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
VOLUME 1 OF 3

James B. Gottstein (7811100)
Law Project for Psychiatric Rights, Inc.
406 G Street, Suite 206
Anchorage, Alaska
(907) 274-7686

Attorney for Appellant
Law Project for Psychiatric Rights

Filed in the Supreme Court of
the State of Alaska, this 23
day of November 2009

Marilyn May, Clerk

By: _____
Deputy Clerk

Table of Contents

Volume 1

Volume 2

Volume 3

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)

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

TABLE OF CONTENTS

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

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

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

(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

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

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

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

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.

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

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.

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

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

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

> 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:

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

> 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.

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

> 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.

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

> 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.

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

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

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

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

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

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.

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

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

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

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

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

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.

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

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

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

(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.

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

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.

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

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

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

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

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

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

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

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

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

---

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

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

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.

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

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.

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

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		

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

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.

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

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,

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

(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,

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

(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.

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

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:

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

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.

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

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,

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

(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.

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

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		

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

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,

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

(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

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

(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

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

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.

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

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,

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

(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

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

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.

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

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)

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

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).

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

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

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

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.

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

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?

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

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?

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

(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?

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

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?

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

(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:

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

(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.

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

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.

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

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,

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

(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

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

PsychRights

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

December 10, 2004

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

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>,
"jeff jessee-mhta.revenue.state.ak.us" <jeff_jessee@mhta.revenue.state.ak.us>,
"DJRICCIO-aol.com" <DJRICCIO@aol.com>,lloydross1@worldnet.att.net,
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

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.

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,
Representative_Ralph_Samuels@legis.state.ak.us,
Representative_Max_Gruenberg@legis.state.ak.us,
Representative_Lindsey_Holmes@legis.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,
"jeff jessee-mhta.revenue.state.ak.us" <jeff_jessee@mhta.revenue.state.ak.us>,
doolttle@ptialaska.net,william_hogan@health.state.ak.us,
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

---

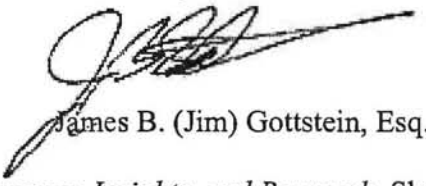
[1] *See*, enclosed copy of affidavit of Robert Whitaker.
[2] PsychRights won its second Alaska Supreme Court case in 2007, *Wetherhorn v. Alaska Psychiatric Institute*, 156 P.3d 371, which held involuntarily committing someone as being gravely disabled under the definition in AS 47.30.915(7)(B) is constitutional 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
P.O. BOX 110300, JUNEAU, ALASKA 99811
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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

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.

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

"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.

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

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.

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

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;

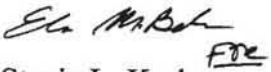
2. The state be awarded reasonable attorneys fees and costs; and

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

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

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
(907) 274-7686 Phone ~ (907) 274-9493 Fax

[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

ATTORNEY GENERAL, STATE OF ALASKA
DIMOND COURTHOUSE
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

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

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

---

[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).

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

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

---

[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.

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

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
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 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

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

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

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 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.

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

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
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, 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

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

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
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 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

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

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.

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

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

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

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

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

---

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]

---

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

[4] *See* AS 47.07.

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

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

---

[5] *See* 7 AAC 43.593.

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

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]

---

[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.

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

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

---

[9] *Id.*

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

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

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

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]

---

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).

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

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.

---

[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

---

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

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.

---

[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).

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

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

---

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.

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

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

---

[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.

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

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

---

[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.").

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

> 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

---

[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.*

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

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

---

[44] *Id.* at 330.

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

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

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

---

[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.*

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

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

---

[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).

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

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

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

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
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 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
(907) 274-7686 Phone ~ (907) 274-9493 Fax

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

[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
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
P.O. Box 110300
Juneau, Alaska 99801-0300
(907) 465-4135 (direct)
(907) 465-3600 (main)
(907) 465-2539 (fax)

--

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.

--

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: [redacted]@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?
--

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.

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
(907) 274-7686 Phone ~ (907) 274-9493 Fax

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 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

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 Meads
Secretary/Deputy Clerk

MAR 16 2009

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

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 normal time, 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. JS

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

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

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).

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

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

---

[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.

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

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

---

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

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

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.

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

> 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.

---

[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

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

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

---

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.

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

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:

---

[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.

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

> 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.

---

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

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

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,

---

[27] Exhibit F.

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

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]

---

[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.

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

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).

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

> 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:

---

[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)

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

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

---

[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.

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

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]

---

[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.

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

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]

---

[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.

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

(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

---

[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

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

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

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

---

[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

---

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

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

> 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

---

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

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

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

---

[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)

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

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

---

[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.

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

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.

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

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.

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

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

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

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.

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

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.

---

[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.

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

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

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
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

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

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

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

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,

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

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:

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

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.

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

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,

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

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

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

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.

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

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]

406 G Street, Suite 206, Anchorage, Alaska 99501 ~ (907) 274-7686 Phone ~ (907) 274-3493 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.

[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 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]

406 G Street, Suite 206, 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.

[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 15th day of February, 2009.

[redacted]
[print name]

406 G Street, Suite 206, 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 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

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 February, 2009.

[redacted]
[print name]

406 G Street, Suite 206, 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.

[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 February, 2009.

[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
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.

--

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
(907) 465-4135 (direct)
(907) 465-3600 (main)
(907) 465-2539 (fax)

--

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

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

--

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.

--

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
```

EXHIBIT F
PAGE 2 OF 8

ZYP-AK-03354

001441

```
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
```

EXHIBIT F
PAGE 3 OF 8

ZYP-AK-03355

001442

```
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 #')
```

EXHIBIT F
PAGE 4 OF 8

ZYP-AK-03356

001443

```
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
```

EXHIBIT F
PAGE 5 OF 8

ZYP-AK-03357

001444

```
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')
```

EXHIBIT F
PAGE 6 OF 8

ZYP-AK-03358

001445

```
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
```

EXHIBIT F
PAGE 7 OF 8

ZYP-AK-03369

001446

MEND

EXHIBIT F
PAGE 8 OF 8

ZYP-AK-03360

001447

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.

###

09-038

International Journal of Risk & Safety in Medicine 19 (2007) 209–221
IOS Press

Pediatric bipolar disorder: An object of study in the creation of an illness

David Healy * and Joanna Le Noury
North Wales Department of Psychological Medicine, Cardiff University, Bangor LL57 2PW, Wales, UK

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

* Address for correspondence: David Healy, North Wales Department of Psychological Medicine, Cardiff University, Bangor LL57 2PW, Wales, UK. Fax: +44 1248 371397; E-mail: healy_hergest@compuserve.com

[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.

References

[1] T. Anglada, *Brandon and the Bipolar Bear*, Trafford Publishing, Victoria, BC, 2004.
[2] K. Applbaum, *The Marketing Era*, Routledge, New York, 2004.
[3] C. Baethge, R. Glovinsky and R.J. Baldessarini, Manic-depressive illness in children: an early twentieth century view by Theodore Ziehen (1862–1950), *Hist. Psychiatr.* **15** (2004), 201–226.
[4] J. Biederman, S. Faraone, E. Mick, J. Wozniak, L. Chen, C. Ouellette, A. Marrs, P. Moore, J. Garcia, D. Mennin and E. Lelon, Attention-deficit hyperactivity disorder and juvenile mania: an overlooked co-morbidity?, *J. Am. Acad. Child Adolesc. Psychiatr.* **35** (1996), 997–1008.
[5] K. Brooks, No Small Burden, Families with mentally ill children confront health care shortcomings, undeserved stigma of 'bad parenting', Dallas Star Telegram, July 19th, 2000, DOI: 1%3A00MENTALHEALTH170719100.html.
[6] C.W. Colton and R.W. Manderscheid, Congruencies in increased mortality rates, years of potential life lost, and causes of death among public mental health clients in eight states, *Prev. Chronic Dis.* (2006). Available from: http://www.cdc.gov/pcd/issues/2006/apr/05_0180.htm.
[7] W. Cooper, P.G. Arbogast, H. Ding, G.B. Hickson, C. Fuchs and W.A. Ray, Trends in prescribing of antipsychotic medications for US children, *Ambul. Pediatr.* **6** (2006), 79–83.
[8] M. De Hert, E. Thys, G. Magiels and S. Wyckaert, *Anything or Nothing. Self-Guide for People with Bipolar Disorder*, Uitgeverij Houtekiet, Antwerp, 2005.
[9] S. Dilsaver, Review of J. Harris, *J. Bipolar Disorders* **4** (2005), 8–9.
[10] C.L. Ernst and J.F. Goldberg, The reproductive safety profile of mood-stabilizers, atypical antipsychotics and broad-spectrum psychotropics, *J. Clin. Psychiatr.* **63**(Suppl. 4) (2002), 42–55.
[11] S.V. Faraone, J. Biederman, D. Mennin, J. Wozniak and T. Spencer, Attention-deficit hyperactivity disorder with bipolar disorder: a familial subtype?, *J. Am. Acad. Child. Adolesc. Psychiatr.* **36** (1997), 1378–1387.

[12] R.L. Findling, R.A. Kowatch and R.M. Post, *Pediatric Bipolar Disorder. A Handbook for Clinicians*, Martin Dunitz, London, 2003.
[13] B. Geller, M. Williams, B. Zimmerman and J. Frazier, Washington University in St. Louis Kiddie Schedule for Affective Disorders and Schizophrenia (Wash-U-KSADS), Washington University, St. Louis, 1996.
[14] B. Geller, J. Craney, K. Bolhoffer, M.P. DelBello, D. Axelson, J. Luby, M. Williams, B. Zimerman, M.J. Nickelsburg, J. Frazier and L. Beringer, Phenomenology and longitudinal course of children with a prepubertal and early adolescent bipolar disorder phenotype, in: *Bipolar Disorder in Childhood and Early Adolescence*, B. Geller and M.P. DelBello, eds, The Guilford Press, New York, 2003, pp. 25–50.
[15] S.N. Ghaemi, On defining 'mood stabilizer', *Bipolar Disorder* **3** (2001), 154–158.
[16] F.K. Goodwin and K.R. Jamison, *Manic Depressive Illness*, Oxford University Press, New York, 1990.
[17] J. Harris, The increased diagnosis of juvenile "bipolar disorder", what are we treating?, *Psychiatr. Serv.* **56** (2005), 529–531.
[18] M. Harris, S. Chandran, N. Chakroborty and D. Healy, Service utilization in bipolar disorders, 1890 and 1990 compared, *Hist. Psychiatr.* **16** (2005), 423–434.
[19] D. Healy, *The Creation of Psychopharmacology*, Harvard University Press, Cambridge, MA, 2002.
[20] D. Healy, *Let Them Eat Prozac*, New York University Press, New York, 2004, Chapter 4.
[21] D. Healy, The Latest Mania. Selling Bipolar Disorder, *PloS Medicine* (2006), http://dx.doi.org/10.1371/journal.pmed.0030185.
[22] D. Healy, *Mania*, Johns Hopkins University Press, Baltimore, MD, 2008.
[23] B. Hebert, *My Bipolar Roller Coaster Feeling Book*, Trafford Publishing, Victoria, BC, 2005.
[24] G. Isaac, *Bipolar not ADHD. Unrecognized Epidemic of Manic-Depressive Illness in Children*, Writers' Club Press, Lincoln, NE, 2001.
[25] M. Joukamaa, M. Heliovaara, P. Knekt, A. Aromaa, R. Partosalo and R. Lehtinen, Schizophrenia, neuroleptic medication and mortality, *Br. J. Psychiatr.* **188** (2006), 122–127.
[26] J. Kluger and S. Song, Young and Bipolar. Once called Manic Depression, the disorder afflicted adults. Now it's striking kids. Why?, *TIME Magazine* **160** (2002), 30–41.
[27] R.A. Kowatch, M. Fristad, B. Birmaher, K.D. Wagner, R.L. Findling, M. Hellander and The Child Psychiatric Workgroup on Bipolar Disorder, Treatment guidelines for children and adolescents with bipolar disorder, *J. Am. Acad. Child Adolesc. Psychiatr.* **44** (2005), 213–235.
[28] Z.A. Kyte, G.A. Carlsson and I.M. Goodyer, Clinical and neuropsychological characteristics of child and adolescent bipolar disorder, *Psychol. Med.* **36** (2006), 1197–1211.
[29] P. Lewinsohn, D. Klein and J. Seeley, Bipolar disorder during adolescence and young adulthood in a community sample, *Bipolar Disorder* **2** (2000), 281–293.
[30] E. Mick, J. Biederman, M. Dougherty and M. Aleardi, Comparative efficacy of atypical antipsychotics for pediatric bipolar disorder [abstract], *Acta Psychiatr. Scand.* **110** (2004), P50, 29.
[31] E. Mick, J. Biederman, M. Dougherty and M. Aleardi, Open trial of atypical antipsychotics in pre-schoolers with bipolar disorder [abstract], *Acta Psychiatr. Scand.* **110** (2004), P51, 29.
[32] R. Moynihan and A. Cassels, *Selling Sickness*, Nation Books, New York, 2005.
[33] National Institute for Health & Clinical Excellence (NICE), Bipolar disorder, *Clinical Guideline* 38, 2006. Available on www.nice.org.uk.
[34] National Institute of Mental Health Research Roundtable on Prepubertal Bipolar Disorder, *J. Am. Acad. Child Adolesc. Psychiat.* **40** (2001), 871–878.
[35] D. Papolos and J. Papolos, *The Bipolar Child*, Random House, New York, 2000.
[36] R.M. Post, Treatment resistance in bipolar disorder, in: *Royal College of Psychiatrists Meeting*, Newcastle, England, October 17th, 2002.
[37] Psychopharmacologic Drugs Advisory Committee, in: *Forty-Fourth Meeting*, NDA 20-320: Depakote, Transcript of Proceedings, Department of Health and Human Services, Washington, DC, February 6th, 1995.
[38] J.G. Storosum, T. Wohlfarth, C.C. Gispen-de Wied, D.H. Linszen, B.P. Gersons, B. van Zwieten and W. van den Brink, Suicide-risk in placebo controlled trials of treatment for acute manic episode and prevention of manic-depressive episode, *Am. J. Psychiatr.* **162** (2005), 799–802.
[39] G.D. Tollefson, Zyprexa Product Team: 4 Column Summary. Zyprexa MultiDistrict Litigation 1596, Document ZY200270343, 1997.
[40] F.R. Volkmar, Changing perspectives on mood disorders in children, *Am. J. Psychiatr.* **159** (2002), 893–894.