No. 10-35887

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

LAW PROJECT FOR PSYCHIATRIC RIGHTS, ex rel. United States of America;
DANIEL I. GRIFFIN, ex rel. United States of America,
Plaintiffs-Appellants
v.
OSAMU H. MATSUTANI, MD; *et al.*,
Defendants-Appellees.

ON APPEAL FROM THE U.S. DISTRICT COURT
FOR THE DISTRICT OF ALASKA,
THE HONORABLE TIMOTHY M. BURGESS PRESIDING
AK U.S. DISTRICT COURT CASE Nos. 3:09-cv-80-TMB & 3:09-cv-246-TMB

EXCERPTS OF RECORD
Volume 2 of 3

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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 H. MATSUTANI, MD, *et al*., Defendants.	Case No. 3:09-CV-00080-TMB
UNITED STATES OF AMERICA, ex rel Daniel I. Griffin, Plaintiff, v.s RONALD A. MARTINO, MD., FAMILY CENTERED SERVICES OF ALASKA, INC., an Alaska corporation, and SAFEWAY, INC., a Delaware corporation, Defendants.	Case No. 3:09-CV-00246-TMB (CONSOLIDATED)

NOTICE OF APPEAL

Notice is hereby given that United States of America *ex rel* Law Project for Psychiatric Rights and United States of America *ex rel* Daniel I. Griffin, plaintiffs/*relators* in the above named case, hereby appeal to the United States Court of Appeals for the Ninth Circuit from the final judgment entered in this action on the 30th Day of September, 2010.

RESPECTFULLY SUBMITTED this 30th day of September, 2010.

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

By: /s/ James B. Gottstein
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on September 30, 2010, a true and correct copy of this document and accompanying 9th Circuit Rule 3-2(b) Representation Statement was served electronically on all parties of record by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail.

/s/ James B. Gottstein
JAMES B. GOTTSTEIN

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release (the "Settlement Agreement") is entered into by and among: the United States of America, acting through the United States Department of Justice on behalf of the Office of Inspector General ("OIG-HHS") of the Department of Health and Human Services ("HHS"), the TRICARE Management Activity ("TMA"), the Veterans' Affairs Administration ("VA"), and the United States Office of Personnel Management ("OPM") (collectively, the "United States"); Forest Laboratories, Inc., and Forest Pharmaceuticals, Inc. (collectively, "Forest"); and Christopher Gobble, Joseph Piacentile, Constance Conrad, and Jim Conrad (collectively, the "Relators"). Collectively, all of the above will be referred to as the "Parties."

II. PREAMBLE

As a preamble to this Settlement Agreement, the Parties agree to the following:

A. At all relevant times, Forest Laboratories, Inc., was a Delaware corporation headquartered in New York, New York, and Forest Pharmaceuticals, Inc., a Delaware corporation headquartered in St. Louis, Missouri, was a wholly owned subsidiary of Forest Laboratories, Inc.

B. At all relevant times, Forest distributed, marketed, and sold pharmaceutical products in the United States, including the drugs sold under the trade names Celexa (generic name citalopram hydrobromide), Lexapro (generic name escitalopram oxalate), and Levothroid (generic name levothyroxine sodium tablets, USP).

C. The Relators listed herein have filed the following *qui tam* actions against Forest (collectively the "Civil Actions"):

1. *United States ex rel. Christopher R. Gobble, et al. v. Forest Laboratories, Inc. & Forest Pharmaceuticals, Inc.*, Civil Action No. 03–10395–NMG (D. Mass.) (the "Gobble *qui tam* action");

2. *United States ex rel. Joseph Piacentile, et al. v. Forest Laboratories, Inc.*, Civil Action No. 05–10201–NMG (D. Mass.) (the "Piacentile *qui tam* action");

3. *United States ex rel. Constance Conrad v. Forest Pharmaceuticals, Inc., et al.*, Civil Action No. 02–11738–NG (D. Mass.) (the "Conrad *qui tam* action"); and

4. [redacted]

D. The United States intervened in the Gobble *qui tam* action and the Piacentile *qui tam* action on November 14, 2008. The District of Columbia and the states of California, Delaware, Florida, Illinois, Massachusetts, Michigan, New York, Oklahoma, Texas, Virginia, and Wisconsin filed notices of intervention in those actions on February 13, 2009. The United

States filed its Complaint in Intervention in those actions (the "United States Complaint in Intervention") on February 13, 2009.

E. On such date as may be determined by the Court, Forest Pharmaceuticals, Inc. ("FPI") will enter a plea of guilty pursuant to Fed. R. Crim. P. 11(c)(1)(C) to an Information, attached as Exhibit A to a plea agreement into which FPI is entering simultaneously with the execution of this Settlement Agreement, to be filed in *United States of America v. Forest Pharmaceuticals, Inc.*, Criminal Action No. [to be assigned] (D. Mass.) (the "Criminal Action").

F. The United States alleges that Forest caused claims for payment for the drugs Celexa, Lexapro, and Levothroid to be submitted to the Medicaid program, 42 U.S.C. §§ 1396–1396w–5, the TRICARE Program (formerly known as the Civilian Health and Medical Program of the Uniformed Services), 10 U.S.C. §§ 1071–1110a, and the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901–8914, and that Forest caused the VA to purchase those drugs (collectively "the Federal Health Care Programs").

G. The United States contends that it and the Medicaid Participating States (as defined below) have certain civil claims against Forest, as specified below, for engaging in the following alleged conduct (hereinafter referred to as the "Covered Conduct"):

1. During the period January 1998 through December 2005, Forest knowingly caused false or fraudulent claims for Celexa and Lexapro to be submitted to the Federal Health Care Programs by promoting the sale and use of Celexa and Lexapro to physicians for pediatric uses (including by disseminating false and misleading information about the safety and efficacy of Celexa and Lexapro in treating pediatric patients), as set forth in the

United States Complaint in Intervention, when those uses were not approved by the Food and Drug Administration ("FDA"), were not medically accepted indications (as defined by 42 U.S.C. § 1396r–8(k)(6)), and were not covered by Federal Health Care Programs.

2. During the period January 1998 through December 2005, Forest knowingly caused false or fraudulent claims for Celexa and Lexapro to be submitted to the Federal Health Care Programs and caused the VA to purchase those drugs by offering and paying illegal remuneration to physicians as set forth in the United States Complaint in Intervention to induce the physicians to promote and to prescribe Celexa and Lexapro, in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a–7b(b)(2).

3. During the period August 2001 through December 2005, Forest knowingly caused false or fraudulent claims to be submitted to the Federal Health Care Programs and caused purchases by the VA through its distribution of a drug, Levothroid, that did not qualify as a covered outpatient drug (as defined in 42 U.S.C. § 1396r–8(k)(2)). In 1997, FDA determined that oral levothyroxine sodium products, including Levothroid, were "new drugs." FDA later announced that it would exercise its discretion not to take enforcement action against a manufacturer for distribution of an unapproved oral levothyroxine sodium product if, among other things, the manufacturer phased down distribution of its unapproved oral levothyroxine sodium product over a two-year period following August 14, 2001. Notwithstanding FDA's announcement, Forest increased distribution of its unapproved oral levothyroxine sodium product, Levothroid, after August 14, 2001, and failed to advise CMS that unapproved Levothroid no longer qualified as a covered outpatient drug under 42 U.S.C. § 1396r–8(k)(2).

they are authorized by Relators to execute this Settlement Agreement. The United States signatories represent that they are signing this Settlement Agreement in their official capacities and that they are authorized to execute this Settlement Agreement.

28. This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Settlement Agreement. Facsimiles of signatures and/or electronic signatures in portable document format (.pdf) shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

29. This Settlement Agreement is binding on Forest's successors, transferees, heirs, and assigns.

30. This Settlement Agreement is binding on Relators' successors, transferees, heirs, and assigns.

31. All parties consent to the disclosure of this Settlement Agreement, and information about this Settlement Agreement, to the public on or after the Effective Date.

32. As used in this Settlement Agreement, the "Effective Date" shall mean the date of the signature of the last signatory to the Settlement Agreement.

THE UNITED STATES OF AMERICA

DATED:_____ **BY:** _____

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United States Department of Justice

DATED: 9/15/10 **BY:** _____

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DATED:_____ **BY:** _____

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Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
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THE UNITED STATES OF AMERICA

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PsychRights®
Law Project for
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April 27, 2009

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Cert. Mail No. 7003 3110 0001 6582 0768

Re: *United States ex rel Law Project for Psychiatric Rights v. Matsutani, et. al.*, Case No. 3:09-cv-00080-TMB, USDC Alaska

Dear Attorney General Holder and Acting US Attorney Loeffler

This letter is being served pursuant to 39 USC §3730(b)(2), providing you with (1) a copy of the complaint, (2) written disclosure of substantially all material evidence possessed by the Law Project for Psychiatric Rights (PsychRights®), and (3) other information, pertaining to the above case.

I. Summary

In the last fifteen years or so, claims to Medicaid for psychiatric drugs prescribed to children and youth has skyrocketed to approximately $9 Billion per year. This increase is largely the result of the fraudulent activities of drug companies in promoting off-label pediatric use of psychiatric drugs. The Government is aware of the fraudulent conduct of certain drug companies and recently proceeded against one of them with the recent $1.4 Billion settlement against Eli Lilly over the illegal promotion of Zyprexa. The Government has also recently become aware that "Key Opinion Leaders" have been paid to make false statements in medical journals, and through Continuing Medical Education presentations, to induce doctors to prescribe psychotropic drugs to children and youth. However, the Government does not seem to be aware that the prescribers, their employers, the pharmacies filling the prescriptions, and state officials authorizing reimbursement are part of this scheme to defraud Medicaid and are liable under the False Claims Act, 39 USC §3729 *et seq.*, therefor.

These parties are not necessarily participating in this fraudulent scheme with actual knowledge the claims are false, but as you know, under the False Claims Act, parties are liable for making or causing false claims to be made if they act in deliberate ignorance or reckless disregard of the truth or falsity of the information used in making the claim. The defendants are liable for their roles in making or causing the false claims to be made or approved for payment because they did so in deliberate ignorance or disregard that the claims are false. Through its *Qui Tam* Complaint, PsychRights is moving on behalf of the Government against such parties in Alaska making or causing such false claims to be made, or authorizing reimbursement of such false claims.

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II. Background

PsychRights is a public interest law firm whose mission is to mount a strategic litigation campaign against forced psychiatric drugging and electroshock around the country. Because children and youth are not the ones making the decisions, they are inherently forced to take the drugs. Starting in December of 2004, due to the unprecedented increase in the use of extremely harmful psychiatric drugs in children and youth, PsychRights attempted to get the State of Alaska to rectify the situation.[1] Failing to reach an agreement, in early September of 2008, PsychRights filed *Law Project for Psychiatric Rights v. State of Alaska, et al.*,[2] seeking declaratory and injunctive relief that Alaskan children and youth have the right not to be administered psychotropic drugs unless and until:

1. evidence-based psychosocial interventions have been exhausted,
2. rationally anticipated benefits of psychotropic drug treatment outweigh the risks,
3. the person or entity authorizing administration of the drug(s) is fully informed, and
4. close monitoring of, and appropriate means of responding to, treatment emergent effects are in place,

and that all children and youth currently receiving such drugs be evaluated and brought into compliance with the above.

As I was working on the case I became aware that it was improper to submit claims to Medicaid for indications that are not approved by the FDA or supported by three specified compendia and filed an amended Complaint on September 29, 2009, which inserted the following as Paragraph 22 of the Complaint:

> 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.

PsychRights' mission does not revolve around litigating for monetary compensation and the foregoing was asserted in *PsychRights v. Alaska* as a basis for obtaining the declaratory and injunctive relief sought, which would include that the State of Alaska not seek Medicaid reimbursement for indications not approved by the FDA or supported by any of the designated compendia. However, PsychRights recently realized this conduct might constitute Medicaid fraud and that the False Claims Act might be an additional avenue to pursue to end the pervasive practice of prescribing harmful, ineffective, psychiatric drugs to children and youth. Thus, PsychRights undertook to investigate whether the conduct constitutes false claims under the False Claims Act and determined it does indeed.

[1] Appendix 1 - 17, 43-58.
[2] Case No. 3AN 08-10115 CI, Superior Court, Third Judicial District, State of Alaska.

III. The False Claims

A. *Per Se* Violation - Alaska Claims for Drugs Submitted To Medicaid Not for a Medically Accepted Indication.

As relevant, under 42 USC 1396R-8(k)(3), "The term 'covered outpatient drug' does not include any . . . drug . . . used for a medical indication which is not a medically accepted indication."

42 USC 1396R-8(k)(6) provides:

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

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

> (I) American Hospital Formulary Service Drug Information;
> (II) United States Pharmacopeia-Drug Information (or its successor publications); and
> (III) the DRUGDEX Information System; and
> (IV) Repealed. Pub.L. 108-173, Title I, § 101(e)(9)(B), Dec. 8, 2003, 117 Stat. 2152.

These provisions establish the "universe" of drugs for which it is permissible to seek Medicaid Reimbursement. This is confirmed by *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d 39, 44-5 (D.Mass. 2001):

> [U]unless a particular off-label use for a drug is included in one of the identified drug compendia, a prescription for the off-label use of that drug is not eligible for reimbursement under Medicaid.

A tremendous percentage of pediatric psychotropic prescriptions submitted to Medicaid for reimbursement are in this category of *per se* violation. For example, no anti-convulsants masquerading as "mood stabilizers," such as Depakote or Tegretol, have been approved for pediatric use or are supported by any of the compendia. With respect to the second generation neuroleptics, no pediatric use of Seroquel, Zyprexa or Geodon is approved by the FDA or supported by any of the designated compendia. Risperdal is approved for very narrow uses, as is Abilify, but even when prescribed for these indications are almost always prescribed concurrently with another drug(s), which is not FDA approved or supported by any of the designated compendia.

The following table of claims and amounts paid for such anti-convulsants and second generation neuroleptics were obtained as a result of an Alaska Freedom of Information Act (Alaska FOIA) request by PsychRights:[3]

[3] Appendix 18-40.

Dates	Anti-Convulsants Claims per Month	Anti-Convulsants Amount Per Month	2nd Generation Neuroleptics Claims per Month	2nd Generation Neuroleptics Amount Per Month
12/1/2004 to 2/28/05	1,393	$ 122,224	1,532	$ 277,746
1/1/2005 to 3/31/2005	1,402	$ 123,963	1,490	$ 285,762
5/1/2005 to 7/31/2005	1,436	$ 136,939	1,705	$ 319,725
2/1/2006 to 4/30/2006	1,240	$ 118,954	1,492	$ 272,717
3/1/2006 to 5/31/2006	1,260	$ 120,047	1,552	$ 281,919
4/1/2006 to 6/30/2006	1,210	$ 114,838	1,521	$ 272,009
5/1/2006 to 7/31/2006	1,225	$ 116,052	1,534	$ 277,940
8/1/2006 to 10/31/2006	1,252	$ 121,346	1,648	$ 284,966
11/1/2006 to 1/31/2007	1,298	$ 121,519	1,800	$ 289,540
1/1/2007 to 3/31/2007	1,259	$ 121,925	1,735	$ 288,238
4/1/2007 to 6/30/2007	1,270	$ 139,718	1,730	$ 312,815
Average	1,295	$ 123,411	1,613	$ 287,580

The State of Alaska represented to PsychRights that it had destroyed the other reports within the time frame of PsychRights' Alaska FOIA request; however there is no doubt the same pattern and rough magnitude exists for time periods before, within, and after those set forth in the above table for the six year statute of limitations period of the False Claims Act.

There is, at most, a trivial percentage of second generation neuroleptics which are not false, so the damages calculation for these *per se* false claims is as follows:

72 Months of Claims at $5,500 per claim	$	1,151,568,000
Treble Damages for 72 Months of Anti-Convulsants	$	26,656,776
Treble Damages for 72 Months of Neuroleptics	$	62,117,280
Total	$	1,240,342,056

B. *Per Se* Violation - Pharmacies: Claims for Drugs Made Under Medicaid Not for a Medically Accepted Indication

While it is the doctors who cause these *per se* false claims to be made, it is the pharmacies that submit the false claims. The pharmacies know or should know when making such claims that they are not for medically accepted indications and are liable under the false claims act therefor. Defendant Wal-Mart makes such false claims in every state and defendants Safeway and Fred Meyer in many. Because so much of pediatric psychopharmacology falls within this *per se* false claim category, probably at least 75% of the $9 Billion per year Medicaid spends on it are for false claims. PsychRights does not know exactly how much of this is submitted by Wal-Mart, Safeway, and Fred Meyer, but it may approach $1 Billion per year. Compensation in the amount of $5,500 for each false claim, plus trebling the damages make the damages astronomical.

C. Claims Where FDA Approval or Support in Any Designated Compendium Was Induced by Fraud.

In addition to claims being false *per se* for indications not approved by the FDA or supported by any of the designated compendia, as the Government has stated:

> 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. Thus, the mere fact that a particular use is a "medically accepted indication" does not eliminate the possibility of fraudulent conduct or abuse that could render the claim false and ineligible for payment.[4]

(1) Alaska SSRI Anti-Depressant Medicaid False Claims

A large percentage of the Medicaid claims for pediatric use of the Selective Serotonin Reuptake Inhibitor (SSRI) anti-depressants is not for medically accepted indications, which means they are also *per se* false claims. In addition, the balance were for medically accepted indications as a result of fraudulent conduct. FDA approval of pediatric uses and their support by the designated compendia was obtained as a result of fraud, through the drug companies hiding negative data and making false statements with respect to the studies they did release or use. This was actually knowable as early as 1999 when there was a big controversy over their use, but this was beaten back by the drug companies' false statements, including through "Key Opinion Leaders" on their payrolls. However, the controversy re-emerged and 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 and now requires a black box warning on SSRIs for pediatric use of SSRIs because they cause a great increase in suicidality. Since then, more and more has come out about the fraud involved in the promotion of SSRIs for pediatric use. Before 2004, prescribers could perhaps have had plausible deniability with regard to knowing of the fraud, but since then, not.

The following table of claims and amounts paid for such anti-depressants obtained as a result of the same Alaska FOIA request by PsychRights referenced above:[5]

[4] United States' Statement of Interest in Response to Defendant's Motion to Dismiss Plaintiff's First Amended Complaint, p. 8, in *United States ex rel., Peter Rost, v. Pfizer et al.*, Dkt No. 03-CV-11084-PBS, D. Mass.

[5] Appendix 18-40.

Dates	Anti-Depressants Claims per Month	Paid Per Month
12/1/2004 to 2/28/05	1,463	$ 72,990
1/1/2005 to 3/31/2005	1,482	$ 73,318
5/1/2005 to 7/31/2005	1,385	$ 70,060
2/1/2006 to 4/30/2006	1,219	$ 56,456
3/1/2006 to 5/31/2006	1,274	$ 57,069
4/1/2006 to 6/30/2006	1,252	$ 55,134
5/1/2006 to 7/31/2006	1,215	$ 53,180
8/1/2006 to 10/31/2006	1,190	$ 49,246
11/1/2006 to 1/31/2007	1,195	$ 46,928
1/1/2007 to 3/31/2007	1,196	$ 49,191
4/1/2007 to 6/30/2007	1,159	$ 52,271
Average	1,275	$ 57,804

There is a downward trend,[6] so in order to be conservative, the last month's figures are used to calculate the compensation.

72 Months of 1,159 Claims @ $5,500 ea.	$	458,964,000
72 Months of $52,271 trebled	$	12,485,664
Total	$	471,449,664

IV. Remedies

A. PsychRights' Interests/Objectives

PsychRights is not motivated by the potential monetary recovery, but by protecting vulnerable children and youth from being forced to suffer the incredible harms of pediatric psychiatric drugging. PsychRights is also very interested in making available the truly helpful, non-medication, approaches that have been shown to actually work.[7] While not motivated by the potential monetary recovery, any such recovery by PsychRights will be effectively deployed to further PsychRights' mission, including supporting non-drug alternatives.

B. Specific Defendants

(1) Matsutani

Matsutani has the reputation as being the most prolific pediatric psychopharmacologist in Alaska. In fact, Matsutani bragged to Michael Ecker's foster mother that he earned $800,000 in 2006 prescribing psychiatric drugs to children and youth, by "getting them in and getting them out." I think he also made similar boasts to Fran Purdy of the Alaska Family and Youth Network (AYFN). Full compensation should be sought from Matsutani for the false claims he caused to

[6] The downward trend is probably due to drug company efforts to move prescribers to the neuroleptics that are still under patent protection as the patents for the anti-depressants expire.

[7] See, Critical Thinkrx Curriculum, Module 8, available on the Internet at http://criticalthinkrx.org/pdf/m8/Module-8-Complete-Slide-Presentation.pdf.

be made, he should be barred from future Medicaid participation, and as far as PsychRights is concerned, he should go to jail.

(2) Other Prescribers

PsychRights is less familiar with the other prescribers named as defendants. In PsychRights' view, the consequences of their causing false claims to be made should depend on their individual circumstances.

(3) Thomson Reuters (Healthcare)

PsychRights understands Thomson Reuters (Healthcare) is paid approximately $1 Billion per year by drug companies to put on Continuing Medical Education Programs at which false statements are made to induce doctors to prescribe off-label. PsychRights claim on behalf of the Government against Thomson Reuters (Healthcare) for causing false claims encompasses the entire United States. The recovery from Thomson should be at least $1 Billion.

(4) State Officials

It appears the State of Alaska is not subject to the False Claims Act under *Vermont Agency Of Natural Re-Sources, Petitioner, v. United States ex rel. Stevens*.[8] However, under *Samuels v. Holmes*,[9] state officials are liable for causing false claims to be made or authorizing reimbursement of false claims. PsychRights named as defendants the commissioner of Alaska's Department of Health and Social Services, William Hogan, and the head of its Medicaid program, William Streur, for authorizing reimbursement by Medicaid of false claims, and Tammy Sandoval, the director of Alaska's Office of Children's' Services and Steve McComb the director of Alaska's Division of Juvenile justice for submitting or causing false claims to be made.

Through ¶22 of its September 29, 2008 Amended Complaint in *PsychRights v. Alaska*, and a contemporaneous e-mail,[10] PsychRights specifically brought to these defendants' attention that the State of Alaska was authorizing reimbursement for and causing false Medicaid claims to be made. Thus, they have continued to authorize reimbursement for and cause false claims to be submitted in the face of specific knowledge of their falsity. Therefore, significant recoveries should be obtained from these defendants, depending on their personal financial situation, and they should be barred from future Medicaid participation. PsychRights does not believe they should go to jail for these transgressions, however.

(5) The Pharmacies

It is the pharmacies that submitted the false Medicaid claims. They know that they are dispensing drugs that are not for medically accepted indications. They are legally obliged to be a check against the doctors prescriptions for indications that are not medically accepted . While PsychRights does not believe pharmacies should be held liable for the doctors' prescriptions where the medically accepted indications were procured by false statements, PsychRights does believe they should be held liable for submitting claims that are *per se* false because they are not

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[8] 529 U.S. 765 (2000).
[9] 538 F.3d 173 (3d Cir. 2008).
[10] Appendix 47.

for medically accepted indications. The pharmacy defendants PsychRights has named are Wal-Mart, Safeway and Fred Meyers, which it is believed are the largest pharmacies in Alaska. They also make Medicaid claims for prescriptions around the country and the Complaint encompasses all of these false claims. A sufficient amount should be recovered from the pharmacies to be painful and deter similar conduct by others. It seems this should be at least $1 Billion each from Wal-Mart and Safeway. It seems impractical and undesirable, however, to bar them from future Medicaid participation.

(6) Northstar Hospital

Northstar is notorious for psychiatrically drugging children and youth in order to reap financial benefits. In PsychRights' view, maximum recovery should be sought from Northstar and it barred from future Medicaid participation.

(7) Other Providers

The other provider defendants are agencies that employ the prescribers, reap financial rewards from the prescribers causing false claims to be made, and some recovery should be had. They vary in culpability, however, and the consequences of their causing false claims to be made should depend on their individual circumstances. Such recovery(ies) should be sufficient to serve notice on other providers around the country that they must cease causing such false claims to be made.

C. Use of the Government's Recovery and Savings to Fund Safe & Effective PsychoSocial Programs for Children and Youth

The fraudulent scheme has resulted in Big Pharma squeezing out non-drug programs that have been proven to be far more effective, especially long term by providing children and youth the tools for successful lives, without the harm caused by psychiatric drugs. The CriticalThinkRx Curriculum,[11] includes a comprehensive list of such proven approaches with respect to children and youth[12] and PsychRights believes the Government should use its recovery and future savings from this action in support of such programs. In fact, in PsychRights' view, the Government shouldn't wait until such a recovery occurs before implementing such programs.

Big Pharma has been so successful in indoctrinating psychiatrists into drugging children for behavior that bothers the adults in their lives that most of them don't know how to do anything else. There, are, however, a cadre of people who do know. Members of the International Center for the Study of Psychiatry and Psychology (ICSPP)[13] are one source of people with this knowledge[14] and PsychRights knows more.

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[11] 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.

[12] *See*, CriticalThinkRx Curriculum, Module 8, available on the Internet at http://criticalthinkrx.org/pdf/m8/Module-8-Complete-Slide-Presentation.pdf..

[13] http://icspp.org/.

[14] For example, David Stein, Ph.D., Carolyn Crowder, PhD, and Dubose Ravenel, MD, have all written books about how to successfully sheppard children and youth through their behavioral difficulties, much of course involves education helping parents to take control. For children in foster care, other approaches such as mentoring have been shown to be extremely helpful.

V. Intervention/Unsealing

Because of the great harm inflicted on America's children and youth through these false claims, PsychRights believes the Complaint should be unsealed as soon as possible. No significant investigation is needed. With the possible exception of Thomson Reuters (Healthcare)'s role in the scheme to defraud Medicaid, it should be easy for the Government to confirm the facts. The real question is, now that PsychRights has brought to the Government's attention that the psychiatrists, their employers, pharmacies, and state employees, are liable for these false claims, whether it has the political will or ability to act against these defendants to stop the fraud. It should be possible to decide that within 60 days.

The scope and lack of morality of the fraudulent scheme revealed here can be analogized to the current economic debacle created by the unrestrained greed facilitated by the failure of government regulators with respect to subprime mortgages. It is much worse, here, however, because children's and youth's future, health, and even lives, have been sacrificed and continue to be sacrificed on the altar of corporate profits.

We will be pleased to answer any questions you might have and look forward to working with you on this matter.

Yours truly,

James B. Gottstein, Esq.

STATE OF UTAH
OFFICE OF THE ATTORNEY GENERAL

MARK L. SHURTLEFF
ATTORNEY GENERAL

RAYMOND A. HINTZE
Chief Deputy

KIRK TORGENSEN
Chief Deputy

October 22, 2007

Steve E. Phurrough, M.D., MPA
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Mail Stop C1-09-06
7500 Security Boulevard
Baltimore, MD 21244

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

Dear Dr. Phurrough:

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

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

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

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

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

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

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

Very truly yours,

David R. Stallard

David R. Stallard, CPA
Assistant Attorney General
(801) 281-1269
dstallard@utah.gov

/DRS

cc: David Frank, Director, Medicaid Integrity Group

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

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and State Operations

DEC 6 2007

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

Dear Mr. Stallard:

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

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

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

Sincerely,

Bill Pearson

Dennis G. Smith
Director

STATE OF UTAH
OFFICE OF THE ATTORNEY GENERAL

MARK L. SHURTLEFF
ATTORNEY GENERAL

RAYMOND A. HINTZE
Chief Deputy

KIRK TORGENSEN
Chief Deputy

December 17, 2007

Dennis G. Smith, Director
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, Maryland 21244-1850

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

Dear Mr. Smith:

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

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

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

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

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

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

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

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

Very truly yours,

David R. Stallard

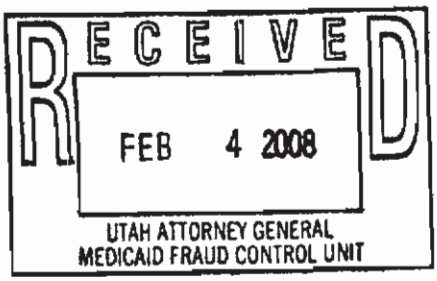
David R. Stallard, CPA
Assistant Attorney General
(801) 281-1269
dstallard@utah.gov
/DRS
cc: Steven E. Phurrough, M.D., MPA, Director, Coverage and Analysis Group
David Frank, Director, Medicaid Integrity Group

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-14-26
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

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

JAN 30 2008



David R. Stallard, CPA
Office of the Attorney General
Medicaid Fraud Control Unit
5272 S. College Drive, #200
Murray, UT 84123

Dear Mr. Stallard:

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

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

I hope this information adequately addresses your concerns.

Sincerely,

for Gale P. Arden
Director

SETTLEMENT AGREEMENT

I. PARTIES

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and the United States Attorney's Office for the Eastern District of Pennsylvania, the Office of Inspector General of the United States Department of Health and Human Services ("OIG-HHS"), the TRICARE Management Activity ("TMA"), and the United States Office of Personnel Management ("OPM") (collectively the "United States"); James Wetta ("Wetta"); Stephan Kruszewski, M.D. ("Kruszewski"); and Astra Zeneca LP and AstraZeneca Pharmaceuticals LP (collectively, "AstraZeneca"), through their authorized representatives. Collectively, all of the above will be referred to as "the Parties."

II. PREAMBLE

As a preamble to this Agreement, the Parties agree to the following:

A. AstraZeneca LP and AstraZeneca Pharmaceuticals LP are Delaware limited partnerships with their principal places of business in Wilmington, Delaware. At all relevant times herein, AstraZeneca distributed, marketed and sold pharmaceutical products in the United States, including a drug sold under the trade name of Seroquel.

B. On July 24, 2004, Wetta filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. James Wetta v. AstraZeneca Corporation, Civil Action No. 04-3479 (hereinafter "Civil Action I").

C. On September 8, 2006, Kruszewski filed a qui tam action in the United States District Court for the Eastern District of Pennsylvania captioned United States of America ex rel. Stephan Kruszewski v. AstraZeneca Pharmaceuticals LP, Civil Action No. 06-4004

(hereinafter "Civil Action II"). Civil Action I and Civil Action II hereinafter may be referred to collectively as the "Civil Actions."

D. AstraZeneca has entered or will be entering into separate settlement agreements, described in Paragraph 1(b), below (hereinafter referred to as the "Medicaid State Settlement Agreements") with certain states and the District of Columbia in settlement of the Covered Conduct. States with which AstraZeneca executes a Medicaid State Settlement Agreement in the form to which AstraZeneca and the National Association of Medicaid Fraud Control Units ("NAMFCU") Negotiating Team have agreed, or in a form otherwise agreed to by AstraZeneca and an individual State, shall be defined as "Medicaid Participating States."

E. The United States and the Medicaid Participating States allege that AstraZeneca caused claims for payment for Seroquel to be submitted to the Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (the Medicaid Program).

F. The United States further alleges that AstraZeneca caused claims for payment for Seroquel to be submitted to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. § 1395-1395hhh; the TRICARE program, 10 U.S.C. §§ 1071-1109; the Federal Employees Health Benefits Program ("FEHBP"), 5 U.S.C. §§ 8901-8914; the Federal Employees Compensation Act Program, 5 U.S.C. § 8101 et seq; and caused purchases of Seroquel by the Department of Veterans' Affairs ("DVA"), Department of Defense, and the Bureau of Prisons ("BOP") (collectively, the "other Federal Health Care Programs").

G. The United States contends that it has certain civil claims, as specified in Paragraph 2, below, against AstraZeneca for engaging in the following conduct during the period January 1, 2001 through December 31, 2006 (hereinafter referred to as the "Covered Conduct"):

(1) AstraZeneca promoted the sale and use of Seroquel to psychiatrists, other physicians (including primary care physicians) and other health care professionals in pediatric and primary care physician offices, in long-term care facilities and hospitals and in prisons for certain uses that were not approved by the Food and Drug Administration as safe and effective for those uses (including aggression, Alzheimer's disease, anger management, anxiety, attention deficit hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, post-traumatic stress disorder, and sleeplessness) ("unapproved uses"). AstraZeneca also promoted the unapproved uses by engaging in the following conduct: AstraZeneca improperly and unduly influenced the content of and speakers in company-sponsored Continuing Medical Education programs; engaged doctors to give promotional speaker programs it controlled on unapproved uses for Seroquel; engaged doctors to conduct studies on unapproved uses of Seroquel; recruited doctors to serve as authors of articles largely prepared by medical literature companies about studies they did not conduct on unapproved uses of Seroquel; and, used those studies and articles as the basis for promotional messages about unapproved uses of Seroquel. These unapproved uses were not medically accepted indications for which the United States and the state Medicaid programs provided coverage for Seroquel.

(2) AstraZeneca offered and paid illegal remuneration to doctors: (a) it recruited to conduct studies for unapproved uses, (b) it recruited to serve as authors of articles written by AstraZeneca and its agents about these unapproved uses of Seroquel, (c) to travel to resort locations to "advise" AstraZeneca about marketing messages for unapproved uses of Seroquel, and (d) it recruited to give promotional lectures to other health care professionals about unapproved and unaccepted uses of Seroquel. The United States contends that these payments were intended to induce the doctors to promote and/or prescribe Seroquel for unapproved uses in violation of the Federal Anti-Kickback Statute, 42 U.S.C. § 1320-7b(b).

As a result of the foregoing conduct, the United States contends that AstraZeneca knowingly caused false or fraudulent claims for Seroquel to be submitted to, or caused purchases by, Medicaid, Medicare and the other Federal Health Care Programs.

THE UNITED STATES OF AMERICA

DATED: 4-27-10 BY: _____
MICHAEL L. LEVY
United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
VIRGINIA A. GIBSON
First Assistant
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
MARGARET L. HUTCHINSON
Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4-27-10 BY: _____
COLIN CHERICO
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: _____ BY: _____
PATRICIA L. HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

THE UNITED STATES OF AMERICA

DATED:_____ BY: _____
MICHAEL L. LEVY
United States Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
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First Assistant
United States Attorney's Office
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DATED:_____ BY: _____
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Chief, Civil Division
United States Attorney's Office
Eastern District of Pennsylvania

DATED:_____ BY: _____
COLIN CHERICO
Assistant U.S. Attorney
United States Attorney's Office
Eastern District of Pennsylvania

DATED: 4/27/10 BY: _____
PATRICIA L. HANOWER
Trial Attorney
Commercial Litigation Branch
Civil Division
United States Department of Justice

DATED: 4/27/10

BY: _____

GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: _____

BY: _____

LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: _____

BY: _____

SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED: _____

BY: _____

DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED:_____ BY: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED: April 23, 2010 BY: Rhonda L. Bershok, Acting Deputy General Counsel
For: LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED:_____ BY: _____
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED:_____ BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

DATED:_____ BY: _____
GREGORY E. DEMSKE
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

DATED:_____ BY: _____
LAUREL C. GILLESPIE
Deputy General Counsel
TRICARE Management Activity
United States Department of Defense

DATED: 4/26/10 BY: _____
SHIRLEY R. PATTERSON
Acting Deputy Associate Director Insurance Operations
Center for Retirement & Insurance Services
United States Office of Personnel Management

DATED: 4/26/2010 BY: _____
DAVID COPE
Debarring Official
Office of the Assistant Inspector General for Legal Affairs
United States Office of Personnel Management

ASTRAZENECA

DATED: 4/27/10 BY: _____

Glenn M. Engelmann
Vice President and General Counsel
AstraZeneca LP
AstraZeneca Pharmaceuticals LP

DATED: 4/27/10 BY: _____

JOHN C. DODDS, ESQ.
Morgan, Lewis and Bockius, LLP

RELATOR JAMES WETTA

DATED:_____ BY: _____
JAMES WETTA

DATED:_____ BY: _____
STEPHEN A. SHELLER, ESQ.

(Counsel to Relator James Wetta)

RELATOR JAMES WETTA

DATED: 4/23/10

BY: James Wetta by Michael Mustokoff
JAMES WETTA

DATED: 4/23/10

BY: Stephen A. Sheller
STEPHEN A. SHELLER, ESQ.

(Counsel to Relator James Wetta)

BY: Michael Mustokoff
MICHAEL MUSTOKOFF
MARK LIPOWICZ
TERESA CAVENAGH
DUANE MORRIS, LLP

BY: Gary M. Farmer by Michael Mustokoff
GARY M. FARMER JR.
FARMER JAFFE WEISSING EDWARDS FISTOS and LEHRMAN

[redacted]

RELATOR STEPHAN KRUSZEWSKI

DATED: 4/23/2010 BY: _____
STEFAN KRUSZEWSKI

DATED: _____ BY: _____
WILLIAM LEONARD, ESQUIRE
(Counsel to Stephan Kruszewski)

RELATOR STEPHAN KRUSZEWSKI

DATED:_____ BY: _____
STEFAN KRUSZEWSKI

DATED: 4/23/10 BY: _____
WILLIAM LEONARD, ESQUIRE
(Counsel to Stephan Kruszewski)

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* CHRISTOPHER R. GOBBLE, *et al.*,	**Civil Action No. 03-10395-NMG**
Plaintiff,	
v.	
FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC.,	**FILED UNDER SEAL**
Defendants.	
UNITED STATES OF AMERICA *ex rel.* JOSEPH PIACENTILE, *et al.*,	**Civil Action No. 05-10201-NMG**
Plaintiff,	
v.	
FOREST LABORATORIES, INC.,	
Defendant.	

UNITED STATES' COMPLAINT IN INTERVENTION

The United States brings this action to recover losses from false claims submitted to federal health care programs as a result of the sustained fraudulent course of conduct of the defendants, Forest Laboratories, Inc. ("Forest Labs"), and Forest Pharmaceuticals, Inc. ("Forest Pharmaceuticals") (collectively, "Forest"). Over the course of more than half a decade, Forest illegally marketed two related antidepressant drugs, Celexa and Lexapro, for off-label use in pediatric patients when both drugs had been approved only for adult use. During much of that

time, Forest misled physicians by promoting the results of a positive study on pediatric use of Celexa while failing to disclose the results of a contemporaneous negative study for the same pediatric use. Forest also illegally paid kickbacks to physicians to induce them to prescribe the drugs. By knowingly and actively promoting these antidepressants for off-label pediatric use without disclosing the results of the negative pediatric study and by paying kickbacks, Forest caused false claims to be submitted to federal health care programs in violation of the False Claims Act ("FCA"), 31 U.S.C. § 3729, *et seq*.

I. NATURE OF ACTION

1. The United States brings this action to recover treble damages and civil penalties under the FCA and to recover damages and other monetary relief under the common law or equitable theory of unjust enrichment.

2. The United States bases its claims on Forest causing the submission of false or fraudulent claims to federal health care programs in violation of 31 U.S.C. § 3729(a)(1).

3. Within the time frames detailed below, Forest engaged in a fraudulent scheme to market and promote Celexa (citalopram) and Lexapro (escitalopram) off-label to treat depression and other psychiatric conditions in pediatric patients. Forest did so even though the Food and Drug Administration ("FDA") had not approved the drugs as safe and effective for any use in the pediatric population. In the case of Celexa, the FDA had specifically denied approval for any pediatric use.

4. In furtherance of its off-label marketing scheme, Forest disseminated and caused others to disseminate false and misleading information to doctors and the public about the safety

estimate of its Medicaid funding needs for the quarter. CMS reviews and adjusts the quarterly estimate as necessary, and determines the amount of federal funding the state will be permitted to draw down as the state actually incurs expenditures during the quarter (for example, as actual provider claims are presented for payment). After the end of each quarter, the state then submits to CMS a final expenditure report, which provides the basis for adjustment to quarterly federal funding (to reconcile the estimated expenditures to actual expenditures).

24. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a.

25. The federal Medicaid statute requires each participating state to implement a plan containing certain specified minimum criteria for coverage and payment of claims. 42 U.S.C. §§ 1396, 1396a(a)(13), 1396a(a)(30)(A).

26. While federal drug coverage is an optional benefit available to the states, most states provide coverage for prescription drugs that meet the definition of a covered outpatient drug, which is defined in the federal Medicaid Rebate Statute, 42 U.S.C. § 1396r-8(k)(2).

27. The Medicaid Rebate Statute generally prohibits federal financial participation for a covered outpatient drug unless there is a rebate agreement in effect with the manufacturer for that drug. Once a drug manufacturer has entered into a rebate agreement for a covered outpatient drug, a state is generally required to cover that drug under the state plan unless "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(i).

28. The Medicaid Rebate Statute defines "medically accepted indication" as any FDA approved use or a use that is "supported by one or more citations included or approved for

inclusion in any of the compendia" set forth in the statute. 42 U.S.C. § 1396r-8(k)(6).

29. A drug does not generally meet the definition of a "covered outpatient drug" if it is being prescribed for a use that is neither FDA-approved nor supported by a citation included or approved for inclusion in the compendia. 42 U.S.C. §§ 1396r-8(k)(2)(A), (k)(3).

30. Thus, even if a drug is FDA-approved for a certain indication, Medicaid ordinarily does not cover off-label uses that do not qualify as medically accepted indications. Many state Medicaid programs prohibit covering such uses. *See, e.g.*, 40-850-026 DEL. CODE REGS. § 3.5.4.1 (2008); IND. CODE § 12-15-35-4.5 (2008); N.J. ADMIN. CODE § 83C-1.14(1) (2008); N.M. CODE R. § 8.325.4 (2008).

B. The TRICARE Program

31. TRICARE, formerly known as CHAMPUS, is a managed health care program established by the Department of Defense. 10 U.S.C. §§ 1071-1110. TRICARE provides health care benefits to eligible beneficiaries, which include, among others, active duty service members, retired service members, and their dependents.

32. The regulatory authority establishing the TRICARE program does not cover drugs not approved by the FDA. *See* 32 C.F.R. § 199.4(g)(15)(i)(A).

33. TRICARE does not cover drugs used for off-label indications unless such off-label use is proven medically necessary and safe and effective by medical literature, national organizations, or technology assessment bodies. *See* 32 C.F.R. §199.4(g)(15)(i)(A)(Note). TRICARE will not knowingly provide reimbursement for off-label use if the prescriptions result from illegal off-label marketing.

VI. FOREST'S SCHEME

A. The Celexa And Lexapro Labels

34. Celexa and Lexapro are closely-related selective serotonin reuptake inhibitor ("SSRIs") drugs. Lundbeck developed both Celexa and Lexapro, which contains the active agent in Celexa, and subsequently licensed both drugs to Forest for marketing in the United States. Forest began selling Celexa in 1998. In 2002, with Celexa soon due to face generic competition, Forest began selling Lexapro.

1. The FDA Has Not Approved Celexa Or Lexapro For Pediatric Use.

35. In 1998, the FDA approved Celexa for the treatment of adult depression. The FDA never approved Celexa for treatment of any conditions other than adult depression, or for any pediatric use.

36. In 2002, the FDA approved Lexapro for the treatment of adult depression. In 2003, Lexapro received approval for treatment of Generalized Anxiety Disorder ("GAD") in adults. Lexapro has not been approved for any other conditions and was not approved for pediatric use.

37. The use of Celexa and Lexapro in pediatric patients is not supported by a citation included or approved for inclusion in any of the compendia. The use of Celexa and Lexapro in pediatric patients is not a "medically accepted" indication for those drugs.

38. If a manufacturer conducts pediatric clinical studies on a drug, a manufacturer may obtain an additional six months of patent exclusivity for the previously-approved, on-label

child psychiatrist a $1,000 gift certificate to Alain Ducasse, a New York restaurant that at the time was one of the most expensive in the United States.

- In June 2001, two Forest sales representatives took a physician and his three sons on a deep sea fishing trip off Cape Cod, Massachusetts.

- In June 2002, a sales representative arranged a salmon fishing charter cruise for four physicians in his territory.

- In February 2002, a sales representative purchased $400 in Broadway theater tickets for a physician and his wife.

- In February 2002, a Division Manager purchased $2,276 in Boston Red Sox tickets for his sales representatives to use, he said, "throughout the next six months with all of our key targets."

- From 2001 to 2005, Forest sales representatives in North Carolina repeatedly arranged social dinners for a psychiatrist who ran multiple offices and reportedly was the highest prescriber of Celexa and Lexapro in the state.

- From 2001 to 2005, Forest sales representatives in Louisiana repeatedly paid for a physician and his family to eat at some of the most expensive restaurants in that state; one of those sales representatives reported that the physician had promised he would "always rxlex [*i.e.*, prescribe Lexapro] #1 aslong [*sic*] as we have fun and take care of him."

95. All of this spending was intended to induce physicians to prescribe Celexa or Lexapro.

VII. FALSE CLAIMS

96. As a result of Forest's fraudulent course of conduct, Forest caused the submission of false or fraudulent claims for Celexa and Lexapro to federal health care programs. These claims were not reimbursable because they were not covered for off-label pediatric use and/or

were ineligible for payment as a result of illegal kickbacks.

97. The chart set forth below identifies examples of false or fraudulent claims caused by Forest's off-label promotion. The chart includes: (a) the prescribing physician; (b) the number of promotional sales calls by Forest to each physician; (c) the number of pediatric Medicaid claims resulting from that physician; and (d) the amount paid for those pediatric claims by Medicaid.

CELEXA			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. A.	58	1927	$110,865
Dr. B.	70	977	$70,311
Dr. C.	133	871	$85,980
Dr. D.	58	777	$42,568
Dr. E.	33	586	$44,280
Dr. F.	50	589	$39,807
LEXAPRO			
Physician	No. of Calls by Forest	Pediatric Claims	Medicaid Payment
Dr. G.	257	1769	$197,052
Dr. H.	118	7790	$428,627
Dr. I.	76	4565	$251,378
Dr. J.	192	3219	$229,469
Dr. K.	296	2441	$252,879

98. The chart set forth below provides examples of false or fraudulent claims caused by Forest's illegal kickbacks to a physician, Dr. L. The chart identifies: (a) the year; (b) the type

of meeting or event Dr. L attended; (c) the amount paid to Dr. L; (d) the number of claims resulting from Dr. L; and (e) the amount paid for those claims by Medicaid.

Year	Type of Meeting or Event	Amount Paid	Claims	Medicaid Payment
2000	Advisory Boards	$500	197	$12,867
2001	Advisory Boards/Speaker Programs	$1,250	221	$14,646
2002	Advisory Boards/Speaker Programs/ Sponsorships	$2,500	367	$25,570
2003	Advisory Boards/Speaker Programs/Sponsorships	$10,250	302	$21,175
2004	Sponsorships	$500	272	$20,402

FIRST CAUSE OF ACTION
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1))

99. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

100. Forest knowingly caused to be presented false or fraudulent claims for payment or approval to the United States for Celexa and Lexapro prescriptions that were not covered for off-label pediatric use, and/or were ineligible for payment as a result of illegal kickbacks.

101. By virtue of the false or fraudulent claims that Forest caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,000 and up to $10,000 for each violation occurring before September 29, 1999, and not less than $5,500 and up to $11,000 for each violation occurring on or after September 29, 1999.

SECOND CAUSE OF ACTION
(Unjust Enrichment)

102. The United States repeats and realleges the preceding paragraphs as if fully set forth herein.

103. The United States claims the recovery of all monies by which Forest has been unjustly enriched.

104. As a consequence of the acts set forth above, Forest was unjustly enriched at the expense of the United States in an amount to be determined which, under the circumstances, in equity and good conscience, should be returned to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Forest as follows:

1. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper.

2. On the Second Count for unjust enrichment, for the damages sustained and/or amounts by which Forest was unjustly enriched or by which Forest retained illegally obtained monies, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

MICHAEL F. HERTZ
ACTING ASSISTANT ATTORNEY GENERAL

MICHAEL J. SULLIVAN
UNITED STATES ATTORNEY

Dated: February 13, 2009 By: 

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Department of Justice

FOR IMMEDIATE RELEASE
Wednesday, September 2, 2009
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TDD (202) 514-1888

Justice Department Announces Largest Health Care Fraud Settlement in Its History

Pfizer to Pay $2.3 Billion for Fraudulent Marketing

WASHINGTON – American pharmaceutical giant Pfizer Inc. and its subsidiary Pharmacia & Upjohn Company Inc. (hereinafter together "Pfizer") have agreed to pay $2.3 billion, the largest health care fraud settlement in the history of the Department of Justice, to resolve criminal and civil liability arising from the illegal promotion of certain pharmaceutical products, the Justice Department announced today.

Pharmacia & Upjohn Company has agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act for misbranding Bextra with the intent to defraud or mislead. Bextra is an anti-inflammatory drug that Pfizer pulled from the market in 2005. Under the provisions of the Food, Drug and Cosmetic Act, a company must specify the intended uses of a product in its new drug application to FDA. Once approved, the drug may not be marketed or promoted for so-called "off-label" uses – *i.e.*, any use not specified in an application and approved by FDA. Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of $1.195 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.

In addition, Pfizer has agreed to pay $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government health care programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolves allegations that Pfizer paid kickbacks to health care providers to induce them to prescribe these, as well as other, drugs. The federal share of the civil settlement is $668,514,830 and the state Medicaid share of the civil settlement is $331,485,170. This is the largest civil fraud settlement in history against a pharmaceutical company.

As part of the settlement, Pfizer also has agreed to enter into an expansive corporate integrity agreement with the Office of Inspector General of the Department of Health and Human Services. That agreement provides for procedures and reviews to be put in place to avoid and promptly detect conduct similar to that which gave rise to this matter.

Whistleblower lawsuits filed under the *qui tam* provisions of the False Claims Act that are pending in the District of Massachusetts, the Eastern District of Pennsylvania and the Eastern District of Kentucky triggered this investigation. As a part of today's resolution, six whistleblowers will receive payments totaling more than $102 million from the federal share of the civil recovery.

The U.S. Attorney's offices for the District of Massachusetts, the Eastern District of Pennsylvania, and the Eastern District of Kentucky, and the Civil Division of the Department of Justice handled these cases. The U.S. Attorney's Office for the District of Massachusetts led the criminal investigation of Bextra. The investigation was conducted by the Office of Inspector General for the Department of Health and Human Services (HHS), the FBI, the Defense Criminal Investigative Service (DCIS), the Office of Criminal Investigations for the Food and Drug Administration (FDA), the Veterans' Administration's (VA) Office of Criminal Investigations, the Office of the Inspector General for the Office of Personnel Management (OPM), the Office of the Inspector General for the United States Postal Service (USPS), the National Association of Medicaid Fraud Control Units and the offices of various state Attorneys General.

"Today's landmark settlement is an example of the Department of Justice's ongoing and intensive efforts to protect the American public and recover funds for the federal treasury and the public from those who seek to earn a profit through fraud. It shows one of the many ways in which federal government, in partnership with its state and local allies, can help the American people at a time when budgets are tight and health care costs are increasing," said Associate Attorney General Tom Perrelli. "This settlement is a testament to the type of broad, coordinated effort among federal agencies and with our state and local partners that is at the core of the Department of Justice's approach to law enforcement."

"This historic settlement will return nearly $1 billion to Medicare, Medicaid, and other government insurance programs, securing their future for the Americans who depend on these programs," said Kathleen Sebelius, Secretary of Department of Health and Human Services. "The Department of Health and Human Services will continue to seek opportunities to work with its government partners to prosecute fraud wherever we can find it. But we will also look for new ways to prevent fraud before it happens. Health care is too important to let a single dollar go to waste."

"Illegal conduct and fraud by pharmaceutical companies puts the public health at risk, corrupts medical decisions by health care providers, and costs the government billions of dollars," said Tony West, Assistant Attorney General for the Civil Division. "This civil settlement and plea agreement by Pfizer represent yet another example of what penalties will be faced when a pharmaceutical company puts profits ahead of patient welfare."

"The size and seriousness of this resolution, including the huge criminal fine of $1.3 billion, reflect the seriousness and scope of Pfizer's crimes," said Mike Loucks, acting U.S. Attorney for the District of Massachusetts. "Pfizer violated the law over an extensive time period. Furthermore, at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws. Today's enormous fine demonstrates that such blatant and continued disregard of the law will not be tolerated."

"Although these types of investigations are often long and complicated and require many resources to achieve positive results, the FBI will not be deterred from continuing to ensure that pharmaceutical companies conduct business in a lawful manner," said Kevin Perkins, FBI Assistant Director, Criminal Investigative Division.

"This resolution protects the FDA in its vital mission of ensuring that drugs are safe and effective. When manufacturers undermine the FDA's rules, they interfere with a doctor's judgment and can put patient health at risk," commented Michael L. Levy, U.S. Attorney for the Eastern District of Pennsylvania. "The public trusts companies to market their drugs for uses that FDA has approved, and trusts that doctors are using independent judgment. Federal health dollars should only be spent on treatment decisions untainted by misinformation from manufacturers concerned with the bottom line."

"This settlement demonstrates the ongoing efforts to pursue violations of the False Claims Act and recover taxpayer dollars for the Medicare and Medicaid programs," noted Jim Zerhusen, U.S. Attorney for the Eastern District of Kentucky.

"This historic settlement emphasizes the government's commitment to corporate and individual accountability and to transparency throughout the pharmaceutical industry," said Daniel R. Levinson, Inspector General of the United States Department of Health and Human Services. "The corporate integrity agreement requires senior Pfizer executives and board members to complete annual compliance certifications and opens Pfizer to more public scrutiny by requiring it to make detailed disclosures on its Web site. We expect this agreement to increase integrity in the marketing of pharmaceuticals."

"The off-label promotion of pharmaceutical drugs by Pfizer significantly impacted the integrity of TRICARE, the Department of Defense's healthcare system," said Sharon Woods, Director, 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 law enforcement partners to investigate and prosecute those that abuse the government's healthcare programs at the expense of the taxpayers and patients."

"Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S.

Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that it must observe those standards and reflects the commitment of federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

"Health care fraud has a significant financial impact on the Postal Service. This case alone impacted more than 10,000 postal employees on workers' compensation who were treated with these drugs," said Joseph Finn, Special Agent in Charge for the Postal Service's Office of Inspector General. "Last year the Postal Service paid more than $1 billion in workers' compensation benefits to postal employees injured on the job."

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Attorney for Law Project for Psychiatric Rights

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. 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, FRONTLINE HOSPITAL, LLC, d/b/a NORTH STAR HOSITAL, KERRY OZER, MD, CLAUDIA PHILLIPS, MD, SOUTHCENTRAL FOUNDATION, an Alaska non-profit corporation, SHEILA CLARK, MD, HUGH STARKS, MD,	**CIVIL ACTION NO. 3:09-CV-00080-TMB** **FALSE CLAIMS ACT MEDICAID FRAUD** **DEMAND FOR JURY TRIAL**

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

PLAINTIFF'S FIRST AMENDED 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.

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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. Congress Amended the False Claims Act again in 2010, to expand the types of cases that could proceed.

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 presentation 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 and DRUGDEX promoting off-label use of psychotropic drugs on children and youth.

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 Frontline Hospital, LLC, d/b/a North Star Hospital is a Delaware 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 is an agency of the City and Borough of Juneau, an Alaska municipality, 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 Curtiss, MD (Curtiss) 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 or require dismissal 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 manufacturer 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 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 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 minute 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. There is little or no empirical evidence to support the use of drug interventions in traumatized children and youth.

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

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

D. Neuroleptics

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

107. 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.

108. 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.

109. 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.

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

111. 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.

112. 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.

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

114. 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.

115. 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.

116. 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.

117. 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.

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

119. 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.

120. 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.

121. 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.

122. 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.

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

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

125. 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.

126. 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

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

128. 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.

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

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

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

132. 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.

E. AntiDepressants

133. 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.

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

135. 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.

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

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

138. 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.

139. 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.

140. 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.

141. 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.

142. 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.

143. 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)."

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

145. 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."

146. 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"

147. 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.

148. 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

149. 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.

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

151. 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.

152. 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.

153. Desired observed behavioral effects of anticonvulsants include:

(a) Reducing aggression and impulsivity, and

(b) Calming restlessness and excitability.

154. 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.

155. 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

156. 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.

157. 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.

158. 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).

159. 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.

160. 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.

161. 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.

162. 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.

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

164. 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.

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

166. The following psychotropic drugs have no medically accepted indication for use in anyone under 18 years of age:

(a) Ambien (zolipidem)
(b) Buspar (buspirone)
(c) Celexa (citalopram)
(d) Clozaril (clozapine)
(e) Cymbalta (duloxetine)
(f) Desyrel (trazadone)
(g) Effexor (venlafaxine)
(h) Geodon (ziprasidone)
(i) Invega (paliperidone)
(j) Limbitrol (chlordiazepoxide/amitriptyline)
(k) Lunesta (eszopiclone)
(l) Paxil (paroxetine)
(m) Pristiq (desvenlafaxine)
(n) Sonata (zaleplon)
(o) Symbyax (fluoxetine hydrochloride/olanzapine)
(p) Wellbutrin (bupropion)

167. The following psychotropic drugs have only the following medically accepted indications for use in anyone under 18 years of age.

(a) Abilify (Aripiprazole)
  (i) Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes; 10 yrs old and up
  (ii) Bipolar I Disorder, monotherapy, Manic or Mixed Episodes; 10-17 years old for acute therapy
  (iii) Schizophrenia; 13-17 years old

(b) Adderall (amphetamine/dextroamphetamine)
  (i) Attention Deficit Hyperactivity Disorder (ADHD); 3 years old and up for immediate-release and 6 years old and up for extended-release
  (ii) Narcolepsy; 6 years old and up for immediate release] drug)

(c) Anafranil (clomipramine)
  (i) Obsessive-Compulsive Disorder; 10 years and up

(d) Ativan (lorazepam)
  (i) Anxiety; oral only, 12 years and older
  (ii) Chemotherapy-induced nausea and vomiting; Prophylaxis
  (iii) Insomnia, due to anxiety or situational stress
  (iv) Seizure
  (v) Status epilepticus

(e) Concerta (methylphenidate)
  (i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old to 12 years old
  (ii) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old and up re ConcertaR

(f) Dalmane (flurazepam)
  (i) Insomnia; 15 years and older

(g) Depakote (valproic acid)
  (i) Absence Seizure, Simple and Complex and/or Complex Partial Epileptic Seizure; 10 years and older
  (ii) Complex Partial Epileptic Seizure; 10 years and older
  (iii) Seizure, Multiple sezure types; Adjunct; 10 years and older

(h) Dexedrine (dextroamphetamine)
  (i) Attention Deficit Hyperactivity Disorder (ADHD); 3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release))
  (ii) Narcolepsy; 6 years old and up

(i) Focalin (dexmethylphenidate)
  (i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years and older

(j) Haldol (haloperidol)
  (i) Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy; 3 years old and up
  (ii) Problematic Behavior in Children (Severe), With failure to respond to non-antipsychotic medication or psychotherapy; 3 years old and up
  (iii) Psychotic Disorder; 3 years old and up but ORAL formulations only
  (iv) Schizophrenia; 3 years old and up but ORAL formulations only

(k) Klonopin (clonazepam)
  (i) Seizure; up to 10 years or up to 30 kg

(l) Lamictal (lamotrigine)
  (i) Convulsions in the newborn, Intractable

(ii) Epilepsy, Refractory
(iii) Lennox-Gastaut syndrome; Adjunct; yes (2 years and older)
(iv) Partial seizure, Adjunct or monotherapy; 13 years and older, extended-release only; 2 years and older, chewable dispersible
(v) Tonic-clonic seizure, Primary generalized; Adjunct; 2 years and older

(m) Lexapro (escitalopram)
(i) Major Depressive Disorder; 12 years old and up

(n) Luvox (fluvoxamine)
(i) Obsessive-Compulsive Disorder; 8 years old and up and immediate release formula only

(o) Mellaril (thioridazine)
(i) Schizophrenia, Refractory

(p) Moban (molindone) - antipsychotic, Dihydroindolone
(i) Schizophrenia; 12 years and older

(q) Neurontin (gabapentin) anticonvulsant
(i) Partial seizure; Adjunct; 3-12 years old

(r) Orap (pimozide)
(i) Gilles de la Tourette's syndrome; 12 years and older

(s) Prozac (fluoxetine)
(i) Major Depressive Disorder; 8 years old and up
(ii) Obsessive-Compulsive Disorder; 7 years old and up

(t) Ritalin (methylphenidate)
(i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years to 12 years old (extended release)
(ii) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old and up (immediate release)
(iii) Narcolepsy; 6 years and up, and Ritalin(R) -SR only

(u) Risperdal (risperidone)
(i) Autistic Disorder, Irritability; 5 years old and up
(ii) Bipolar I Disorder; 10 years old and up
(iii) Schizophrenia; 13 years old and up (Orally)

(v) Seroquel (quetiapine)
(i) Bipolar disorder, maintenance; 10-17 regular release only (12/4/09)
(ii) Manic bipolar I disorder; 10-17 regular release only (12/4/09)
(iii) Schizophrenia; 13-17, regular release only (12/4/09)

(w) Sinequan (doxepin)
(i) Alcoholism - Anxiety - Depression; 12 years old and up
(ii) Anxiety - Depression; 12 years old and up

(iii) Anxiety - Depression - Psychoneurotic personality disorder; 12 years old and up

(x) Strattera (atomoxetine)
(i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old and up

(y) Tegretol (carbamazepine)
(i) Epilepsy, Partial, Generalized, and Mixed types

(z) Tofranil (imipramine)
(i) Nocturnal enuresis; 6 years old and up

(aa) Topamax (topiramate)
(i) Lennox-Gastaut syndrome, Adjunct; 2 years and older
(ii) Partial seizure, Initial monotherapy; 10 years and older
(iii) Partial seizure; Adjunct, 10 years and older
(iv) Tonic-clonic seizure, Primary generalized; Adjunct, 2 to 16 years old
(v) Tonic-clonic seizure, Primary generalized (initial monotherapy), 10 years and older

(bb) Tranxene (clorazepate)
(i) Partial seizure; Adjunct, 9 years and older

(cc) Trileptal (oxcarbazepine)
(i) Partial Seizure, monotherapy 4 years old and up
(ii) Partial seizure; Adjunct, 2 years old and up

(dd) Vyvanse (lisdexamfetamine)
(i) Attention Deficit Hyperactivity Disorder (ADHD); 6 years old to 12 years

(ee) Zoloft (sertraline)
(i) Obsessive-Compulsive Disorder; 6 years old and up

(ff) Zyprexa (olanzapine)
(i) Bipolar 1, Disorder, Acute Mixed or Manic Episodes, 13-17, oral only (12/4/09)
(ii) Schizophrenia 13-17, oral only (12/4/09).

168. Except for an extremely limited number of psychotropic drugs, such as the use of Abilify in combination with lithium or valproate for manic or mixed episodes of Bipolar I disorder, polypharmacy is not for a medically accepted indication.

H. False Claims Act

169. 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).

170. 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).

171. 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.

172. 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.

173. 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.

174. 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.

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

176. 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.

177. 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.

178. 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.

179. 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, including what are and are not medically accepted indications for each drug they prescribe.

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

181. 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.

182. 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: All Defendants

183. Each of the defendants presented or caused the presentment of one or more of the following Medicaid claims for reimbursement of pediatric psychotropic medications to Alaskan children and youth that were not for a medically accepted indication:

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

,

(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.

184. 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 presented and caused to be presented, and continue to be presented or caused to be presented, including by all of the defendants.

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

185. On or about September 29, 2008, Defendants Sandoval and McComb were informed, through paragraph 22 of the amended complaint in *Law Project for Psychiatric Rights v. Palin, et al*., Case No. 3AN 08-10115 CI, Anchorage Superior Court, Third Judicial District, State of Alaska that presenting or causing the presentment of Medicaid claims that are not for medically accepted indications are false claims.

186. 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.

187. Sandoval caused the following false claims for prescriptions to M.G., Claim Recipient Id No. 0600223318, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

	Amoung	Date	Drug
$	54.18	7/9/2007	Cymbalta
$	36.38	7/30/2007	Cymbalta
$	36.38	7/18/2010	Cymbalta
$	36.38	8/6/2007	Cymbalta
$	41.33	10/9/2007	Cymbalta
$	137.83	12/17/2007	Cymbalta
$	39.42	9/4/2007	Cymbalta
$	40.83	9/24/2007	Cymbalta
$	41.33	12/4/2007	Cymbalta
$	41.33	11/6/2007	Cymbalta
$	41.33	11/27/2007	Cymbalta
$	39.42	8/28/2007	Cymbalta
$	39.42	8/22/2007	Cymbalta
$	39.42	8/16/2007	Cymbalta
$	41.33	11/20/2007	Cymbalta
$	41.33	12/11/2007	Cymbalta
$	41.33	11/12/2007	Cymbalta
$	39.42	9/10/2007	Cymbalta
$	40.83	9/17/2007	Cymbalta
$	41.33	10/29/2007	Cymbalta
$	41.33	10/22/2007	Cymbalta
$	51.41	8/8/2007	Cymbalta
$	41.33	10/15/2007	Cymbalta
$	48.09	10/9/2007	Risperdal
$	45.76	7/30/2007	Risperdal
$	45.76	7/16/2007	Risperdal
$	48.09	8/20/2007	Risperdal
$	48.09	9/4/2007	Risperdal
$	45.76	6/11/2007	Risperdal
$	45.76	5/14/2007	Risperdal
$	64.58	1/24/2007	Risperdal
$	45.26	2/26/2007	Risperdal

	Amoung	Date	Drug
$	48.09	9/10/2007	Risperdal
$	45.26	3/25/2007	Risperdal
$	45.76	7/2/2007	Risperdal
$	45.26	3/4/2007	Risperdal
$	45.76	8/13/2007	Risperdal
$	48.09	9/24/2007	Risperdal
$	45.76	6/18/2007	Risperdal
$	45.26	3/18/2007	Risperdal
$	45.76	6/4/2007	Risperdal
$	45.76	5/27/2007	Risperdal
$	48.09	8/27/2007	Risperdal
$	48.09	9/17/2007	Risperdal
$	45.76	7/9/2007	Risperdal
$	45.76	5/21/2007	Risperdal
$	45.26	3/11/2007	Risperdal
$	45.26	2/2/2007	Risperdal
$	45.26	2/8/2007	Risperdal
$	45.26	2/14/2007	Risperdal
$	45.26	2/20/2007	Risperdal
$	45.76	8/6/2007	Risperdal
$	45.76	4/29/2007	Risperdal
$	45.76	5/6/2007	Risperdal
$	45.76	4/2/2007	Risperdal
$	45.76	4/9/2007	Risperdal
$	45.76	4/16/2007	Risperdal
$	45.76	4/22/2007	Risperdal
$	66.41	3/18/2007	Risperdal
$	66.41	3/25/2007	Risperdal
$	66.41	2/26/2007	Risperdal
$	66.40	2/20/2007	Risperdal
$	66.41	2/14/2007	Risperdal
$	66.91	5/14/2007	Risperdal
$	66.91	4/9/2007	Risperdal
$	66.91	4/16/2007	Risperdal
$	66.91	4/22/2007	Risperdal
$	66.91	4/29/2007	Risperdal
$	66.91	5/6/2007	Risperdal
$	97.81	1/24/2007	Risperdal

	Amoung	Date	Drug
$	66.41	3/4/2007	Risperdal
$	66.91	4/2/2007	Risperdal
$	66.41	3/11/2007	Risperdal
$	66.41	2/2/2007	Risperdal
$	66.41	2/8/2007	Risperdal
$	83.31	11/13/2006	Zoloft
$	83.31	12/11/2006	Zoloft
$	83.31	10/16/2006	Zoloft

188. Sandoval also caused the following false claims for prescriptions to A.L., Claim Recipient Identification No. 0600311008, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

	Amount	Date	Drug
$	1,034.45	4/26/2006	Abilify
$	13.27	9/15/2009	Lexapro
$	185.04	7/21/2009	Geodon
$	189.04	8/21/2009	Geodon
$	185.04	7/27/2009	Geodon
$	232.45	3/16/2009	Geodon
$	499.10	6/29/2009	Geodon
$	457.00	4/9/2009	Geodon
$	457.00	6/4/2009	Geodon
$	457.00	5/6/2009	Geodon
$	224.55	7/27/2009	Geodon
$	7.58	4/26/2006	Ativan
$	38.95	1/8/2008	Risperdal
$	39.50	12/24/2007	Risperdal
$	38.95	12/31/2007	Risperdal
$	143.49	3/20/2008	Risperdal
$	143.49	4/1/2008	Risperdal
$	200.08	3/6/2008	Risperdal
$	143.49	3/14/2008	Risperdal
$	143.49	4/21/2008	Risperdal
$	143.49	4/28/2008	Risperdal
$	143.49	4/7/2008	Risperdal
$	143.49	4/14/2008	Risperdal

	Amount	Date	Drug
$	90.99	12/11/2007	Risperdal
$	90.99	12/18/2007	Risperdal
$	90.44	1/8/2008	Risperdal
$	90.99	12/24/2007	Risperdal
$	90.44	12/31/2007	Risperdal
$	47.62	10/12/2007	Risperdal
$	127.32	3/20/2008	Risperdal
$	127.32	4/1/2008	Risperdal
$	171.46	3/6/2008	Risperdal
$	127.31	3/14/2008	Risperdal
$	127.32	4/21/2008	Risperdal
$	127.32	4/28/2008	Risperdal
$	147.95	11/30/2007	Risperdal
$	334.48	7/31/2008	Risperdal
$	127.32	4/14/2008	Risperdal
$	127.32	4/7/2008	Risperdal
$	127.32	3/26/2008	Risperdal
$	147.95	10/17/2007	Risperdal
$	147.95	11/9/2007	Risperdal
$	87.37	10/12/2007	Risperdal
$	541.67	7/31/2008	Risperdal
$	401.59	10/17/2007	Risperdal
$	401.59	11/13/2007	Risperdal
$	240.24	8/7/2008	Risperdal
$	240.24	9/4/2008	Risperdal
$	122.12	10/10/2008	Risperdal
$	201.38	12/12/2008	Risperdal
$	201.38	11/19/2008	Risperdal
$	201.40	10/10/2008	Risperdal
$	201.40	9/16/2008	Risperdal
$	235.85	10/31/2008	Risperdal
$	663.65	8/31/2007	Seroquel
$	215.28	3/21/2007	Seroquel
$	215.28	6/25/2007	Seroquel
$	215.28	5/24/2007	Seroquel
$	215.28	4/25/2007	Seroquel
$	215.28	2/20/2007	Seroquel
$	203.32	7/30/2007	Seroquel

Amount	Date	Drug
$ 263.52	4/26/2006	Seroquel
$ 344.93	7/30/2007	Seroquel
$ 327.96	4/25/2007	Seroquel
$ 327.96	3/21/2007	Seroquel
$ 327.96	6/25/2007	Seroquel
$ 327.96	5/24/2007	Seroquel
$ 327.96	2/20/2007	Seroquel
$ 403.64	2/9/2009	Zyprexa
$ 403.64	3/31/2009	Zyprexa
$ 395.74	7/22/2009	Zyprexa
$ 403.64	4/28/2009	Zyprexa
$ 403.64	1/8/2009	Zyprexa
$ 403.64	5/27/2009	Zyprexa
$ 380.92	12/4/2008	Zyprexa
$ 597.61	9/2/2009	Zyprexa
$ 601.51	2/24/2009	Zyprexa
$ 593.61	8/8/2009	Zyprexa
$ 611.23	10/5/2009	Zyprexa
$ 601.51	3/30/2009	Zyprexa
$ 254.25	11/20/2008	Zyprexa
$ 283.94	9/11/2009	Zyprexa

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

189. 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.

190. Fred Meyer presented the following false claims to Medicaid or CHIP for prescriptions to A.L., Claim Recipient Identification No. 0600311008, that were not for a medically accepted indication:

Amount	Date	Drug
$ 47.62	10/12/2007	Risperdal
$ 147.95	11/30/2007	Risperdal
$ 334.48	7/31/2008	Risperdal
$ 147.95	10/17/2007	Risperdal
$ 147.95	11/9/2007	Risperdal
$ 87.37	10/12/2007	Risperdal
$ 541.67	7/31/2008	Risperdal
$ 401.59	10/17/2007	Risperdal
$ 401.59	11/13/2007	Risperdal

191. Fred Meyer presented the following false claims to Medicaid or CHIP for prescriptions to R.T., Claim Recipient Identification No. 0600226463, that were not for a medically accepted indication:

Amount	Date	Drug
$ 141.51	3/9/2006	Wellbutrin
$ 141.51	1/20/2006	Wellbutrin

192. Safeway presented the following false claims to Medicaid for prescriptions to F.H., Claim Recipient Id No. 0600217257, that were not for a medically accepted indication:

Date	Drug	Amount
8/10/2007	Trazadone	$ 9.82
9/28/2007	Zoloft	$ 106.90
9/28/2007	Trazadone	$ 9.82
9/28/2007	Seroquel	$ 123.53

193. Safeway also presented the following false claims to Medicaid for prescriptions to D.G., Claim Recipient Id No. 060101584, that were not for a medically accepted indication:

Date	Drug	Amount
10/26/2004	Trazadone	$ 11.01
11/9/2004	Abilify	$ 335.70
11/19/2004	Zoloft	$ 163.49
12/3/2004	Trazadone	$ 11.01
12/6/2004	Zoloft	$ 163.49
12/27/2004	Abilify	$ 171.65
12/28/2004	Trazadone	$ 11.01
1/11/2005	Zoloft	$ 171.38
1/19/2005	Abilify	$ 335.00
1/25/2005	Trazadone	$ 14.43
2/9/2005	Zoloft	$ 179.56
2/15/2005	Abilify	$ 335.70
2/24/2005	Trileptal	$ 132.29
2/26/2005	Trazadone	$ 14.43
3/7/2005	Zoloft	$ 179.56
3/17/2005	Abilify	$ 335.70
3/24/2005	Trileptal	$ 194.65
4/7/2005	Trazadone	$ 14.43
4/18/2005	Abilify	$ 335.70
4/23/2005	Trileptal	$ 198.99
5/10/2005	Trazadone	$ 14.43
5/10/2005	Zoloft	$ 179.56
5/16/2005	Abilify	$ 335.70
5/21/2005	Trileptal	$ 210.55
6/20/2005	Abilify	$ 335.70
7/5/2005	Trileptal	$ 210.55
7/18/2005	Zoloft	$ 179.56
7/26/2005	Abilify	$ 335.70
8/9/2005	Zoloft	$ 179.56
8/19/2005	Trileptal	$ 210.55
8/20/2005	Trazadone	$ 14.43
8/31/2005	Abilify	$ 350.45

9/19/2005	Trazadone	$	11.01
9/19/2005	Trileptal	$	210.55
9/19/2005	Zoloft	$	179.56
9/29/2005	Abilify	$	350.45
10/19/2005	Trazadone	$	11.01
10/19/2005	Trileptal	$	210.55
10/19/2005	Zoloft	$	179.56
10/22/2005	Abilify	$	350.45

194. Walmart presented the following false claim to Medicaid for a prescription to A.L., Claim Recipient Identification No. 0600311008, that was not for a medically accepted indication:

	Amount	Date	Drug
$	344.93	7/30/2007	Seroquel

195. Walmart also presented the following false claims to Medicaid for prescriptions to S. M. Claim Recipient Id No. 0600207089, that was not for a medically accepted indication:

Date	Drug		Amount
2/28/2005	Zoloft	$	170.68
1/29/2005	Zoloft	$	170.68
11/24/2004	Zoloft	$	162.62

Count 4: Thomson

196. One of Thomson's scientific and health-care division's biggest operations during at least part of the applicable period was or 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.

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

198. Thomson's false statements in favor of 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.

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

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

200. 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.

201. Denali caused the following false claims for prescriptions to F.H., Claim Recipient Id No. 0600217257, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

Date	Drug	Amount
6/21/2007	Trazodone	$ 12.57
7/5/2007	Trazodone	$ 13.69

202. Denali caused the following false claims for prescriptions to M.G., Claim Recipient Id No. 0600223318, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

	Amount	Date	Drug
$	54.18	7/9/2007	Cymbalta
$	36.38	7/30/2007	Cymbalta
$	36.38	7/18/007	Cymbalta
$	36.38	8/6/2007	Cymbalta
$	41.33	10/9/2007	Cymbalta
$	137.83	12/17/2007	Cymbalta
$	39.42	9/4/2007	Cymbalta
$	40.83	9/24/2007	Cymbalta
$	41.33	12/4/2007	Cymbalta
$	41.33	11/6/2007	Cymbalta
$	41.33	11/27/2007	Cymbalta
$	39.42	8/28/2007	Cymbalta
$	39.42	8/22/2007	Cymbalta
$	39.42	8/16/2007	Cymbalta
$	41.33	11/20/2007	Cymbalta
$	41.33	12/11/2007	Cymbalta
$	41.33	11/12/2007	Cymbalta
$	39.42	9/10/2007	Cymbalta
$	40.83	9/17/2007	Cymbalta
$	41.33	10/29/2007	Cymbalta
$	41.33	10/22/2007	Cymbalta
$	51.41	8/8/2007	Cymbalta
$	41.33	10/15/2007	Cymbalta

	Amount	Date	Drug
$	48.09	10/9/2007	Risperdal
$	45.76	7/30/2007	Risperdal
$	45.76	7/16/2007	Risperdal
$	48.09	8/20/2007	Risperdal
$	48.09	9/4/2007	Risperdal
$	45.76	6/11/2007	Risperdal
$	45.76	5/14/2007	Risperdal
$	64.58	1/24/2007	Risperdal
$	45.26	2/26/2007	Risperdal
$	48.09	9/10/2007	Risperdal
$	45.26	3/25/2007	Risperdal
$	45.76	7/2/2007	Risperdal
$	45.26	3/4/2007	Risperdal
$	45.76	8/13/2007	Risperdal
$	48.09	9/24/2007	Risperdal
$	45.76	6/18/2007	Risperdal
$	45.26	3/18/2007	Risperdal
$	45.76	6/4/2007	Risperdal
$	45.76	5/27/2007	Risperdal
$	48.09	8/27/2007	Risperdal
$	48.09	9/17/2007	Risperdal
$	45.76	7/9/2007	Risperdal
$	45.76	5/21/2007	Risperdal
$	45.26	3/11/2007	Risperdal
$	45.26	2/2/2007	Risperdal
$	45.26	2/8/2007	Risperdal
$	45.26	2/14/2007	Risperdal
$	45.26	2/20/2007	Risperdal
$	45.76	8/6/2007	Risperdal
$	45.76	4/29/2007	Risperdal
$	45.76	5/6/2007	Risperdal
$	45.76	4/2/2007	Risperdal
$	45.76	4/9/2007	Risperdal
$	45.76	4/16/2007	Risperdal
$	45.76	4/22/2007	Risperdal
$	66.41	3/18/2007	Risperdal
$	66.41	3/25/2007	Risperdal
$	66.41	2/26/2007	Risperdal

	Amount	Date	Drug
$	66.40	2/20/2007	Risperdal
$	66.41	2/14/2007	Risperdal
$	66.91	5/14/2007	Risperdal
$	66.91	4/9/2007	Risperdal
$	66.91	4/16/2007	Risperdal
$	66.91	4/22/2007	Risperdal
$	66.91	4/29/2007	Risperdal
$	66.91	5/6/2007	Risperdal
$	97.81	1/24/2007	Risperdal
$	66.41	3/4/2007	Risperdal
$	66.91	4/2/2007	Risperdal
$	66.41	3/11/2007	Risperdal
$	66.41	2/2/2007	Risperdal
$	66.41	2/8/2007	Risperdal

203. Fairbanks Psychiatric caused the following false claims for prescriptions to D.G., Claim Recipient Identification No. 0601015843, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

Date	Drug	Amount
10/26/2004	Trazadone	$ 11.01
11/9/2004	Abilify	$ 335.70
11/19/2004	Zoloft	$ 163.49
12/3/2004	Trazadone	$ 11.01
12/6/2004	Zoloft	$ 163.49
12/27/2004	Abilify	$ 171.65
12/28/2004	Trazadone	$ 11.01
1/11/2005	Zoloft	$ 171.38
1/19/2005	Abilify	$ 335.00
1/25/2005	Trazadone	$ 14.43
2/9/2005	Zoloft	$ 179.56
2/15/2005	Abilify	$ 335.70
2/24/2005	Trileptal	$ 132.29
2/26/2005	Trazadone	$ 14.43
3/7/2005	Zoloft	$ 179.56
3/17/2005	Abilify	$ 335.70

3/24/2005	Trileptal	$	194.65
4/7/2005	Trazadone	$	14.43
4/18/2005	Abilify	$	335.70
4/23/2005	Trileptal	$	198.99
5/10/2005	Trazadone	$	14.43
5/10/2005	Zoloft	$	179.56
5/16/2005	Abilify	$	335.70
5/21/2005	Trileptal	$	210.55
6/8/2005	Trazadone	$	12.56
6/8/2005	Zoloft	$	181.11
6/20/2005	Abilify	$	335.70
7/5/2005	Trileptal	$	210.55
7/18/2005	Zoloft	$	179.56
7/26/2005	Abilify	$	335.70
8/9/2005	Zoloft	$	179.56
8/19/2005	Trileptal	$	210.55
8/20/2005	Trazadone	$	14.43
8/31/2005	Abilify	$	350.45
9/19/2005	Trazadone	$	11.01
9/19/2005	Trileptal	$	210.55
9/19/2005	Zoloft	$	179.56
9/29/2005	Abilify	$	350.45
10/19/2005	Trazadone	$	11.01
10/19/2005	Trileptal	$	210.55
10/19/2005	Zoloft	$	179.56
10/22/2005	Abilify	$	350.45

204. Northstar caused the following false claims for prescriptions to F.H., Claim Recipient Id No. 0600217257, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

Date	Drug	Amount	
3/16/2005	Trileptal	$	193.07
3/16/2005	Seroquel	$	59.04
4/3/2005	Trileptal	$	235.22
4/3/2005	Seroquel	$	112.06

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

205. Matsutani, Curtiss, Baisi, Dukoff, Ozer, Phillips, Clark, Stark, Bautista, Lopez-Coonhohn, Martino, Schults, Stauffer, Rothrock and Kiele (Prescribers) have written and, upon information and belief, with the exception of Rothrock, 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.

206. Matsutani caused the following false claims for prescriptions to M.G., Claim Recipient Id No. 0600223318, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

	Amount	Date	Drug
$	54.18	7/9/2007	Cymbalta
$	36.38	7/30/2007	Cymbalta
$	36.38	7/18/2010	Cymbalta
$	36.38	8/6/2007	Cymbalta
$	41.33	10/9/2007	Cymbalta
$	137.83	12/17/2007	Cymbalta
$	39.42	9/4/2007	Cymbalta
$	40.83	9/24/2007	Cymbalta
$	41.33	12/4/2007	Cymbalta

	Amount	Date	Drug
$	41.33	11/6/2007	Cymbalta
$	41.33	11/27/2007	Cymbalta
$	39.42	8/28/2007	Cymbalta
$	39.42	8/22/2007	Cymbalta
$	39.42	8/16/2007	Cymbalta
$	41.33	11/20/2007	Cymbalta
$	41.33	12/11/2007	Cymbalta
$	41.33	11/12/2007	Cymbalta
$	39.42	9/10/2007	Cymbalta
$	40.83	9/17/2007	Cymbalta
$	41.33	10/29/2007	Cymbalta
$	41.33	10/22/2007	Cymbalta
$	51.41	8/8/2007	Cymbalta
$	41.33	10/15/2007	Cymbalta
$	48.09	10/9/2007	Risperdal
$	45.76	7/30/2007	Risperdal
$	45.76	7/16/2007	Risperdal
$	48.09	8/20/2007	Risperdal
$	48.09	9/4/2007	Risperdal
$	45.76	6/11/2007	Risperdal
$	45.76	5/14/2007	Risperdal
$	64.58	1/24/2007	Risperdal
$	45.26	2/26/2007	Risperdal
$	48.09	9/10/2007	Risperdal
$	45.26	3/25/2007	Risperdal
$	45.76	7/2/2007	Risperdal
$	45.26	3/4/2007	Risperdal
$	45.76	8/13/2007	Risperdal
$	48.09	9/24/2007	Risperdal
$	45.76	6/18/2007	Risperdal
$	45.26	3/18/2007	Risperdal
$	45.76	6/4/2007	Risperdal
$	45.76	5/27/2007	Risperdal
$	48.09	8/27/2007	Risperdal
$	48.09	9/17/2007	Risperdal
$	45.76	7/9/2007	Risperdal
$	45.76	5/21/2007	Risperdal
$	45.26	3/11/2007	Risperdal

	Amount	Date	Drug
$	45.26	2/2/2007	Risperdal
$	45.26	2/8/2007	Risperdal
$	45.26	2/14/2007	Risperdal
$	45.26	2/20/2007	Risperdal
$	45.76	8/6/2007	Risperdal
$	45.76	4/29/2007	Risperdal
$	45.76	5/6/2007	Risperdal
$	45.76	4/2/2007	Risperdal
$	45.76	4/9/2007	Risperdal
$	45.76	4/16/2007	Risperdal
$	45.76	4/22/2007	Risperdal
$	66.41	3/18/2007	Risperdal
$	66.41	3/25/2007	Risperdal
$	66.41	2/26/2007	Risperdal
$	66.40	2/20/2007	Risperdal
$	66.41	2/14/2007	Risperdal
$	66.91	5/14/2007	Risperdal
$	66.91	4/9/2007	Risperdal
$	66.91	4/16/2007	Risperdal
$	66.91	4/22/2007	Risperdal
$	66.91	4/29/2007	Risperdal
$	66.91	5/6/2007	Risperdal
$	97.81	1/24/2007	Risperdal
$	66.41	3/4/2007	Risperdal
$	66.91	4/2/2007	Risperdal
$	66.41	3/11/2007	Risperdal
$	66.41	2/2/2007	Risperdal
$	66.41	2/8/2007	Risperdal

207. Baisi caused the following false claims for prescriptions to F.H., Claim Recipient Id No. 0600217257, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

Date	Drug	Amount
3/16/2005	Trileptal	$ 193.07
3/16/2005	Seroquel	$ 59.04
4/3/2005	Trileptal	$ 235.22

4/3/2005 Seroquel $ 112.06

208. Bautista caused the following false claims for prescriptions to A.L., Claim Recipient Identification No. 0600311008, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

	Amount	Date	Drug
$	143.49	3/20/2008	Risperdal
$	200.08	3/6/2008	Risperdal
$	143.49	3/14/2008	Risperdal
$	47.62	10/12/2007	Risperdal
$	127.32	3/20/2008	Risperdal
$	171.46	3/6/2008	Risperdal
$	127.31	3/14/2008	Risperdal
$	334.48	7/31/2008	Risperdal
$	147.95	10/17/2007	Risperdal
$	127.32	3/26/2008	Risperdal
$	87.37	10/12/2007	Risperdal
$	541.67	7/31/2008	Risperdal
$	401.59	10/17/2007	Risperdal

209. Clark caused the following false claims for prescriptions to M.G., Claim Recipient Id No. 0600223318, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

	Amount	Date	Drug
$	83.31	11/13/2006	Zoloft
$	83.31	12/11/2006	Zoloft
$	83.31	10/16/2006	Zoloft

210. Martino caused the following false claims for prescriptions to D.G., Claim Recipient Id No. 060101584, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

Date	Drug	Amount

10/26/2004	Trazadone	$	11.01
11/9/2004	Abilify	$	335.70
11/19/2004	Zoloft	$	163.49
12/3/2004	Trazadone	$	11.01
12/6/2004	Zoloft	$	163.49
12/27/2004	Abilify	$	171.65
12/28/2004	Trazadone	$	11.01
1/11/2005	Zoloft	$	171.38
1/19/2005	Abilify	$	335.00
1/25/2005	Trazadone	$	14.43
2/9/2005	Zoloft	$	179.56
2/15/2005	Abilify	$	335.70
2/24/2005	Trileptal	$	132.29
2/26/2005	Trazadone	$	14.43
3/7/2005	Zoloft	$	179.56
3/17/2005	Abilify	$	335.70
3/24/2005	Trileptal	$	194.65
4/7/2005	Trazadone	$	14.43
4/18/2005	Abilify	$	335.70
4/23/2005	Trileptal	$	198.99
5/10/2005	Trazadone	$	14.43
5/10/2005	Zoloft	$	179.56
5/16/2005	Abilify	$	335.70
5/21/2005	Trileptal	$	210.55
6/8/2005	Trazadone	$	12.56
6/8/2005	Zoloft	$	181.11
6/20/2005	Abilify	$	335.70
7/5/2005	Trileptal	$	210.55
7/18/2005	Zoloft	$	179.56
7/26/2005	Abilify	$	335.70
8/9/2005	Zoloft	$	179.56
8/19/2005	Trileptal	$	210.55
8/20/2005	Trazadone	$	14.43
8/31/2005	Abilify	$	350.45
9/19/2005	Trazadone	$	11.01
9/19/2005	Trileptal	$	210.55
9/19/2005	Zoloft	$	179.56
9/29/2005	Abilify	$	350.45
10/19/2005	Trazadone	$	11.01

10/19/2005	Trileptal	$	210.55
10/19/2005	Zoloft	$	179.56
10/22/2005	Abilify	$	350.45

211. Ozer caused the following false claims for prescriptions to A.L., Claim Recipient Identification No. 0600311008, that were not for a medically accepted indication to be presented to Medicaid and/or CHIP for reimbursement:

	Amount	Date	Drug
$	38.95	1/8/2008	Risperdal
$	39.50	12/24/2007	Risperdal
$	38.95	12/31/2007	Risperdal
$	90.99	12/11/2007	Risperdal
$	90.99	12/18/2007	Risperdal
$	90.44	1/8/2008	Risperdal
$	90.99	12/24/2007	Risperdal
$	90.44	12/31/2007	Risperdal

Count 7: Hogan and Streur Liability For Authorizing False Claims

212. Defendants Hogan and Streur are responsible for the administration of Alaska's Medicaid program, including CHIP/Denali Kid Care

213. Defendants Hogan and Streuer are liable under the False Claims Act for Alaska authorizing false claims for reimbursement by the Government of the United States Government's federal financial participation share, as defined in 42 CFR §400.203 (FFP), when doing so

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false.

214. 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.

215. Defendants Hogan and Streur approved or presented the specific false claims identified above to the Government for FFP

(1) with actual knowledge;

(2) in deliberate ignorance; or

(3) in reckless disregard

that such claims are false.

Count 8: Prescribers Liability For Misdiagnoses

216. 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 9: Prescribers Liability for Pediatric SSRI Prescriptions

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

218. 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 10: Pediatric Risperdal Prescriptions

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

220. 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. DEFENDANTS' LIABILITY

221. 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.

222. 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.

223. 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.

VIII. 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: May 6, 2010.

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

By: /s/ James B. Gottstein

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Alaska Bar Association #7811100

Attorney for *relator*, Law Project for Psychiatric Rights

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on May 6, 2010 a true and correct copy of this document and accompanying proposed order was served electronically on all parties of record by electronic means through the ECF system as indicated on the Notice of Electronic Filing, or if not confirmed by ECF, by first class regular mail.

/s/ James B. Gottstein
JAMES B. GOTTSTEIN, ABA #7811100
Law Project for Psychiatric Rights