next modules, diagnosing children with Bipolar Disorder I is a questionable and controversial practice

35

Rebecca, the youngest child, was first medicated at age 2

- By age 4, she was taking Seroquel (antipsychotic), Depakote (anticonvulsant), and clonidine (antihypertensive)
- She also took 2 over-the-counter cold medicines

36

Dec. 13, 2006: Rebecca Riley is found dead on her parents' bedroom floor

- Autopsy later indicated cause of death as **"intoxication due to the combined effects"** of clonidine, Depakote, and two cough medications
- *"The amount of clonidine alone in Rebecca's system was fatal."*

(Commonwealth of Massachusetts, Feb. 5, 2007)

37

Parents indicted …

Michael Riley, 34, and Carolyn Riley, 32, indicted in 2007 for the 1st degree murder of their daughter Rebecca (charge later reduced to 2nd degree murder)

- Parents charged with giving her "excessive amounts" of clonidine
- Child's doctor told mother Rebecca "was already on a high dose of clonidine" and a higher dose could kill the child

(Commonwealth of Massachusetts, Feb. 5, 2007)

38

Case leads to resignations…

GOODBYE TO DSS CHIEF

Agency has been under fire
since parents accused of killing Hull girl

By KEN MAGUIRE
Associated Press

BOSTON - The embattled head of the state's child welfare system is resigning five months after his agency was criticized for its action - or lack of action - in the death of a 4-year-old girl in Hull.

Lewis "Harry" Spence

Lewis "Harry" Spence, commissioner of the Department of Social Services since 2001, has been under fire for the agency's handling of the Hull case in which the parents of the dead girl are charged with killing her with an overdose of prescription drugs.

He also has been criticized for the department's handling of another high-profile child-abuse case involving a comatose child from Westfield.

Gov. Deval Patrick plans to replace Spence with Angelo McClain, a former DSS worker who now works for ValueOptions, a New Jersey-based health care company, according to a person with direct knowledge of the decision.

Patrick planned to announced Spence's departure today along with other changes in top positions, a source told The Associated Press.

Spence did not return calls to his cell phone seeking comment.

39

… puts careers on the line

February, 2007

Psychiatrist to suspend practice; denies wrongdoing

The Boston Globe

By Liz Kowalczyk, Globe Staff | February 8, 2007

Dr. Kayoko Kifuji, the psychiatrist who treated Rebecca Riley in the months before the Hull girl died from an overdose of prescription drugs, agreed yesterday to immediately stop treating patients while the state investigates her role in the case.

April, 2008

HOME / NEWS / LOCAL

Doctor is sued in death of girl, 4

The Boston Globe

Her psychiatrist treated her with powerful drugs

By Shelley Murphy
Globe Staff / April 4, 2008

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CBS EVENING NEWS

March 10, 2007

(CBS) Rebecca Riley's death shocked the Boston community. Did her parents deliberately give her overdoses of psychiatric drugs as prosecutors suggest? Or are her doctors to blame — as defense lawyers argue — for prescribing powerful medications when she was just 2 years

41

Girl's pill numbers disputed: The prescriptions Carolyn Riley gave 4-year-old were very close to allowed amount, defense says

By JULIE JETTE
The Patriot Ledger

The Patriot Ledger

March 10, 2007

42

Case shines light on therapists' roles…

An LCSW made 12 home visits in summer 2006, working with Rebecca and her 6-year-old sister

- Therapist was "initially concerned" about the medication regimen, since she "did not observe any behavior consistent with the diagnoses"

(Commonwealth of Massachusetts, Feb. 5, 2007)

43

… and on school personnel

In her pre-school, Rebecca was observed to be very lethargic and have "a tremor in her hand"

Mother was observed to be "lethargic" and "fall asleep during interviews"

44

Case stirs heated debate among doctors over bipolar diagnoses

The Boston Globe

Backlash on bipolar diagnoses in children
MGH psychiatrist's work stirs debate

By Scott Allen, Globe Staff | June 17, 2007

45

Leads one doctor to hold another "morally culpable"

LAWRENCE DILLER
Misguided standards of care
The Boston Globe

By Lawrence Diller | June 19, 2007

"… I felt compelled to name Joseph Biederman, head of the Massachusetts General Hospital's Pediatric Psychopharmacology clinic, as morally culpable in providing the 'science' that allowed Rebecca to die."

-- *Lawrence Diller, M.D.*

46

FDA "black box" warnings on Depakote ignored?

FDA-approved Depakote black box warning label :

"HEPATOTOXICITY: HEPATIC FAILURE RESULTING IN FATALITIES HAS OCCURRED IN PATIENTS RECEIVING VALPROIC ACID AND ITS DERIVATIVES. EXPERIENCE HAS INDICATED THAT CHILDREN UNDER THE AGE OF TWO YEARS ARE AT A CONSIDERABLY INCREASED RISK OF DEVELOPING FATAL HEPATOTOXICITY....

"PANCREATITIS: CASES OF LIFE-THREATENING PANCREATITIS HAVE BEEN REPORTED IN BOTH CHILDREN AND ADULTS RECEIVING VALPROATE. SOME OF THE CASES HAVE BEEN DESCRIBED AS HEMORRHAGIC WITH A RAPID PROGRESSION FROM INITIAL SYMPTOMS TO DEATH."

47

Case 2:
"Susan," 10 years old

Parents divorced 5 years ago, custody awarded to mother

Father seeking shared custody—only sees Susan a few times a year

Susan presented behavior problems since the age of 3

48

Loss and instabililty

Susan's life filled with losses of friends, pets, homes, adopted-away brother

Since age 5, Susan moved 10 times, attended 7 schools, was assessed by 20 physicians and therapists

49

Multiple diagnoses

Diagnosed with ADHD, OCD, bipolar disorder

Lives in a residential treatment center

Her file describes many behavioral outbursts, attributed to "bipolar disorder"

50

Since age 5, Susan has taken:

- ✓5 antipsychotics
- ✓4 anticonvulsants
- ✓3 stimulants
- ✓3 antidepressants
- ✓2 benzodiazepines
- ✓2 other sedatives (incl. antihypertensive)
- ✓lithium

51

Susan now takes:

- ✓2 anticonvulsants
- ✓1 antipsychotic
- ✓1 stimulant, and
- ✓1 antihypertensive

No evaluations of medication…

A psychologist and a social worker conducted separate assessments of Susan's situation for the Court

Neither commented on Susan's drug treatment or suggested any connections between the medications and her behavioral outbursts

53

No one expressed any concern about giving 5 psychiatric drugs (including 4 central nervous system depressants) to a 10-year-old

54

55

56

- What are the client's symptoms or observed behaviors of concern, who has observed them?
- Has the client experienced any recent or chronic life events or stressors that may contribute to the problems?

57

- Could any of client's problems be caused by current medication?

- Does the client's psychiatric diagnosis truly reflect the client's problems? Is the diagnosis useful to plan for interventions with this client?
- What interventions have been tried to address client's problems? By whom, and with what results?
- Are alternative interventions available to address client's problems? Why have they not yet been tried?

59

- Why is medication being prescribed for this client? What other medication has been prescribed currently or in the past?
- How long before we see improvements? How will the improvements be measured?
- How long will the patient be on the medication? How will a decision to stop be made?

60

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

61

62

- Why is this particular medication prescribed for this client?
- How long has it been on the market? Is it FDA-approved for use in children? Are there any FDA "black box" warnings about this medication?
- What is the recommended dosage? How often will the medication be taken? Who will administer it?

63

- Have any studies been evaluated by professionals working with this child?
- How much scientific support is there for its helpfulness with other children with similar conditions?
- How much scientific evidence exists to support safety and efficacy of this drug in children, alone or in combination with other psychotropic medications?

64

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

65

- Do any laboratory tests need to be done before, during, after use of this medication?
- Are there other medications or foods the child should avoid while on this medication?
- What are all the potential positive and adverse effects of this medication?

66

- How will the effects of the medication be monitored? By whom? Where will they be documented? What should be done if a problem develops?
- How will the use of medication impact other interventions being provided?

67

- How much does this medication cost and who is paying for it?
- Are there cheaper, generic versions of this medication?

68

69

- What is the experience of the physician prescribing the medication?
- Would you consider the physician's prescribing habits as cautious and conservative?
- Does this physician have any financial relationships with pharmaceutical companies? Have these been disclosed to patients?

70

- Have all the risks and benefits of this medication, and those of alternate interventions, been evaluated and discussed by the physician with the client or the client's family?
- Is there an adequate monitoring schedule and follow-up?

71

- 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?

72

- Has a comprehensive assessment (e.g., biopsychosocial, holistic, integral) been conducted? Does it offer plausible reasons for the client's problems?
- Are there other explanations for the child's behavior?

74

- If necessary, do I have access to supervision to help me think through the medication issues?
- How knowledgeable is my supervisor about psychotropic medications?

75

- Am I familiar with all the risks and benefits of this medication, as well as those of alternate interventions? Have I discussed them with the client/client's family?
- Do I know how the client/client's family feel about the use of medication?

76

- What is my role and has it been clearly delineated with all other providers?
- Has the client/client's family been provided with all the information necessary to provide informed consent? Do they understand their choices?

77

- Do I feel confident that I can recognize the effects, adverse or otherwise, of this medication on my client? How should I record my observations?
- Will I be able to educate my client about these effects so he/she can raise concerns with the prescribing physician?

78

- What alternative services/interventions does this family need or want?
- Can I provide these or help them obtain access?

79

This course, in the remaining modules, is intended to help you answer the preceding questions

80

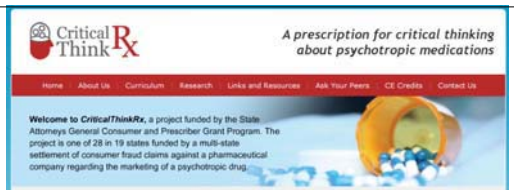
A Critical Curriculum
on Psychotropic Medications

Module 1

The End

www.CriticalThinkRx.org

81



A Critical Curriculum on Psychotropic Medications

Critical Think Rx

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
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- **Research Coordinator:**
  - Inge Sengelmann, M.S.W.
- **Professional Consultants:**
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  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
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- **Voice narration and Flash editing:**
  - Saul McClintock

Critical Think Rx

www.CriticalThinkRx.org

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Module 2

Increasing Use of Psychotropics

Public Health Concerns

Part A

Medicating Youth

Surveys and insurance databases show increasing use

5-8 million children in the U.S.
(8-11% of all children)
receive prescriptions
for psychotropic medications

(Medco, 2006; St. Luke's Health Initiatives, 2006)

6

Prescriptions of psychotropics to youths **tripled in the 1990s** and are still rising in this decade

In some drug classes, rates in children rival adult rates

(Olfson et al. 2002, 2006; Thomas et al. 2006; Zito et al. 2000, 2002, 2003)

7

Drug treatment without any other form of therapy is becoming the norm

(Olfson et al. 2002, 2006; Thomas et al. 2006; Zito et al. 2000, 2002, 2003)

8

A worldwide phenomenon…

…but the proportion of children prescribed psychiatric drugs remains **2 to 20 times higher** in the U.S., Canada, and Australia than in other developed nations

(Wong et al. 2004)

9

In the U.S., "cultural" differences remain

White children are **twice as likely** as Black and Latino children to receive prescriptions

- Difference appears unrelated to socio-demographic, access, or clinical factors, and may relate to parental attitudes

(Cooper et al. 2006; Dos Reis et al. 2005; Leslie et al. 2003)

10

Off-Label Uses and Polypharmacy

The New York Times

November 23, 2006

Proof Is Scant on Psychiatric Drug Mix for Young

11

"Off-label" use common

The practice of administering medications for indications or age groups not approved by the FDA, as indicated on the drug's "label"

(Vitiello, 2001; Zito et al. 2003)

12

75% of all medication use in children is off-label

(Vitiello, 2001; Zito et al. 2003)

13

Concerns about off-label use

"Bearing in mind that some off-label use is perfectly justifiable, it is fair to say that much of it is not justifiable. If there is not evidence presented to the FDA about a given indication, it is certainly a user-beware situation."

- **Jerry Avorn, M.D.**, Professor of Pharmacology, Harvard Medical School, and author, *Powerful Medicines* (2005)

14

Polypharmacy common

40% or more of all psychiatric drug treatments today involve polypharmacy

(Bhatara et al. 2004; Olfson et al. 2002; Safer et al. 2003)

15

Polypharmacy: *concomitant* or *multiple* psychotropic medication use

16

Concomitant = ≥ 2 drugs taken on the same day

Multiple = ≥ 2 drugs taken during a given period

Concerns about polypharmacy

Basic empirical support of efficacy in children is lacking for *most individual* medication classes

No studies have established the safety and efficacy of combination treatments in children

(Bhatara et al. 2004; Jensen et al. 1999; Martin et al. 2002; Vitiello, 2001)

18

Increases behavioral toxicity

Behavioral toxicity =
drug-induced adverse effects and behavioral changes, including apathy, agitation, aggression, mania, suicidal ideation and psychosis

(Safer, Zito & dosReis, 2003)

19

The "prescribing cascade"

Adverse effects are often **confused with symptoms** of disorders, leading to co-morbid diagnoses, and even more complex drug regimens

(Safer, Zito & dosReis, 2003)

20

Examples of behavioral toxicity

TABLE 4. Single Case Reports of Adverse Drug Events Associated With Use of Concomitant Psychotropic Medication for Youths

Study	Medications	Diagnosis	Age	Gender	Adverse Drug Events
Sallee et al. (89)	Fluoxetine, promethazine, methylphenidate, clonidine	ADHD, conduct disorder, and Tourette's syndrome	9	Male	Death
Preda et al. (90)	Perphenazine, carbamazepine, valproic acid, lorazepam, thioridazine	Bipolar I disorder and adjustment disorder	10	Female	Psychosis
Budman et al. (91)	Pemoline, paroxetine, haloperidol	OCD, ADHD, and Tourette's syndrome	12	Male	Acute dystonia
Levy et al. (92)	Amitriptyline, fluoxetine,	ADHD and conduct disorder	7	Male	Serotonin syndrome
Fisman et al. (93)	Risperidone, clomipramine, erythromycin	ADHD, OCD, and Tourette's syndrome	15	Male	Deteriorated mental state

(Safer, Zito & dosReis, 2003)

21

Medicating Preschoolers

22

Similar patterns in preschoolers

Use of most classes of psychotropics among 2-4 year-olds continues to increase

- Almost half of those receiving prescriptions received two or more medications

(Coyle, 2000; Rappley, 2006; Zito et al. 2000)

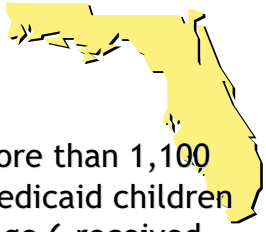
23

Newer drugs top the list

Fastest increases have been in newer drugs without established efficacy or safety profiles

(Pathak et al. 2004; Rappley, 2006; Zito et al. 2000)

24



2006: more than 1,100 Florida Medicaid children under age 6 received atypical antipsychotics

(*St. Petersburg Times*, 2007)

25

Concerns

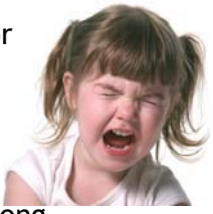
Treatment of preschoolers with psychiatric drugs has barely been studied

(Rappley, 2006 ; Vitiello, 2001; Waller et al. 2005; Zito et al. 2000)

26

Insufficient evidence to…

- Provide guidelines for treatment
- Establish efficacy of treatment
- Guarantee safe use
- Evaluate short- and long-term consequences on development



(Rappley, 2006 ; Vitiello, 2001; Waller, Lewellen & Bresson, 2005; Zito et al. 2000)

27

SCIENTIFIC AMERICAN

May 30, 2007

Kids on Meds -- Trouble Ahead

Antidepressants, designed for adults, may be altering the brains of kids who take them

By Paul Raeburn

28

Youths in Foster Care

29

CBS EVENING NEWS

Double-click any word (What's this?)

Are Drugs Being Misused On Foster Kids?

There's Growing Concern That Anti-Psychotic Drugs Are Being Misused On Children In Foster Care

msnbc

States wrestle with medicating foster kids

Critics worry psychiatric drugs flow too freely to forgotten children

USA TODAY Home News Travel Money Sports Life Tech

Health and Behavior Inside News

For foster kids, oversight of prescriptions is scarce

Updated 5/2/2006 12:21 AM ET

E-mail | Save | Print | RSS

National foster care

Children in child welfare settings are **2 and 3 times more likely** to be medicated than children in the general community

(Breland-Noble et al. 2004; Raghavan et al. 2005)

31

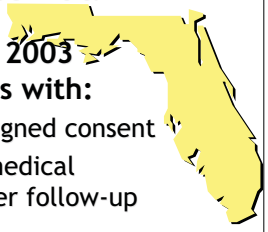
Group homes

After controlling for demographic *and* clinical factors, youths in group homes still **twice as likely** to be medicated than youths in therapeutic foster care

(Breland-Noble et al. 2004; Raghavan et al. 2005)

32

Concerns in Florida



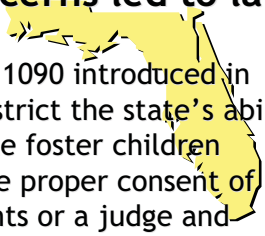
Reports in 2001 and 2003 highlighted problems with:

- Medication without signed consent
- Medication without medical evaluations and proper follow-up monitoring
- High rates of polypharmacy

(Green, Hawkins & Hawkins, 2005; Florida Statewide Advocacy Council, 2003)

33

Florida concerns led to law



Senate Bill 1090 introduced in 2005 to restrict the state's ability to medicate foster children without the proper consent of their parents or a judge and required improved tracking of these children

34

"No List of Kids on Mood Drugs"

The Miami Herald / el Nuevo Herald (September, 2006)

Child welfare officials acknowledged lacking an accurate list of children in state care receiving psychiatric drugs

- Advocates called use of these drugs in children "chemical restraints" used to control behavior

35

Part B

Public Health Concerns

36

37

Numbers of American children on psychotropics: 2006

Stimulants: 3.6 million
Antidepressants: 2 million
Anticonvulsants: 900,000
Antipsychotics: 540,000

The New York Times
(Medco Health Solutions, 2006)

38

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2006 FDA warning on cardiovascular effects also alerts doctors to stimulant-induced psychosis and hallucinations

The New York Times

F.D.A. Strengthens Warnings on Stimulants

By GARDINER HARRIS

39

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2004: FDA issued a **"Public Health Advisory"** about all antidepressants, warning of drug-induced:

- Anxiety and panic attacks
- Agitation and insomnia
- Irritability and hostility
- Impulsivity and severe restlessness
- Mania and hypomania

40

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

FDA "black box" warns:

"Antidepressants increase the risk of suicidal thinking and behavior (suicidality) in short-term studies in children and adolescents with Major Depressive Disorder and other psychiatric disorders"

41

CBS NEWS FDA Orders Antidepressant Warning

msnbc Home » Health » Mental Health

A Fuller Spectrum of News

Health

FDA urges new warnings on antidepressants

2005: FDA extends "black box" warnings to children and adolescents

2007: FDA extends "black box" warnings to young adults 18-24

42

Antipsychotics

Skyrocketing numbers despite safety concerns

43

44

45

Antipsychotics = Fastest rise

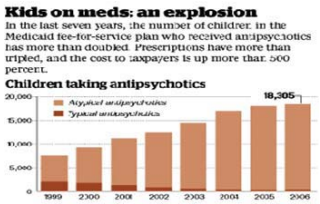
Number of non-institutionalized 6-18 year-olds on antipsychotics:

1993:	50,000
2002:	532,000

(Olfson et al. 2006)

St Petersburg Times (2007)

More than **18,000 kids** on Florida Medicaid prescribed atypical antipsychotics in 2006



47

Nationwide, antipsychotics typically prescribed to children for non-psychotic conditions

Most frequent diagnoses:

- disruptive behavior disorders, including ADHD (38%), and mood disorders (32%)

(Olfson et al. 2006)

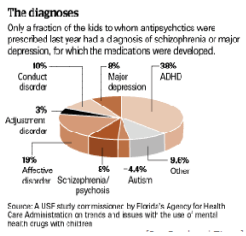
48

In Florida too…

2006: Only 8% of Florida Medicaid children receiving antipsychotics had a diagnosis of psychosis

- Half were diagnosed with attention or conduct disorders

St Petersburg Times (2007)



49

Antipsychotics = polypharmacy

77% to 86% of youths taking antipsychotics do so with other drugs

(Medco, 2006; Olfson et al. 2006)

Safety and efficacy unknown

"We don't know the first thing about safety and efficacy of these drugs even by themselves in these young ages, let alone when they are mixed together."

Dr. Steven Hyman, former NIMH director, Harvard University provost

The Boston Globe (2006)

51

Adverse effects of "atypicals"

	Clozaril	Risperdal	Zyprexa	Seroquel	Geodon	Abilify
Clinical name	Clozapine	Risperidone	Olanzapine	Quetiapine	Ziprasidone	Aripiprazole
Major symptoms reported						
Diabetes	Severe	Mild	Severe	Moderate	Minimal	Minimal
Weight gain	Severe	Moderate	Severe	Moderate	Mild	Mild
Sedation	Severe	Mild	Moderate	Moderate *	Minimal	Minimal
Tardive dyskinesia	None	Minimal	Minimal	Minimal	Minimal	Minimal

(Correll, 2006; *USA Today*, 2006)

52

medco

"Doctors need to be judicious when prescribing antipsychotic drugs to children. The use of these drugs can have the pediatric patient trading a behavioral condition for a lifelong metabolic condition that can lead to significant health complications"

—**Robert Epstein, M.D.**, chief medical officer, Medco

53

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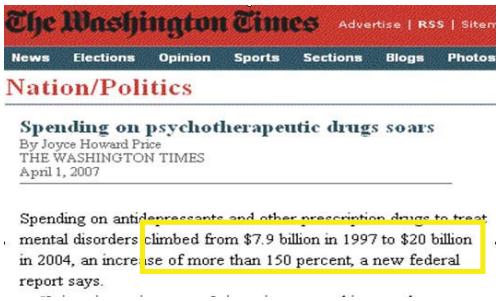
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Nation/Politics

Spending on psychotherapeutic drugs soars

By Joyce Howard Price
THE WASHINGTON TIMES
April 1, 2007

Spending on antidepressants and other prescription drugs to treat mental disorders climbed from $7.9 billion in 1997 to $20 billion in 2004, an increase of more than 150 percent, a new federal report says.

55

2004: 17% of total drug spending for children was for psychotropics

- *greater than cost of antibiotics and asthma drugs*

medco (2004)

State insurance increases likelihood of medication

Medicaid-enrolled children are more likely to:

- Receive psychotropics
- Be treated with multiple medications
- Receive medications as sole treatment

(Goodwin et al. 2001; Martin et al. 2002, 2003)

57

Use of newer antipsychotics grows faster

1996-2001: increased most dramatically in these Medicaid populations:

- Preschool children (61%)
- Ages 6-12 (93%)
- Ages 13-18 (116%)

(Cooper et al. 2004; Olfson et al. 2006; Patel et al. 2005)


Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

MEDICAID'S MENTAL HEALTH DRUG EXPENDITURES

INSPECTOR GENERAL

AUGUST 2003

Medicaid pays more for psychotropic drugs than other Federal buyers…

59

Medicaid programs struggle to contain costs

1997 - 2004: Tripling of Medicaid spending on psychotropics attributed to the expanding use of expensive atypical antipsychotics

(Duggan, 2005; Stagnitti, 2007; OIG, 2003)

Antipsychotics top Medicaid spending on psychiatric drugs

10 state Medicaid programs paid $562 million on 25 psychotropic drugs

- 67% of this total spent on nine antipsychotics

(Duggan, 2005; OIG, 2003; Stagnitti, 2007)

Average prescription price for top 2 antipsychotics, 1993 vs. 2001

1993: Haldol, Mellaril = $29

2001: Zyprexa, Risperdal = $286

(Duggan, 2005)

62

Florida Medicaid (fee-for-service) spending on atypical antipsychotic drugs, 2002-2007

$1.1 billion

(Farley, R., *St. Petersburg Times*, April 12, 2008)

Part D

Conclusions and Recommendations

64

Usage is increasing

Usage of all psychiatric drug classes has skyrocketed during past decade in all age groups, all ethnic/racial groups, all settings

65

Ongoing debate

Debate persists on whether disorders are under- or over-diagnosed, and under- or over-treated, with heated arguments from supporters and critics in professional and public discourse

66

Supporters argue…

- Up to 1/5 of youth have a "DSM-diagnosable disorder"
- Popularly-accepted causes of disorders are neurobiological
- Medications remove "blame"
- Stimulants greatly impact ADHD-like behavior

Critics reply…

- Medication use outpaces research evidence
- Growing use leads to increase in pediatric adverse effects
- Medicating the developing brain may lead to long-term negative changes in functioning
- No pathophysiological variable is associated with any DSM disorder

68

Fastest rise: Antipsychotics

Antipsychotics with serious adverse effects growing faster than any other drug class

- More frequently used in polypharmacy and for non-psychotic disorders, with no research evidence

Racial issues

Black children: fastest-growing group being prescribed antipsychotics

- Increase related to enormous rise in the diagnosis of bipolar disorder in this population

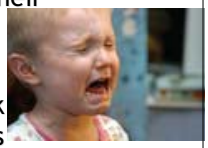
Soaring State Medicaid spending

Largest spending increases on antipsychotics

- Until now, states appear unable to contain such fast-rising drug costs

Young children

Children are particularly vulnerable to harm by psychiatric drugs because their brains are still developing



Research is needed to track subtle changes in children's developing personality resulting from drug's impact on brain

72

Children in foster care

Little empirical evidence exists to support the use of drug interventions in traumatized children

- Clinicians need to consider risk/benefit analysis of drugs vs. evidence of effective psychosocial interventions

73

Children in foster care

Experts recommend antipsychotics should not be considered first-line treatment for childhood trauma because of their serious adverse effects

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A Critical Curriculum on Psychotropic Medications

Module 2

The End

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A Critical Curriculum on Psychotropic Medications

A Critical Curriculum on Psychotropic Medications

Principal Investigator:
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www.CriticalThinkRx.org

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Module 3

The Drug Approval Process

All drugs intended for prescription in this country must be ***approved*** by the U.S. Food & Drug Administration (FDA)

There are huge financial and health stakes in drug approvals

7

The FDA was established by Congress in 1906 to enforce standards on purity of medicinal compounds

Today, the FDA's **Center for Drug Evaluation and Research (CDER)** oversees testing and approval of medications

8

The CDER conducts no drug tests of its own—drug firms (sponsors) pay for and conduct all tests

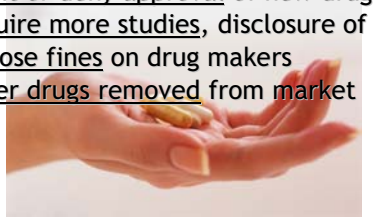
Based on data submitted by sponsors, CDER judges a drug's "efficacy" and "safety"

(Avorn, 2004)

9

Some FDA mandates

- ☑ grant permission to test drugs on humans
- ☑ review data on safety and efficacy
- ☑ set criteria for drug approval
- ☑ grant or deny approval of new drugs
- ☑ require more studies, disclosure of risks
- ☑ impose fines on drug makers
- ☑ order drugs removed from market



10

1938 Federal Food, Drug and Cosmetic Act:

Basis for FDA regulation of drugs

- Passed after 100 deaths in 1937 from a toxin in a batch of sulfa drugs

(Ballentine, no date)

11

FDA's drug testing rules tightened after **thalidomide**, prescribed to pregnant women in Europe in 1960, caused birth defects

12

As a result, 1962 amendments to *Food, Drug, & Cosmetic Act* of 1938 required sponsors to:

- ✓demonstrate efficacy in controlled trials
- ✓report serious adverse effects to FDA
- ✓list all known risks (on drug label and in drug ads to doctors)

13

More recent FDA laws have been controversial

Some scientists, advocacy groups, and legislators often accuse the FDA of treating industry, not the public, as its client

(Hawthorne, 2005; Sharav, 2007)

14

Prescription Drug User Fee Act, 1992

To speed up approval times, FDA collects fees from sponsors

User fees now make up over 50% of CDER's budget

(Avorn, 2007)

Impact of user fees

Since 1992 and the birth of user fees, the FDA has slashed its own testing laboratories and network of independent drug safety experts in favor of hiring more people to approve drugs for the pharmaceutical industry

(Harris, 2004)

16

"User fees have undoubtedly constrained the FDA's independence and influenced its decisions."

Marcia Angell, former editor, *New England Journal of Medicine*

FDA's User-Fee Habit

washingtonpost.com

By Cindy Skrzycki

Tuesday, April 3, 2007; D01

17

Draft Guidance on Direct-to-Consumer Advertising, 1997

After 15 years of industry pressure, the FDA allowed sponsors to advertise prescription drugs directly to consumers

- *DTCA is praised for providing drug information to consumers*
- *DTCA is criticized for increasing drug costs and promoting least effective drugs*

(Gellad & Lyles, 2007; Hollon, 1999)

18

Pediatric Research Equity Act, 2003 & *Pediatric Exclusivity Act*, 2004

FDA can request studies to be conducted on children, giving sponsors an extra 6 months of exclusive marketing for every drug studied

- *Acts are praised for stimulating research on drug effects and indications in children*
- *Acts are criticized for griving drug firms unneeded profits and using kids as guinea pigs for unnecessary drug testing*

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Part B

FDA's Drug Approval Process

20

Few drugs make it to market

5,000 molecules screened in the lab = 1 obtains FDA approval as a medication

From start to finish, sponsor will spend $100 - $400 million to obtain FDA approval

(Goozner, 2004; Ng, 2004)

21

FDA requires that drugs intended for prescription undergo pre-clinical and clinical testing

22

Pre-clinical testing: 2-4 years

A promising molecule is tested in laboratory and on animals

- to establish its main biological activity and
- to rule out that it causes cancer, mutations, and birth defects

23

If drug remains promising after pre-clinical testing, sponsor may apply to start clinical trials on humans

Phase I trials: 1-2 years

Drug is given to 20-80 healthy volunteers to establish safe dosage levels, main adverse effects, "abuse potential"

25

Phase II trials: 2-3 years

Drug is given to 300-500 people with the illness for which the drug is supposed to be marketed

- The goal is to show promising therapeutic effects in order to justify the next phase of trials

26

Phase III trials: 2-4 years

In *randomized controlled trials* (RCTs), 1000-3000 diagnosed patients from many sites are *randomly* assigned to receive either the drug or a placebo

- Neither investigators nor patients are supposed to know who is receiving what ("double-blind")

27

FDA approval requires only 2 positive Phase III trials, even if more trials are negative

Positive trial: on a symptom rating scale, drug-treated group shows *statistically significant* advantage over placebo-treated group

(FDA, 1998)

A drug showing "efficacy"

✓has shown <5% chance of being worse than placebo

✓has *not* shown that it helps patient's condition to remit, or that it works better than another drug

(Avorn, 2004)

29

With 2 positive Phase III trials, sponsor can make a **New Drug Application (NDA)**, requesting FDA approval to market drug for a specific indication and age group covered in the trials

30

FDA reviews pre-clinical and clinical studies and decides whether the drug's benefits outweigh its risks

31

Drug label

- Label summarizes information from pre-clinical and clinical trials
- Exact contents are <u>negotiated</u> in private by FDA and sponsor
- A shortened form must appear in all drug packaging and advertising, except broadcast
- Label is considered the authoritative drug information

32

Phase IV trials: Post-marketing surveillance

- As a condition for approval, FDA usually requests sponsor to conduct post-marketing trials
- These trials evaluate the drug under ordinary conditions, with ordinary patients
- Phase IV trials give more realistic view of drug's harms and benefits

33

Part C

Limitations of Clinical Trials

34

To discover new drugs for physical diseases

Researchers start with a *target* of drug action identified by understanding how a disease affects the body at the cellular/molecular levels

35

Not the same process for mental disorders…

- Cellular/molecular biology of mental disorders is *unknown*—drugs tested for these problems don't target known biological anomalies
- These drugs are selected based on their *effects on animal behavior* and *expected effects on people's complaints and behavior*

(Moncrieff & Cohen, 2005)

36

No biological markers exist

To repeat – mental and emotional problems ***are not*** equivalent to physical diseases

No cause has been shown to be exclusively biological

There is ***no biological marker*** for any DSM "primary mental disorder," including schizophrenia

(Charney et al., 2002)

37

Flaws in clinical trials

Analysts and critics have revealed many problems with the design and conduct of clinical trials of psychotropic drugs

Overall conclusion:

Clinical trials do not provide definite basis to determine benefits or risks of drugs

(Cohen, 2002; Safer, 2002)

38

Trials at all phases neglect most psychoactive effects

Practice: Trials focus on measuring narrowly selected complaints and behavior

Problem: Main psychological alterations produced by drugs remain unknown

(Jacobs & Cohen, 1999; Cohen & Jacobs, 2007)

39

Phase II & III trials are very short

Practice: Most last only 3-8 weeks, and up to 70% of subjects drop out before trial's end

Problem: Only some acute effects are detected—not those emerging over a longer time

(Cohen & Jacobs, 2007)

40

Subjects are wrongly assumed to have the "same" disorder

Practice: In a depression drug trial, a subject meeting DSM criteria for depression is eligible

Problem: 200 distinct symptom combinations = DSM diagnosis of depression

Also, subjects usually meet DSM criteria for *several* diagnoses

The "sameness" of subjects' problems—needed for a valid comparison of treatments—is not established

(Beutler & Malik, 2002; Cohen & Jacobs, 2007; Emslie et al. 2002)

41

Inert pills are used as comparisons

Practice: Drugs with psychoactive effects are compared to inert sugar pills

Problem: Placebos can be active (causing physical sensations) or inert (no sensations)

Because they are more powerful, active placebos are almost never used

Also, sponsors routinely screen and exclude placebo responders from clinical trials

(Abboud, 2004; Fisher & Greenberg, 2003)

42

The "blind" is often broken

Practice: It's assumed that patients and investigators are "blind" to treatment status

Problem: Obvious side effects in drug-treated subjects cue everyone about which treatment they're getting. This breaks the "blind"—making objective studies impossible

(Fisher & Greenberg, 1993)

43

High doses of comparison drugs are used

Practice: When comparing a new drug to an older drug, very high doses of the older drug are used

Problem: The older drug produces more side effects, making the newer drug appear safer

(Geddes et al., 2000)

44

Outcomes are researcher-rated rather than patient-rated

Practice: Main outcome measures are rated by *researchers*

Problem: In all Phase III pediatric trials of antidepressants, *not one of 10* parent- or child-rated scales showed advantage for the drug

(Jureidini et al., 2004)

45

Adverse effects are carelessly investigated

Practice: Most trials elicit side effects by asking subjects general questions once a week, or waiting for subjects to report them *spontaneously*

Problem: This *underestimates* rates of side effects, especially psychological and behavioral ones, giving false impression of drug's safety

(Greenhill et al., 2003)

46

Adverse effects are mis-coded

Practice: Sponsor decides which effects qualify as "adverse drug events" and how to name them

Problem: Many adverse events are coded as something else, giving false impression of drug's safety

(Breggin, 2002)

47

Strattera pediatric trial:

Mis-coding why patients dropped out

What the researcher wrote	How the sponsor coded it	How it was re-coded after FDA reanalysis
"Parents felt 'too many side effects'; stopped drug early; Abdominal pain, nausea, anxiety"	*Protocol Violation*	*Adverse Event*
"Increasing behavior problems, worsening oppositional behavior; depression"	*Physician Decision*	*Adverse Event*

(Lillytrials.com, 2007)

48

Post-treatment ratings unreported

Practice: Sponsor gathers data for weeks *after* subjects stop treatment, but does not submit them to FDA

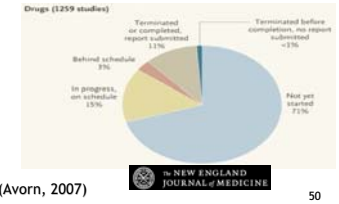
Problem: How subjects rate their treatment *once they're off drugs* may contradict their ratings while *on* drugs. This discrepancy is rarely discussed or explored

(Healy & Farqhar, 1998)

49

Post-marketing trials rarely conducted

As of late 2006, more than 70% of promised Phase IV trials had not yet started…



(Avorn, 2007)

50

The preceding limitations of clinical trials give clinicians and policymakers false ideas about how medications can help and how they can harm people

- FDA approval by itself does not guarantee that a drug is either *safe* or *efficacious* for its intended uses

(Strom, 2006)

51

The increasing involvement of industry in clinical trials has further muddled this worrisome situation

52

Part D

Blurring Science and Marketing

53

Huge payoffs can follow an FDA drug approval

Zyprexa sales since 1996: ***$20 billion***

These create enormous incentives to turn clinical trials into marketing tools

(Smith, 2005)

For the FDA, a clinical trial is a limited test of the efficacy of a product

For the sponsor, it's a ticket to get its product past the FDA hurdle—and possibly to blockbuster status

(Smith, 2003)

55

How sponsors turn trials into marketing tools

- ☑ design studies solely to get positive results
- ☑ suppress and twist negative results
- ☑ publish positive results multiple times

(Quick, 2001)

56

(2008) The NEW ENGLAND JOURNAL of MEDICINE

Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy

Erick H. Turner, M.D., Annette M. Matthews, M.D., Eftihia Linardatos, B.S., Robert A. Tell, L.C.S.W., and Robert Rosenthal, Ph.D.

"According to the published literature, it appeared that 94% of the trials conducted were positive. By contrast, the FDA analysis showed that 51% were positive."

57

Contract Research Organizations (CROs)

To get drugs approved by the FDA, sponsors outsource clinical trials to CROs, a $15 billion/year business

These private firms make it easier to:

- Enroll thousands of subjects
- Conduct more multi-site trials
- Shield trials from public scrutiny

(Hunley, 2007)

58

Conflicts in research

"It's a house of cards built on a fundamental conflict of interest. The problem is that drug companies have inordinate influence over the evaluation of their own products. That, on the face of it, doesn't make sense."

- **Marcia Angell**, former editor, *New England Journal of Medicine*, author, *The Truth About the Drug Companies*

59

Funder's drugs come out ahead

In 90% of studies pitting one newer antipsychotic against another, the best drug was the study sponsor's drug

THE AMERICAN JOURNAL OF PSYCHIATRY

(Heres et al., 2006)

60

Independent studies don't favor newer drugs

NIMH's (CATIE) study compared 5 antipsychotics in largest schizophrenia trial. Older, cheaper drug worked as well (or as poorly)

- Regardless of drug, ¾ of patients stopped treatment because they did not improve or had intolerable side effects

The NEW ENGLAND JOURNAL of MEDICINE

(Lieberman et al., 2005)

61

The New York Times

November 22, 2002

Madison Ave. Has Growing Role In the Business of Drug Research

By MELODY PETERSEN

"You cannnot separate advertising and marketing from the science anymore."

- **Arnold S. Relman, MD**, Professor Emeritus, Harvard Medical School, and former editor, *New England Journal of Medicine*

THE WEEK

The Best of the U.S. and International Media

The Corruption of Medicine

Several top medical journals recently admitted that studies they published on new medications have been tainted by undisclosed financial ties between researchers and drug companies. Does Big Pharma have too much influence over drug research?
9/22/2006

63

Part E

Problems in Drug Safety After Marketing

64

Because of the limitations of clinical trials, detecting adverse effects from drugs falls to **post-marketing surveillance**, when drugs are commonly prescribed, and used for longer periods, in more natural conditions, by more varied patients

(Strom, 2006)

This is when most adverse effects, and a more accurate portrait of the drug's risk-benefit ratio, emerge

Yet such post-marketing monitoring also appears spotty

(Lasser et al., 2002)

66

Newer drugs more likely to have hidden risks

50% of warnings occur within 7 years of a drug's introduction

Half of the withdrawals occur within 2 years

(Lasser et al., 2002)

67

Black Box Warnings

If the adverse drug reaction is serious enough to require extraordinary monitoring or special screening, the FDA will ask the drug sponsor to insert a "*black box warning*" in all marketing and product information to alert clinicians and consumers of the nature of the risk

68

Safety questions are "answered" post-marketing

51% of drugs get label changes

20% of drugs get new black box warnings

3-4% of drugs are withdrawn

(Strom, 2006)

69

Former and current FDA officials, outside scientists, and advocates for patients say the FDA's efforts to monitor the ill effects of drugs on the market are insufficient

70

USA TODAY

Report: FDA so underfunded, consumers are put at risk

(December 3, 2007; http://www.usatoday.com/news/washington/2007-12-02-fda_N.htm)

abc NEWS

FDA Is Broken, Endangers American Lives

Report Blames Congress for Cutting FDA's Budget

December 6, 2004

The New York Times

At F.D.A., Strong Drug Ties and Less Monitoring

Example: Prozac, 2004

Prozac was on the market for 17 years before FDA warned of increased suicidality

Sponsors of several SSRIs have been accused of not disclosing all the data from clinical trials

72

Example: Vioxx, 2004

Vioxx was taken by 20 million Americans before Merck withdrew it after links to heart attacks and strokes

Merck accused of not disclosing all the data from clinical trials

FDA Public Health Advisory: Safety of Vioxx

73

Serious Adverse Events (SAEs)

- Fatal or life-threatening, cause disability or require hospital stay

Only 1% to 10% of all drug-related SAEs are actually reported to the FDA through MedWatch

Medwatch The FDA Safety Information and Adverse Event Reporting Program

(Moore, Cohen & Furberg, 2007)

74

Thousands die annually

Reports to Medwatch of fatal drug reactions tripled between 1998-2005

- Over **80,000** deaths suspected from medications were reported by health professionals and others during that 7-year period

(Moore, Cohen & Furberg, 2007)

75

26,000 deaths suspected to be linked to 15 drugs, including:

3 antipsychotics and

1 antidepressant

Clozaril, Risperdal, Zyprexa, Paxil

(Moore, Cohen & Furberg, 2007)

76

Table 4. Most Frequent Suspect Drugs in Death and Serious Nonfatal Outcomes, 1998-2005

Drug Name	Rank/Deaths	Drug Class
Death outcome		
Oxycodone	1/5548	Opioid analgesic
Fentanyl	2/3545	Opioid analgesic
Clozapine	3/3277	Antipsychotic
Morphine	4/1616	Opioid analgesic
Acetaminophen	5/1393	Analgesic
Methadone	6/1258	Opioid analgesic
Infliximab	7/1228	DMARD
Interferon beta	8/1178	Immunomodulator
Risperidone	9/1093	Antipsychotic
Etanercept	10/1034	DMARD
Paclitaxel	11/1033	Antineoplastic
Acetaminophen-hydrocodone	12/1032	Combination analgesic
Olanzapine	13/1005	Antipsychotic
Rofecoxib	14/932	NSAID
Paroxetine	15/850	Antidepressant

77

(Moore, Cohen & Furberg, 2007)

Part F

Conclusions and Recommendations

78

FDA's independence in question

As a result of inordinately close ties to drugmakers, the FDA appears to have compromised its independence and its mandate to protect the public from dangerous products

79

Clinical trials provide skewed portrait of drug risks and benefits

Predictable limitations of trials suggest that their positive findings cannot generalize to real-life clinical conditions

Trials are especially poor at detecting adverse effects

80

Most psychological alterations produced by drugs are unstudied

Drugs' main psychological and behavioral effects can remain unknown even years after their approval by FDA and use by millions of people

Clinical trials ≠ objective evaluations of drug effects

Excessive involvement of sponsors in testing drugs may have tainted the research process, turning many clinical trials into "infomercials"

82

Conflicts of interest = suppression of negative trial findings

"Selective reporting of clinical trial results may have adverse consequences for researchers, study participants, health care professionals, and patients."

(Turner et al. 2008)

83

Need for skepticism and vigilance

Professionals should view announcements of clinical trial findings with skepticism and review them critically

84

Use new drugs cautiously

The first users of a newly marketed FDA-approved drug are the true research subjects

Public Citizen recommends waiting 7 years after marketing to use new drugs

"The public misunderstands drug safety, believing that a drug is safe at the time of marketing."

(Strom, 2006)

85

Your role in post-marketing surveillance?

Non-medical professionals and consumers can play an important role in *observing* and *reporting* adverse drug reactions to FDA, thus helping to create a more accurate portrait of medications and their impact on people's lives

86

A Critical Curriculum on Psychotropic Medications

Module 3

The End

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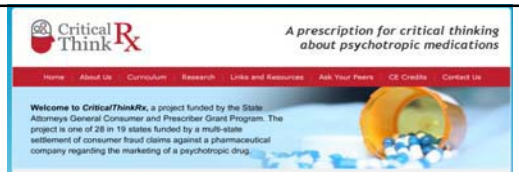

A Critical Curriculum on Psychotropic Medications

Critical Think Rx

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  - Inge Sengelmann, M.S.W.
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  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

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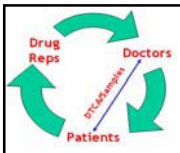


Module 4

Pharmaceutical Industry Influences on Prescribing

Part A

Expanding Drug Markets

5

Pharmaceutical drugs = Big business

World sales:

$643 billion in 2006

$685 billion projected for 2008

(IMS Health, 2006, 2007; *Pharmaceutical Executive*, 2007; *Los Angeles Times*, 2007) 6

Brand-name drugs

Manufacturer holds an exclusive patent to market them for about 15 years

- 40% of prescription volume
- 90% of revenues

(IMS Health, 2007; *Pharmaceutical Executive*, 2007) 7

Generic drugs

Once patent on marketing a brand-name drug expires, drug becomes a "generic," and sells for much less, as other manufacturers may apply to market it

(IMS Health, 2007; *Pharmaceutical Executive*, 2007) 8

"Blockbuster" drugs

Generate more than $1 billion of revenue each year

Are heavily marketed, so their manufacturer can make profits during the marketing exclusivity period

7 of the top 10 companies have 1 psychotropic drug among their top 3 blockbusters

(*Pharmaceutical Marketing*, 2006) 9

Antidepressants, antipsychotics, anticonvulsants: among top 6 drug classes sold in U.S.

(*Pharmaceutical Executive*, 2007; IMS Health, 2006)

Growing consensus:

Psychotropics are not popular because they are particularly effective

…"medicalization" and "disease mongering" also stimulate drug use

11

"Medicalization"

- Defining or treating a problem as a ***medical*** disease, requiring ***medical*** treatments

(Conrad & Leiter, 2004; Mintzes, 2002) 12

"Disease mongering"

- Turning ordinary ailments into diseases
- Framing conditions as being severe and widespread
- Seeing mild symptoms as serious
- Seeing risks as diseases

(Moynihan, Health, & Henry, 2002; Moynihan, 2002)

13

Disorders Made to Order

Pharmaceutical companies have come up with a new strategy to market their drugs: First go out and find a new mental illness, then push the pills to cure it.

Brendan I. Koerner
July/August 2002 Issue

MotherJones

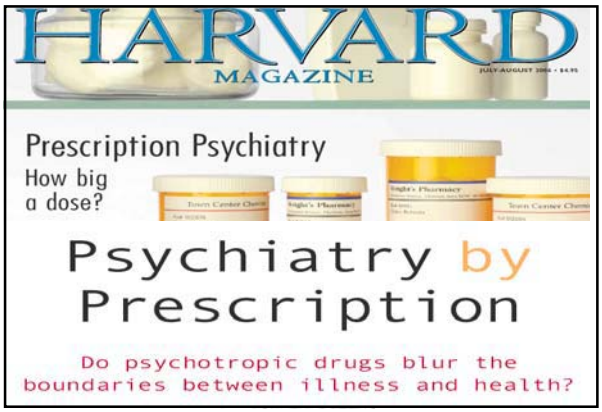
Disease awareness campaigns turn healthy people into patients

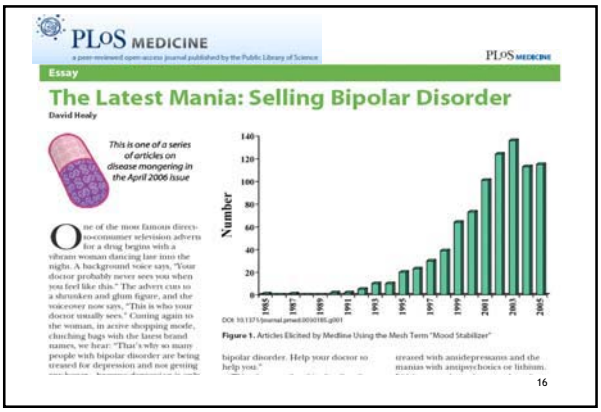
Owen Dyer *London*

DOI: 10.1371/journal.pmed.0030189.g001

Pills are often marketed as a solution to human anxieties and dissatisfactions

14





16

Part B

Marketing Expands Drug Markets

17

Cost of marketing and promoting drugs in U.S.

Industry estimates: $29.9B

Independent estimates: $57.5B

The NEW ENGLAND JOURNAL of MEDICINE

(Donohue, Cevasco & Rosenthal, 2007)

PLoS MEDICINE

(Gagnon & Lexchin, 2008)

18

Drug company marketing targets *all players* in the health care system

19

It influences physicians to prescribe through:

Gifts:

- *free lunches*
- *drug samples*
- *continuing medical education*
- *payments* for lecturing, consulting and research

20

It influences physicians to prescribe by:

- ✓funding countless activities of professional organizations
- ✓drug advertising in professional journals
- ✓paying doctors to serve on "expert committees" that create and promote guidelines for drug treatments used by other doctors

21

It influences consumers to seek drugs through:

- ✓direct-to-consumer-advertising (DTCA)
- ✓"disease awareness" campaigns
- ✓funding "patient advocacy" groups
- ✓online medical information and promotions

22

It influences legislators and government agencies to approve drugs and create favorable conditions for drugmakers through:

- ✓lobbying at all levels of government
- ✓large donations to political parties
- ✓payment of "user fees" to the FDA

23

It influences experts to evaluate drugs positively by:

- ✓paying researchers to run clinical trials and develop treatment guidelines
- ✓signing "secrecy agreements" with researchers to conceal negative drug information
- ✓paying academics and researchers to lend their names to articles they have not written ("ghostwriting")

24

Drug Reps

25

100,000 drug reps in the United States

~ 1 for every 6 doctors

(Oldani, 2004; Greene, 2004; Fugh-Berman & Ahari, 2007)

26

Doctors who meet frequently with reps:

- ✓increase prescribing of newer, costlier drugs
- ✓reduce prescribing of generics
- ✓increase nonrational prescribing
- ✓use rep as main information source

(Dana & Loewenstein, 2003; Reist & VandeCreek, 2004, Schwartz et al. 2001; Wazana, 2000)

27

Reps know just which doctors to target and how

Health Information Organizations combine purchased pharmacy data, AMA physician data, and patient data to determine which drugs individual physicians prefer for which diagnoses and which patient groups

This *prescription tracking* is used to tailor marketing to physicians and evaluate effects of promotions on their prescribing behavior

(Fugh-Berman, 2008)

28

Gift-giving

Very effective, *even when doctors don't think so*

29

The Boston Globe

Does a drug firm's free lunch influence doctors?

By Scott Lassman | May 18, 2007

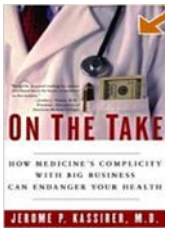
Physicians and the Pharmaceutical Industry

Is a Gift Ever Just a Gift?

JAMA

30

Are doctors "on the take"?



31

The NEW ENGLAND JOURNAL of MEDICINE

A National Survey of Physician–Industry Relationships

Among a sample of 3,200 physicians:

- 83% received food at work
- 78% received drug samples
- 35% were reimbursed for CME
- 28% were paid to give lectures or recruit patients in trials

(Campbell et al., 2007)

32

The New York Times

Psychiatrists Top List in Drug Maker Gifts

By GARDINER HARRIS
Published: June 27, 2007

1997- 2005: drug companies paid Minnesota doctors $57 million

- **psychiatrists received $6.7 million**

(Ross et al., 2007; *The New York Times*, 2007)

33

1 in 3 Minnesota psychiatrists received money from drugmakers

"One in three Minnesota psychiatrists has received funding from drug manufacturers in the past five years, including seven past presidents of the Minnesota Psychiatric Society, two state drug policy advisers and 17 faculty psychiatrists at the University of Minnesota."

(Olson, 2007)

34

The New York Times
May 10, 2007

Psychiatrists, Children and Drug Industry's Role

By GARDINER HARRIS, BENEDICT CAREY and JANET ROBERTS

Psychiatrists receiving money from drug companies more likely to prescribe "off-label" antipsychotics to children

"Free" samples…

- ✓introduce drug into doctor's office
- ✓generate sales, influence brand choice
- ✓Mostly go to wealthy/insured patients
- ✓63% of total promotional spending

Return-on-investment:

$10 in sales for every $1 spent

(Adair & Holmgren, 2005; Backer et al. 2000; Chew et al. 2000; Cutrona et al. 2008; ugh-Berman & Ahari, 2007)

36

Small gifts are powerful

Studies suggest that ***the most powerful form of influence might be small gifts***

The more gifts a doctor received, the more he/she believed that they had no influence on prescribing

(Reist & VandeCreek, 2004; Dana & Loewenstein, 2003; Oldani, 2004) 37

The "gift cycle"

A three-way exchange of gifts between doctors, drug reps, and patients

(Reist & VandeCreek, 2004; Dana & Loewenstein, 2003; Oldani, 2004) 38

"Ask your doctor…"

39

1997: FDA allows full-scale, direct-to-consumer advertising (DTCA) of prescription drugs

- DTCA only allowed in the U. S. and New Zealand

(Gellad et al. 2007) 40

DTCA increases drug use by

- ✓encouraging people to visit doctor
- ✓encouraging patients to request advertised drugs
- ✓influencing doctor's behavior through patient requests

(Gellad et al., 2007; Donohue & Bernd, 2004; Wolfe, 2002; *Consumer Reports*, 2007) 41

DTCA increases spending by

stimulating sales of newer, costlier drugs above older generics

(Gellad et al., 2007; Donohue & Bernd, 2004) 42

Accuracy of DTC ads questioned

1995 to 2004: FDA sent 1,359 warning letters to drug companies for false or misleading advertising

Only 4 FDA staffers review thousands of ads

(Donohue et al., 2007; Zalesky, 2006)

43

Example: 2007 Geodon ad "false and misleading"

2007 FDA letter: maker exaggerated claims of efficacy and did not mention risks of neuroleptic malignant syndrome, tardive dyskinesia, hyperglycemia and diabetes

GEODON "exaggerated claims, downplayed risks"

44

Industry funds "patient advocacy" groups

2005-2006: $29 million to 6 groups
- 7%-91% of the groups' budgets

Groups rarely disclose funding

Funds decline when drugmakers don't benefit

(*Philadelphia Inquirer*, 2006; *Los Angeles Times*, 2007)

45

- ***National Alliance on Mental Illness*** received $11.7 million from 18 drugs firms in three years
- ***Children and Adults with Attention Deficit/Hyperactivity Disorder*** is funded by Shire PLC, the #1 ADHD drugmaker
- ***Depression and Bipolar Support Alliance*** receives more than half its funding from drug firms

(*Philadelphia Inquirer*, 2006; *Los Angeles Times*, 2007)

46

NAMI, CHADD, and DPSA, among "patient advocacy" groups receiving most industry funding, promote view of distress as *chronic brain disease*, requiring latest drugs and neurobiological research

47

Continuing Medical Education

"Educating" to expand markets?

48

Medical Education Communication Companies (MECCs)

earned over $1 billion in 2004 to deliver industry-sponsored continuing medical education (CME)

(Relman, 2001; Elliott, 2004; Wazana, 2000)

49

Industry-sponsored CME highlights sponsor's drugs and is associated with increased prescriptions of those drugs

(Relman, 2001; Elliott, 2004; Wazana, 2000)

50

Concerns in U.S. Senate

Concern over drug firms' influence on CME, and its impact on off-label drug use

COMMITTEE STAFF REPORT TO THE CHAIRMAN AND RANKING MEMBER

USE OF EDUCATIONAL GRANTS BY PHARMACEUTICAL MANUFACTURERS

COMMITTEE ON FINANCE
UNITED STATES SENATE

MAX BAUCUS, *Chairman*
CHARLES E. GRASSLEY, *Ranking Member*

APRIL 2007

(Report to Committee on Finance, US Senate, April 2007)

51

"Ghost" Marketing

Industry marketers and scientific journals

52

"Ghostwriting"

Pharmaceutical firms hire MECCs to write academic papers favorable to their products

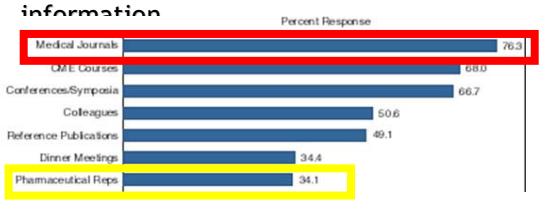
MECCs then hire academics to publish the articles under their name without disclosure about the true source

(Moffat & Elliott, 2007)

53

"Ghostwriting" works because…

~ 76% of doctors consider medical journals their most important source of information



(Source: www.RxPromoROI.org; Fugh-Berman et al. 2006)

54

Even without ghost-writing…

A drug firm may pay a journal $1 million for reprints, creating enormous incentive for the journal to publish a favorable article

- A former editor of *British Medical Journal* called journals "extensions of marketing arms" of drug firms and urged journals to *stop publishing all clinical trials*, and only evaluate them critically

(Moffat & Elliot, 2007; Smith, 2004; *The New York Times*, 2002)

55

56

Pharmaceutical Researchers and Manufacturers of America (PhRMA) represents pharmaceutical and biotechnology companies in the U.S.

PhRMA
New Medicines. New Hope.

57

PhRMA hired hundreds of lobbyists to help pass the Medicare Part D bill in 2004

Originally estimated to cost taxpayers $534 billion, Medicare Part D forbids the government from negotiating drug prices

PhRMA head is Billy Tauzin, former Republican congressman from Louisiana

Drug industry lobbyists outnumber Congressmen 2:1

2006: Drug interests employed about **1,100** lobbyists, including **40** former members of Congress

CBS NEWS
Under The Influence
NEW YORK, April 1, 2007

(Center for Public Integrity, 2007; *CBS News/60 Minutes*, 2007)

59

Large investments in lobbying

2005 - 2006: $182 million spent on federal lobbying

2005 - 2006: $100 million spent on campaign contributions

Sales of top 20 lobbying spenders = 77% of the US drug market

(*CBS News/60 Minutes*, 2007; Center for Public Integrity, 2007)

60

Defending industry interests

Main goal in 2007:

- Oppose laws that would strengthen FDA's ability to monitor drug safety
- Fight bills that would allow Medicare to negotiate drug prices, which could reduce government drug spending by 60%

(*CBS News/60 Minutes*, 2007; Center for Public Integrity, 2007)

61

Part C

Conclusions and Recommendations

62

Conclusions

Industry promotion of expensive drugs permeates all phases of the life-cycle of drugs

Deceptive drug marketing is "pervasive, dangerous and primarily aimed at doctors"

63

Skepticism of industry grows

Previously "hidden" practices are increasingly exposed and scrutinized

Government hearings and legislative efforts highlight concerns over public health and public spending

64

Some doctors call for limits

Asking for stringent regulation to eliminate conflicts of interest:

- no gifts, no speaking at industry-sponsored CME, no ghostwriting, disclose research and consulting contracts, replace free samples with vo[illegible] to patients

(Troyen et al., 2006; *Washington Post*, 2006)

Medical students take action

More Med Schools Show Pharma The Door

July 2nd, 2007 8:56 am By Ed Silverman

Last month, the American Medical Student Association ranked med schools based on their freebie policies, using a PharmFree scorecard. Since then, several schools reacted with embarrassment over their rankings.

- **Only 5 of 116 medical schools got an "A" for having a policy restricting drug industry access to students and faculty**

66

But medical schools lag behind

- The International Committee of Medical Journal Editors (ICMJE) requires full disclosure of drug companies' role in research
- But even major journals still can't ensure transparency
- A study of 108 medical schools' agreements to conduct research for drug firms found that ICMJE guidelines were rarely followed
- Researchers have little access to data or power over publishing

(Rivera & Cummings, 2002) (Schulman et al., 2002) 67

States attempt legislation and sue drug firms

Most states have introduced bills or resolutions aimed at marketing

Several states are suing drugmakers for off-label promotion of antipsychotics and for hiding drug risks (see Module 5)

(Reist & VandeCreek, 2004; Zalesky, 2006) 68

9 in 10 Americans favor reforms

Consumer Reports **survey finds strong backing for drug reforms**

As Congress prepares to vote on the most significant prescription drug safety legislation in 45 years, a new *Consumer Reports* poll finds that the American public strongly backs a number of reforms. Safety issues rose to the top, with 9 of every 10 Americans supporting reforms that would require warning labels and follow-up studies on drugs with safety problems, and public disclosure of all clinical drug trials.

ConsumerReports (2007)

69

Recommended reforms to research

Create a public registry of all clinical trials

Fund clinical trials publicly, and cease drugmakers' ties to clinical research

Make *raw* clinical trial data accessible for independent analyses

(Antonuccio & Healy, 2008; NJPIRG Law & Policy Center, 2006) 70

Researchers' commitment?

Because research participants expose themselves to risk, information derived from them should not be misused, suppressed, or distorted

Researchers should promise to make *all raw research data available publicly*, or forego approval from Institutional Review Boards

(Antonuccio & Healy, 2008) 71

Teach prescribers, academics and consumers to:

✓critically evaluate drug marketing

✓rely on independent sources of information

✓implement best practices to minimize industry influence in schools, professional organizations, and mental health providers

(NJPIRG Law & Policy Center, 2006) 72

A Critical Curriculum
on Psychotropic Medications

Module 4

The End

www.CriticalThinkRx.org

73

A Critical Curriculum on Psychotropic Medications

A Critical Curriculum on Psychotropic Medications

- **Principal Investigator:**
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- **Research Coordinator:**
  - Inge Sengelmann, M.S.W.
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  - Kia J. Bentley, Ph.D. (social work)
  - R. Elliott Ingersoll, Ph.D. (counseling & psychology)
  - Stefan P. Kruszewski, M.D (psychiatry)
  - Robert E. Rosen, J.D., Ph.D. (law)
- **Flash production and design:**
  - Sane Development, Inc., and Cooper Design, Inc.
- **Voice narration and Flash editing:**
  - Saul McClintock

www.CriticalThinkRx.org

CriticalThinkRx was made possible 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 the prescription drug Neurontin®

Module 5

Specific Drug Classes: Use, Efficacy, Safety

4

5

"Psychotropic" or "psychoactive" drugs

affect the central nervous system and alter feeling, thinking, and behaving

6

"Approved use" means…

FDA has reviewed limited data on safety and efficacy for one indication, usually in one population

A "label" for the drug is established to guide dosage and describe observed side effects

FDA Drug Approvals List

7

Fewer than 10% of psychotropic drugs are FDA-approved for any psychiatric use in children

8

Focus: Stimulants

9

Stimulants approved by FDA for pediatric use

Brand Name	Generic Name	Psychiatric Indication	Age group
Adderall, Adderall XR, Dexedrine, Dextrostat	amphetamine, dextroamphetamine	ADHD, narcolepsy	3 +
Concerta, Ritalin, Daytrana, Metadate Focalin, Focalin XR	methylphenidate, dexamethylphenidate	ADHD	6 +
Vyvanse	lisdextroamphetamine		
Strattera (*not considered a stimulant*)	atomoxetine		

10

Stimulants act quickly

Stimulants change behavior *within one hour* in 60-70% of children who take them

11

Long-term evidence of benefits doubtful

APA Report noted lack of data supporting long-term efficacy or safety

- Stimulants show minimal efficacy in general life domains of the child, including social and academic success

(APA Working Group on Psychoactive Medications for Children and Adolescents, 2006; MTA Cooperative Group, 2004)

12

Short-term desirable effects of stimulants at usual doses

- ✓Increase alertness and wakefulness
- ✓Induce sense of well-being (euphoria)
- ✓Improve accuracy on brief physical and mental tasks

(Bezchlibnyk-Butler & Jeffries, 2005)

Effects misconstrued as therapeutic in children

- ✓Increased repetitive, persistent behavior
- ✓Decreased exploration and social behavior
- ✓Increased compliance

(Breggin, 1998)

14

Undesirable *behavioral* effects of stimulants

- Nervousness, restlessness
- Insomnia
- Agitation
- Depression, "zombie" look
- Irritability, Aggression
- Psychological dependence
- Mania, Psychosis

(Bezchlibnyk-Butler & Jeffries, 2005)

15

Undesirable *physical* effects of stimulants

- Increased blood pressure
- Dizziness, headaches
- Palpitations
- Stomach cramps, nausea
- Apetite/weight loss
- Stunted growth
- Cardiac arrest

(Bezchlibnyk-Butler & Jeffries, 2005)

16

Stunted growth

Decreases in growth averaging ¾" and 6 lbs. without evidence of rebound 3 years after stopping treatment

(Swanson et al., 2007)

17

Emergency room visits

2,500 children visited ERs in 2004 after taking stimulants for ADHD, most due to accidental overdoses

- 1 in 4 children had heart or blood pressure symptoms including palpitations, chest pain or fainting

(Waters, 2007)

18

2006: FDA warning on stimulants

- ✓increased risk of sudden death in patients with heart problems
- ✓increased aggression, mania and/or psychotic symptoms (including hallucinations)

The New York Times

August 22, 2006

F.D.A. Strengthens Warnings on Stimulants

19

Definite risk of tolerance and dependence

Stimulants prescribed to children are Drug Enforcement Administration (DEA) "Schedule II Drugs," indicating a high risk of tolerance and dependence

RITALIN LA® is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep RITALIN LA® in a safe place to prevent misuse and abuse. Selling or giving away RITALIN LA® may harm others, and is against the law.

20

Focus: Antidepressants

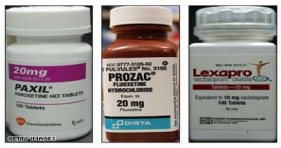
21

FDA-approved antidepressants for pediatric use

Brand Name	Generic Name	Psychiatric Indication	Age group
Sinequan	doxepin	OCD	12+
Anafranil	clomipramine		10+
Luvox	fluvoxamine		8 +
Zoloft	sertraline		6 +
Tofranil	imipramine		
Prozac	fluoxetine	Depression, OCD	7 +

22

CDC: Antidepressants most prescribed drugs in U.S.



Antidepressants such as Paxil, Prozac and Lexapro are among America's most-prescribed drugs.

CNN.com /health 2007

23

But are they effective?

Meta-analyses of drug vs. placebo studies show 75-82% of the response was duplicated by placebo

- 57% of studies submitted to FDA failed to show a difference between drug and placebo

(Moncrieff et al., 2004; Kirsch et al., 2002; Kirsch & Sapirstein, 1998)

24

Unimpressive evidence from FDA's complete adult database

"[I]n 189 trials of 53,048 adult subjects with psychiatric disorders … Approximately 50% of subjects who received active drug and 40% of subjects who received placebo were designated as responders."

(Stone & Jones, 2006)

The entire scientific case for antidepressants rests on this 10% difference—which may result from biases in the conduct of clinical trials

25

FDA analysis of pediatric trials concurs

Only 3 of 15 published and unpublished randomized controlled trials show SSRIs as more effective than placebo in depressed children

None of the studies found drugs better on client- or parent- rated measures

(Laughren, 2004)

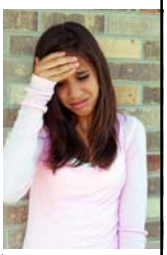
26

No evidence that older antidepressants (tricyclics or MAO inhibitors) have any efficacy with depressed youths

(Somers-Flanagan & Somers-Flanagan, 1996)

27

Short-term desirable effects at usual doses



- ✓Increased physical activity
- ✓Elevated mood
- ✓Decreased expressions of distress such as crying, hopelessness
- ✓Improved sleep and appetite

(Bezchlibnyk-Butler & Jeffries, 2005)

28

Undesirable *behavioral* effects of antidepressants

- Anxiety, nervousness
- Agitation, irritability
- Mood swings, mania
- Aggressiveness
- Thoughts of suicide
- Attempted or actual suicide

(Antonuccio et al., 1999; Preda et al., 2001; Healy, 2003)

29

Undesirable *physical* effects of antidepressants

- Gastrointestinal distress (nausea, vomiting, stomach pain, constipation, diarrhea)
- Sexual problems (loss of libido, anorgasmia, erectile dysfunction)
- Sleep disruption (insomnia, hypersomnia)
- Urinary retention
- Blurred vision
- Weight gain
- Headaches, dizziness

(Antonuccio et al., 1999; Preda et al., 2001; Healy, 2003)

30

Six clusters of withdrawal effects likely upon abrupt discontinuation of SSRI antidepressants

1. Neurosensory (vertigo, tingling & burning)
2. Neuromotor (tremor, spasms, visual changes)
3. Gastrointestinal (nausea, vomiting, diarrhea, weight loss)
4. Neuropsychiatric (anxiety, depression, crying spells, irritability, suicidal thinking)
5. Vasomotor (heavy sweating, flushing)
6. Other (insomnia, vivid dreaming, fatigue)

(Schatzberg et al., 2006)

31

Antidepressants double risk of suicidality

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2005: FDA issues "black box" warning of "Suicidality in Children and Adolescents":

"Antidepressants increase the risk of suicidal thinking and behavior (suicidality)"

- *(22 RCTs testing 9 antidepressants: **2.3%** rate of serious suicidal events among drug-treated children, vs. **1.2%** among placebo treated—no completed suicides)*

32

"Activation" syndrome: A more common risk

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

(Breggin, 2006)

33

Concern over "prescription cascade"

Continued exposure to the drug can lead to effects misinterpreted as psychiatric symptoms (such as mania), leading to increases in dosage or additional drugs—when reducing or stopping the drug would relieve the patient's discomfort

(Breggin, 2006)

34

Focus: Anticonvulsant Drugs

35

Anticonvulsants on U.S. market (antiepileptics, antiseizure drugs)

Brand Name	Generic Name	Yr of intro
Tegretol, Equetro	carbamazepine	1968, 2004
Neurontin	gabapentin	1993
Lamictal	lamotrigine	1994
Depakene, Depakote	valproate	1995
Topamax	topiramate	1997
Trileptal	oxcarbazepine	2000

36

Anticonvulsants FDA-approved for pediatric seizure disorders

Brand Name	Generic Name	Approved Indications	Age
Tegretol, Equetro	carbamazepine	NO PSYCHIATRIC INDICATIONS	Any
Gabitril	iagabine		12 +
Depakote Depakene	divalproex sodium, valproate		10 +
Topamax	topiramate		
Neurontin	gabapentin		3 +
Lamictal	lamotrigine		2 +
Trileptal	oxcarbazepine		

37

Anticonvulsants widely promoted as "mood stabilizers"

Use started in 1980s-1990s due to dissatisfaction with lithium and antipsychotics in treatment of Bipolar Disorder

Use spread rapidly with the promotion of "mood stabilizer" expression and of Bipolar Disorder diagnosis in children

(Healy, 2006)

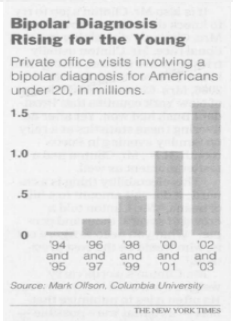
38

39

The New York Times

Bipolar Illness Soars as a Diagnosis for the Young

40-fold increase in less than a decade



(Moreno et al., 2007)

40

Polypharmacy without psychotherapy

More than 90% of children diagnosed with Bipolar Disorder received more than 1 psychoactive drug

Less than 40% received psychotherapy

(Moreno et al., 2007)

41

Scant empirical support

No studies confirm the efficacy and safety of anticonvulsants to treat Bipolar Disorder in children and adolescents

*"Despite the frequent use of antiepileptic drugs in the treatment of **juvenile bipolar disorder**, migraine, and neuropathic pain, the data are insufficient to make recommendations regarding the efficacy of antiepileptics in these conditions in children and adolescents."* *(Golden et al., 2006)*

(Kowatch et al., 2000, 2005; National Institute of Mental Health, 2000; Ryan, Bhatara & Perel, 1999)

42

Most trials are open, small, and show limited response in youth

Half of all participants in an open trial of lithium, divalproex, or carbamezepine did not respond to treatment

- 58% received *at least one* mood stabilizer *plus* a stimulant, an atypical antipsychotic, or an antidepressant

(Lopez-Larson & Frazier, 2006)

43

Desired behavioral effects of anticonvulsants

✓Reduce aggression and impulsivity

✓Calm restlessness and excitability

(Bezchlibnyk-Butler & Jeffries, 2005)

44

FDA U.S. Food and Drug Administration U.S. Department of Health and Human Services

2008: FDA warns anticonvulsants *double risk* of suicidal behavior or ideation

Risk is highest in treatment of epilepsy—which rules out psychiatric status as confounding variable

45

Undesired *behavioral* effects of anticonvulsants

- Depression, sedation
- Hostility and irritability
- Anxiety, nervousness
- Hyperactivity
- Abnormal thinking
- Confusion and amnesia
- Slurred speech
- Sedation, sleepiness

(Bezchlibnyk-Butler & Jeffries, 2005)

46

Undesired *physical* effects of anticonvulsants

- Nausea and dizziness
- Vomiting and abdominal pain
- Headaches and tremors
- Fatal skin rashes
- Hypothyroid
- Blood disorders
- Pancreatitis, liver disease
- Birth defects and menstrual irregularities
- Withdrawal seizures

(Bezchlibnyk-Butler & Jeffries, 2005; Gonzalez-Heydrich et al., 2003)

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Birth defects of concern given new patient profiles

Anticonvulsants cross placenta and increase the risk of fetal malformations and cognitive impairments in children exposed in utero

- *Highest rates for valproate and carbamazepine*

(Adab et al., 2006)

FDA black-box warnings

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

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"Atypical" (newer, 2nd generation) antipsychotics on U.S. market

Brand Name	Generic Name	Yr of intro
Clozaril	clozapine	1989
Risperdal	risperidone	1994
Zyprexa	olanzapine	1996
Seroquel	quetiapine	1997
Geodon	ziprasidone	2001
Abilify	aripriprazole	2002
Invega	paliperidone	2007

51

FDA-approved psychiatric indications of atypicals

Risperdal	Autism, bipolar mania, schizophrenia	5 +
Abilify	Schizophrenia	10+
Clozaril	Treatment resistant schizophrenia	Adults only
Zyprexa	Bipolar mania, schizophrenia	
Seroquel		
Geodon		
Symbyax		
Invega		

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FDA-approved psychiatric indications of typicals for children

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

Typicals make up less than 5% of FL Medicaid prescriptions of antipsychotics

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"Typical" & "Atypical" antipsychotics

Since 1950s, antipsychotics were used to treat psychoses, despite high toxicity and limited effectiveness

Newer, expensive "atypical" antipsychotics were heavily promoted in the 1990s as safer and more effective

54

Yet, newer no better than older…

The NEW ENGLAND JOURNAL of MEDICINE

2005: largest-ever schizophrenia treatment study finds atypicals neither more effective *nor* better tolerated than older drug

- 75% of patients quit either drugs within 18 months due to inefficacy or intolerable side effects

(Lieberman et al., 2005)

55

Non-psychotic diagnoses in children treated with atypicals

Diagnosis	% of Florida Medicaid children on antipsychotics (2006)
ADHD / Conduct Disorder	48
Nonpsychiatric, Anxiety, Other Psychiatric	27
Bipolar / Depression	13
Schizophrenia / Psychosis	8
Austism / Mental Retardation	4

Times (2007)

56

"Aggression" said to account for most of the antipsychotic prescribing in children and adolescents

(Patel et al., 2005)

57

But do antipsychotics effectively control aggression?

The latest randomized-controlled trial found ***placebo more effective*** than either a typical (haloperidol) or atypical (risperidone) antipsychotic to reduce aggression in patients with intellectual disability

Trial had no drug company sponsorship

(Tyrer et al., 2008)

58

"Antipsychotic drugs should no longer be regarded as acceptable routine treatment for aggressive behavior in people with intellectual disability."

(Tyrer et al., 2008)

59

Few pediatric clinical trials of atypicals for *any* indication

As of 2006, only a few studies of direct AAP comparisons with placebo

Most studies are short-term (3-6 weeks) and results favor the funder's drugs

(McDonagh et al., 2006)

60

"There are no studies that have shown (atypicals) are safe, or for that matter, that they are effective for children…The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness."

Ronald Brown, Chair,
2006 American Psychological Association
Task Force on Psychotropic Drug Use in Children

St Petersburg Times (2007)

61

Dopamine-blocking action of all antipsychotics explains

- ✓indifference, sedation, drowsiness, apathy
- ✓reduced spontaneity and affect
- ✓reduced ability to monitor one's state
- ✓increased abnormal movements
- ✓cognitive and motor impairments
- ✓confusion and memory problems
- ✓depression, mood swings, agitation

(Bezchlibnyk-Butler & Jeffries, 2005)

62

Desirable effects of antipsychotics at usual doses

- ✓suppress psychotic symptoms (delusions, hallucinations, agitation)
- ✓suppress manic symptoms (euphoria, expansiveness, irritability)

(Bezchlibnyk-Butler & Jeffries, 2005)

63

Effects misconstrued as therapeutic

- ✓increased indifference
- ✓reduced spontaneity and affect
- ✓reduced ability to monitor one's state
- ✓increased compliance with social norms

(Bezchlibnyk-Butler & Jeffries, 2005)

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Undesirable *behavioral* effects of antipsychotics

- Cognitive and motor impairments
- Sedation, drowsiness
- Confusion and memory problems
- Anxiety
- Depression, mood swings
- Abnormal thinking
- Hostility, aggression

(Bezchlibnyk-Butler & Jeffries, 2005)

65

Undesirable *physical* effects of antipsychotics

- Weight gain, high blood sugar
- Abnormal movements (all body parts)
- Diabetes
- Cardiac problems
- Liver problems, jaundice
- Neuroleptic malignant syndrome
- Death

(Bezchlibnyk-Butler & Jeffries, 2005; Lindenmayer et al., 2003; Meyer, 2001)

66

Hormonal dysfunctions

Elevated prolactin levels cause:

- ✓sexual and menstrual disturbances
- ✓infertility
- ✓decreased bone density

(Bezchlibnyk-Butler & Jeffries, 2005; Correll & Carlson, 2006; Patel et al., 2005)

67

Extrapyramidal symptoms (abnormal movements)

Akathisia: inner distress, rocking, pacing, agitation

Dystonia: sudden, bizarre muscle spasms

Dyskinesia: rhythmic movements of face, mouth and tongue, sometimes of hands and feet

Parkinsonism: rigid muscles, loss of facial expression, unsteady gait, drooling

(Campbell, Rapaport & Simpson, 1999)

68

Tardive dyskinesia risk highest for typical antipsychotics

Long-lasting abnormal movements affect 12% to 35% of children who receive typical antipsychotics for more than 3 months

(Campbell, Rapaport & Simpson, 1999)

69

Weight gain and diabetes

50% of patients on antipsychotics gain 20% of their weight (primarily as fat)

Weight gain linked to "metabolic syndrome"

3 Schizophrenia Drugs May Raise Diabetes Risk, Study Says

By ERICA GOODE
Published: August 25, 2003

The New York Times

(Bezchlibnyk-Butler & Jeffries, 2005; Correll & Carlson, 2006; Patel et al., 2005)

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Neuroleptic malignant syndrome

Can occur with any antipsychotic agent, at any dose, at any time

Symptoms: extreme muscular rigidity, high fever, & altered consciousness

1-2% rate per year

Fatal if untreated

(Bezchlibnyk-Butler & Jeffries, 2005; Silva et al., 1999)

71

3 atypicals suspected in nearly 4,500 deaths reported to FDA, 1998-2005

Clozaril:	3,277 deaths
Risperdal:	1,093 deaths
Zyprexa:	1,005 deaths

(Moore, Cohen & Furberg, 2007)

72

FDA "black-box" warnings

All atypicals	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	Risk of suicidality in children and adolescents

73

"For many adults, and a small number of children, these agents can be an important component of treatment. However, it's so rare to find an example where evidence-based alternatives were exhausted prior to starting an atypical antipsychotic in a child that I have not found one yet in three years of searching."

Mark E. Helm, MD, MBA
Medical Director, Evidence-Based Prescription Drug Program
University of Arkansas Medical Sciences
College of Pharmacy, 2007

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Part B

Lawsuits against drug makers shed light on illegal promotion and serious risks

The New York Times

December 18, 2006

Drug Files Show Maker Promoted Unapproved Use

By ALEX BERENSON

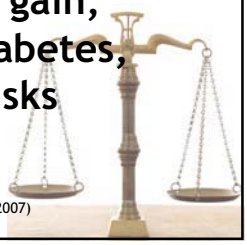
75

States sue drug makers for illegal marketing of unapproved uses

to recover money states paid to purchase atypical antipsychotics and the costs of medical care for the people injured by these drugs

(Pringle, 2007; Kesselheim & Avorn, 2007)

Patients sue, charging that drug makers did not adequately warn about severe weight gain, pancreatitis, diabetes, and other risks



(Pringle, 2007; Kesselheim & Avorn, 2007)

The New York Times

January 5, 2007

Lilly Settles With 18,000 Over Zyprexa

By ALEX BERENSON

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Zyprexa lawsuits

2007: Several states sue Eli Lilly for downplaying or hiding data linking use of the drug to weight gain and hyperglycemia

- *Most of those states' Medicaid spending on antipsychotics is for Zyprexa*

79

2007: Zyprexa settlements top $1.2 billion, *so far*

Eli Lilly has paid more than **$1.2 billion** to settle 30,000+ Zyprexa lawsuits

- The settlements required data on rates of adverse effects be kept *secret*

(Berenson, 2008)

80

2008: Feds, Eli Lilly negotiate $1 billion Zyprexa fine

If a deal is reached, it would be the largest fine ever paid by a drug company for breaking the federal laws governing how drugmakers can promote their medicines

The New York Times
Thursday, February 7, 2008

Lilly Considers $1 Billion Fine To Settle Case

81

Department of Justice

FOR IMMEDIATE RELEASE
FRIDAY, SEPTEMBER 28, 2007
WWW.USDOJ.GOV

2007: Bristol-Myers Squibb pays $515 million over illegal marketing and pricing of Abilify, Serzone, other drugs

82

Litigation has

☑ exposed shady practices of pharmaceutical manufacturers

☑ uncovered previously hidden data about adverse events

☑ helped doctors reassess risks and benefits of some drugs and think critically about the available "evidence"

(Kesselheim & Avorn, 2007)

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Part C

Conclusions and Recommendations

84

Evidence "poor" for the use of psychotropics in children

- *Little or no evidence of efficacy and safety* of long-term use of these drugs in children
- *Clear evidence of harm* and risk of serious adverse events, including death
- *Risk-benefit ratio especially poor* for antidepressants, anticonvulsants, and antipsychotics

85

Need to rethink risk-benefit ratio

Risks for adverse events, including death, increase with the number of concomitant drugs administered

Risks for adverse events are higher in children, who are receiving adjusted adult dosages of drugs rarely studied in children

(Brown & Sammons, 2002; Riddle, Kastelic & Frosch, 2001; Vitiello, 2001) 86

Side effects leading to multiple medications?

After initial medication, side effects may be viewed as mental disorders and drugged, in a "prescribing cascade" of polypharmacy that keeps children at risk with no sign of behavioral improvement

87

Available evidence does not justify use of psychotropic drugs as **first-line** treatments for children and adolescents

Reassess all cases?

Given known risks and dearth of valid studies showing benefits, cases of children receiving psychiatric medications should be reassessed

Children are involuntary patients. To support continuing psychotropic drug treatment, ***rock-solid*** rationale should be provided in every single case

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A Critical Curriculum on Psychotropic Medications

Module 5

The End

www.CriticalThinkRx.org

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A Critical Curriculum on Psychotropic Medications

Critical Think Rx

A Critical Curriculum on Psychotropic Medications

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Critical Think Rx
www.CriticalThinkRx.org

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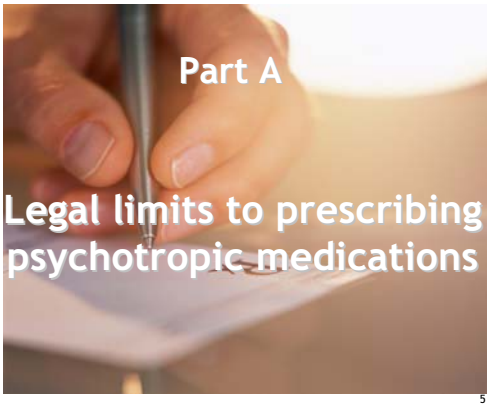
Module 6

Non-Medical Professionals and Psychotropic Medications:

Legal, Ethical and Training Issues



5

Who can prescribe?

Most states grant full or partial prescriptive authority to licensed **physicians, dentists, advanced nurse practitioners, pharmacists, podiatrists,** and **optometrists**

(NASW, 2005;Norfleet, 2002; Wiggins & Wedding, 2004)

6

Who cannot prescribe?

Social workers, mental health counselors, and most psychologists are not authorized to **prescribe, dispense, or administer** any medication

(NASW, 2005;Norfleet, 2002; Wiggins & Wedding, 2004) 7

Discussing ***any and all*** medication issues with clients is *OK*

For example, Florida and California *do not* prohibit non-medical professionals to discuss any medication issue with clients

A review of case law indicates that this could not be construed as practicing medicine without a license

(Cohen, 2007; Ingersoll, Bauer, & Burns, 2004; Littrell, 2003; Litrell & Ashford, 1995) 8

Psychologists have gained limited authority to prescribe in 2 states and 1 U.S. territory

New Mexico (2002)

Louisiana (2004)

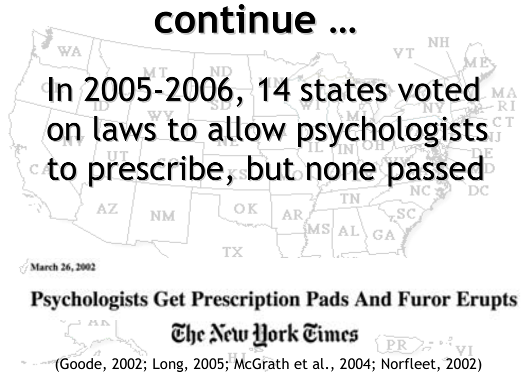
Guam (1998)

Specially-trained Department of Defense psychologists also may prescribe

9

Psychologists' efforts continue …

In 2005-2006, 14 states voted on laws to allow psychologists to prescribe, but none passed



(Goode, 2002; Long, 2005; McGrath et al., 2004; Norfleet, 2002)

Issue is debated…

- Who needs psychologists to prescribe?
- What special training is needed?
- Is it simply about more money?
- Is psychology selling its soul for a mess of (pharmaceutical) pottage?

but the discussion has shifted from "Should psychologists prescribe?" to "When will they prescribe and how should they prepare?"

(Heiby, 2002; Kenkel, 2006; Sanua, 2003) 11

Are counselors next?

Among members of the American Mental Health Counselors Association,

- 41% would like to pursue independent prescription privileges
- 64% would like to obtain dependent privileges
- > 90% want psychopharmacology training in their curriculum

(Scovel, Christensen, & England, 2002)

How about social workers?

Survey of a national sample of 176 practitioners in late 1990s

- 52% opposed to obtaining prescription privileges
- 19% in favor
- the rest said "maybe" or did not respond

(Piotrowski & Doelker, 2001)

Professional associations' stances

American Psychological Association supports psychologists' efforts to gain prescriptive authority

National Association of Social Workers views prescription as beyond the scope of the profession

American Psychiatric Association actively opposes all such initiatives from non MDs

Part B

Ethical and Legal Issues:

Competence and Training
Informed Consent
Confidentiality

15

Professional *competence* is a core principle in the codes of ethics and standards for practice of various helping professions

(ACA, AMHCA, APA, NASW)

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To maintain competence, professional codes recommend

Education and training
Consultation
Supervision
Continuing education

(ACA, AMHCA, APA, NASW)

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Competence requires

- ✓knowledge of valid information relevant to practice
- ✓regular critical review of literature and emerging information
- ✓participation in relevant and unbiased CE

(ACA, AMHCA, APA, NASW)

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No specific standards address working with clients and others around medication-related issues

In the absence of standards, Codes advise exercising careful judgment and taking responsible steps to ensure competence and protect clients from harm

(ACA, AMHCA, APA, NASW)

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Knowledge = Competence
Training = Knowledge

Without knowledge about drugs, counselors, psychologists and social workers are ill-prepared to meet their clients' needs

Psychopharmacology should be part of training for non-medical practitioners

(Barnett & Neel, 2000; Bauer, Ingersoll & Burns, 2004; Bentley, 2005; Carlson, Thaler & Hirsch, 2005; Dziegielewski & Leon, 1998; Farmer, Walsh & Dziegielewski, 1998; Ingersoll, 2000)

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Knowledge increases confidence and empowers non-medical professionals to participate fully in multidisciplinary environments

(Farmer, Walsh & Bentley, 2006; Dziegelewski, 1998; Littrell, 2003)

Education vs. indoctrination

Students & practitioners must be *educated* rather than *indoctrinated*, and should be exposed to controversies, uncertainties in knowledge, and well-argued alternatives to popular views

(Dziegelewski, 1998; Gomory & Lacasse, 2001; Litrell, 2003)

22

Special guidelines needed

Use of polypharmacy

Integrating psychosocial and biological therapies

Specific groups, such as children, older persons, pregnant women

Ethical and critical thinking skills in the age of "Big Pharma"

(Buelow & Chafetz, 1996; Chafetz & Buelow, 1994; Dunivin & Southwell, 2000; Freimuth, 1996; Levant & Shapiro, 2002; Smyer et al., 1993)

23

24

Why obtain informed consent?

Informed consent is the bedrock of professional practice in a free society

- It promotes the **right to self determination, prevents harm** and provides for the **client's best interest**

(Cohen & Jacobs, 2000; Strom-Gottfried, 1998; Littrell & Ashford, 1995; Littrell, 2003)

25

What is informed consent?

A systematic ***process*** intended to guarantee the client's right to choose, to privacy and to safety

(Dell et al 2008; Littrell & Ashford, 1995; Litrell, 2003; Strom-Gottfried, 1998)

What is *not* informed consent?

Having a client sign-off on services without a clear understanding of the information, including uncertainties about the treatment

(Cohen & Jacobs, 2000; Littrell & Ashford, 1995; Reamer, 2003) 27

Validity of consent forms

Blanket consent forms lack specificity and have been challenged in court

Signing a blank consent form to be completed later *is not* valid consent

(Littrell & Ashford, 1995; Reamer, 2003; Strom-Gottfried, 1998) 28

Standards for valid consent

1. Avoid coercion and undue influence
2. Assess client competence to consent
3. Specify procedures or actions in the form
4. Inform clients of the right to refuse or withdraw consent
5. Provide adequate information on risks, benefits **and** alternatives to treatment

(Reamer, 2003) 29

Coercion or undue influence

Practitioners who *want* clients to agree to treatments or procedures may be exercising undue influence and will jeopardize validity of their consent

(Dell et al 2008; Littrell & Ashford, 1995; Reamer, 2003; Strom-Gottfried, 1998) 30

"Adequate" information

- ✓Critical findings on usefulness, ineffectiveness and **reported information on harm**
- ✓Description of the hoped-for benefits and **how success will be evaluated**
- ✓**Alternatives** to treatment being proposed
- ✓Costs of treatment

(Littrell, 2003; Littrell & Ashford, 1995; Strom-Gottfried, 1998) 31

Knowledge of alternatives

Lack of knowledge about the alternatives to proposed treatment **invalidates** informed consent

*Competence by providers in a variety of treatment methods is **essential** to informed consent*

(Littrell, 2003; Littrell & Ashford, 1995; Strom-Gottfried, 1998) 32

Encourage questions

Informed consent should serve to empower clients to make intelligent decisions about their care, not protect practitioners from liability

*Practitioners must ensure the persons receiving the information understand it, and should **encourage questions***

(Littrell, 2003; Cohen & Jacobs, 2000; Strom-Gottfried, 1998; Tan et al., 2007) 33

Competence to consent

"The capacity to act on one's own behalf, to understand and weigh potential outcomes, to anticipate future consequences of a decision."

(Tan et al., 2007) 34

Assessing competence to consent

In youths, assessment considers intelligence and cognitive functioning, maturity, impact of any distress, seriousness and urgency of situation, and impact of youth's relationships

Refusing to consent does not mean incompetence

(Dell et al 2008; Tan et al 2007)

Cognitive capacity of children

By about age 9, children reach the same conclusions as adults, but by different strategies

By about age 14, minors show the same risk-benefit reasoning as adults and can participate in the consent process

(Dell et al 2008; Spetie & Arnold, 2007)

Respect for autonomy

Older children and adolescents should participate in the consent process in order to protect them from being subjected to treatment procedures against their will, and to respect their developing autonomy and personhood

(Dell et al 2008; Spetie & Arnold, 2007)

37

Third-party representation

Those who cannot give consent require a third party to act "in their best interests"

There are many views on just what this means…

(Spetie & Arnold, 2007)

38

What about preschoolers?

Are parents fully able to carry out their advocacy role?

Their capacity to act in their young child's best interest warrants careful evaluation

(Dell et al 2008; Spetie & Arnold, 2007)

39

"The clinician must be watchful for caregivers who may have ulterior motives and want a child to be medicated for their own convenience, or because pharmacotherapy may simply be 'easier' than behavioral therapy, or as is more often the case, caregivers who have <u>unrealistic expectations</u> about what benefits a treatment may potentially hold for the child."

(Dell et al., 2008, p. 105)

Constitutional right to refuse or withdraw consent

Clients have the right to refuse or withdraw consent at any time and must be informed of this right

State and federal courts have consistently ruled that it is unfair to allow forced medication without "adequate" procedural guidelines

(Bentley, 1993)

41

Forced treatment remains a most controversial issue

Although a fixture of mental health interventions, involuntary treatment must be <u>*literally*</u> **"option of last resort"**

Opponents of forced treatment assert that it violates one's fundamental human rights, creates distrust of helpers, and undermines the foundation for recovery

(Bassman, 2005)

42

Taking psychotropic medications, having a psychiatric diagnosis, or experiencing major distress, does not by itself provide grounds for being denied the right to refuse or withdraw consent

(Bentley, 1993)

43

Confidentiality

44

Confidentiality vs. privacy

U.S. Constitution guarantees **privacy** rights, not confidentiality, to the individual

Confidentiality is essential to develop trust between client and professional

(Corcoran, Gorin & Moniz, 2005; Hanson & Sheridan, 1997; Millstein, 2000)

45

"Duty to protect"

However, the state can breach confidentiality if it has a rationale for seeing the information, such as the "duty to protect" client or others from harm

(Corcoran, Gorin & Moniz, 2005; Millstein, 2000)

46

Relinquishing confidentiality

Managed care organizations and publicly-funded payers require information from providers about clients'

- psychiatric diagnoses
- treatment procedures
- progress and outcomes

(Bilynsky & Vernaglia, 1998;
Corcoran, Gorin & Moniz, 2005; Millstein, 2000)

47

Ethical mandates

Clients must be informed of, ***and authorize***, all disclosures made to insurers and advised of the potential risks of such disclosure ***before*** disclosure is made

(Reamer, 2001; Millstein, 2000)

48

Part C

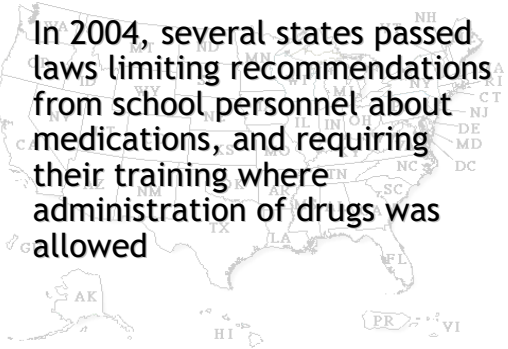
Emerging Legislative Issues

Concerns over medicating children lead to new laws

49

States respond to concerns

In 2004, several states passed laws limiting recommendations from school personnel about medications, and requiring their training where administration of drugs was allowed



2005: U.S. House of Representatives passes *Child Medication Safety Act* (H.R. 1790)

- Bill seeks to *protect children from being forced to take psychotropic drugs as a pre-condition for* attending public school, and intends to restore parental authority over decisions about their children's health

51

Florida limits school's roles F.S. 1006.0625

Public schools cannot require students to receive psychotropic medication as a condition for attending school

"Any medical decision made to address a student's need is a matter between the student, the student's parent, and a competent health care professional chosen by the parent."

52

F.S. 39.407 places limits on medicating children in state custody

Children under state care can be medicated **only** after obtaining ***express and informed consent*** from the parent, or, if parental rights have been terminated, receiving authorization from a judge

Florida and other states now require state agencies to keep list of foster care children on meds—but no register in U.S. tracks health effects of prescriptions on kids

53

Mental health screening debate

Joining the list of issues hotly debated is a 2003 Presidential task force recommendation to screen all school-aged children for mental health problems

(President's New Freedom Commission Report on Mental Health, 2003)

Early detection or pharmaceutical ploy?

Pros: early detection and treatment of disorders

Cons: invalid diagnoses and screening instruments; drug companies attempt to increase market share for psychiatric drugs

55

Part D

Psychotropic Medications and Children:

"First Do No Harm"

56

"Children and adolescents are deemed vulnerable populations, at risk of being harmed by unethical or suboptimal practice and research and are in need of protection."

(Spetie & Arnold, 2007, p. 15)

57

Medications have socio-cultural implications and impact children's identities

(Dell et al, 2008; Floersch, 2003)

58

How do children interpret their taking drugs?

To make sense of everyday medication treatment, children develop "illness narratives"

They may learn to see themselves as "defective" and unable to control their actions

(Dell et al 2008; Floersch, 2003)

59

Medication "messages"

"Better living through chemistry":

Children learn to use drugs to deal with behavioral, emotional, academic and social difficulties

(Dell et al 2008; Floersch, 2003; Jacobs, 2006)

60

Competent practice involves listening and responding to how youths make sense of their medication experience

This requires therapeutic and personal interpretation

(Dell et al 2008; Floersch, 2003; Rappaport & Chubinsky, 2000)

61

In child and adolescent psychiatry, medication decisions are infrequently guided by scientific knowledge, as data on safety and efficacy for most psychotropics in youths remains limited

(Jensen et al., 1999: Matsui et al. 2003; Spetie & Arnold, 2007; Vitiello, 2003)

"The bottom line is that the use of psychiatric medications far exceeds the evidence of safety and effectiveness"

Ronald Brown, Chair,
2006 American Psychological Association (APA)
Working Group on Psychoactive Medications for Children and Adolescents

St Petersburg Times (2007)

63

"Whether one subscribes to the Hippocratic dictum 'first, do no harm' or takes a risk-benefit approach to treatment, it is impossible to discount possible unwanted treatment effects."

(APA Working Group on Psychoactive Medications for Children and Adolescents, 2006, p. 27)

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Part E

Conclusions and Recommendations

65

Non-medical professionals may neither prescribe, dispense, or administer drugs, but they may *discuss* any medication-related issue with their clients, including how their clients can attain their goals with the use or non-use of medications

66

Legal implications

Even professionals who do not prescribe are being called to testify in court about matters that directly concern treatment of clients with psychotropic medications

67

Training for competence

To remain competent in this emerging field requires basic education and training, including critical perspectives on drug use and marketing

68

Professionals working with children receiving psychotropic drugs must take responsibility for their education, and be accountable to clients and society for *their own decisions* about medication-related issues

69

Ethical standards

A practitioner's involvement in referring children for medication, encouraging medication compliance, and monitoring effects, must rest on the *highest* ethical standards

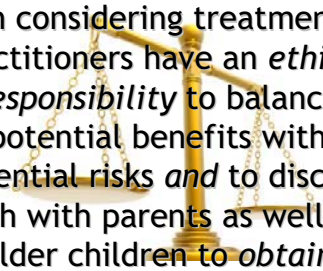
70

Can anyone ethically reassure clients about the safety of psychiatric drugs for children when information is not yet available?

(Littrell, 2003)

71

Balancing risks and benefits



When considering treatments, practitioners have an *ethical responsibility* to balance potential benefits with potential risks *and* to discuss both with parents as well as older children to *obtain informed consent from both*

72

"The potential for benefit from these medications must be balanced against the risks of not only the physical side effects, but also the social stigma, cost, inconvenience, and even family disapproval that can accompany even the most seemingly clear-cut, evidence-based treatment recommendation."

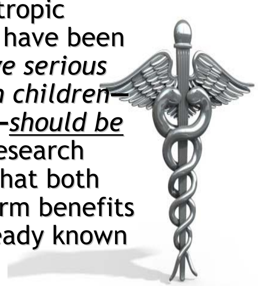
(Dell et al., 2008, p. 99)

Given all the known risks associated with psychotropic drugs, attempting psychosocial therapies to treat problems in children ***prior to considering medication*** is an ***ethical priority***

74

"First do no harm"

Use of psychotropic medications that have been *reported to have serious adverse effects in children—* ***including death—should be halted*** until research demonstrates that both short- and long-term benefits outweigh the already known risks



Avoid psychotropic drug use in young children until

- ✓evidence-based psychosocial interventions have been exhausted
- ✓rationally-anticipated benefits outweigh the likelihood of risks
- ✓parents/guardians are fully informed
- ✓close monitoring is in place

(Vitiello, 2001)

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A Critical Curriculum on Psychotropic Medications

Module 6

The End

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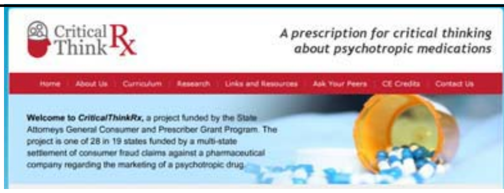

A Critical Curriculum on Psychotropic Medications

Critical ThinkRx

A Critical Curriculum on Psychotropic Medications

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- **Research Coordinator:**
  - Inge Sengelmann, M.S.W.
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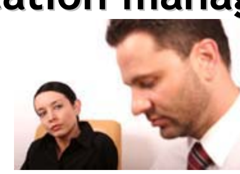
Module 7

Medication Management: *Professional Roles and Best Practices*

Part A

Non-medical roles and medication management



Historical roles of non-medical helpers

To serve as resources for physicians and allied professionals:

- First, giving clients information about their medications;
- Then, identifying obstacles to compliance;
- Later, advocating for clients

(Bentley, Walsh, & Farmer, 2005)

6

A 2001 national survey of clinical and mental health social workers identified 31 possible tasks and activities related to medication

(Bentley, Walsh, & Farmer, 2005)

Survey found some tasks "frequently" performed with clients

- ✓Discussing clients' feelings about taking medications
- ✓Making referrals to physicians
- ✓Discussing how medications may work with other interventions

(Bentley, Walsh, & Farmer, 2005) 8

Tasks "often" performed with clients

- ✓Helping weigh pros and cons of taking medication
- ✓Monitoring clients' compliance with medication
- ✓Discussing medication problems

(Bentley, Walsh, & Farmer, 2005) 9

Tasks "rarely" performed

- ✓Assessing and documenting adverse effects
- ✓Educating about medications
- ✓Suggesting changes in medications to physicians

(Bentley, Walsh, & Farmer, 2005) 10

Assuming roles is complicated by:

- ✓priority of some professional values and ethics, such as client's right to self-determination
- ✓questions about validity of medical model for explaining human distress
- ✓gaps and uncertainties in evidence about medications
- ✓influence of pharmaceutical companies on the entire mental health system

(Walsh, Farmer, Taylor & Bentley, 2003) 11

Increasing demands to regulate medicated clients clash with professional values, creating a "professional dissonance"

(Taylor & Bentley, 2005) 12

Public and professional attitudes

Overall, the public does not embrace psychiatric medications as a solution to children's problems

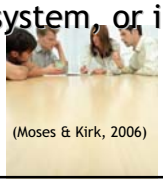
- *70% of adult Americans refuse to use medication for children labeled "oppositional" or "hyperactive"*
- *Only 10% see medication as the most effective component of treatment, and 66% believe it is used as a substitute for other interventions*

(McLeod, et al. 2004)

Practitioners divided

Some find drug treatment of youth helpful or essential

Others find drugs used as a form of social control, misused as a remedy for frustrated parents or overtaxed system, or ineffective



(Moses & Kirk, 2006)

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Helping parents find solutions

When faced with a distressed child, parents may perceive few options in a world where insurers, medical providers and schools pressure them to medicate their children

(McLeod et al., 2004)

16

Unbiased sources of information

Non-medical professionals should serve as "unbiased sources of information" to help parents find the right solutions for their children and to promote alternatives based on critically-evaluated evidence

(Bradley, 2003; Buccino, 2006; McLeod et al., 2004)

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"Vigilant and critically minded"

Non-medical professionals are urged to maintain an ***"informed but critical"*** stance by developing adequate knowledge about the benefits and adverse effects of psychotropic drugs, and remain ***"vigilant, and critically minded"***

(Moses & Kirk, 2006, pp. 220-221)

18

Yet be familiar with basic psychopharmacology

including uses, side effects, dosages, and drug interactions in order to be effective in this complex environment

(Bradley, 2003; Buccino, 2006)

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Part B

Evolving roles in medication management

In today's *collaborative, multi-disciplinary environment*, non-medical practitioners are called upon to play many roles on behalf of clients taking medication

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Physician's Assistant

Traditionally the most common role for professionals legally limited in their scope of work with medications, they

- Help clients follow doctor's recommendations
- Not expected to give advice about decisions involving the prescription

(Bentley & Walsh, 2006)

Consultant

Evaluates client to assess for referral to physicians

Prepares clients to talk with the prescribing physician

Monitors client's subjective experience of medication

Assesses client's ability to pay for expensive drugs

(Bentley & Walsh, 2006)

23

Counselor

Coaches and teaches by providing information and advice about medications

Teaches problem solving, helps identify alternatives, assists in making decisions

(Bentley & Walsh, 2006)

24

Monitor

Helps client observe positive and negative effects of medication

Evaluates client's medication responses, in psychological, interpersonal, and social realms, and effects on self-image and identity

Discusses the monitoring process with clients, families and physicians

(Bentley & Walsh, 2006) 25

Advocate

Presents client's expressed wishes to those in the medical or mental health system

Ideally, has a peer relationship with the physician and participates in all phases of medication decision-making

Possesses knowledge of psychopathology, medications, and related laws and regulations

(Bentley & Walsh, 2006) 26

Teacher

Provides educational materials and other information to clients about:

- The purposes, actions and effects of medications
- Problem-solving regarding medication issues and adverse effects
- Practical suggestions to help clients take medication appropriately

(Bentley & Walsh, 2006) 27

Researcher

Conducts and publishes research in medical and non-medical literature about the full range of psychotropic medication issues

(Bentley & Walsh, 2006) 28

An emerging clinical role: *easing clients off meds*

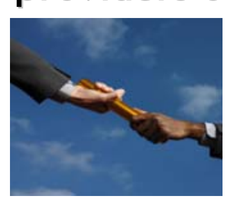
Helping clients withdraw from psychiatric drugs or helping simplify medication regimen

Contingent on practitioner competence and a "rational, person-centered" approach

Guidelines exist for non-medical practitioners to recognize and address discontinuation effects

(Cohen, 2007; Meyers, 2007; Rivas-Vasquez et al., 1999) 29

Effective collaboration with clients, physicians and other providers of care



Traditional

Reflects dominance of medical profession

Characterized by limited, unclear or subservient roles of non-medical professionals

(Bentley & Walsh, 2006, Bronstein, 2003)

Interdisciplinary

Improves services to the client and work satisfaction for professionals

- May not translate in all environments and training in effective models is needed

(Bentley & Walsh, 2006; Bronstein, 2003)

32

Transformational

Enhances the contributions of all members of a team

Assumes non-hierarchical relationships where physicians integrate psychosocial aspects of care and involve non-medical professionals in decision-making

(Bentley & Walsh, 2006; Bronstein, 2003)

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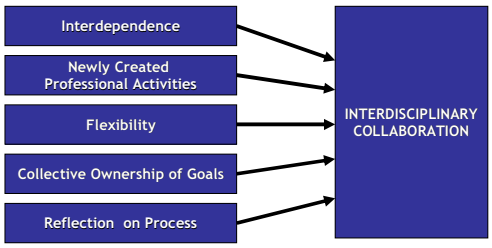
Components of an Interdisciplinary Model



(Bronstein, 2003)

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Elusive qualities of successful collaboration?

- A favorable political and economic climate
- Shared vision, attainable goals
- Open and frequent communication
- Trust, adaptability, respect
- Clear roles but flexibility in assuming them
- Competent, well-trained practitioners
- A leader with strong interpersonal skills

Unfortunately, these qualities may be absent in interdisciplinary settings

(Bentley & Walsh, 2006; Bronstein, 2003)

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Collaboration to enhance client's self-determination

Collaboration between clients, families and professionals as ***partners*** in the helping process is key to respecting the client's right to self-determination

When partnership with other professionals is difficult, focus should be on empowering clients with information so that they make choices in collaboration with prescribers

(Bentley & Walsh, 2006; Cohen, 2007; Slavin, 2004; Weene, 2002)

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Needed—but difficult to accomplish: A balance between…

- ✓the rights of individuals, families and society
- ✓the costs and benefits of using psychotropic medication
- ✓the non-medical practitioner's role in medication management and the legitimacy and uniqueness of other helping professions

(Bentley & Walsh, 2006) 37

Integrating drugs and psychosocial treatment introduces complex dynamics that require attention and management

Managing parallel treatment requires navigating

- ✓the relationships among client, prescriber and therapist
- ✓competing ideologies held by providers

(Bentley & Walsh, 2006; Bradley, 2003) 39

Dimensions of partnership in medication management

Dimension	Traditional model	Partnership model
Goals of medication	Reduce symptoms	Improve quality of life; emphasis on client priorities
Who selects medication	Physician provider	Client collaboration to help define options
Education focus	Increasing compliance	Improving client's ability to manage recovery
Monitoring and evaluating	Physician evaluates clinical status and compliance	Client and providers evaluate range of outcomes and options
Self-care by client	Largely ignored in mental health	Integrated into consultations with client and family
Control and status	Providers control processes and hold status positions	Emphasis on client control, and client's experiences valued
Refusal and reluctance	Seen as related to denial and paranoia	Seen as a right to be respected in all but emergency situations

(Bentley & Walsh, 2006, p. 223) 40

Part C

Tools for Competence

Assessments, Referrals, Court Affidavits and Medication Monitoring

Comprehensive assessments

Understanding the person in the context of their experiences

Working Definition

An ongoing, systematic data collection about a client's functioning

A process of problem selection and specification guided by a person-in-environment, systems orientation

(Jordan & Franklin, 2003)

43

An individualized process

views the whole person in context, including all factors contributing to their distress and strengths, and changes required to improve coping and mastery

- the person's own perspective is key to understand their situation

(Austrian, 2005; Jordan & Franklin, 2003)

44

Elements of assessment

1. ***Exploration*** of client's unique story and facts
2. ***Inferential thinking*** to evaluate meaning of the facts of their story
3. ***Evaluation*** to assess client functioning, strengths and weaknesses in context
4. ***Problem definition*** based on the first three steps and in collaboration with client
5. ***Intervention planning*** based on preceding four steps and in context of environment

(Austrian, 2005; Jordan & Franklin, 2003)

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Mental status examination

☑Appearance, speech, attitude, motor behavior

☑Mood, range and appropriateness of affect

☑Hallucinations, depersonalization, derealization

☑Remote, recent, and immediate memory

☑Level of consciousness, orientation

☑Impulse control

☑Judgment and insight

(Austrian, 2005; Jordan & Franklin, 2003)

46

"Integral" assessment approach requires knowledge of

- the client's experience (the individual viewed subjectively/from within)
- the client's behavior (the client viewed objectively/from without)
- the client's culture (the client's system viewed subjectively/from within)
- the client's social system (the client's system viewed objectively/from without)

(Marquis, 2008; Ingersoll, 2002)

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Referrals

Best practices in referring clients for psychiatric evaluation

Few empirical evaluations

Few researchers have investigated effective referral practices, despite frequency of this activity

Tentative guidelines are offered

(Bentley, Walsh & Farmer, 2005)

49

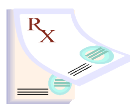
Quality referrals

1. Establish and maintain collaborative relationships with prescribers
2. Share ***up-to-date*** information about medications with clients and families
3. Help clients and families articulate and manage the meaning of medication
4. Prepare clients and families for the medication evaluation
5. Follow up on the referral
6. Manage legal and ethical concerns

(Bentley, Walsh & Farmer, 2005)

50

- Prescription
- Reason for the prescription
- Expectations of benefit
- Probability of benefits
- Alternative treatments available
- Risks of the medication
- Expenses involved (direct/indirect)
- Decision



(Chewning & Sleath, 1996, in Bentley & Walsh, 2006)

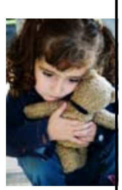
51

A medication evaluation should be requested only if the child's symptoms do not improve or worsen significantly after good psychosocial interventions have been attempted

52

If drugs are considered, all practitioners should evaluate if there is clear evidence of favorable benefit-to-risk ratio

Drugs unapproved for that age group cannot be recommended without special consideration



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Affidavits to judges regarding medication suggestions for children in state care

A recommended checklist

Psychosocial situation and stressors

1. Describe the observed behaviors of concern & who has observed them, when and where
2. Describe past, recent, or chronic stressors in the child's life that may be contributing to any of the observed behaviors

55

Psychosocial assessment

3. Summarize the results of your own assessment of this child's situation: what, in your judgment, could explain how this child is now acting?

4. If the child has been on medication, could the symptoms be adverse effects of the medication? List sources to justify your conclusion

56

Assessment of interventions

5. Describe any previous interventions to address the problems identified in your assessment
6. Describe how these interventions have been evaluated, and their results
7. What other interventions might address this child's problems? To what extent are they available for this child? Why or why not?

57

Medication history

8. List medications (names, dosages, times per day) the child takes now and over the past 2 years
9. Have you participated in evaluating the child's progress on medication? What specific goals have been expected, how has their attainment been evaluated?

58

Medication monitoring, evaluation

10. Have you evaluated for adverse effects, behavioral or other? Have you used any rating scales? How well, <u>in your ***own*** careful, overall judgment</u>, is this child tolerating his or her medication?

59

Informed consent

11. Do you have any information on this child's attitude to the medication?
12. How have the risks and benefits of the medication, as well as those of alternate interventions, been assessed and discussed with parents or caregivers?

60

Future monitoring

13. If the child is placed on medication, describe your specific role in monitoring its effects.
14. What reasons do you have to expect that the proposed medication will be beneficial to this child?

61

Medication monitoring

Attending to anticipated and unanticipated effects

Monitoring helps clients and families

- Keep track of medication effects
- Cope with bothersome effects
- Solve medication-related issues
- Make decisions about treatment using critically-evaluated information
- Prevent medication errors

(Shojania, 2006)

63

Clients may not know

Clients typically fail to link behavioral drug effects to their drug, and may incorrectly believe they are suffering from additional unrelated physiological or psychological symptoms

Do not dismiss unusual effects, watch out for amplified usual effects, and educate clients about risk of "prescribing cascade"

(Otis & King, 2006)

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Formal monitoring essential

Without formal monitoring, only a fraction of drug problems are recognized

Structured medication reviews have been shown to be more valid and improve client's quality of life

(Otis & King, 2006; Greenhill et al, 2004; Jordan et al., 2004; Kalachnik, 1999)

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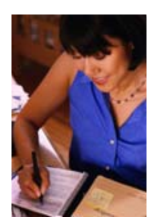
Tools for monitoring

Drug effect checklists — existing or individualized for client's situation *(see checklist handout in website)*

- Use before starting the medication
- Use after starting the medication



(Jordan et al., 2004)

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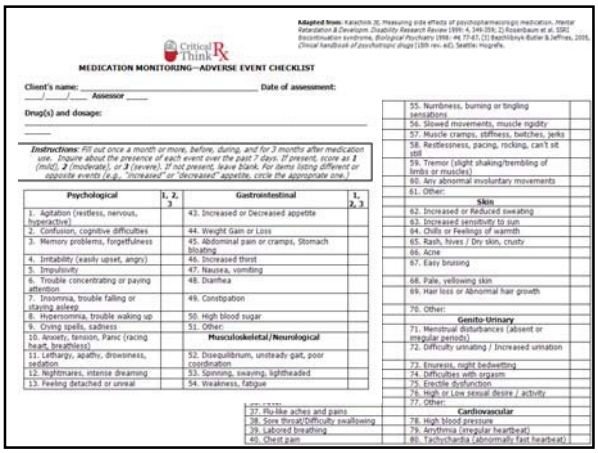

Adapted from: Kalachnik JE. Measuring side effects of psychopharmacologic medication. Mental Retardation & Developm. Disability Research Review 1999; 4: 349-359; 2) Rosenbaum et al. SSRI discontinuation syndrome, Biological Psychiatry 1998; 44: 77-87; 3) Bezchlibnyk-Butler & Jeffries, 2006, Clinical handbook of psychotropic drugs (18th rev. ed). Seattle: Hogrefe.

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MEDICATION MONITORING—ADVERSE EVENT CHECKLIST

Client's name: _____ Date of assessment: ___/___/___ Assessor ____

Drug(s) and dosage:

_____

_____

Instructions: Fill out once a month or more, before, during, and for 3 months after medication use. Inquire about the presence of each event over the past 7 days. If present, score as 1 (mild), 2 (moderate), or 3 (severe). If not present, leave blank. For items listing different or opposite events (e.g., "increased" or "decreased" appetite, circle the appropriate one.)

Psychological	1, 2, 3	Gastrointestinal	1, 2, 3
1. Agitation (restless, nervous, hyperactive)		43. Increased or Decreased appetite	
2. Confusion, cognitive difficulties		44. Weight Gain or Loss	
3. Memory problems, forgetfulness		45. Abdominal pain or cramps, Stomach bloating	
4. Irritability (easily upset, angry)		46. Increased thirst	
5. Impulsivity		47. Nausea, vomiting	
6. Trouble concentrating or paying attention		48. Diarrhea	
7. Insomnia, trouble falling or staying asleep		49. Constipation	
8. Hypersomnia, trouble waking up		50. High blood sugar	
9. Crying spells, sadness		51. Other:	
10. Anxiety, tension, Panic (racing heart, breathless)		**Musculoskeletal/Neurological**	
11. Lethargy, apathy, drowsiness, sedation		52. Disequilibrium, unsteady gait, poor coordination	
12. Nightmares, intense dreaming		53. Spinning, swaying, lightheaded	
13. Feeling detached or unreal		54. Weakness, fatigue	
		55. Numbness, burning or tingling sensations	
		56. Slowed movements, muscle rigidity	
		57. Muscle cramps, stiffness, twitches, jerks	
		58. Restlessness, pacing, rocking, can't sit still	
		59. Tremor (slight shaking/trembling of limbs or muscles)	
		60. Any abnormal involuntary movements	
		61. Other:	
		Skin	
		62. Increased or Reduced sweating	
		63. Increased sensitivity to sun	
		64. Chills or Feelings of warmth	
		65. Rash, hives / Dry skin, crusty	
		66. Acne	
		67. Easy bruising	
		68. Pale, yellowing skin	
		69. Hair loss or Abnormal hair growth	
		70. Other:	
		Genito-Urinary	
		71. Menstrual disturbances (absent or irregular periods)	
		72. Difficulty urinating / Increased urination	
		73. Enuresis, night bedwetting	
		74. Difficulties with orgasm	
		75. Erectile dysfunction	
		76. High or Low sexual desire / activity	
		77. Other:	
		Cardiovascular	
		78. High blood pressure	
		79. Arrhythmia (irregular heartbeat)	
		80. Tachycardia (abnormally fast heartbeat)	

37. Flu-like aches and pains			
38. Sore throat/Difficulty swallowing			
39. Labored breathing			
40. Chest pain			

Systematic monitoring must be carried out to evaluate the wide-ranging effects of medications on behavior, mood, as well as physical and emotional development

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Children should be evaluated for

Emotional development (to examine whether the drug induces or worsens certain problems)

Cognitive development

Physical growth (i.e., weight and height)

Pubertal development (to examine drug effects on course of puberty)

(Greenhill et al., 2003)

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Medication guidelines for child welfare

Medication should only be used as part of a comprehensive treatment plan integrating behavioral interventions

- not used in lieu of other treatments or supports
- based on adequate information, including full biopsychosocial and medical assessment
- resting on informed consent

(Bellonci & Henwood, 2006)

70

With children (*after rock-solid justification for medication has been provided*)

✓adjust doses to a minimum to minimize side effects

✓periodically attempt to take child off medication

✓avoid polypharmacy

✓continually reassess risk-to-benefit ratio

(Bellonci & Henwood, 2006)

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Medical monitoring schedule

Children on psychotropic medications should be seen no less than every three months *at a bare minimum*

FDA guidelines for antidepressants require more frequent monitoring due to risks

(Bellonci & Henwood, 2006)

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Red flags: Additional monitoring concerns

- ☑Children under five years of age
- ☑Children on 2 or more medications
- ☑Children in state custody

(Bellonci & Henwood, 2006)

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"Psychotropic medications for young children should be used only when anticipated benefits outweigh risks. Parents should be fully informed and decisions made only after carefully weighing these factors. Children and adolescents must be carefully monitored and frequently evaluated as the side effects common to some medications are particularly difficult for children."

National Alliance for Mental Illness (NAMI)
Policy Research Institute, 2004

Part D

Conclusions and Recommendations

Beyond biology…

…medications affect the psychological and social concerns of clients, leading non-medical providers to be increasingly involved in medication issues

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What is needed?

Education and training about psychiatric medications for non-medical professionals

Guidelines regarding responsibilities with respect to medication, including dealing with ethical and legal issues such as obligations to report adverse effects

Improved collaboration with *clients as partners* and with medical providers as part of interdisciplinary teams—though key concern remains empowering clients to make their own decisions

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Training on

- ☑ the impact of meanings of medication-taking
- ☑ monitoring clients for adverse effects
- ☑skills in educating clients about risks and benefits of psychotropic medications
- ☑ finding and critically evaluating research on specific medications
- ☑ understanding the strong ideological, economic and political influences on prescription writing in the U.S.

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Research on

- ☑ how medications and psychosocial interventions interact
- ☑ how medications affect child's self-control, self-image, and personal responsibility (autonomy)
- ☑ how medications affect therapeutic relationships

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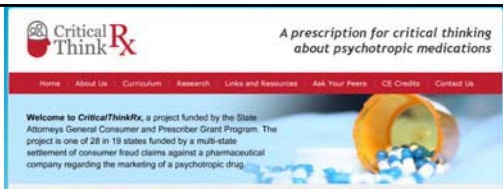

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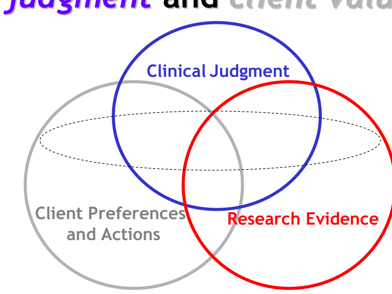
Module 8

Alternatives to Medication: *Evidence-Based Psychosocial Interventions*

Part A

What is Evidence-Based Practice?

The integration of ***best research evidence*** with ***clinical judgment*** and ***client values***



(Gambrill, 2006)

6

A philosophy *and* a process designed to unite research and practice in order to

maximize chances to help clients

minimize harm to clients (in the name of helping)

(Gambrill, 2006)

Deeply participatory

EBP is "anti-authoritarian"—it urges all involved to question claims about what is known *and unknown* about treatments

(Gambrill, 2006)

8

EBP difficulties

- ☑ Threats to business-as-usual
- ☑ Limited training and supervision
- ☑ Concerns about cultural sensitivity
- ☑ Worries that "cook book" methods mask real-world complexity

(Barratt, 2003; Chorpita et al. 2007; Duncan & Miller, 2006)

9

An intervention should have *at least some* unbiased observations or tests supporting its usefulness with particular problems and clients

10

Some criteria for judging an intervention

- ☑ Sound theoretical basis
- ☑ Low risk for harm
- ☑ *Unbiased* research exists
- ☑ Therapist and client concur

11

Available "evidence" no guarantee of usefulness

Published evidence is influenced by funding sources, researcher biases, and conventional wisdom

Statistically significant differences between treatment groups means simply that more clients in one group had some type of response (partial to complete)

(Hoagwood et al. 2001; Ingersoll & Rak, 2006)

12

However, on average, *all major therapies produce equivalent results.*

Clients' improvement may result from *factors common to every therapy*

(Elkins, 2007; Hubble, Duncan, & Miller, 1999) 13

Most improvement has little to do with therapy or technique

Factor	% improvement explained
Client + outside therapy factors	87
Client-therapist alliance	8
Therapist allegiance to model	4
Therapist technique	1

(Hubble, Duncan, & Miller, 1999; Wampold, 2001) 14

Healthy skepticism

"We would do well … to remain optimistically humble on the matter of evidence-based practices in mental health" by accepting that all assumptions are "provisional and reversible"

(Norcross, Beutler & Levant, 2006, p. 11) 15

A clinician's "rubric" for EBP

"Adhere when possible, adapt when necessary, assess along the way"

(Amaya-Jackson & DeRosa, 2007, p. 388) 16

Choosing proper interventions rests on

☑ a clear understanding of the problem from a person-in-situation perspective

☑ addressing the complexity of the problem

☑ a policy of **"First, do no harm"**

Part B

Deconstructing the Diagnosis:

What is this child's problem in behavioral terms?

Bio-psycho-social or bio-bio-bio?

✓Complex problems in living reduced to "brain disorders"

✓Complex life events reduced to "triggers"

✓Medicalization of distress and disability leading to false hopes of "quick fix" via pills

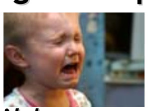
(Read, 2005) 19

We often ignore environmental influences on behavior

☑ Poor parenting, neglect, abuse
☑ Schools' failure to motivate children
☑ Poverty, lack of access to resources
☑ Violence in media, society, neighborhood
☑ Culture's emphasis on instant gratification
☑ Drug culture ("take," not "talk")
☑ Lack of tolerance for differences

(Bentley & Collins, 2006) 20

Children's distress:
"Disorders" or complex adaptations to distressing life experiences?

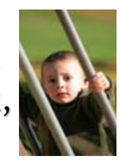


*By seeing children as real persons with their own view of their situation, one ascribes a different **meaning** to their behavior*

(Donovan & McIntyre, 1990) 21

"Understanding" rather than "diagnosing"

A developmental-contextual approach views actions as "communicative": attempts by individuals to cope, adapt, struggle with their life experiences



(Donovan & McIntyre, 1990) 22

Here's a list of feelings and behaviors from DSM-IV-TR criteria of "disorders" commonly diagnosed in children

Note the similarities…

"Attention-Deficit/ Hyperactivity Disorder (ADHD)"

Feels:
- Angry, irritable, frustrated

Acts:
- Fidgets, squirms
- Easily distracted, forgetful (difficulty thinking, concentrating)
- Interrupts others (acts impulsively)
- Acts aggressively

24

"Major Depressive Disorder"

Feels:
- Sad, empty
- Afraid, anxious
- Angry, irritable, frustrated

Acts:
- Eats, sleeps too little (or too much)
- Moves, speaks slowly
- Acts impulsively
- Acts aggressively
- Easily distracted (difficulty thinking, concentrating)

25

"Anxiety Disorder"

Feels:
- Afraid, anxious
- Angry, irritable, frustrated

Acts:
- Cries, throws tantrums
- Freezes, clings
- Fidgets (psychomotor agitation)

26

"Conduct Disorder"

Feels:
- Angry, irritable, frustrated, hostile

Acts:
- Bullies and threatens
- Fights
- Steals, lies
- Runs away
- Destroys property

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"Oppositional Defiant Disorder"

Feels:
- Angry, irritable, frustrated, hostile

Acts:
- Disobedient
- Loses temper
- Argues with adults
- Annoys people
- Refuses to follow rules

28

"Bipolar Disorder"

Feels:
- Alternating sad and euphoric
- Alternating fearful and reckless
- Angry, irritable, frustrated

Acts:
- Easily distracted (difficulty thinking, concentrating)
- Moves, speaks fast (agitation)
- Acts impulsively
- Acts aggressively
- Does not sleep well

29

"Psychotic Disorder"

Feels:
- Sad, empty
- Blunted feelings, expressionless
- Angry, irritable, frustrated
- Afraid, anxious

Acts:
- Apathetic
- Refuses to speak
- Dresses inappropriately
- Cries frequently
- Sees or hears things

30

"Post-Traumatic Stress Disorder"

Feels:
- Sad
- Afraid, anxious
- Angry, irritable, frustrated
- Helpless, guilty, shameful

Acts:
- Agitated, impulsive, re-enacts trauma
- Hypervigilant: distrustful, withdraws
- Dissociated: forgets and can't focus

31

"Reactive Attachment Disorder"

Feels:
- Afraid, anxious
- Angry, irritable, frustrated

Acts:
- Watchful, frozen
- Avoids attachments
- Seeks approval or can't be comforted
- Disregards danger cues

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The common elements

Experiencing negative emotions
(sadness, fear, anger, irritability)

Difficulty controlling oneself
(impulsivity, aggression, inattention)

Seeing self and world negatively
(hopelessness, helplessness, shame, withdrawal)

33

What are we medicating?

Negative emotions leading to disruptive actions—especially under stressful conditions that tax the child's adaptive capacities

(Schore, 1994, 2003)

34

Most commonly medicated

Impulsive aggression

"a key therapeutic target across multiple disorders"

(Jensen et al. 2007, p. 309)

35

DSM's scientific value seriously challenged in all disciplines

- ✓ internal inconsistency in the manual (rejects categorical approach in intro but then lists 300+ categories)
- ✓ overlap between categories leads to "co-morbidity"—with no increase in understanding
- ✓ persistent problems of unreliability, especially with children's diagnoses
- ✓ lack of fit between categories and empirically observed symptom clusters

(Caplan, 1995; Duncan et al. 2007; Maj, 2005; Kirk & Kutchins, 1992, 1994; Jacobs & Cohen, 2004; Mirowsky & Ross, 1990)

36

More recent DSM critiques…

- ✓ more behaviors now seen as “mental disorders” (from 106 in 1952 to 365 in 1994)
- ✓ political lobbying determines inclusion or exclusion of diagnoses
- ✓ all DSM task force members on mood and psychotic disorders tied to drug industry
- ✓ practitioners focus on diagnosis rather than client, losing client’s actual story
- ✓ still no “gold standard” validity—no specific bio-marker linked to *any* disorder

(Andreasen, 2006; Tucker 1998; Charney et al. 2005; Kutchins & Kirk, 1998)

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Critical list of DSM “accomplishments”

- ☑ increases people’s interest to classify psychosocial problems as medical disorders
- ☑ Helps justify more studies to see how many people can fit how many DSM categories (which often change)
- ☑ led to modest increase in diagnostic reliability since 1980
- ☑ now used by most practitioners in main schools of thought—mostly to obtain third-party reimbursement?
- ☑ brings financial revenues to the American Psychiatric Association from sales of DSMs and training materials
- ☑ strengthened psychiatry’s leadership in mental health system (as official definer of mental distress)

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Part C

Empirically-supported psychosocial interventions for children and adolescents

Focus: Trauma, Resilience and Child Welfare

Trauma and early loss

For thousands of children every year, loss and trauma due to disrupted attachments to biological parents result in foster care placements

(Jones Harden, 2004; Racussin et al. 2005)

41

Additional, placement-related traumas

- ✓ Emotional disruption of out-of-home placement
- ✓ Adjusting to a foster care setting
- ✓ Relative instability of foster care
- ✓ High turnover of workers

(Jones Harden, 2004; Racussin et al. 2005)

42

Neurobiology of attachment

Brains develop in a *socially dependent manner*, through secure attachments and *consistent*, *competent* adults attuned to the needs of the child

(Schore, 1994, 2001, 2003; van der Kolk, 2003)

43

Child's "job": to form close, trusting attachments with caregivers

Adolescent's "job": to expand attachments using secure base with caregivers

(Gunnar et al. 2006; Mash & Barkeley, 2006; Moran, 2007; Wolfe & Mash, 2006)

44

Trauma, abuse, and neglect

- ☑ disrupt a child's ability to form secure attachments
- ☑ impair brain development and regulation
- ☑ make self-control difficult
- ☑ alter identity and sense of self

(Bowlby, 1988; Cook et al. 2005; Courtois, 2004; Creeden, 2004; Jones Harden, 2004; van der Kolk, 1994)

45

Resilience

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

(Agaibi & Wilson, 2005, Masten et al. 1990; Schofield & Beek, 2005)

46

- ✓Risk and protective factors in the foster child, foster-families, agencies, and birth family interact to produce upward or downward spirals

- ✓Understanding resilience helps create interventions that produce positive turning points in children's lives

(Schofield & Beek, 2005)

47

Three key elements

1. Secure base: *is child strengthening sense of security and able to use foster-parents as a secure base?*
2. Sense of permanence: *is placement stable and foster-parents offering family membership?*
3. Social functioning: *is child functioning well in school, with peers?*

(Schofield & Beek, 2005)

48

Treatment goals

✓Enhance sense of personal control and self-efficacy
✓Maintain adequate level of functioning
✓Increase ability to master, rather than avoid, experiences that trigger intrusive re-experiencing, numbing, and hyper-arousal

(Ford et al. 2005; Kinniburgh et al. 2005) 49

What could help?

Activating child's internal reparative mechanisms through *dyadic interventions* and creating secure attachments

– dyadic therapy mobilizes the completion of interrupted biological and emotional developmental processes

(Amaya-Jackson & DeRosa, 2007; Courtois, 2004; Ford et al. 2005; Pearlman & Courtois, 2005) 50

A sensorimotor approach

Children's internal stimuli, can trigger dysregulated arousal, causing emotions to escalate

– Integration of cognitive, emotional and sensorimotor levels is crucial for recovery

(Ogden, 2006) 51

Why would this help?

Child develops the ability to take in, sort out, process, and interrelate information from the environment — leading to self-organization of internal states and self-control of behavior

(DeGangi, 2000; Kinniburgh et al. 2005; Schore, 2003; van der Kolk, 2006) 52

How would this help?

By enhancing children's:

✓social skills
✓ability to understand and express feelings
✓ability to cope with anger and distress
✓ability to problem-solve and think helpful thoughts
✓skills to self-direct and create goals

(Bloomquist, 1996; Kinniburgh et al. 2005) 53

Alternatives to medication

☑ Consistent, structured, <u>supportive</u> adult supervision
☑ Opportunities for self-expression and physical activity, to give children a sense of mastery over their minds and bodies

(DeGangi, 200; Faust & Katchen, 2004) 54

Helpful activities

- ☑ Teaching problem-solving and pro-social skills
- ☑ Modeling appropriate behaviors
- ☑ Teaching self-management
- ☑ Helping children learn to comply and follow rules

(DeGangi, 2000; Faust & Katchen, 2004) 55

Helpful interactions

- ☑ Desensitizing hyper-reactivity
- ☑ Promoting self-calming and modulation of arousal states
- ☑ Organizing sustained attention
- ☑ Facilitating organized, purposeful activity

(DeGangi, 2000)

Expected outcomes

Children learn to develop appropriate responses, self-organization and control, which in turns leads to

MASTERY AND SELF-ESTEEM

(Kinniburgh et al. 2005) 57

Many treatment alternatives

Symptom-focused: Behavioral, cognitive-behavioral, and interpersonal therapies, attachment-based therapies, trauma-focused therapies

System-focused: Treatment foster care (TFC), Multi-dimensional treatment foster care (MTFC)

(Farmer et al. 2004; Racussin et al. 2005)

Focus: Dysregulated "moods"

"Depression" and "Anxiety"

60

The New York Times

Talk Therapy Pivotal for Depressed Youth

February 6, 2007

In Rigorous Test, Talk Therapy Works for Panic Disorder

By BENEDICT CAREY

61

Link to child maltreatment

Abuse leads to "hypervigilance" to threat, resulting in anxiety and hopelessness

Neglect results in dysregulated "moods"

(Greenwald, 2000; Lee & Hoaken, 2007)

62

"Traumatized children tend to communicate what has happened to them … by responding to the world as a dangerous place by activating neurobiologic systems geared for survival, even when objectively they are safe"

(van der Kolk, 2003, p. 309)

Therapy or no therapy?

Some 30-40% recover without intervention

Approximately 50% of treated patients improve within 8 weeks

A friendly sympathetic attitude and encouragement are key

(Roth & Fonagy, 1996)

64

Consensus strongly favors cognitive-behavioral therapy (CBT) as **first-line** treatment *above* medications

(APA Working Group, 2006; March, 1995; Roth & Fonagy, 1996; Velting et al. 2004)

65

Other effective interventions

1. Interpersonal psychotherapy
2. Psychodynamic psychotherapy
3. Exposure-based contingency management
4. Problem-solving and coping-skills training

(APA Working Group, 2006; Roth & Fonagy, 1996)

66

Patient preference

When given a choice, patients express a preference for psychosocial interventions over medications

(APA Working Group, 2006)

67

"Bipolar Disorder" and "Schizophrenia"

68

Very rare in children (~1%)

Diagnosis controversial:

- no laboratory "test"
- "symptoms" may be manifestations of ordinary developmental differences

(Birmaher, 2003; Birmaher & Axelson, 2006; Cepeda, 2007; Correll et al. 2005; Danielson et al. 2004; Irwin, 2004; Findling, Boorady & Sporn, 2007; Roth & Fonagy, 1996)

69

High risk of over-diagnosis

NIMH Review: 95% of 1500 children referred for high clinical suspicion of childhood-onset schizophrenia did not meet DSM criteria after careful inpatient observation *off all medications*

No evidence that they would have developed psychosis if left untreated

(Shaw & Rapoport, 2006)

70

Link to child maltreatment

Child abuse and neglect considered a causal factor for psychosis and "schizophrenia"

- Content and severity of psychotic symptoms related to severity of past abuse

(Cepeda, 2007; Morrison et al. 2005; Read & Ross, 2003; Read et al. 2004, 2005)

71

Many children improve when treated with family-based psychosocial interventions, *even without medications*

- High rates of "relapse" observed on medication

(Birmaher, 2003; Birmaher & Axelson, 2006; Cepeda, 2007; Correll et al. 2005; Danielson et al. 2004; Findling et al. 2007; Irwin, 2004; Roth & Fonagy, 1996)

72

Effective psychosocial treatments

Child- and Family-Focused CBT combined with interpersonal and "social rhythm" therapy to stabilize mood, activities and sleep

Community support and social acceptance through day programs and sports/cultural activities

(Findling et al. 2007)

73

Who recovers and why?

Psychiatric literature is mostly silent about the characteristics of people who fully recover from psychosis and how and why they do so

(Siebert, 2000)

74

Focus: Disruptive behaviors

Disruptive behaviors: the most frequent reason for referral of children to mental health services

(Brestan & Eyberg, 1998; Butler & Eyberg, 2006)

76

For disruptive behaviors and conduct "disorders"

☑ **Family-based behavioral interventions**

(APA Working Group, 2006; Brestan & Eyberg, 1998; Diamond & Josephson, 2005; Kazdin, 2005, 2000, 2000b; Kazdin & Weisz, 2003; Thomas, 2006)

The New York Times (2006, December 22)

TROUBLED CHILDREN

Parenting as Therapy for Child's Mental Disorders

Fabrizio Costantini for The New York Times

TJ Van de Wal's attention deficit problems have improved in response to parenting techniques, his mother Dawn, right, said.

78

Effective parenting: the most powerful way to reduce child and adolescent problem behaviors

(Caspe & Lopez, 2006; Johnson et al. 2005; Kumpfer et al. 2003) 79

Strongest evidence base

1. Parent management training (PMT)
2. Problem-solving skills training (PSST)
3. Brief strategic family therapy (BSFT)
4. Functional family therapy (FFT)

(Brestan & Eyberg, 1998; Butler & Eyberg, 2006; Farley et al. 2005; Kazdin, 2003; Kazdin & Whitley, 2003; Springer 2006; Thomas, 2006) 80

Goals of parent training

☑ Promote parent competencies & strengthen parent-child bonds

☑ Increase consistency, predictability & fairness of parents

☑ Produce behavior change in children

(Kazdin, 2003; McCart et al. 2006; Webster-Stratton & Reid, 2003) 81

"Problem" children or "problem" adults?

Coercive parenting was the only factor linked to children's failure to improve their conduct after family treatment

(Webster-Stratton, Reid & Hammond, 2001) 82

Maltreatment consistently linked to aggressive behaviors

☑ History of trauma virtually *universal* in youth with conduct "disorders"

(Greenwald, 2000; Lee & Hoaken, 2007) 83

Children in foster care

✓have socio-emotional problems ***3 to 10 times more often*** than other kids

✓Coercive interactions only result in escalation of aggressive behaviors

(Nilsen, 2007) 84

Parent-training in child welfare

Promising programs exist to train biological and foster parents

Goal is to break the cycle of coercive parenting and child oppositional behavior

(Barth et al. 2005; Nilsen, 2007)

85

"ADHD"

Large evidence base exists for behavioral interventions, incl. parent training, social skills training, and school-based services

- Results equivalent to stimulant medications ***without the health risks***

(APA Working Group; Chronis et al. 2004, 2006)

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Focus: Mentoring

Children's development depends upon reciprocal activity with others with whom they have a strong and lasting bond

(Jones Harden, 2004; Rhodes et al. 2006)

Mentorship

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

(Dallos & Comley-Ross, 2005; Rhodes et al. 2006)

Significant effects

Meta-analysis of 55 studies found significant effects of mentoring programs

- Community-based programs more effective than school-based programs

(DuBois & Silverthorn, 2005)

90

Mentoring in foster care

Survey of 29 programs found mentoring provides a bridge to employment and higher education, helps with transitional problem-solving

(Mech, Pryde & Rycraft, 1995)

91

Common factors for success

- ☑ Frequent contacts
- ☑ Emotional closeness (attunement)
- ☑ Longer duration
- ☑ Structured activities
- ☑ Ongoing training for mentors

(DuBois & Silverthorn, 2005; Gilligan, 1999; Rhodes et al. 2006) 92

Mentors enhance resilience

Sensitive mentoring increased self-esteem and well-being, reduced aggression and opened new relationships beyond care system

- *prevents negative outcomes as youth leave foster care*

(DuBois & Silverthorn, 2005; Gilligan, 1999; Lemon et al. 2006; Legault et al. 2005; Rhodes et al. 1999, 2006; Schofield & Beek, 2005) 93

Reduces violence

"Having someone to count on when needed" softened the impact of trauma and reduced likelihood of youth engaging in violent offenses

(Maschi, 2006) 94

Part D

Conclusions and Recommendations

Medicalized approach to distress and disability pathologizes children's behaviors and ignores the context of their experiences

- "Understanding" rather than "diagnosing" changes the meaning of those behaviors and can lead to more helpful interventions

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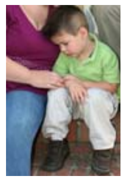
Abuse, neglect and trauma disrupt secure attachment and impair the child's ability to self-regulate

- "Repair" occurs through the formation of secure attachments, rather than by medication



Irritability, impulsivity and aggression appear in criteria for most DSM diagnostic labels used on children

- We are medicating children's negative emotions and immature self-control

98

Growing consensus

Just Say 'No' to Drugs as a First Treatment for Child Problems

(Duncan, Sparks, Murphy, & Miller, 2007)

99

Attempt psychosocial interventions *before* initiating medication

Ample evidence supports their use as effective first-line options for children's behavioral problems, *with no apparent risk of medical harm*

100

Fundamental issues of efficacy and safety of psychotropic medications in children remain unresolved

Therefore, medicating children should be avoided

101

A Critical Curriculum on Psychotropic Medications

Module 8

The End

Critical Think Rx
www.CriticalThinkRx.org

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COMPLETE CURRICULUM REFERENCES

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Facing Foster Care in Alaska

Mental Health Services and Foster Care

Facing Foster Care in Alaska
Mental Health Services

Our Mission is to improve the foster care system through sharing our experiences, supporting and educating youth and social services and implementing positive change in society as a whole.

In 2003, a group of dedicated foster care youth and alumni from across Alaska came together to share their issues and form a Youth Advisory Board. In 2004, the group adopted the name Facing Foster Care in Alaska (FFCA). FFCA is dedicated to improving the lives of children and youth in foster care through developing and sustaining a statewide organization that will continue to work towards supporting foster youth and improving the foster care system. FFCA members are dedicated to advocating for improvements in the areas of education, mental health, permanency, disproportionality, independent living, and the overall well-being of children and youth in Alaska's foster care system.

Since their inception, the members of FFCA have been speaking out about mental health and treatment services of children and youth in foster care, and offering alternative solutions. With overwhelming feedback from youth and alumni of foster care regarding the issues of mental health and treatment services, the members FFCA came together in November of 2008 to brainstorm ideas and create possible solutions or alternatives to traditional treatment. This document encompasses their ideas and gives insight into what youth and alumni across Alaska believe is the best way to deal with the issues they face when being placed in foster care.

The content of this document reflects only the opinions and ideas of Facing Foster Care in Alaska members, and should not be viewed as the opinions or ideas from any state or private agencies.

Facing Foster Care in Alaska
Mental Health Services

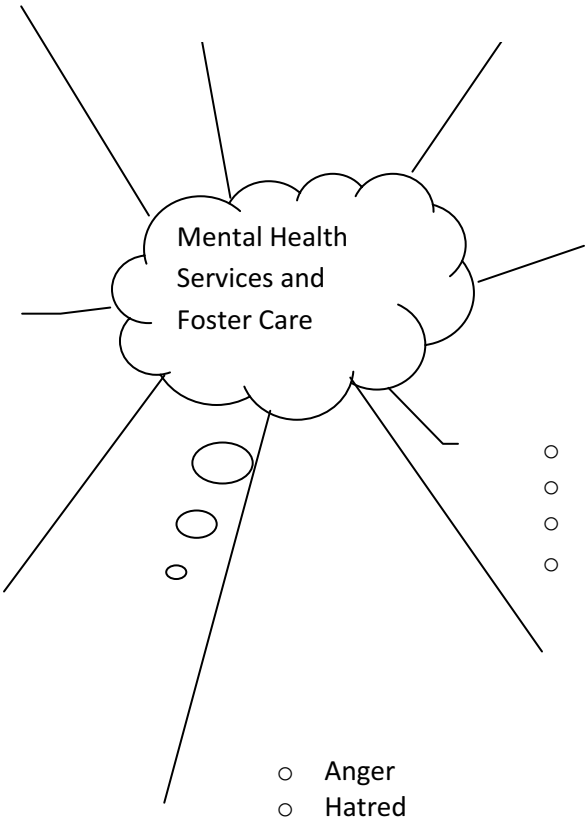
- Uncomfortable
- Hard to explain to peers
- Bull shit
- Miscommunication
- Too young for drugs

- confusion
- false accusations
- loss of personality
- breaks up families
- loss of support systems (friends)
- counseling

- Worse Afterwards
- Groups NA, AA
- No Advocating What-so-ever
- Subjective Hearing
- Subjective opinion thinking

- Addiction
- Flashbacks
- Suicides
- Runaways
- Depression

- Lies & deception
- Untrustworthy
- Messes with life
- Makes you worse
- Hard to cope



- Not enough research
- Guinea pigs
- Other alternatives
- Treatment center-last

- Psycho Roommates
- Stereotypes
- No Choice
- No Mutual Support
- Constant Labeling
- Judging

- Overrated
- No reason
- Forced
- Negative effects

- More money
- Criticism
- Therapy
- Friends-Shitty School
- Med. Adjustment

- Over medicating
- Disorders
- Prolific diagnosis
- North star
- Embarrassment
- Switching SW
- Taking away childhood

- Constant changes w/treatment plan
- Bad communication
- Comic strip story time
- Abandonment
- Hazard-don't really know side affects

- Anger
- Hatred
- Not confidential
- Exhaustion
- Diagnosis
- No independence
- No freedom

- Misdiagnosing
- Treatment facilities
- Brain washing
- Manipulation
- Disconnected
- In hell
- Ashamed

- Hard to remember for busy schedule
- misconceptions
- Normality's-shouldn't we be like this?
- Test subjects
- Profit centers
- Rehab centers
- Unreasonable delays of service

Youth and alumni were asked to share thoughts and ideas around what came to mind when they heard the words, "Mental Health" and "Treatment Services."

Alternatives and Possible Solutions

The decreased use of psychiatric medications

In their 2008 Policy Agenda, FFCA members called for Decreased use of Psychotropic Medication for Alaska's foster youth. Many of Alaska's youth and alumni complain about being prescribed psychotropic medications after entering the foster care system for symptoms of depression, anxiety, trauma, attachment issues, and misbehavior. The youth and alumni of FFCA feel that these are all normal symptoms of child maltreatment and dealing with all that comes out of being placed in foster care. There has been a national focus on the use of psychotropic medications being over-prescribed for children and youth in foster care. FFCA members have also complained about side-effects caused by these medications resulting in a decreased ability to focus on their education as well as function in everyday society. The youth and alumni of FFCA would like to see that the prescription of psychotropic medications for Alaska's foster children and youth is decreased and reviewed more closely.

The right to be informed

Many of Alaska's foster children and youth don't know their rights in regards to mental health and treatment services. The members of FFCA believe that service providers should inform children and youth in foster care about their rights in regards to their treatment plan. During the November 2008 FFCA retreat, one member commented that he did know his rights, but if he did refuse medication he would be placed in North Star. FFCA members would like to see that all children and youth in foster care are informed of their rights and the repercussions if they choose not to comply with their treatment plan.

Building Relationships

The members of FFCA believe that one of the best ways to deal with the emotional issues they face when entering foster care is through building and maintaining healthy relationships with family, friends, and permanent connections with a caring adult. The bulleted list below outlines the ideas FFCA members came up with regarding relationships.

- Trust Building opportunities
- Freedom
- Personal time
- Family Relationships/connections/visits
- Mentors
- Having good listeners
- Supporting dreams/hopes
- Non-judgmental relationships
- Permanent connection
- Getting to know us
- Talking/venting
- Acknowledgment
- Praise
- Constant affective communication
- Not relishing diagnosis/medication
- Cut out the unnecessary
- Understanding
- More homes
- Preparation for the real world
- Being placed in a stable understating home
- Extra time with peers
- Keeping siblings together
- Listen to what we have to say
- Pay attention to our needs
- We need more communication w/family & friends
- Do not separate youth and children
- If meds are absolutely necessary inform us what there for and what the side effects are
- Effective communication with social workers and GAL's

Creating a plan with the client/self determination

Over the years, FFCA members have continuously complained about treatment plans being written for them rather than with them. Many of the youth and alumni speak out about how they have no idea what's in their treatment plan or case plan. The members of FFCA believe that they cannot affectively work on their treatment plan or case plan if they do not know what is in it or don't have a say in the process of creating it. FFCA would like to see that service providers are working with children and youth to develop a plan that outlines what the children and youth feel they need to work on in order to become productive members of society.

The right to be "Normal"

Many of Alaska's foster children and youth complain about standing out among their peers and not being able to participate in the same activities as other young people. They say they are constantly going to appointments for counseling, medication adjustments, group therapy, family therapy, ect. The members of FFCA believe that the best treatment for depression, anxiety, attachment issues, and other behaviors that are often diagnosed in foster children and youth, can be treated by giving them the opportunity to be involved with school, community, and family events. The bulleted lists below outlines the ideas that FFCA members came up with as alternatives to the various therapy and other treatment related appointments.

Extra Curricular Activities

- Sports/Clubs
- Banking/financial skills
- Therapeutic activities
- Massage
- Journaling
- Self advocacy/empowerment
- No drugs
- Foster home with a pet
- FFCA
- Service Projects

Self Expression

- Star watching
- Poetry
- Music
- Art
- Cooking
- Life skills
- Freedom/choice

Definitions (According to FFCA)

Youth- A young person in foster care

Alumni- A person who was in foster care at some point during their life

For more information about Facing Foster Care in Alaska please visit

http://www.alaskacasa.org/facing_foster_care_in_alaska.htm

or

http://www.myspace.com/ffca

This document was drafted by FFCA President Amanda Metivier using the feedback from the FFCA members that attended that November 2008 FFCA retreat in Anchorage. For questions regarding the content of this document please contact Amanda Metivier at facing_fostercare@yahoo.com or call 230-8237.

James B. Gottstein, Esq.

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jg@touchngo.com
907-274-7686

Curriculum Vitae

(September 12, 2008)

Experience:

1985-Present:	Owner - Law Offices of James B. Gottstein
1995-Present:	CEO - Touch N' Go Systems, Inc.
2002-Present:	President/Chief Executive Officer (since 2005) & Board Member, Law Project for Psychiatric Rights (PsychRights®)
2004-Present:	Treasurer & Board Member of the Board of Directors, National Association of Rights Protections and Advocacy (NARPA)
2005-Present:	Board Member, International Center for the Study of Psychiatry and Psychology (ICSPP)
2002-Present	Board Member, Peer Properties, Inc., (currently President).
1991-Present:	Board Member, The Gottstein Family Foundation
2003-2007	President & Board Member, CHOICES, Inc.
2003-2007	President & Board Member, Soteria-Alaska, Inc.
2003-2005:	Board of Directors - Alaska World Affairs Council
1998-2004:	Member - Alaska Mental Health Board
1998-2002:	Board of Directors - Alaska Mental Health Consumer Web
1986-1996:	Board of Directors - Mental Health Consumers of Alaska
1983-1985:	Staff Attorney - Carr-Gottstein Inc.
1982-1983:	Associate Attorney - Delaney, Wiles, Hayes, Reitman and Brubaker
1980-1982:	Partner - Goldberg and Gottstein
1978-1980:	Associate Attorney - Robert M. Goldberg and Associates

Bar Memberships

1994:	United States Supreme Court
1978:	Alaska
1978:	United States District Court, District of Alaska
1978:	United States Court of Appeals; Ninth Circuit

Education:

1978 (Class of '77):	J.D., Harvard Law School
1974:	B.S., Business Administration with Honors (Finance), University of Oregon.

Publications:

- Involuntary Commitment and Forced Psychiatric Drugging In the Trial Courts: Rights Violations as a Matter of Course, 25 *Alaska Law Review* 51 (2008).

- How the Legal System Can Help Create a Recovery Culture in Mental Health Systems, contributed chapter in R. Halgin, *Clashing Views in Abnormal Psychology*, 5th Ed., McGraw Hill, New York, New York, (2008): 17-29.

- Rights and Alternatives: Enforcing legal rights as a mechanism for creating non-medical model alternatives, contributed chapter in Beyond Psychiatry (2007), P. Lehmann & P. Stastny, Eds., 308-17.

- Psychiatrists' Failure to Inform: Is There Substantial Financial Exposure? James B. Gottstein, Esq., JD, Ethical Human Psychology and Psychiatry, Volume 9, Number 2, 2007.

Presentations

- "Advocacy and the Transformation Triangle," International Network Towards Alternatives in Recovery (INTAR) conference on International Recovery Perspectives: Action on Alternatives, University of Toronto, June 6, 2008, Toronto, Canada.

- Panel member Soteria--The Proven Model for Recovery Communities, "The Development of Soteria-Alaska,"INTAR conference on International Recovery Perspectives: Action on Alternatives, University of Toronto, June 5, 2008, Toronto, Canada.

- "Over-Prescription of Psychiatric Drugs: Changing an Irrational Policy," Contemporary Social Policy and Change, University Alaska Anchorage, April 2008.

- Roundtable, Program in Psychiatry and the Law @ BIDMC Psychiatry of Harvard Medical School, October 24, 2007, Boston, Massachusetts.

- "Forced Psychiatric Drugging: A Misguided Atrocity," Hampshire College, Massachusetts, October 22, 2007.

- "The Transformation Triangle," Region Ten Consumer Advisory Council 2nd Annual Conference, Charlottesville, Virginia, October 17, 2007.

- "The Psychiatric Drugging of America's Children: Legal Rights of Children and Parents," ICSPP Annual Conference, October 14, 2007.

- *Myers*, *Wetherhorn* & More: Litigating for Consumer Driven Services," Mental Helath Consumer and Family Education & LeadershipConference, May 17, 2007.

- Psychiatric Drugs in America: Who's Crazy? Or Through the DSM Looking Glass, ANT A655 Advanced Medical Anthropology, March 26, 2008, University of Alaska Anchorage.

- Strategic Litigation to Achieve Meaningful Change: The *Myers* Case, Alaska and a National Initiative, National Association of Rights Protection and Advocacy (NARPA) annual conference, November 16, 2006, Baltimore, Maryland.

- "The Public Mental Health System, University of Alaska Anchorage, November 2, 2006.

- The Public Mental Health System: Analysis and Suggestions for Improvement, Alaska Pacif University, October 26, 2006, Anchorage, Alaska.

- A Coordinated Campaign To Successfully Change the Mental Illness System, ICSPP annual conference, October 9, 2006, October 9, 2006.

- Panel member: "Free Your Mind A discussion about psychiatric rights and how we value people in our communities," David A. Clarke School of Law, Washington, DC, October 6, 2006.

- "CHOICES, Inc., Soteria-Alaska, & Peer Properties: Agents for Positive Change,"Harvard & Yale Clubs, April 4, 2006, Anchorage, Alaska.

- "CHOICES, Inc., Soteria-Alaska, & Peer Properties: Agents for Positive Change," Alaska Mental Health Consumer Web, March 31, 2006, Anchorage, Alaska.

- "CHOICES, Inc., Soteria-Alaska, & Peer Properties: Agents for Positive Change," NAMI-Anchorage Annual Meeting, March 16, 2006.

- "Multi-faceted Grassroots Efforts to Bring About Meaningful Change to Alaska's Mental Health Program," National Association of Rights Protection and Advocacy (NARPA) annual conference, November 19, 2005, Hartford, Connecticut.

- "Involuntary Mental Health 'Treatment:' Utilizing Valid Scientific Information and Client Views to Win Cases," Massaschusetts, Mental Health Law Unit Continuing Legal Education for the Committee for Public Counsel Services, November, 2005, Boston, Massachusetts.

- Member of Panel Discussion of Involuntary Treatment in the U.S., International Society for the Psychological Treatment of Schizophrenia and Other Psychoses, November, 2005, Boston, Massachusetts.

- "Grass Roots, Multi-Organizational Efforts in Support of Human Rights in Mental Illness," International Center for the Study of Psychiatry and Psychology, Flushing, NY, October 8, 2005.

- "Involuntary Commitment and Medication in Alaska: or Just Because I'm Paranoid Doesn't Mean They Aren't After Me," SWK 643 Human Diversity and Special Populations, University of Alaska Anchorage, September 19, 2005.

- "Human Rights in Mental Health: Let's Do It," MindFreedom Action Conference, April 30, 2005, Washington, DC.

- "Forced Psychiatric Drugging in Alaska," presented to the Health Law Section of the Alaska Bar Association, February 3, 2005.

- "PsychRights' Legal Campaign Against Forced Drugging and How You Can Participate," International Center for the Study of Psychiatry and Psychology, Flushing, New York, October 10, 2004.

- "Involuntary Commitment in Alaska and Beyond," Alaska Libertarian State Convention, April 24, 2004, Anchorage, Alaska.

- "The Law Project for Psychiatric Rights: Progress and Directions," for the National Rights Protection and Advocacy (NARPA) Conference, November 23, 2003, Austin, Texas.

- Co-presented Alaska Mental Health Board's FY 2005 Request for Recommendations to the Alaska Mental Health Trust Authority, August, 2003.

- Alaska Mental Health Board Budget Committee's "Mental Health Budget Summit," parts 1 and 2 on March 8, 2003, in Juneau Alaska and April 11-12, 2003 in Anchorage, Alaska, respectively.

- "Unwarranted Court Ordered Medication: A Call to Action," for the National Rights Protection and Advocacy (NARPA) Conference (off-agenda), November, 2002, Portland, Oregon.

- Board Training at the Family and Consumer Conference, May 2, 2002, in Anchorage, Alaska.

- "Real Estate in the Land of the Midnight Sun," presented to the International Real Estate Society's International Congress, July 27, 2001, Girdwood, Alaska.

- "Protecting Your Privacy On-Line: Privacy, Threats, and Countermeasures," co-presented with Lara Baker, September 7, 2001, in Anchorage, Alaska.

- Board Training at the Family and Consumer Conference, April 13, 2001, in Anchorage, Alaska.

- Alaska Mental Health Board's Program and Evaluation Committee's Report on the Alaska Psychiatric Institute, presented as chair of the committee to the full board, February 16, 2000, Fairbanks, Alaska.

- Internet Strategies for the Paralegal in Alaska: A paralegals guide to the information super-highway," for the Institute for Paralegal Education, November 1998, in Anchorage, Alaska.

- "Grant Writing, 1, 2, 3," various times 1998-2002, in Anchorage, Alaska.

- "Web Page Design," Alaska Mental Health Consumer Web various times, 1998-2002.

- "Lawyers and the Internet," October 23, 1995, in Anchorage, Alaska.

- Many public presentations on the Alaska Mental Health Trust Lands litigation and proposed settlements, including radio and television appearances and testimony to legislative committees, 1986-1994

Chambers of
Dana Fabe
Chief Justice

Supreme Court
State of Alaska

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June 28, 2007

James Gottstein
Law Office of James B Gottstein
406 G St., Suite 206
Anchorage, AK 99501

Dear Mr. Gottstein:

Thank you for agreeing to serve on the Probate Rules Subcommittee on Involuntary Commitments and the Involuntary Administration of Psychotropic Medication. We look forward to receiving your help and expertise in revising the procedural rules that govern these difficult and important cases. Judge Morgan Christen will be chairing the subcommittee, and her staff will be contacting you to schedule the first meeting. Again, thank you for your assistance in this important work.

Sincerely,

Dana Fabe
Chief Justice

DF:jmh

cc: Stephanie Cole, Administrative Director
Judge Morgan Christen
Doug Wooliver, Administrative Attorney

The Washington Post

Debate Over Drugs For ADHD Reignites

Long-Term Benefit For Children at Issue

By Shankar Vedantam
Washington Post Staff Writer
Friday, March 27, 2009; A01

New data from a large federal study have reignited a debate over the effectiveness of long-term drug treatment of children with hyperactivity or attention-deficit disorder, and have drawn accusations that some members of the research team have sought to play down evidence that medications do little good beyond 24 months.

The study also indicated that long-term use of the drugs can stunt children's growth.

The latest data paint a very different picture than the study's positive initial results, reported in 1999.

One principal scientist in the study, psychologist William Pelham, said that the most obvious interpretation of the data is that the medications are useful in the short term but ineffective over longer periods but added that his colleagues had repeatedly sought to explain away evidence that challenged the long-term usefulness of medication. When their explanations failed to hold up, they reached for new ones, Pelham said.

"The stance the group took in the first paper was so strong that the people are embarrassed to say they were wrong and we led the whole field astray," said Pelham, of the State University of New York at Buffalo. Pelham said the drugs, including Adderall and Concerta, are among the medications most frequently prescribed for American children, adding: "If 5 percent of families in the country are giving a medication to their children, and they don't realize it does not have long-term benefits but might have long-term risks, why should they not be told?"

The disagreement has produced a range of views among the researchers about how to accurately present the results to the public. One e-mail noted that an academic review of the group's work, called the Multimodal Treatment Study of Children With ADHD (MTA), asked why the researchers were "bending over backward" to play down negative implications for drug therapy.

Peter Jensen, one of Pelham's fellow researchers, responded that Pelham was biased against the use of drugs and was substituting his personal opinion for science.

Jensen said Pelham was the only member of the team of researchers who took away "the silly message" that the study raised questions about the long-term utility of drugs, but interviews and e-mails show that Pelham was not alone.

The MTA was designed to test whether children diagnosed with attention-deficit hyperactivity disorder, or ADHD, do better when treated with drugs, with drugs plus talk therapy, with talk therapy alone or with routine medical care alone. Children with the disorder have trouble paying attention, are restless and hyperactive, and are sometimes disruptive in school.

The initial 14-month analysis published in 1999 randomly assigned children to one of four treatment options and showed clearly that those treated with medication did much better than those who got only talk therapy or routine care. The drugs' manufacturers distributed thousands of reprints of the article to physicians at a

time when diagnoses of ADHD were spiraling upward. Because children given drugs alone appeared to do about as well as those treated with both drugs and talk therapy, the study skewed treatment in the direction of medication.

In a second phase of the study, the researchers followed the children and compared how they fared, but researchers no longer randomly assigned them to the various treatment options, making this phase less scientifically rigorous.

In August 2007, the MTA researchers reported the first follow-up data, which by then no longer showed differences in behavior between children who were medicated and those who were not. But the data did show that children who took the drugs for 36 months were about an inch shorter and six pounds lighter than those who did not.

A news release issued by the National Institute of Mental Health (NIMH) at the time, however, presented the results in a more favorable light. The release, dated July 20, 2007, was titled "Improvement Following ADHD Treatment Sustained in Most Children." The release noted that the initial advantages of drug treatment were no longer evident, but it quoted Jensen as saying this did not mean that long-term drug therapy was ineffective.

Jensen said, "We were struck by the remarkable improvement in symptoms and functioning across all treatment groups." And rather than saying the growth of children on medication was stunted, the release said children who were not on medication "grew somewhat larger."

As the MTA study continued to find smaller and smaller behavioral differences between children who were medicated and those who were not, use of the drugs soared. Pelham said most parents and doctors took away the message that the study had found drug therapy effective over the long run. In 2004, physicians wrote 28.3 million prescriptions for ADHD drugs; last year, they wrote 39.5 million, according to data provided by IMS Health.

With the MTA having followed the children for eight years, the latest data have confirmed that there are no long-term differences between children who were continuously medicated and those who were never medicated. Some of the data were published online yesterday in the Journal of the American Academy of Child and Adolescent Psychiatry.

In a telephone interview, Jensen denied that the researchers had misled the public, pointing out that some children getting the drugs did do better over the long term. Looking at overall results was not as useful as studying how particular groups of children fared, he said.

Jensen and another co-author, L. Eugene Arnold at Ohio State University, who are both psychiatrists, emphasized the importance of individualizing treatment -- and warned parents against abruptly terminating drug therapy.

The subgroup analysis found that children in homes that were socially and economically stable did the same in the long term with or without medication. Children from troubled or deprived backgrounds slid backward as soon as the intensive therapy stopped and they went back to their communities. About one-third -- those with the least impairment to begin with -- continued to improve over the long term.

Jensen and co-author Benedetto Vitiello at the NIMH said drugs may not have shown an overall long-term benefit because the quality of routine care that children received may have been inferior to the care they got during the initial part of the study. Jensen said the take-home message is that community care needs improvement.

Brooke Molina, also a co-author and a University of Pittsburgh associate professor of psychology and

psychiatry, argued in an e-mail that if the researchers wanted to draw attention to subgroups that might be helped by medication over the long run, they also should acknowledge that "long-term treatment with medication may not be efficacious" for others.

In an interview, Molina said the data do not "support that children who stay on medication longer than two years have better outcomes than children who don't." In an e-mail she shared with Pelham, she noted that academic "reviewers thought we were bending over backward (inappropriately) to dismiss the failure to find medication effects at 8 years."

James Swanson, another MTA co-author and a psychologist at the University of California at Irvine, said he believes that the researchers have been open about the diminishing benefits of medication therapy. He cited a variety of scientific publications in which he and others reported data showing that medications lost effectiveness over time and stunted growth.

"If you want something for tomorrow, medication is the best, but if you want something three years from now, it does not matter," he said. "If you take medication long-term beyond three years, I don't think there is any evidence that medication is better than no medication."

Pelham, who has conducted many drug therapy studies, said the drugs have a valuable role: They buy parents and clinicians time to teach youngsters behavioral strategies to combat inattention and hyperactivity. Over the long term, he said, parents need to rely on those skills.

A yet-to-be-published study, Pelham added, found that 95 percent of parents who were told by clinicians to first try behavioral interventions for ADHD did so. When parents were given a prescription for a drug and then told to enroll their children in behavioral intervention programs, 75 percent did not seek out the behavioral approaches.

Post a Comment

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

LAW PROJECT FOR PSYCHIATRIC RIGHS, 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 STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

REC'D APR 0 2 2009

MAR 16 2009

Case No. 3AN-08-10115 CI

ORDER GRANTING STATE OF ALASKA'S MOTION TO STAY DISCOVERY

Having reviewed the State of Alaska's and the remaining above-named defendants' Motion to Stay Discovery and any responses thereto, IT IS SO ORDERED:

Discovery in this matter is hereby STAYED pending the court's decision on the Department's Motion for Judgment on the Pleadings.

DATED this 31st day of March, 2008.

Jack W. Smith
Superior Court Judge

I certify that on 4-1-09 a copy of the above was mailed to each of the following at their addresses of record. Hottstein, Kraly, Bakalar

R Meek
Secretary/Deputy Clerk

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

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

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

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

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

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

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

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

(a) are not medically necessary, or

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

(c) both.

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

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

B. Permanently enjoin the defendants and their successors from:

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

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

(a) are not medically necessary, or

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

(c) both.

This motion is accompanied by a memorandum in support hereof.

DATED: April 3, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA
THIRD JUDICIAL DISTRICT

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

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

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

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

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

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

(Medicaid Violation Allegation).

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.
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3. Amend ¶B of the Prayer for Relief to read as follows:

B. Permanently enjoin the defendants and their successors from:

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

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

(a) are not medically necessary, or

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

(c) both.

(Medicaid Violation Injunction).

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

A. CITIZEN-TAXPAYER AMENDMENT

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

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

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

B. MEDICAID VIOLATION AMENDMENT

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

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

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

---

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

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

C. MEDICAID VIOLATION INJUNCTION

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

D. CONCLUSION

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

DATED: April 3, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein, ABA # 7811100

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services, Defendants.	Case No. 3AN-08-10115 CI

STATE OF ALASKA'S CONDITIONAL NON-OPPOSITION TO MOTION FOR LEAVE TO AMEND COMPLAINT

The State of Alaska and the remaining above-named defendants do not oppose plaintiffs' Motion for Leave to Amend Complaint, filed April 3, 2009, in the above-captioned matter. However, the Department explicitly reserves the argument that the mere assertion of standing to bring this action does not confer standing. This position

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

is set forth at length in the Department's Reply to plaintiff's Opposition to Motion for Judgment on the Pleadings, filed contemporaneously herewith.

Dated this 10 day of April, 2009, at Juneau, Alaska.

WAYNE ANTHONY ROSS
ATTORNEY GENERAL

By: Stacie L. Kraly for
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

WAYNE ANTHONY ROSS
ATTORNEY GENERAL

By: Stacie L. Kraly
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services, Defendants.	Case No. 3AN-08-10115 CI

STATE OF ALASKA'S REPLY TO PLAINTIFF'S OPPOSITION TO MOTION FOR JUDGMENT ON THE PLEADINGS

The State of Alaska and the remaining above-named defendants (hereinafter "the Department"), reply as follows to PsychRights' Opposition to the Department's Motion for Judgment on the Pleadings.

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I. ARGUMENT

A. The Department's Motion is in Good Faith and Procedurally Proper.

As a threshold matter, the Department addresses PsychRights' assertion that the Department's motion is untimely and/or made in bad faith. Trial in this matter is set for February 2010, almost a year from the Department's filing. Clearly the motion is not an eleventh-hour maneuver calculated to obstruct discovery and delay trial. To the contrary, it was the Department's attempts to prepare for a deposition and comply with PsychRights' discovery requests that prompted the Department to ask the court to decide this dispositive jurisdictional issue so that the parties can move forward. Regardless, the assertion that a party lacks standing implicates the court's subject matter jurisdiction under the actual controversy requirement of the Declaratory Judgment Act. The court not only can—but must—address such an assertion at any time.[1] The Department's motion is both proper and timely.

B. PsychRights Cannot Establish Citizen-Taxpayer Standing

PsychRights concedes it lacks interest-injury standing (i.e. an adverse interest in the outcome of the litigation), dismissing this argument as extraneous and claiming that the Department's sole ground for its motion is an asserted lack of citizen-taxpayer standing.[2] But PsychRights fails to achieve even citizen-taxpayer standing,

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[1] See Alaska Rule of Civil Procedure 12(h)(3). "*Whenever* it appears by suggestion of the parties or otherwise that the court lacks jurisdiction of the subject matter the court shall dismiss the action." (emphasis added).

[2] Opposition at p. 1.

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because notwithstanding its unsubstantiated prediction that the State would exact retribution and punishment against a truly adverse litigant,[3] the corporation has shown no adversity of interest, is unaffected by the challenged conduct, and advances no compelling argument that it is an appropriate plaintiff. It is well-established that in order to establish citizen-taxpayer standing in Alaska's courts, a plaintiff must show:

> "... [T]hat the case in question is one of public significance and the plaintiff is appropriate in several respects. This appropriateness has three main facets: the plaintiff must not be a sham plaintiff with no true adversity of interest; he or she must be capable of competently advocating his or her position; *and he or she may still be denied standing if there is a plaintiff more directly affected by the challenged conduct in question who has or is likely to bring suit.*[4]

PsychRights makes a number of arguments, none of which supports standing. Initially, PsychRights argues that it will amend its Complaint to allege citizen taxpayer standing, that there are issues of public significance raised in the Complaint, that there are no more directly affected plaintiffs likely to bring suit, that the State would not be a proper plaintiff, and that that no affected child or parent would be likely to sue. However, simply making these statements does not make them true.

1. Amending the Complaint is insufficient to establish citizen-taxpayer standing.

PsychRights clearly seeks to avoid an adverse ruling by arguing that the Department's motion is based upon a mere technicality. To wit, by simply amending the

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3 *Id.* at p. 13-14.

4 *Ruckle v. Anchorage School District*, 85 P.3d 1030, 1034 (Alaska 2004) (emphasis added); *Keller v. French*, Slip. Op. 13296 (April 3, 2009).

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Complaint to assert standing, PsychRights will have standing and therefore can defeat the Department's motion. While courts routinely grant leave to amend pleadings, as PsychRights has recently asked the court to do,[5] simply asserting standing does not confer standing. If merely typing a sentence in a complaint were sufficient to confer standing then everyone would do so and the black letter law of standing would be rendered meaningless. Establishing standing to bring suit is not a mere technicality – PsychRights statement it has citizen-taxpayer standing does not moot defeat this motion.

2. While the Complaint may raise issues of public significance, PsychRights is not best suited to seek redress from the courts; there are more appropriate plaintiffs, such as the parents and children who are allegedly harmed by the State's practices.

According to PsychRights, the most important relief sought in the case is an injunction against the State directing the Department to—in so many words—do what PsychRights wants and believes is in the best interests of children in state custody.[6] However, PsychRights still does not explain how a corporate entity unconnected to any affected individual, in a state where there is no procedure for a *qui tam* action, possesses citizen-taxpayer standing to assert claims on behalf of children in State custody and/or Medicaid recipients and demand that the court impose a series of sweeping remedies. PsychRights argues that there is no one more directly affected to bring this suit than itself, because if a minor or parent brought suit, the State would somehow retaliate

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[5] Alaska Rule of Civil Procedure 15. See also *Prentzel v. State, Dept. of Public Safety*, 169 P.3d 573 (Alaska 2007).

[6] Opposition at p. 8.

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against such a litigant and the relief that PsychRights is seeking could not be obtained. This is not the case, and PsychRights supplies no basis for these assertions.

A review of the pleadings in this case and of the PsychRights website leaves no doubt that PsychRights believes it is authorized to seek judicial relief for the alleged wrongs stated in its Complaint.[7] However, the advocacy and interest that PsychRights so clearly espouses does not render it the only—let alone the most appropriate—plaintiff to bring this case. PsychRights' beliefs, no matter how strongly held, do not give the corporation standing to sue for redress of any and all of the alleged wrongs related to psychotropic medication and children. Parents and children themselves are the best suited to address these issues and questions on behalf of themselves. PsychRights may believe that there are wrongs to be righted, but PsychRights' advocacy mission to "stop the forced drugging" of children in this State is simply insufficient to subject the defendants to litigation.

In a case just decided by the Alaska Supreme Court last week, the question of citizen-taxpayer standing was discussed and the analysis presented there clearly favors dismissal in this case. In *Keller v. French*[8], the Alaska Supreme Court was asked to address whether the plaintiff in that case (five state legislators) had standing to bring suit against other state legislators claiming a violation of the fair and just treatment clause. After considerable procedural maneuvering at the superior court and Supreme Court levels, an appeal remained related to two issues – whether the plaintiffs had standing to

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7 See www.psychrights.org.

8 Slip Opinion 13296, April 3, 2009.

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sue and whether the entire case was not justiciable. The bases for standing in that case were predicated upon "citizen-taxpayer standing. In the *Keller* case, the court agreed that the plaintiffs were not sham plaintiffs and that the issue was one of public significance, but did not agree that plaintiffs were best suited to bring suit. While the plaintiffs argued there were no other potential plaintiffs, the court held that argument ignored the persons who were truly at risk from the investigation by the senate – those people who had been subpoenaed to appear and the Governor herself. As stated by the court, "that individuals who are more directly affected have chosen not to sue despite their ability to do so does not confer citizen-taxpayer standing on an inappropriate plaintiff." [9]

Additionally, the defendants in the *Keller* case argued that the plaintiffs were "attempting to assert the individual rights of potential or 'imaginary' third parties." The Supreme Court stated emphatically that the Court has "never allowed citizen-taxpayer standing to be used that way." [10] the Court further stated "'[g]enerally, a litigant lacks standing to assert the constitutional rights of another." [11]

This case is particularly germane to the instant matter, and as elaborated further below, Psych Rights is attempting to assert the rights of individuals and imaginary third parties, which is not appropriate. Additionally, Psych Rights is not an

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[9] *Id.* at page 9.

[10] *Id.* at page 11.

[11] *Id.* Citing to *State ex. rel. Dept's of Transp & Labor v. Enserch Alaska Constr., Inc.*, 787 P.2d 624, 630 n. 9 (Alaska 1989) (citing *Falcon v. Alaska Pub. Offices Comm'n*, 570 P.2d 496, 475 n. 20 (Alaska 1977) *Wagstaff v. Superior Court*, 535 P.2d 1220, 1225 (Alaska 1975).

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appropriate plaintiff to seek redress of the alleged ills and wrongs in the Complaint. There are better and more directly affected individuals who should bring this case. The fact that they (the parents and children who are directly affected) have not sued does not impart citizen-taxpayer standing on Psych Rights. Like *Keller* plaintiffs, Psych Rights lacks citizen-taxpayer standing and this case should be dismissed.

3. The State has sued the pharmaceutical industry under its consumer protections powers and continues to do. Therefore, the State would be a proper plaintiff as to the allegations against the pharmaceutical industry.

On this latter point, its worth noting that contrary to PsychRights' assertions, the Office of the Attorney General has been far from derelict in protecting Alaska's citizens—specifically Medicaid recipients—from wrongdoing by the pharmaceutical industry[12]. As PsychRights is aware, the consumer protection section of this Office recently brought a lawsuit against the pharmaceutical giant Eli Lilly to address the company's illegal marketing of the psychotropic medication Zyprexa, and

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[12] It appears that PsychRights is seeking to sue on behalf of the State to protect its citizens against the predatory pharmaceutical industry. As stated above, in order for this type of action to occur there would need to be some sort of *qui tam* authority by which PsychRights stands in the proverbial shoes of the State. No such statute exists in Alaska at this time, nor is there any way for a private citizen or corporate entity to seek relief under Alaska consumer protection laws, which is precisely what PsychRights is attempting to do. Alaska's citizens are being ably protected through successful litigation against the pharmaceutical industry as evidenced by cases brought by the consumer protection section of the Department of Law. (See http://www.law.state.ak.us/pdf/newsetters/2008-03-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2006-10-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2008-10-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2008-07-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2005-12-MR.pdf; http://www.law.state.ak.us/pdf/newsetters/2008-10-MR.pdf).

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settled the case against the company for $15 million dollars.[13] In prior lawsuits, the State has sued 41 pharmaceutical manufacturers for inflated drug pricing, settling with at least one of the manufacturers for $1.5 million, and took on both Pfizer and Merck pharmaceutical companies for their misleading drug marketing.[14] The State is also continuing to explore litigation against the manufacturers of Seroquel, Abilify, Geodon, and Risperdol. So the State of Alaska and PsychRights are very much aligned with respect to curbing the illegal and misleading conduct of the pharmaceutical industry.

C. The State Has Not Abdicated its Duties with Respect to Children in State Custody.

PsychRights also makes erroneous assertions and conclusions about the State's conduct toward children in state custody and the conduct of the Department of Law and the courts on this subject, based upon the Department's arguments in the opening motion. As described in the opening motion, under existing law the Department's use of and payment for psychotropic medication for children in state custody must be accomplished through parental/guardian consent and/or a court order.[15] Yet PsychRights accuses the Department of abdicating its custodial responsibilities because the Department has identified the pharmaceutical industry—not the named

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[13] 3AN-06-5630 CI. PsychRights attempted to obtain sealed court records in this case.

[14] See Department of Law links cited at n. 10. 3AN-06-12026 CI (*State of Alaska v. Alpharma Branded Products Division, Inc. et al.*); 3AN-05-14292 CI (*State of Alaska v. Merck and Company*, Inc.).

[15] Motion at p. 3-6.

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defendants—as the genuine target of this Complaint. PsychRights' opposition only supports the Department's position:

> Psychiatrists ought to be able to rely on the information they receive through medical journals and continuing medical education. The State ought to be able to trust that psychiatrists recommending the administration of psychiatric drugs are basing these recommendations on reliable information. Unfortunately, neither of these things, which ought to be true, are true. Thus, one of the key questions in this case is why psychiatrists are prescribing and custodians are authorizing the administration of harmful psychotropic drugs of little or no demonstrated benefit to children and youth. *The answer is that the pharmaceutical companies have been very effectively illegally promoting their use... the drug companies have provided the psychiatrists with inaccurate information. PsychRights will develop this in discovery and through presenting the evidence to this Court.*[16]

This statement goes squarely to the issue of standing and PsychRights' propriety to bring this action against the named defendants. By PsychRights' own admission, blame lies with the pharmaceutical industry. Even assuming *arguendo* that everything in the Complaint were true and every remedy requested should be implemented, if the answer to the problem (to paraphrase PsychRights) lies with a corrupt industry that has misled medical professionals and the public, including, presumably, the named defendants, how can the State rectify those alleged misdeeds in the context of this ligation brought by PsychRights, which lacks standing to sue? In other words, the State is the easy—but not actual—target of this Complaint. That is the point the Department was trying to make in its motion—not, of course, that the Department is not responsible for the welfare of children in its care. PsychRights'

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[16] Opposition at p. 21 (emphasis added).

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attempt to twist the State's position is inflammatory, and it is not supported by the facts and the law.

II. CONCLUSION

In sum, PsychRights concedes it has no true adversity—the crux of standing—yet asks the court to make the procedural and substantive leap of allowing a corporation to stand in the shoes of the State and prosecute what is effectively an unauthorized *qui tam* action on behalf of the public, against State defendants whom PsychRights has admitted are not the true cause of the conduct alleged.

The concept of standing in this case goes beyond its mere assertion: the doctrine addresses the substantive propriety of PsychRights to bring this lawsuit against the named defendants for the claims the corporation asserts. The court should evaluate the propriety of individual plaintiffs with respect to citizen-taxpayer standing on a case-by-case basis.[17] Citizen-taxpayer is appropriate where "no one seemed to be in a better position than the plaintiffs to complain of the illegality" of the conduct in question.[18] As argued in its opening motion, a policy agenda and a sweeping critique of alleged state actions perpetrated on unnamed individuals—by persons Psych Rights itself claims are not ultimately responsible for the alleged misconduct—do not constitute the "true adversity of interest" required to maintain citizen-taxpayer standing. There are more

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[17] *Ruckle v. Anchorage School District*, 85 P.3d 1030, 1037 (Alaska 2004); *Keller v. French*, Slip. Op 6532 (April 3, 2009).

[18] 736 P.2d at 328 (citing *State v. Lewis*, 559 P.2d 630 (Alaska 1977)).

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appropriate, adverse plaintiffs who could raise such issues and because of their true adversity, would be able to do so less abstractly.

The Department's arguments regarding standing and the court's jurisdiction in this matter are not refuted. PsychRights lacks standing and the complaint should be dismissed.

Dated this 10th day of April, 2009, at Juneau, Alaska.

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ATTORNEY GENERAL

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

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

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, Backalar

R Meade
Secretary/Deputy Clerk

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APR - 3 2009

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

LAW PROJECT FOR PSYCHIATRIC RIGHTS,

Plaintiff,

vs.

STATE OF ALASKA, et al.,

Defendants.

Case No. 3AN-08-10115CI

BEFORE THE HONORABLE J. SMITH
DECISION ON RECORD

Pages 1 - 22
Wednesday, May 27, 2009
11:15 A.M.
Anchorage, Alaska

ANCHORAGE, ALASKA; WEDNESDAY, MAY 27, 2009
11:15 A.M.
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THE COURT: All right. This is the time for the Court to place on record its decision in defendant's motion for judgment on the pleadings in case 3AN-08-10115CI, which is captioned Law Project for Psychiatric Rights, an Alaska Nonprofit Corporation, vs. The State of Alaska, Sarah Palin, Governor of the State of Alaska, the Alaska Department of Health and Social Services, William Hogan as Commissioner of the Department of Health and Social Services, Tammy Sandoval, the 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, and William Streur, Deputy Commissioner and Director of the Division of Health Care Services, as defendants.

Plaintiff, an Alaska nonprofit corporation, is a public interest law firm whose mission is described as mounting a strategic litigation campaign against forced psychiatric drugging and electroshock treatment of minor patients.

Plaintiff filed a 54-page Complaint arguing that the current procedures employed by the state in authorizing psychiatric medication and treatment of juveniles violates the constitutional rights of Alaskan children and youth.

Plaintiff seeks, one, a declaratory judgment that Alaskan children and youth have the constitutional and statutory right not to be administered psychotropic drugs unless and until evidence-based psychosocial interventions have been exhausted, rationally anticipated benefits of psychotropic drug treatment outweigh the risks, the person or entity authorizing administration of the drugs is fully informed of the risks and potential benefits, and close monitoring of and appropriate means of responding to treating-emergent effects are in place.

Two, an injunction against the defendants and their successors from authorizing or paying for the administration of psychotropic drugs to Alaska children and youth without conformance with paragraph 1 and approving or applying for Medicaid reimbursements to pay for outpatient psychotropic drug prescriptions to Alaskan children and youth that are not medically necessary or for indications that

are not approved by the Food and Drug Administration or included in the American Hospital Formulary Service drug information, the United States Pharmacopoeia Drug Information or Drugdex Information System or both.

And three, order that all children and youth in state custody currently being administered psychotropic drugs and all children and youth to whom the State of Alaska currently pays for the administration of psychotropic drugs be assessed in accordance with and brought into compliance with the specifications of CriticalThinkRX, which the Court will describe as the training program to educate individuals involved in prescribing and administrating psychotropic medications about, quote, critical thinking, end quote, of alternatives, especially nonmedication action. And that training must be by a contractor knowledgeable of the CriticalThinkRX curriculum. And such other relief as the Court finds just in the premises.

Plaintiff filed the action, the Complaint, on September 2nd, 2008. An Amended Complaint was filed on September 29, 2008. Defendant filed this motion for judgment on the pleadings on March 16, 2009. Oral argument was not requested by either

party.

The defendant argues in its motion that pursuant to Alaska Rules of Civil Procedure 12(c), that judgment on the pleadings is appropriate because plaintiff failed to meet the actual controversy requirement under the Declaratory Judgment Act because plaintiff lacked standing to sue.

Defendant argues that AS 22.10.020, subparagraph G, explicitly requires the presence of an actual controversy before the Court may issue declaratory relief and that this matter does not meet the actual controversy requirement because plaintiff lacks standing to sue. Therefore, defendant argues the Court should dismiss the Complaint.

Defendant recognizes that Alaska case law has broadly interpreted the concept of standing to promote liberal access to the courts. See Brause vs. State of Alaska, Brause is B-R-A-U-S-E, at 21 P3d 357, an Alaska Supreme Court case from 2001.

In fact, in Alaska a complaint seeking declaratory relief requires only a simple statement of facts demonstrating that the Superior Court has jurisdiction and that an actual justiciable case or controversy is presented. And again, that's from Brause.

To this end, Alaska courts recognize two forms of standing, an interest injury standing, and citizen taxpayer standing. That's from North Kenai Peninsula Road Maintenance Service Area vs. Kenai Peninsula Borough at 850 P2d 636, an Alaska Supreme Court case from 1993.

However, Defendant argues that even under Alaska's liberal requirements, Plaintiff satisfies neither type of standing. Defendant argues that to establish interest injury standing, a plaintiff must have an interest adversely affected by the conduct complained of.

Generally, a plaintiff may not assert another's constitutional rights unless a special relationship exists between the plaintiff and the third party. See Gilbert v. State at 139 P3d 581, another Alaska Supreme Court case from 2006.

Here plaintiff does not assert interest injury standing or claim an adverse interest, nor does plaintiff claim any sort of relationship at all to any relevant individual. Therefore, defendant argues plaintiff has not asserted standing under the interest injury doctrine.

Finally, defendant argues plaintiff also lacks citizen taxpayer standing. Defendant argues

that while the criteria for citizen taxpayer standing in Alaska are liberal, plaintiff has shown no true adversity of interest.

Furthermore, there clearly exist parties more affected by the challenged conduct who are better suited to pursue these claims. Defendant argues plaintiff is not a child in need of aid, does not allege guardianship of such a child, and has not purported to represent a child or class of children subject to the department's duty of care.

Plaintiff is engaged in a campaign to change the manner and procedure under which the department operates without any alleged harm inflicted by the department on plaintiff or anyone plaintiff represents.

Defendant concludes that a policy agenda and a sweeping critique of alleged state actions perpetrated on no one in particular do not constitute the true adversity of interest required to maintain citizen taxpayer standing. Defendant asserts there are more appropriate plaintiffs to raise such issues and because of their true adversity would presumably be able to do so in a more concrete manner.

Plaintiff, in opposition to the motion, argues that under the standard espoused in Trustees

for Alaska vs. State at 736 P2d 324, an Alaska Supreme Court case from 1987, it has citizen taxpayer standing to pursue these claims.

Plaintiff argues that this case raises issues of public significance and that there is no more directly affected plaintiff likely to bring this suit, and plaintiff argues it has therefore satisfied the adversity requirement. Plaintiff also argues it is able to competently advocate the position asserted.

Finally, plaintiff argues that the state, represented by the attorney general, would not be a proper plaintiff to pursue these claims. Contrary to the defendant's assertion that representation of the general public interest of children in state custody rests with the attorney general, plaintiff argues the state has ignored its responsibilities and refused to take appropriate action.

Plaintiff argues the state has ignored its responsibilities by not acting on the issues in this case, and therefore the state would not be a more appropriate plaintiff for bringing this suit.

Plaintiff argues there is every reason to presume that no affected child, youth, parent or guardian is likely to sue in this case because none

of these parties have yet to file a suit, and it is likely they will never bring this claim. Plaintiff argues these children and youth, as well as their parents, lack the resources to file suit, and the potential for being subjected to an award of attorneys fees against them is a powerful disincentive to bringing suit.

Plaintiff argues the Law Project for Psychiatric Rights was founded in late 2002 in order to mount a strategic litigation campaign against forced psychiatric drugging and electroshock therapy and notes that because it is the adults in their lives rather than they who are making the decisions, children are essentially forced to take phychiatric drugs, and thus this lawsuit fits squarely within the psych rights mission. Therefore, plaintiff claims it has adversity.

Plaintiff also argues that the motion for judgment on the pleadings is untimely, that Rule 12(c) requires that a motion for judgment on the pleadings be brought within such time as to not delay the trial and that the instant motion filed on March 12, 2009, some six months after the action was commenced, is going to interfere with the trial, which is set to commence on February 1, 2010.

In its reply, defendant reiterated that plaintiff lacks citizen taxpayer standing to pursue these claims. Defendant argues the parents and children themselves are the best suited to address these issues and questions on behalf of themselves.

Defendant argues that Keller v. French, a slip opinion at 13296 from April 3rd, 2009, an Alaska Supreme Court case, supports granting its motion in this case.

The Alaska Supreme Court in that case held that the plaintiffs did not have citizen taxpayer standing because there were other potential plaintiffs better suited to bring suit and plaintiffs were truly -- plaintiffs who were truly at risk from the actions at issue.

As the Court stated in that case, individuals who are more directly affected have chosen not to sue despite their ability to do so, and that does not confer citizen taxpayer standing on an inappropriate plaintiff.

Looking at the law surrounding this case, the Court would note the following. Under Alaska Civil Rule 12(c), a party will prevail on a motion for judgment on the pleadings if there are no allegations in the plaintiff's pleading that, if

proven, would permit recovery. Accordingly, a 12(c) motion only has utility when all material allegations of fact are admitted in the pleadings and only questions of law remain.

One of the issues that needs to be decided is whether plaintiff has standing. In Alaska, it has been held that all that is required of a complaint seeking declaratory relief is a simple statement of facts demonstrating that the Superior Court has jurisdiction and that an actual justiciable case or controversy is presented. See Ruckle vs. Anchorage School District at 85 P3d 1030, an Alaska Supreme Court case from 2004, which was quoting Jefferson vs. Asplund at 458 P2d 995, a prior Supreme Court case from 1969.

Under Alaska case law, the actual case or controversy language encompasses a number of more specific reasons for not deciding cases, including lack of standing, mootness and a lack of rightness.

Standing in Alaska is not a constitutional doctrine. Rather, it is a rule of judicial self-restraint based on the principle that courts should not resolve abstract questions or issue advisory opinions.

And again, see Trustees For State of

Alaska -- or for Alaska versus the state that was cited previously.

The basic requirement for standing in Alaska is adversity. Alaska case law has discussed two differing kinds of standing, interest injury standing and citizen taxpayer standing.

Under the interest injury approach, a plaintiff must have an interest adversely affected by the conduct complained of. Plaintiff has not argued it has an interest injury standing in this case. However, in order to determine if a party has citizen taxpayer standing, the court must examine each case and decide if several criteria have been met.

First, the case in question must be one of public significance. The plaintiff raising constitutional issues is likely to meet this first requirement. See Sonemann vs. State at 969 P2d 632.

Here it seems clear that plaintiff's Complaint raises questions of public significance. The asserted issue involves state and federal constitutional rights, state laws, municipal codes, and some unknown number of Alaska children and youth potentially impacted. Defendant indicates that the Complaint may in fact raise issues of public

significance.

Second, the plaintiff must be an appropriate party to bring the case. And again, see Trustees for Alaska vs. State.

This appropriateness has three main facets. First, plaintiff must have a truly adverse interest. Second, plaintiff must be capable of competently advocating the position asserted. And third, plaintiff may still be denied standing if there is a plaintiff more directly affected by the challenged conduct in question who has or is likely to bring suit.

Therefore, what needs to be determined is whether or not the plaintiff in this case is the appropriate party to bring this action.

For the plaintiff to be the appropriate party as noted above, it must have an adverse interest, be capable of competently advocating its position, and there must not be a party more directly affected who has or is likely to bring suit.

Let's stop for a second.

(Off record.)

THE COURT: Plaintiff's sincerity in opposing the alleged state's practice seems unquestioned. However, that adversity is based on

plaintiff's mission statement, which, if accepted, would indicate any individual or group can create adversity by simply creating a nonprofit and drafting a mission statement opposing whatever issue they wish to challenge.

Plaintiff's attorney, Mr. Gottstein, is also its founder, president and CEO. Mr. Gottstein has been practicing law in Alaska since 1978. From 1998 to 2004, Mr. Gottstein served on the Alaska Mental Health Board. Without going into further detail regarding the experience of plaintiff and its counsel, it seems clear plaintiff is capable of competently advocating the position asserted by plaintiff.

But plaintiff apparently has no individual client or group of clients or their custodians who have actually had either psychotropic medications or electroshock therapy administered against their wishes.

Plaintiff starts with the premise that children and juveniles are being forced to undergo phychiatric medication and/or electroshock therapy, that their parents, their guardians, the state and the health care providers are allowing or doing this without determining the best interests of the

children or juveniles; and that they, as plaintiffs, can ensure a more appropriate decision is made if allowed to identify these children and juveniles.

Certainly plaintiff can espouse its identified mission effectively, but approaching an issue with the foregone conclusion that children and juveniles are being forcefully medicated and treated by their parents, guardians, health care providers and/or the state raises concerns plaintiffs -- that plaintiff has an inherent bias to use of medication or therapies that may in fact be the most beneficial to the recipient.

The last factor determining whether plaintiff is an appropriate party is whether or not there is a more directly affected plaintiff who has or is likely to bring suit. The parties highly contest this factor.

The Court in Trustees for Alaska vs. The State stated that taxpayer citizen standing has never been denied in any decision of this Court except on the basis that the controversy was not of public significance or on the basis that the plaintiff was not a taxpayer.

But starting with that case, the Court set out the requirement that no more appropriate

plaintiff exists, and since that time, a line of cases has denied citizen taxpayer standing where a more appropriate plaintiff has or is likely to bring suit. In Trustees, the Court reasoned that the crucial inquiry is whether the more directly concerned potential plaintiff has sued or seems likely to sue in the foreseeable future.

In Clevin vs. Yukon-Koyukuk School District, a former school administrator filed suit against the school district, challenging his reassignment to a position of lower pay and responsibility. That's at 853 P2d 518, Alaska Supreme Court case from 1993.

The Court finds -- this Court finds the analysis in that case instructive. One of the main issues before that court was whether an employee who starts a grievance process and subsequently resigns has standing to force the employer to continue with the process and remedy problems presumably for the benefit of those employees who remain.

Upon review, the Court determined that Clevin lacks citizen taxpayer standing. The Court stated, "Because the Yukon-Koyukuk School District's remaining employees are certainly in a better position to raise the grievances Clevin cites and because we have no reason to believe that current

Yukon-Koyukuk School District employees would be indisposed to press legitimate grievances, we agree with the trial court that Clevin has failed to establish citizen taxpayer standing."

The Court would note that plaintiffs in this case have failed to establish any parent or guardian with a legitimate grievance on behalf of their juvenile or child has declined to sue.

In Fannon vs. Matanuska Susitna Borough at 192 P3d 982, another Supreme Court case from 2008 cited by the parties, the Court finds it's distinguishable that the plaintiffs in this case have not established any legitimate claim has gone unpursued.

Finally, in a very recent decision, the Supreme Court reviewed a case involving a claim that a legislative investigation into the Governor's dismissal of the public safety commissioner violated the Alaska Constitution's fair-and-just-treatment clause. See Keller v. French previously cited, but it's at opinion No. 6352, April 3rd, 2009.

After the investigation began, the group of five state legislators, the Keller plaintiffs filed a complaint claiming the investigation was improper for a number of reasons. Shortly thereafter, a different

group of state employees who had been subpoenaed to appear before the senate judiciary committee commenced a separate lawsuit. The Court referred to them as the Kiesel plaintiffs.

Upon review, the Supreme Court held that the five legislators did not have standing to claim there was a violation of the fair-and-just-treatment clause. The Court determined that the Keller plaintiffs were truly adverse and capable of competently advocating their position but that there was nonetheless a substantial question here as to whether other persons who are more directly affected have sued or are likely to sue.

In deciding that the Keller plaintiffs lacked standing, the Court stated that the Kiesel plaintiffs were among the classes of persons in this investigation most obviously protected by the fair-and-just-treatment clause.

The Kiesel plaintiffs were more directly affected by the investigation, and they had actually sued some of the defendants. The Court reasoned that the Kiesel plaintiffs did not allege any violation of the fair-and-just-treatment clause, but had they thought they were being mistreated, there would have been far more appropriate plaintiffs to make that

claim than the Keller plaintiffs, none of whom self-identified as either a witness or a target of the investigation.

In addition, the Supreme Court in that case discussed the Governor's potentially more appropriate plaintiffs, stating, quote: Even if the Governor did not intend to sue, there is no indication that if she thought her rights were being violated she would be unable to do so. The Keller plaintiffs do not contend that the Governor or any other potential plaintiffs were somehow limited in their ability to sue. That individuals who are more directly affected have chosen not to sue despite their ability to do so does not confer citizen taxpayer standing on an inappropriate plaintiff. End quote.

In this case, plaintiff argues parents or guardians are unlikely to sue, but that statement reflects plaintiff's opinion that parents and guardians are incapable of recognizing what plaintiffs identify as, quote, forced, end quote, medication and treatment.

Plaintiff seeks to be placed in the role of decision maker for the children and juveniles receiving psychotropic medication and electroshock therapy in lieu of parents or guardians. Otherwise,

clearly they are not the most appropriate plaintiff.

Let's stop for a second.

(Off record.)

THE COURT: As the Court concluded in Keller, it appears the Keller plaintiffs are attempting to assert the individual rights of potential or imaginary third parties, and the Court in that case indicated they had never before allowed citizen taxpayer standings to be used in that way.

Comparing the present case with those discussed above, it becomes clear that the facts of this case support a finding of plaintiff lacks standing.

There is no adversity of interest with plaintiff except as they created with their mission statement. And just like in Ruckle and Keller, there appears to be a more directly affected party here that would make a more appropriate plaintiff than the Law Project.

As defendant argues, the affected children, their parents or guardians or even the state would make a more appropriate plaintiff if a legitimate grievance existed.

The motion for judgment on the pleadings is granted in this case. Parties will be given a copy

of the disk with the Court's decision, and this case will be dismissed.

We'll be off record.

(Proceedings adjourned at 11:39 a.m.)

* * * * *

CERTIFICATE

I, DIANE M. BONDESON, Registered Professional Reporter and Notary Public in and for the State of Alaska, do hereby certify that the foregoing pages numbered 1-21 are a true, accurate and complete transcript of proceedings in Case No. 3AN-08-10115CI, Law Project for Psychiatric Rights vs. State of Alaska, transcribed by me from a copy of the electronic sound recording to the best of my knowledge and ability;

And further, that I am not a party to nor have I any interest in the outcome of the action herein contained.

IN WITNESS WHEREOF, I have hereunto set my hand this SIXTH day of JUNE, 2009.

_____

Diane M. Bondeson, RPR

My Commission Expires 9/6/10

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

LAW PROJECT FOR PSYCHIATRIC RIGHS, 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 STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants

REC'D MAY 28 2009

Case No. 3AN-08-10115 CI

ORDER GRANTING STATE OF ALASKA'S MOTION FOR JUDGMENT ON THE PLEADINGS

Having reviewed the State of Alaska's and the remaining above-named defendants' Motion for Judgment on the Pleadings and any responses thereto, IT IS SO ORDERED:

The defendants' Motion is GRANTED. Plaintiff has failed to present an actual case or controversy under the Declaratory Judgment Act and lacks standing to bring this action. Accordingly, the Complaint is hereby dismissed with prejudice.

DATED this 27th day of May, 2009.

Jack W. Smith
Superior Court Judge

I certify that on 5.27.09 a copy of the above was mailed to each of the following at their addresses of record. (List names if not an agency)
☐ CSED ☐ AG ☐ PD ☐ DA Gittlen

Deputy Clerk / Secretary

MAR 16 2009

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

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

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

REC'D JUN 17 2009

Case No. 3AN-08-10115 CI

JUN 05 2009

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

FINAL JUDGMENT

THIS COURT, having dismissed the action brought by plaintiff in this case upon motion of the defendants on May 27 2009, and being otherwise fully advised,

HEREBY ORDERS that final judgment is entered with prejudice in favor of the defendants in this case, and against plaintiff Law Project for Psychiatric Rights.

THE COURT FURTHER ORDERS that, after proper application, the Attorney General's Office shall recover attorney's fees from and have judgment against plaintiff, as follows: to be determined after filing per CR 79 and 82

i. Attorney's Fees $ _____;

Date awarded _____;

Judge _____.

ii. Costs: _____;

Date awarded _____;

Judge _____.

iii. **TOTAL JUDGMENT** $_____.

iv. Post-Judgment Interest Rate: _____.

DATED this 16th day of June, 2009.

Jack W. Smith
Superior Court Judge

I certify that on 6-16-09 a copy of the above was mailed to each of the following at their address of record. [illegible]

Secretary/Deputy Clerk

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services, Defendants.	REC'D JUN 24 2009 Case No. 3AN-08-10115 CI

MOTION FOR AWARD OF ATTORNEY'S FEES

On June 16, 2009, the court entered final judgment for defendant State of Alaska, Department of Health and Social Services, and the remaining above-named defendants in the above-captioned matter ("Department"). Pursuant to Rule 82(b)(2) of the Alaska Rules of Civil Procedure, the Department hereby moves for a total fee

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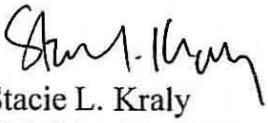
award of $3,876.00 in attorney's fees. This fee claim reflects the Rule 82(b)(2) prevailing party schedule.

This motion is supported by the accompanying affidavit of counsel, memorandum of law, and Exhibit A, detailing the time spent litigating this matter.

Dated this 22nd day of June, 2009.

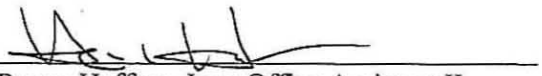
DANIEL S. SULLIVAN
ATTORNEY GENERAL

By: 
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: 
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

Certificate of Service
I hereby certify that on this day of June 22, 2009, true and correct copies of the foregoing MOTION, MEMO, AFFIDAVIT, EXHIBIT A, and proposed ORDER were served via U.S. mail, first class, postage prepaid to the following attorney of record:

James B. Gottstein, Esq.
Law Project for Psychiatric Rights, Inc.
406 G Street, Suite 206
Anchorage, AK 99501


H. Raven Haffner, Law Office Assistant II

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
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PHONE: 465-3600

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

Case No. 3AN-08-10115 CI

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS' MOTION FOR AWARD OF ATTORNEY'S FEES

INTRODUCTION

On May 27, 2009, this court dismissed plaintiff's lawsuit in favor of the State of Alaska, Department of Health and Social Services, and the remaining above-named defendants (hereinafter the "Department"). The court entered a final judgment

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on June 16, 2009. As the prevailing party in this action, the Department moves for an award of attorney's fees pursuant to Civil Rule 82.

ARGUMENT

I. The Department is Entitled to Fees Under Civil Rule 82(b)(2)

Alaska Civil Rule 82 provides that defendants who are prevailing parties in cases that do not go to trial are entitled to an award of 20 percent of their actual reasonable fees.

> In cases in which the prevailing party recovers no money judgment, the court shall award the prevailing party in a case … resolved without trial 20 percent of its actual attorney's fees which were necessarily incurred. The actual fees shall include fees for legal work customarily performed by an attorney but which was delegated to and performed by an investigator, paralegal or law clerk.[1]

The purpose of Civil Rule 82 is to partially compensate a prevailing party for the expense of litigation. *City of Valdez v. Valdez Development Co.*, 523 P.2d 177, 184 (Alaska 1974).

Although the Attorney General, as counsel for the state, bills client agencies at a rate far below the market rate of attorneys in private practice, it is well settled that when the state is the prevailing party, it may request reimbursement of attorney's fees at a reasonable market rate. The Attorney General is not limited to

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[1] Alaska Rule Civ. Proc. 82(b)(2).

ATTORNEY GENERAL, STATE OF ALASKA
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recovering fees based on the Department of Law's inter-agency billing rate.[2] There is clear authority for awarding attorney's fees under Civil Rule 82 based on market rates instead of the department's overhead rate. *Atlantic Richfield Co. v. State*, 723 P.2d 1249, 1251-52 (Alaska 1996) (Alaska Supreme Court ruled it appropriate to use average of hourly billing rates charged by private attorneys to calculate fee award for legal work performed by assistant attorneys general); *Amfac Hotels v. State, Dept. of Transportation*, 659 P.2d 1189, 1194 (Alaska 1983) (approved fee award based on "the average private billing rate"—$75 per hour, 25 years ago); *Morrison-Knudsen Co., Inc. v. State,* 519 P.2d 834, 844 (Alaska 1974) (argument rejected that state could not recover attorney's fees at a rate higher than hourly salary of highest paid assistant attorney general who worked on case).

The Attorney General has worked to identify a uniform reasonable market rate upon which to base attorney fee requests that will more fairly reimburse the State of Alaska and state represented officials for their fees as a prevailing party. *See* Affidavit of Counsel. This was necessary because the department's historic rate formulae and the newer universal blended rate formula all produce figures far below the

---

[2] The Department of Law has formulated a blended attorney "overhead rate" for any assistant attorney general (regardless of years of practice), which has been $121.98 during this calendar year. The previous blended rate was $116.50. This is a uniform rate used to bill client agencies for legal services, regardless of the experience level or salary range of the individual assistant attorney general who actually handled the legal matter.

ATTORNEY GENERAL, STATE OF ALASKA
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market rate and value of the services rendered, and because Civil Rule 82 provides for only partial reimbursement of actual fees.

Based on the recommendations of a working group tasked with assessing the Department of Law's policy on attorney fee requests, the Attorney General established in 1997 a policy to request $150 per hour as the market rate for journey level attorneys (Attorneys III and above). *Id.* This decision was based on the working group's review of attorney billing rates statewide, a similar policy in the U.S. Attorney's Office, and the fact that the average rate (typically reflecting a discount for the state) that the Department pays experienced private practitioners to provide legal services to the state under contract exceeds $150 per hour. *Id.* The rate of $125 per hour was approved for less experienced attorneys. *Id.* The courts have awarded the state fees based on these rates for over a decade.

As the prevailing party, the Department is entitled to recover 20 percent of its attorney's fees. A copy of the billing printout detailing the work done and time spent relative to this case is attached as Exhibit A. The Department therefore requests a Civil Rule 82(b)(2) fee award as calculated in section II.

II. Calculation of Total Fees Requested

The defense counsel of record in this case, Stacie Kraly, holds an Attorney VI position, and has been practicing law for almost 15 years. Co-counsel of record, Elizabeth Bakalar, holds an Attorney III position and has been practicing law

ATTORNEY GENERAL, STATE OF ALASKA
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for almost three years. Other Assistant Attorneys General who assisted on this case, Kelly Henriksen and Nevhiz Calik, also hold Attorney III positions and have been practicing law for approximately 15 and three years respectively. The attorney hours expended in defending this action total 129.2 hours.[3] Using the market rate of $150, total fees came to $19,380.00, 20% of which is $3,876.00.[4]

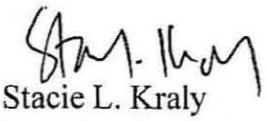
CONCLUSION

Based on the foregoing, the Department respectfully requests that the court award total attorney's fees in the amount of $3,876.00.

DATED this 22nd day of June, 2009.

DANIEL S. SULLIVAN
ATTORNEY GENERAL

By: 
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: 
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

ATTORNEY GENERAL, STATE OF ALASKA
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[3] Exhibit A.

[4] *Id.*

Cost of Suit for Matter 223090064

Timekeeper	Date	Hours	Fees	Description
Elizabeth M. Bakalar	9/18/08	2.5	$304.95	Began researching and drafting a motion to dismiss.
	9/30/08	1.5	$182.97	Reviewed first amended complaint/drafted answer to same.
	10/7/08	0.5	$60.99	Discussed case with Tammy Sandoval.
	10/8/08	3.5	$426.93	Revieed documents from Dave Campana and continued drafting pleadings.
	10/9/08	1.5	$182.97	Revised and Reviewed answer.
	10/20/08	1.0	$121.98	File review, talked to Jim Gottstein, drafted pretrial order.
	10/23/08	1.5	$182.97	Continued working on Rule 26 disclosures.
	10/27/08	2.5	$304.95	Worked on discovery, spoke to Dave Campana.
	10/28/08	0.5	$60.99	File review and scheduling.
	10/29/08	0.5	$60.99	Finalized disclosures for Ms. Kraly's review.
	11/4/08	1.0	$121.98	Extensive revisisons to pretrial disclosures.
	11/12/08	1.0	$121.98	Met with client to discuss case.
	11/12/08	0.5	$60.99	Worked on Rule 26 Disclosures.
	11/13/08	0.5	$60.99	Added to pretrial disclosures.
	11/18/08	0.5	$60.99	Email with Jim Gottstein; clients; discuss issues w/Ms. Kraly; attempts to schedule ADR.
	11/20/08	0.5	$60.99	Reviewed final Rule 26 and strategized discovery issues w/client.
	12/9/08	0.3	$36.59	Reviewed motion to amend complaint.
	12/10/08	0.3	$36.59	Read motion to amend complaint; drafted response.
	12/24/08	0.3	$36.59	Pretrial scheduling conference.
	12/29/08	1.0	$121.98	Read Medicaid/Foster Care/Psychotropics materials from Oregon in anticpation of upcoming settlement meeting.
	1/7/09	3.0	$365.94	Reviewed file for upcoming meeting with Jim Gottstein; drafted lengthy case assessment email to clients.
	1/8/09	1.0	$121.98	Continued file review, emails with clients, document review, etc. in anticipation of settlement meeting tomorrow.
	1/9/09	1.7	$207.37	Met with Jim Gottstein and principals for initial settlement talks.
	1/14/09	3.0	$365.94	Continued review of case file (pleadings and documentation); emailed pertinent information to Ms. Raymond; reviewed additional information and materials from principals.
	1/15/09	1.6	$195.17	Continued file review, case strategizing.
	1/20/09	0.5	$60.99	Reviewed additional materials from Jim Gottstein.
	1/23/09	0.4	$48.79	Reviewed new materials from Jim Gottstein; reviewed with client (Brita Bishop, et al) parameters for Bring the Kids Home meeting and possible issues related to plaintiff's presence at same.
	1/29/09	0.3	$36.59	Corresponded with Jim Gottstein and client re: participation in upcoming mental health teleconference.
	2/4/09	0.5	$60.99	Finalized notice and motion for protective order, and proposed protective order.
	2/4/09	1.0	$121.98	Reviewed plaintiff's Motion for Protective Order; drafted Limited Opposition; discussed with Ms. Kraly; finalized for filing.
	2/5/09	0.5	$60.99	Drafted letter re: impact of public relations on settlement to Jim Gottstein.
	2/6/09	0.4	$48.79	Continued working on email/settlement info to Jim Gottstein/Stacie Kraly.
	2/9/09	1.5	$182.97	Reviewed file; Met with Richard Nault/Karen Forrest re: "gold standard" for psych meds.
	2/11/09	0.6	$73.19	Corresponded w/Jim Gottstein re: depositions.
	2/17/09	0.6	$73.19	Coordinated and strategized issues related to pending depositions.
	2/19/09	0.3	$36.59	Continued coordinating discovery in psych rights matter.
	2/20/09	1.5	$182.97	Continued to work on discovery and deposition prep.
	2/23/09	5.6	$683.09	Continued to research and draft motion for judgment on pleadings.
	2/24/09	3.1	$378.14	Continued to draft Motion for Judgment on Pleadings.
	2/26/09	4.9	$597.70	Began research and drafting on motion to dismiss/judgment on pleadings; worked on motion to quash deposition; strategized same with Stacie Kraly.
	2/26/09	1.0	$121.98	Deposition prep with Dave Campana and discussion with Ed Sniffen.
	3/4/09	0.8	$97.58	Worked on motion for judgment on pleadings and motion to stay discovery.
	3/5/09	1.3	$158.57	Continued working on 12(c) motion; incorporated some of Ed Sniffen's suggested edits.
	3/9/09	6.0	$731.88	Worked on motion for judgment on pleadings/motion to stay discovery.
	3/10/09	4.7	$573.31	Continued working on 12c and discovery motions.

Cost of Suit for Matter 223090064

Timekeeper	Date	Hours	Fees	Description
	3/11/09	3.4	$414.73	Continued to work on motino for judgment on pleadings.
	3/12/09	0.8	$97.58	Finalized dispositive motion and motion to stay discovery for filing.
	3/17/09	0.6	$73.19	Reviewed response to motion for expedited consideration of motion to stay discovery/strategized with Ms. Kraly.s
	3/18/09	1.3	$158.57	Reviewed pending discovery and worked on reply to opposition to motion for EC.
	4/1/09	2.5	$304.95	Reviewed plaintiffs' opposition to motion for judgment on pleadings; began formulating reply; strategized with Ms. Kraly re: website postings on plaintiffs' website and necessary action.
	4/2/09	2.5	$304.95	Worked on reply to opposition to motion for judgment on pleadings.
	4/3/09	2.4	$292.75	Worked on reply to opposition.
	4/6/09	4.0	$487.92	Continued working on reply to opposition to motion for summary judgment and limited opposition to motion for leave to amend.
	4/8/09	1.3	$158.57	Worked on finalizing reply to opposition to motion for judgment on pleadings and conditional non-opposition to motion for leave to amend.
	4/9/09	2.1	$256.16	Finalized reply brief (to op to mot for judgment on pleadings).
	4/30/09	0.4	$48.79	Reviewed materials and read articles on psych rights web page re: pending litigation.
Elizabeth M. Bakalar		**88.5**	**$10,795.20**	
Nevhiz E. Calik	3/27/09	1.0	$121.98	Edited and filed for Libby Bakalar and Stacie Kraly.
Nevhiz E. Calik		**1.0**	**$121.98**	
Kelly E. Henriksen	3/11/09	2.2	$268.36	Review and edit motion for judgment on the pleadings.
	3/16/09	0.4	$48.79	Conference iwth Bakalar re strategy re M/expedited consideration.
	3/17/09	0.2	$24.40	Conference wth Libby re procedural question.
	3/24/09	0.4	$48.79	Review and respond to Kraly re opposition to motion to stay discovery.
	3/25/09	0.2	$24.40	Conference with Kraly re motion to stay discovery.
	3/26/09	1.7	$207.37	Review and edit Reply to Motion to Stay per Kraly.
	4/9/09	0.5	$60.99	Review reply per Kraly.
Kelly E. Henriksen		**5.6**	**$683.10**	
Stacie L. Kraly	9/18/08	0.6	$73.19	Discuss answer and motion to dismsis issue with Ms. Bakalar.
	9/29/08	0.5	$60.99	Work on complaint, pretrial order with Ms. Bakalar and Mr. Gottstein.
	10/8/08	0.4	$48.79	Work on Answer.
	10/9/08	1.5	$182.97	Continue to work on answer.
	10/27/08	0.3	$36.59	Discuss options re meeting with Mr. Gottstien with Ms. Bakalar.
	10/29/08	0.5	$60.99	Review draft initial disclosures.
	11/6/08	0.4	$48.79	Work on initial disclosures.
	11/12/08	0.8	$97.58	Attend Meeting with senior staff at DHSS related to settlement and initial dislcosures.□ □
	11/20/08	0.7	$85.39	Work on initial disclosures; discuss data collection with DJJ.
	1/7/09	1.0	$121.98	Staff case with Ms. Bakalar, review email re same.
	1/8/09	0.3	$36.59	Prepare for meeting tomorrow.
	1/9/09	2.0	$243.96	Prepare for and attend settlement conference with Mr. Gottstien, Commisisoenr Hogan, Ms. Sandavol, Mr. McComb and Ms. Bakalar.
	1/14/09	0.8	$97.58	Review data from OCS and DJJ, update Ms. Raymond.
	2/2/09	0.3	$36.59	Work on discovery isuses with Ms. Bakalar.
	2/6/09	0.5	$60.99	Work on email/repsosne to Mr. Gottstein re public vetting of liigation issues.
	2/10/09	0.8	$97.58	Work with Ms. Bakalar on discovery strategy.
	2/17/09	0.6	$73.19	Work on deposition issues.
	2/24/09	1.0	$121.98	Work on deposition issues, discuss motion practice re same.
	3/4/09	0.5	$60.99	Work on motion to dismiss re standing.
	3/5/09	0.4	$48.79	Work on motion to dismiss.
	3/9/09	0.7	$85.39	Work on dispositive motions with Ms. Bakalar.

Cost of Suit for Matter 223090064

Timekeeper	Date	Hours	Fees	Description
	3/10/09	2.0	$243.96	Work on motions with Ms. Bakalar.
	3/11/09	0.5	$60.99	Discussion with Mr. Jesse (mental health trust) re options and isuses in litigation.
	3/11/09	1.5	$182.97	Work on Motion to Dismiss with Ms. Bakalar.
	3/17/09	0.5	$60.99	Discuss reply strategy re motion for expedited consideration with Ms. Bakalar.
	3/24/09	0.7	$85.39	Review opposition to motion to stay.
	3/25/09	4.2	$512.32	Work on reply brief.
	3/26/09	3.0	$365.94	Work on reply brief.
	3/27/09	1.5	$182.97	Work on reply brief.
	4/2/09	0.5	$60.99	Work on reply to motion for judgment on the pleadings.
	4/3/09	0.6	$73.19	Work on reply brief; review motion to amend.
	4/6/09	1.0	$121.98	Work on reply brief.
	4/7/09	2.0	$243.96	Work on reply brief.
	4/9/09	1.5	$182.97	Work on reply brief.
Stacie L. Kraly		34.1	$4,159.51	
Total Fees		129.2	$15,759.79	

Costs	Date	Amount	Description
	3/18/09	$113.50	#23353895 STACIE L KRALY
	3/18/09	$19.00	#01411513 US TRAVEL, LLC
	3/18/09	$99.00	#01411516 HICKEL INVESTMENT CO
	3/18/09	$495.00	#01411510 ALASKA AIRLINES INC.
	4/9/09	$62.00	#01428019 ALASKA AIRLINES INC.
	4/9/09	$100.00	#01428024 ALASKA AIRLINES INC.
	4/9/09	$19.00	#01428027 US TRAVEL, LLC
Total Costs		$907.50	
Total Fees and Costs		$16,667.29	

Exhibit A page 3 of 3

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

Case No. 3AN-08-10115 CI

AFFIDAVIT OF COUNSEL

STATE OF ALASKA)
) ss.
FIRST JUDICIAL DISTRICT)

I, Elizabeth M. Bakalar, having been duly sworn, hereby state as follows:

1. I am an Assistant Attorney General employed by the Department of Law and one of the attorneys of record in the above-captioned case on behalf of the

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

State of Alaska. I submit this affidavit in support of the Motion for Attorney's Fees on behalf of the State as the prevailing party.

2. Attorney's fees in the amount of $15,759.79 were incurred on behalf of the Department in defending this litigation. This includes 88.5 hours of work performed by me personally, at an hourly rate of $121.98. Exhibit A, attached, contains an itemized listing of the dates, descriptions of work accomplished, and the time expended. I have reviewed this report for accuracy and applicability.

3. I have determined both that the information presented in Exhibit A is correct, and that the time listed was necessarily spent in defending this matter. I do not believe that any of the work performed in this case was unnecessary or duplicative. I believe the total amount of time and money expended on behalf of the Department is reasonable.

4. Although the state bills client agencies at a rate far below the market rate of attorneys in private practice, in 1997 the Attorney General established a policy that would more fairly reimburse the state for its fees as a prevailing party. To that end, the Attorney General approved the hourly rate of $150 as the market rate for journey level attorneys (Attorneys III and above). This rate was based on the recommendations of a working group tasked with assessing the Department of Law's policy on attorney fee requests. After reviewing attorney billing rates statewide, the policy in place at the U.S. Attorney's Office, and the fees paid by the state to experienced private practitioners who provide legal services to the state, the working

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group determined that $150 per hour was a reasonable rate that would more fairly reimburse the state for its legal services. The rate of $125 per hour was approved for less experienced attorneys.

5. I have been practicing law in the State of Alaska for almost three years and am an Attorney III. Based on the foregoing, a request for reimbursement for the time spent on this case by me at a rate of $150 per hour is reasonable.

6. The actual, reasonable attorney's fees that were necessarily incurred in this matter amount to a total of $19,380.00.

DATED this 22nd day of June, 2009.

Elizabeth M. Bakalar
Alaska Bar No. 0606036

SUBSCRIBED AND SWORN TO before me this 22ND day of June, 2009.

STATE OF ALASKA
OFFICIAL SEAL
HEIDI HAFFNER
NOTARY PUBLIC
My Commission Expires With Office

Notary Public, State of Alaska
My commission expires with office

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

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

LAW PROJECT FOR PSYCHIATRIC RIGHTS, Inc., an Alaskan non-profit corporation,
Plaintiff,
vs.
STATE OF ALASKA, *et al.*,
Defendants,
Case No. 3AN 08-10115CI

OPPOSITION TO
MOTION FOR AWARD OF ATTORNEY'S FEES

Plaintiff, the Law Project for Psychiatric Rights (PsychRights®) opposes the defendants' Motion for Award of Attorney's Fees. Civil Rule 82(3)(I) provides:

> (3) The court may vary an attorney's fee award calculated under subparagraph (b)(1) or (2) of this rule if, upon consideration of the factors listed below, the court determines a variation is warranted:
>
> (I) the extent to which a given fee award may be so onerous to the non-prevailing party that it would deter similarly situated litigants from the voluntary use of the courts;

Any award is likely to deter litigants from the voluntary use of the courts. This was raised in §II.B., of PsychRights Opposition to Motion for Judgment on the Pleadings and is incorporated herein by reference.

DATED: January 30, 2009.

Law Project for Psychiatric Rights

By: _____
James B. Gottstein
ABA # 7811100

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

IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

REC'D JUL 10 2009

Case No. 3AN-08-10115 CI

DEFENDANTS' REPLY TO OPPOSITION TO MOTION FOR AWARD OF ATTORNEY'S FEES

The State of Alaska and the remaining above-named defendants (hereinafter "the Department") reply as follows to plaintiff's Opposition to Motion for Award of Attorney's Fees.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

In its Motion, the Department requested $3,876.00 in attorney's fees as a prevailing party under Civil Rule 82. Plaintiff in opposition asks the court to deviate from the standard prevailing party fee schedule and vary the fee award because the requested fees would "be so onerous to the non-prevailing party, that it would deter similarly situated litigants from the voluntary use of the courts."[1]

Plaintiff then refers the court to §II.B of its Opposition to Motion for Judgment on the Pleadings, in which plaintiff: (1) asserts without explanation that it is "reluctant" to add individual plaintiffs to achieve interest-injury standing; (2) claims it has citizen-taxpayer standing even though it contradicts this claim by stating individual plaintiffs could be substituted for plaintiff's law firm; and (3) makes unsubstantiated (and factually incorrect) allegations against the Attorney General's Office purported policy to "always" seek attorney's fees "against people on welfare" and other non-prevailing parties, "even if they can't afford them."[2]

Plaintiff—a law firm, albeit a non-profit one—makes no averments as to why the requested fee award would be onerous. Furthermore, litigants similarly situated to this plaintiff arguably *should* be deterred from the voluntary use of the courts. The reason for dismissal of this action and the Department's ensuing status as a prevailing party is that the plaintiff—who is a law firm and not a "person on

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[1] Civil Rule 82(b)(3)(I).

[2] Plaintiff's Opposition to Motion for Judgment on the Pleadings, p. 23-24.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
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welfare"—lacked both interest-injury and citizen taxpayer standing to sue.[3] A law firm without standing should not be permitted to squander judicial resources forcing defendants to prove the point.

In short, plaintiff gives the court no reason to vary the fee award from the standard Rule 82 fee schedule. The court should grant the Department's Motion for Award of Attorney's Fees as requested.

Dated this 8th day of July, 2009.

DANIEL S. SULLIVAN
ATTORNEY GENERAL

By: _____
Elizabeth M. Bakalar
Assistant Attorney General
Alaska Bar No. 0606036

By: _____
Stacie L. Kraly
Chief Assistant Attorney General
Alaska Bar No. 9406040

Certificate of Service
I hereby certify that on this day of July 8, 2009, true and correct copies of the foregoing REPLY was served via U.S. mail, first class, postage prepaid to the following attorney of record:

James B. Gottstein, Esq.
Law Project for Psychiatric Rights, Inc.
406 G Street, Suite 206
Anchorage, AK 99501

_____
H. Raven Haffner, Law Office Assistant II

[3] Court's Order on Record, May 27, 2009.

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
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IN THE SUPERIOR COURT FOR THE STATE OF ALASKA

THIRD JUDICIAL DISTRICT AT ANCHORAGE

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, and WILLIAM STREUER, Deputy Commissioner and Director of the Division of Health Care Services,

Defendants.

REC'D JUL 30 2009

Case No. 3AN-08-10115 CI

JUN 24 2009

ORDER GRANTING DEFENDANT'S MOTION FOR ATTORNEY'S FEES

THE COURT, having considered the Department's Motion for Attorney's Fees, any opposition and any responses thereto, and being fully advised,

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600

HEREBY ORDERS that the motion is GRANTED. The defendant is entitled to a total fee award under Civil Rule 82(b)(2) of $3,876.00. This amount shall be entered in the final judgment with post-judgment interest to run from

16 June 2009

DATED: 7-28-09

Jack W. Smith
Superior Court Judge

I certify that on 7-29-09 a copy of the above was mailed to each of the following at their address of record. Sattstun, Kraly, Bakalar

Secretary/Deputy Clerk

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
P.O. BOX 110300, JUNEAU, ALASKA 99811
PHONE: 465-3600