IN THE UNITED STATES DISTRICT COURT
DISTRICT OF ALASKA

UNITED STATES OF AMERICA *Ex rel.* Law Project for Psychiatric Rights, an Alaskan non-profit corporation, Plaintiff, vs. OSAMU ~~OSAMI~~ H. MATSUTANI, MD, WILLIAM HOGAN, individually, and as Commissioner of the Department of Health and Social Services, TAMMY SANDOVAL, Individually and as Director of the Alaska Office of Children's, Services, STEVE McCOMB, individually and as Director of the Alaska Division of Juvenile Justice, WILLIAM STREUR, individually, and as Director of the Alaska Division of Health Care Services, JUNEAU YOUTH SERVICES, Inc., an Alaskan non-profit corporation, PROVIDENCE HEALTH & SERVICES, an Alaskan non-profit corporation, ELIZABETH BAISI, MD, RUTH DUKOFF, MD, CHARTER NORTH STAR BEHAVIORAL HEALTH SYSTEM, an Alaska Limited Liability Company, KERRY OZER, MD, CLAUDIA PHILLIPS, MD, SOUTHCENTRAL FOUNDATION, an Alaska non-profit corporation, SHEILA CLARK, MD, HUGH STARKS, MD, LINA JUDITH BAUTISTA, MD, HEIDI F. LOPEZ-COONJOHN, MD, ROBERT D. SCHULTS, MD, MARK H. STAUFFER, MD, RONALD A. MARTINO, M.D., IRVIN ROTHROCK, MD, JAN KIELE, MD, ALTERNATIVES COMMUNITY MENTAL HEALTH SERVICES, d/b/a DENALI	**CIVIL ACTION NO._____** **FILED *IN CAMERA* AND UNDER SEAL** **FALSE CLAIMS ACT MEDICAID FRAUD** **DEMAND FOR JURY TRIAL**

FAMILY SERVICES,)
ANCHORAGE COMMUNITY MENTAL)
HEALTH SERVICES, an Alaska non-profit)
Corporation, LUCY CURTIS, MD,)
FAIRBANKS PSYCHIATRIC AND)
NEUROLOGIC CLINIC, PC)
PENINSULA COMMUNITY HEALTH)
SERVICES OF ALASKA, INC.,)
BARTLETT REGIONAL HOSPITAL)
FOUNDATION, INC., THOMSON REUTERS)
(Healthcare) INC., WAL-MART STORES,)
INC., SAFEWAY, INC., FRED MEYER)
STORES, INC.,)
)
Defendants.)
)

PLAINTIFF'S COMPLAINT PURSUANT TO 31 U.S.C §§ 3729-3732 OF THE FEDERAL FALSE CLAIMS ACT

The United States of America, by and through *qui tam* relator Law Project for Psychiatric Rights, an Alaska non-profit corporation (PsychRights), brings this action under 31 U.S.C §3729, *et seq.*, as amended (False Claims Act) to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States.

TABLE OF CONTENTS

I. PRELIMINARY STATEMENT

1. This is an action to recover damages and civil penalties on behalf of the United States of America, for violations of the False Claims Act arising from false or fraudulent records, statements, or claims, or any combination thereof, made, used or caused to be made, used, or presented, or any combination thereof, by the defendants, their agents, employees, or co-conspirators, or any combination thereof, with respect to false claims for outpatient psychotropic medications prescribed to children and youth for which claims were made to the federal Medicaid Program and Children's Health Insurance Program (CHIP).

2. The False Claims Act was enacted during the Civil War. Congress amended the False Claims Act in 1986 to enhance the Government's ability to recover losses

sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the False Claims Act, which Congress characterized as the primary tool for combating government fraud, was in need of modernization. Congress intended that the amendments create incentives for individuals with knowledge of fraud against the government to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit legal resources to prosecuting fraud on the Government's behalf.

3. The False Claims Act provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the U.S. Government for payment or approval is liable for a civil penalty of up to $11,000 for each such claim, plus three times the amount of the damages sustained by the Government. The False Claims Act defines "knowingly" to include acts committed with "actual knowledge," as well as acts committed "in deliberate ignorance" or in "reckless disregard" of their truth or falsity. Liability attaches when a defendant seeks, or causes others to seek, payment that is unwarranted from the Government.

4. The Act allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

5. As a result of aggressive drug company promotion of the prescription of psychotropic drugs to children and youth for conditions not approved by the federal Food and Drug Administration (FDA), known as "off-label" use, including,

(a) sponsoring and/or conducting fraudulent research and the publication thereof in medical journals,

(b) paying what is known as Key Opinion Leaders (KOLs) to support such off-label use,

(c) suppressing research showing negative results,

(d) domination of psychiatrists' and other prescribers' training and continuing medical education programs,

(e) speaking fees to promote the off-label prescription of drugs, and

(f) free meals and other gifts to prescribers,

psychiatrists and other prescribers pervasively prescribe psychotropic drugs knowing that false claims will be presented to Medicaid and CHIP within the meaning of the False Claims Act.

6. Under Medicaid and CHIP,

(a) psychiatrists and other prescribers,

(b) mental health agencies,

(c) pharmacies, and

(d) state officials,

all have specific responsibilities to prevent false claims from being presented and are liable under the False Claims Act for their role in the submission of false claims.

7. The defendants in this action are:

(a) psychiatrists who prescribed drugs that were not lawfully reimbursable under Medicaid or CHIP knowing that claims would be made to Medicaid and/or CHIP,

(b) mental health agencies employing such psychiatrists knowing that such claims would be made to Medicaid and/or CHIP,

(c) pharmacies who filled such prescriptions and made claims to Medicaid and/or CHIP for reimbursement,

(d) employees of the State of Alaska, individually and in their official capacities, who were and are responsible for authorizing reimbursement of false claims, and

(e) Thomson Reuters (Healthcare), which made false statements in continuing medical education programs promoting off-label pediatric use of psychotropic drugs.

8. This is an action for treble damages and penalties for each false claim and each false statement under the False Claims Act, 31 U.S.C. §3729, et seq., as amended.

II. PARTIES

9. Relator, the Law Project for Psychiatric Rights, Inc., is an Alaskan non-profit corporation (PsychRights), whose mission is to mount a strategic litigation campaign in the United States against psychiatric drugging and electroshocking people against their will. PsychRights has made a priority the massive, mostly ineffective, and extremely harmful, over-drugging of children and youth with psychiatric drugs.

10. Defendant Osamu H. Matsutani, MD (Matsutani), is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

11. Defendant William Hogan (Hogan) is a resident of the State of Alaska and the Commissioner of the State of Alaska's Department of Health and Social Service (DHSS), and in such capacity is responsible for the administration of Alaska's Medicaid program and CHIP, including Alaska authorizing reimbursement for psychiatric drugs prescribed to children and youth.

12. Defendant Tammy Sandoval (Sandoval) is a resident of the State of Alaska and the Director of the Office of Children's Services within DHSS (OCS). OCS has custody of children and youth whom it has been determined are in need of assistance because of abuse or neglect, and submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to such children and youth.

13. Defendant Steve McComb (McComb) is a resident of the State of Alaska and the Director of the Division of Juvenile Justice within DHSS (DJJ). DJJ takes custody of Alaskan children and youth offenders and submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to such children and youth.

14. Defendant William Streur (Streur) is a resident of the State of Alaska and the Director of the Division of Health Care Services within DHSS (HCS). HCS authorizes

reimbursement by Medicaid and CHIP for psychiatric drugs prescribed to Alaskan children and youth.

15. Defendant Providence Health & Services, is an Alaskan non-profit corporation, doing business in the District of Alaska (Providence). Providence submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

16. Defendant Juneau Youth Services, Inc., is an Alaskan non-profit corporation doing business in the District of Alaska (JYS). JYS submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

17. Defendant Charter North Star Behavioral Health System, L.L.C., is an Alaskan Limited Liability Company doing business in Alaska (North Star). North Star submitted and/or submits, or caused and/or causes claims to be submitted, to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

18. Defendant Alternatives Community Mental Health Services, d/b/a Denali Family Services (Denali), is an Alaska non profit corporation, and submitted and/or submits, or caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

19. Defendant Peninsula Community Health Services of Alaska, Inc. successor to Central Peninsula Mental Health Association, Incorporated, is an Alaskan non-profit corporation doing business in Alaska (Peninsula). Peninsula submitted and/or submits, or

caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

20. Defendant Bartlett Regional Hospital Foundation, Inc. is an Alaskan non-profit corporation doing business in Alaska (Bartlett). Bartlett submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

21. Defendant Fairbanks Psychiatric And Neurologic Clinic, PC, is an Alaskan professional corporation doing business in Alaska (Fairbanks Psychiatric). Fairbanks Psychiatric submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

22. Defendant Anchorage Community Mental Health Services, Inc., is an Alaskan non profit corporation doing business in Alaska (ACMHS). ACMHS submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

23. Defendant Southcentral Foundation is an Alaskan non-profit corporation doing business in Alaska (SCF). SCF submitted and/or submits, or caused and/or causes, claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

24. Defendant Lina Judith Bautista, MD (Bautista), is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

25. Defendant Elizabeth Baisi, MD (Baisi) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

26. Defendant, Ronald A. Martino, MD (Martino) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

27. Defendant , Sheila Clark, MD (Clark), is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

28. Defendant, Kerry Ozer, MD (Ozer), is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

29. Defendant, Hugh Starks, MD (Starks), is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

30. Defendant, Ruth Dukoff, MD (Dukoff), is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

31. Defendant, Claudia Phillips, MD (Phillips) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

32. Defendant, Lucy Curtis, MD (Curtis) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

33. Defendant, Heidi F. Lopez-Coonjohn, MD (Lopez-Coonjohn) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

34. Defendant, Robert D. Schults, MD,(Schults) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

35. Defendant, Mark H. Stauffer, MD (Stauffer) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

36. Defendant, Irvin Rothrock, MD, (Rothrock) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

37. Defendant, Jan Kiele, MD (Kiele) is a resident of the District of Alaska and caused and/or causes claims to be submitted to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

38. Defendant Thomson Reuters (Healthcare) Inc. (Thomson), does business in the District of Alaska, conducts continuing medical education programs promoting off-label pediatric use of psychiatric drugs, and publishes DRUGDEX, a pharmaceutical

compendium, which includes entries regarding psychiatric drugs prescribed to children and youth.

39. Defendant, Wal-Mart Stores, Inc. (Wal-Mart), does business in the District of Alaska, is a national retailer, including of prescription drugs, and submitted and continues to submit claims to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

40. Defendant, Safeway, Inc. (Safeway), does business in the District of Alaska, is a national retailer, including of prescription drugs, and submitted and continues to submit claims to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

41. Defendant, Fred Meyer Stores, Inc. (Fred Meyer), does business in the District of Alaska, is a national retailer, including of prescription drugs, and submitted and continues to submit claims to Medicaid and/or CHIP for reimbursement of psychiatric drugs prescribed to children and youth.

III. JURISDICTION AND VENUE

42. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730.

43. There have been no public disclosures of allegations or transactions that bar jurisdiction under 31 U.S.C. §3730(e).

44. This Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and

because all the defendants have at least minimum contacts with the United States, and can be found in, reside, or transact or have transacted, business in the District of Alaska.

45. Venue exists in the United States District Court for the District of Alaska pursuant to 31 U.S.C. § 3730(b)(1) because all of the defendants have at least minimum contacts with the United States, and all the defendants can be found in, reside, or transact or have transacted business in the District of Alaska.

IV. BACKGROUND

A. The FDA Drug Approval Process

46. 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.

47. 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.

48. Drug companies pay for and conduct all tests and trials considered by CDER in the drug approval process, and CDER judges a drug's efficacy and safety based on the data submitted by the sponsoring drug company (Sponsor) in support of what is called a New Drug Application (NDA).

49. 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.

50. 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.

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. 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.

53. 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.

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

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

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

57. Sponsors announce in their study protocols that they will gather data for weeks after clinical trial subjects stop treatment, but do not submit these data to the FDA even though subjects often rate their experience differently once the mind-altering drug has been discontinued.

58. 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.

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

60. Sponsors often distort negative results to make them appear positive.

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

62. In conducting clinical trials, sponsors now extensively use Contract Research Organizations, which are private, for profit companies that get paid to achieve positive results for the Sponsors.

63. In 90 percent of studies pitting one newer neuroleptic, also misleadingly called "antipsychotic," against another, the best drug was the Sponsor's drug.

64. 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.

65. An example is two studies involving Paxil for adolescents, "Study 329" and "Study 377," in which the drug manufacturer did not submit the data to the FDA because it demonstrated Paxil should not be approved for this population.

66. Another example is the manufacturer of Seroquel hiding the results of Trials 15, 31, 56, and the COSTAR Trial.

B. Drug Company Sponsored False statements

67. Prior to the 1990s, most drug research was funded by the government and conducted in academic centers.

68. By the 1990s that was largely over, and most of the funding is now coming from the pharmaceutical industry.

69. One result is that medical journals became a marketing arm for the drug companies.

70. Drug companies pay Medical Science Liaisons (MSLs) to induce "Key Opinion Leaders" (KOLs) to make false statements in support of prescribing their psychotropic drugs for non FDA pediatric approved uses, including having such false statements published in peer-reviewed journals.

71. Drug companies pay Key Opinion Leaders to make false statements to influence prescribers to prescribe particular psychotropic drugs for pediatric uses not authorized by the FDA, including having such false statements published in peer-reviewed journals.

72. Drug companies write articles for publication in peer-reviewed journals that make false statements in support of prescribing particular psychotropic drugs for

pediatric uses not approved by the FDA, and pay Key Opinion Leaders and other supposed researchers, to represent that they are the author(s) of such articles, in what is known as "Ghost Writing."

73. An example of drug company sponsorship of peer-reviewed articles making false statements in support of prescribing a psychotropic drug for pediatric uses not approved by the FDA is a paper on "Study 329" containing false statements published by the Journal of the American Academy of Child and Adolescent Psychiatry (JAACAP) in July 2001, in which its listed authors claimed that Paxil was "generally well tolerated and effective for major depression in adolescents." The paper became one of the most cited in the medical literature in supporting the use of antidepressants in child and adolescent depression Paxil's manufacture claimed it demonstrated "REMARKABLE Efficacy and Safety."

74. Drug companies pay psychiatrists to make false statements to other prescribers to induce them to prescribe particular psychotropic drugs for pediatric uses not approved by the FDA.

75. Drug companies pay for Continuing Medical Education (CME) programs in which false statements are made to induce prescribers to prescribe psychotropic drugs to children and youth for uses not approved by the FDA.

76. Drug companies pay prescribers to attend CME programs in which false statements are made to induce prescribers to prescribe psychotropic drugs for pediatric uses not approved by the FDA.

77. Drug companies pay sales representatives to make false statements to prescribers to induce them to prescribe particular psychotropic drugs to children and youth for uses not approved by the FDA.

78. Drug companies give or gave gifts to prescribers to induce them to prescribe particular psychotropic drugs to children and youth for uses not approved by the FDA.

79. Drug companies make false statements to induce prescribers to misdiagnose pediatric patients for indications that can then be used to justify prescribing their drugs as being for FDA approved indications, or supported by one or more of the Compendia.

80. The drug industry spent $7 billion in 2004 on marketing directly to doctors.

81. The drug industry spends three times as much on marketing as for research and development.

82. There is one drug sales representative to every two and one half doctors in the United States.

83. Less than one minutes spent by sales representatives with doctors results in a 16 percent change in such doctors' prescribing in favor of the drug companies' drug(s).

84. After three minutes with a sales representative there is a 52 percent change in such doctors' prescribing in favor of the drug companies' drug(s).

C. Pediatric Psychopharmacology: In General

85. 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.

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

87. At least forty percent of all psychiatric drug treatments today involve concomitant or multiple psychotropic medication use, commonly referred to as "polypharmacy."

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

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

90. 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.

91. Psychotropic drugs given to children and youth cause drug-induced adverse effects and behavioral changes, including apathy, agitation, aggression, mania, suicidal ideation and psychosis, known as "behavioral toxicity."

92. 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.

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

94. 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.

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

96. 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.

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

98. Treatment of preschoolers with psychotropic drugs has barely been studied.

99. 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.

100. 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.

101. 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.

102. 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.

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

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

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

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

D. Neuroleptics

107. As of June, 2008, The following "second-generation" neuroleptics have been approved by the FDA for the following pediatric uses:

<table>
<tr><th>Brand Name</th><th>Generic Name</th><th>Approved Use</th><th>Approved Ages</th></tr>
<tr><td>Risperdal</td><td>risperidone</td><td>Autism, bipolar mania, schizophrenia</td><td>5+</td></tr>
<tr><td>Abilify</td><td>aripriprazole</td><td>Schizophrenia</td><td>10+</td></tr>
<tr><td>Clozaril</td><td>clozapine</td><td>Treatment-Resistant schizophrenia</td><td rowspan="7">Adults only</td></tr>
<tr><td>Zyprexa</td><td>olanzapine</td><td rowspan="6">Bipolar mania, schizophrenia</td></tr>
<tr><td>Seroquel</td><td>quetiapine</td></tr>
<tr><td>Geodon</td><td>ziprasidone</td></tr>
<tr><td>Symbyax</td><td>olanzapine & fluoxetine</td></tr>
<tr><td>Invega</td><td>paliperidone</td></tr>
</table>

108. Dr. Joseph Biederman of Harvard Medical School was paid by the manufacturer of Risperdal to conduct research to generate and disseminate false

statements supporting the pediatric use of Risperdal, which were used to gain FDA approval for pediatric use.

109. 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+

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

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

112. 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.

113. Neuroleptics are most often prescribed to children and youth to suppress aggression rather than for psychosis.

114. 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.

115. 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.

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

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

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

(a) Increased indifference, including to psychotic symptoms,

(b) Reduced spontaneity and affect,

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

(d) Increased compliance with social norms.

119. 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.

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

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

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

(c) Diabetes (second-generation) and other endocrine problems, Cardiac problems,

(d) Liver problems and jaundice,

(e) 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, and

(f) Death.

121. 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.

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

123. 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.

124. 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.

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

126. 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.

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

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

129. 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.

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

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

131. A government sponsored study showed a lifespan decrease of twenty-five years for people diagnosed with schizophrenia who take these medications long-term.

132. Another study showed a 20 fold increase in suicide rates for patients diagnosed with schizophrenia who were given neuroleptics from 1994-1998 compared to those in the period from 1875-1924 who were not given neuroleptics.

133. Between 1993 and 2002, the number of non-institutionalized six to eighteen year olds on neuroleptics increased from 50,000 to 532,000.

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

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

136. 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.

137. The sales of atypical neuroleptics have skyrocketed in recent years, propelling overall sales of neuroleptic drugs past all other classes, to $14.6 billion in 2008.

E. AntiDepressants

138. 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+

139. 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.

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

141. Only three of fifteen (20%) published and unpublished controlled pediatric trials of the 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.

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

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

144. 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.

145. Undesirable observed behavioral effects of antidepressants include:

(a) Anxiety and nervousness,

(b) Agitation and irritability,

(c) Mood swings, including mania,

(d) Aggressiveness,

(e) Thoughts of suicide,

(f) Apathy, and

(g) Attempted and actual suicide.

146. 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),

(d) Urinary retention,

(e) Blurred vision,

(f) Weight gain, and

(g) Headaches and dizziness.

147. 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.

148. In 2004, the FDA issued a "Public Health Advisory" about all antidepressants, warning they 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.

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

151. 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."

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.

F. Anticonvulstants Promoted as "Mood Stabilizers"

153. Starting in the 1980s and 1990s drug companies promoted the use of anticonvulsants, i.e., antiepileptics and antiseizure drugs, for people diagnosed with Bipolar Disorder.

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

155. 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

156. 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.

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

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

159. 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.

160. 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.

161. Desired observed behavioral effects of anticonvulsants include:

(a) Reducing aggression and impulsivity, and

(b) Calming restlessness and excitability.

162. 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.

163. Undesired observed physical effects of anticonvulsants include:

(a) Nausea and dizziness,

(b) Vomiting and abdominal pain,

(c) Headaches and tremors,

(d) Fatal skin rashes,

(e) Hypothyroidism,

(f) Blood disorders,

(g) Pancreatitis, liver disease,

(h) Birth defects and menstrual irregularities, and

(i) Withdrawal seizures.

V. APPLICABLE LAW

G. Medicaid & CHIP

164. Medicaid is a public assistance program providing for payment of medical expenses for low-income patients. Funding for Medicaid is shared between the federal government and state governments. The Medicaid program subsidizes the purchase of more prescription drugs than any other program in the United States.

165. Although Medicaid is administered on a state-by-state basis, the state programs must adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses that the federal government will pay for through its funding of state Medicaid programs. Federal reimbursement for prescription drugs under the Medicaid program is, as relevant, limited to "covered outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3).

166. Outpatient drug prescriptions, as relevant, are covered under Medicaid, *i.e.*, reimbursable only if the drug is prescribed for a medically accepted indication, defined as indications approved by the Food and Drug Administration (FDA), or supported by one or more of the following Compendia:

(i) American Hospital Formulary Service Drug Information,

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

(iii) DRUGDEX Information System,

(Covered Outpatient Drugs).

167. Whether a particular use is supported by a compendium depends on a variety of factors, including the type of drug and indication at issue, the compendium's assessment of the drug's efficacy in treating the indication, the content of the compendium citation, and the scope and outcome of the studies as described in the compendium.

168. State Medicaid programs are not allowed to authorize reimbursement for prescriptions that are not for an indication that is either approved by the FDA or supported by one or more of the Compendia.

169. States are required to have a drug use review program to assure that prescriptions are (i) appropriate, (ii) medically necessary, and (iii) not likely to result in adverse medical results.

170. Among other things, such drug review programs, informed by the Compendia, must review each prescription before it is filled to ensure it is properly reimbursable under Medicaid.

171. Every Medicaid provider must agree to comply with all Medicaid requirements.

172. CHIP is a partnership between states and the United States to provide medical insurance for eligible children and youth who do not qualify for Medicaid but who lack the economic means to afford private health insurance.

173. Alaska participates in CHIP, which is called "Denali Kid Care," and has adopted Medicaid for its benefits package.

H. False Claims Act

174. False Claims Act liability attaches to any person who knowingly presents or causes a false or fraudulent claim to be presented for payment, or to a false record or statement made to get a false or fraudulent claim paid by the government. 31 U.S.C. §3729(a)(1)&(2).

175. Under the False Claims Act, "knowing" and "knowingly" mean that a person, with respect to information:

(1) has actual knowledge of the information;

(2) acts in deliberate ignorance of the truth or falsity of the information; or

(3) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required. 31 U.S.C. §3729(b).

176. The False Claims Act reaches beyond demands for money that fraudulently overstate an amount otherwise due; extending to all fraudulent attempts to cause the Government to pay out sums of money.

177. False statements include not only affirmative misrepresentations but also material omissions so that the existence of either one suffices to satisfy the false statement requirement of the False Claims Act.

178. A claim for a prescription is rendered false if a drug manufacturer falsified studies or engaged in other unlawful, fraudulent conduct to procure FDA approval or inclusion in a compendium.

179. A claim for a prescription is rendered false if a drug manufacturer falsified studies or engaged in other unlawful, fraudulent conduct in the promotion of a drug that resulted in the prescription.

180. Illegal off-label marketing that results in the submission of impermissible claims for reimbursement states a claim under the False Claims Act.

181. A claim is false if a physician submitted a claim for reimbursement for which he or she received a kickback in exchange for prescribing a particular drug.

182. The False Claims Act is violated not only by a person who makes a false statement or a false record to get the government to pay a claim, but also by one who engages in a fraudulent course of conduct that causes the government to pay a claim for money.

183. The mere fact that a particular use is a medically accepted indication does not eliminate the possibility of fraudulent conduct or abuse that renders the claim false and ineligible for payment.

184. It is the duty and responsibility of psychiatrists and other prescribers to keep abreast of and inform themselves of the actual benefits and risks of drugs and not ignore information contradicting drug company sponsored false statements when such information becomes available.

185. Psychiatrists and other prescribers derive substantial income from Medicaid, including CHIP/Denali Kid Care, through the prescribing of psychotropic medication to children and youth.

186. Mental health agencies employing psychiatrists and other prescribers derive substantial income from Medicaid, including CHIP/Denali Kid Care, through the prescribing of psychotropic medication to children and youth.

187. The State of Alaska derives substantial income from Medicaid, including CHIP/Denali Kid Care, for reimbursement of prescriptions of psychotropic medication to children and youth.

VI. CAUSES OF ACTION

Count 1: Hogan and Streur Liability For Authorizing False Claims

188. Defendants Hogan and Streur are responsible for the administration of Alaska's Medicaid program, including CHIP/Denali Kid Care, and are liable under the False Claims Act for Alaska authorizing false claims for reimbursement by the Government, when doing so

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false.

189. Defendants Hogan and Streur

(1) had or have actual knowledge;

(2) acted or act in deliberate ignorance; or

(3) acted or act in reckless disregard,

in having Alaska authorize claims for reimbursement of outpatient pediatric prescriptions for psychotropic drugs by Medicaid and/or CHIP that are not for an indication approved by the FDA or supported by one or more of the Compendia, and are liable under the False Claims Act therefor.

Count 2: Sandoval and McComb Liability For Submitting or Causing False Claims to be Submitted

190. Defendants Sandoval and McComb administer programs that have submitted and continue to submit, or have caused and continue to cause to be submitted, or both, claims to Medicaid and/or CHIP for reimbursement of outpatient pediatric prescriptions for psychotropic drugs that are not for an indication that is approved by the FDA or supported by one or more of the Compendia,

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 3: Wal-Mart, Safeway and Fred Meyer Liability For Uncovered Drugs

191. Wal-Mart, Safeway, and Fred Meyer (Pharmacies) have submitted and continue to submit claims to Medicaid and/or CHIP for reimbursement of outpatient pediatric prescriptions for psychotropic drugs that are not for an indication that is approved by the FDA or supported by one or more of the Compendia

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 4: Thomson False Statements in DRUGDEX

192. In 2002, Thomson's scientific and health-care division, which includes DRUGDEX, accounted for $780 million of Thomson's $7.8 Billion in revenue.

193. One of Thomson's scientific and health-care division's biggest operations is running continuing medical education seminars paid by pharmaceutical companies which promote off-label prescribing of such drug companies' drugs under patent through making false statements exaggerating their effectiveness and downplaying their harms.

194. Thomson, through DRUGDEX, makes false statements in supporting the prescription of psychotropic drugs to children and youth for indications not approved by the FDA.

195. Thomson's false statements supporting the prescription of psychotropic drugs to children and youth through continuing medication seminars and DRUGDEX for indications not approved by the FDA were made knowing they would be used to support claims being paid or approved by Medicaid and/or CHIP, and Thomson is liable under the False Claims Act therefor.

Count 5: JYS, ACMHS, SCF, North Star, Providence, Fairbank Psychiatric, Denali, Peninsula & Bartlett Liability for Uncovered Drugs

196. JYS, ACMHS, SCF, North Star, Providence, Fairbank Psychiatric, Denali, Peninsula, and Bartlett (Providers) have submitted and continue to submit, and/or have

caused and continue to cause claims to be submitted to Medicaid and/or CHIP for reimbursement of outpatient pediatric prescriptions for psychotropic drugs that are not for an indication that is approved by the FDA or supported by one or more of the Compendia

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 6: Matsutani, Baisi, Dukoff, Ozer, Phillips, Clark, Stark, Bautista, Lopez-Coonjohn, Schults, Stauffer, Rothrock and Kiele liability For Uncovered Drugs

197. Matsutani, Baisi, Dukoff, Ozer, Phillips, Clark, Stark, Bautista, Lopez-Coonhohn, Schults, Stauffer, Rothrock and Kiele (Prescribers) have written and, upon information and belief, continue to write prescriptions for pediatric prescriptions for psychotropic drugs that are not for an indication approved by the FDA or supported by one or more of the Compendia, thereby causing claims for such prescriptions to be made to Medicaid and/or CHIP for reimbursement

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 7: Prescribers Liability For Misdiagnoses

198. Prescribers make false statements misdiagnosing children and youth for indications to justify prescribing drugs approved by the FDA or supported by one or more

of the Compendia, thereby causing claims for such prescriptions to be made to Medicaid and/or CHIP for reimbursement,

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false, and are liable under the False Claims Act therefor.

Count 8: Prescribers Liability for Pediatric SSRI Prescriptions

199. Drug companies procured FDA approval and support in the Compendia for pediatric use of SSRI antidepressants through falsified studies or other unlawful, fraudulent conduct.

200. When writing pediatric prescriptions for SSRI antidepressants, Prescribers

(1) had or have actual knowledge;

(2) acted or act in deliberate ignorance; or

(3) acted or act in reckless disregard

that FDA approval and support in the Compendia for pediatric use of SSRI antidepressants was obtained through falsified studies or other unlawful, fraudulent conduct, and are liable under the False Claims Act for such claims made to Medicaid, including CHIP/Denali Kid Care.

Count 9: Pediatric Risperdal Prescriptions

201. FDA approval and support in the Compendia of Risperdal for pediatric use was the result of falsified studies or other unlawful, fraudulent conduct.

202. At least from November 25, 2008, when the New York Times reported that the pediatric research center established by Dr. Biederman through funding by Johnson & Johnson, the manufacturer of Risperdal, was established to "move forward the commercial goals" of Johnson & Johnson and "the rationale of [the] center is to generate and disseminate data supporting the use of risperidone in" children and youth, Prescribers

(1) had or have actual knowledge;

(2) acted or act in deliberate ignorance; or

(3) acted or act in reckless disregard

that FDA approval and support in the Compendia for pediatric use of Risperdal was obtained through falsified statements or other unlawful, fraudulent conduct and are liable under the False Claims Act for claims made to Medicaid, including CHIP/Denali Kid Care, for false claims caused by such prescriptions.

VII. MEDICAID CLAIMS

203. At least the following Medicaid claims for reimbursement of pediatric psychotropic medications to Alaskan children and youth were made for the following date ranges:

Dates	Anti-depressants	Anti-Convulsants	2nd Generation Neuroleptics
12/1/2004 to 2/28/05	4,389	4,179	4,596
1/1/2005 to 3/31/2005	4,446	4,205	4,471
5/1/2005 to 7/31/2005	4,155	4,309	5,114
2/1/2006 to 4/30/2006	3,656	3,719	4,476
3/1/2006 to 5/31/2006	3,823	3,781	4,655
4/1/2006 to 6/30/2006	3,755	3,629	4,563
5/1/2006 to 7/31/2006	3,645	3,675	4,602
8/1/2006 to 10/31/2006	3,570	3,756	4,944
11/1/2006 to 1/31/2007	3,585	3,895	5,399
1/1/2007 to 3/31/2007	3,589	3,776	5,205
4/1/2007 to 6/30/2007	3,476	3,809	5,191

204. Prior to, within, and after the time frame of the table in the previous paragraph, the same rough pattern and magnitude of false claims to Medicaid were made, and continue to be made.

205. Wal-Mart, Safeway, and Fred Meyer have submitted millions of false Medicaid claims for reimbursement of pediatric psychotropic medications as set forth herein.

206. As a result of the false statements made by Thomson through its continuing medication programs and/or in DRUGDEX, millions of false Medicaid claims for reimbursement of pediatric psychotropic medications have been made.

VIII. DEFENDANTS' LIABILITY

207. By virtue of the acts described above, defendants knowingly (a) submitted, (b) caused to be submitted, or (c) authorized payment, of false or fraudulent claims to the United States Government for payment or approval.

208. The Government, unaware of the falsity of the claims made or caused to be made by the defendants, paid and continues to pay the false claims.

209. By reason of the defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid hundreds of thousands of such claims through State of Alaska submissions and, through the Pharmacy Defendants, through other states, amounting to many hundreds of millions of dollars, for reimbursement of claims for pediatric psychotropic prescriptions that are not allowed under Medicaid.

IX. PRAYER FOR RELIEF

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

A. That defendants be ordered to cease and desist from violating 31 U.S.C. §3729 *et seq*.

B. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

C. That PsychRights be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act.

D. That PsychRights be awarded all costs of this action, including attorneys' fees and expenses; and

E. That PsychRights recover such other relief as the Court deems just and proper.

DATED: April 27, 2009.

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

James B. Gottstein, Esq.

Digitally signed by James B. Gottstein, Esq.
DN: cn=James B. Gottstein, Esq., o=Law Project for Psychiatric Rights, Inc., ou, email=jim.gottstein@psychrights.org, c=US
Date: 2009.04.27 12:34:38 -08'00'

By: _____
James B. Gottstein, Esq.

James B. Gottstein, Esq.
Law Project for Psychiatric Rights, Inc.
406 G Street, Suite 206
Anchorage, Alaska 99501
Tel: (907) 274-7686
Fax: (907) 274-9493
E-mail: jim.gottstein@psychrights.org

Certificate of Service

The undersigned hereby certifies that a copy of this Complaint and written disclosure of substantially all material evidence and information PsychRights possesses will be served on the Government as provided in FRCP 4.

Dated: James B. Gottstein, Esq.

Digitally signed by James B. Gottstein, Esq.
DN: cn=James B. Gottstein, Esq., o=Law Project for Psychiatric Rights, Inc., ou, email=jim.gottstein@psychrights.org, c=US
Date: 2009.04.27 12:35:13 -08'00'

_____
James B. Gottstein, Esq.