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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

Chambers Copy With Exhibits D & E Omitted

MOTION FOR PRELIMINARY INJUNCTION AGAINST DEFENDANTS HOGAN AND STREUR

Qui tam relator Law Project for Psychiatric Rights (PsychRights®) moves for a preliminary injunction prohibiting defendants William Hogan and William Streur, their agents, servants, employees and attorneys, and any persons who are in active concert or participation with them, from presenting claims or causing claims to be presented to Medicaid for reimbursement or payment of the United States Government's federal

financial participation (FFP) share[1] of outpatient prescriptions for psychotropic drugs to recipients under the age of 18 (children and youth) that are not for a medically accepted indication.

I. BACKGROUND

This is a case under the federal False Claims Act, 31 U.S.C. §3729, *et seq*., to:

(a) recover for false claims presented to and paid by Medicaid for outpatient psychiatric drugs prescribed to children and youth that were not for a "medically accepted indication;" and

(b) order the defendants to cease and desist from presenting or causing the presentment of such false claims.

This motion seeks to enjoin Defendants William Hogan and William Streur, their agents, servants, employees and attorneys, and any persons who are in active concert or participation with them from presenting claims or causing claims to be presented to Medicaid for outpatient prescriptions for psychotropic drugs to children and youth that are not covered under that program. Defendant Hogan is the Commissioner of the Alaska Department of Health and Social Services (DHSS), and Defendant William Streur is the Director of the Division of Health Care Services (HCS) within DHSS. Defendant Streur is in charge of the administration of the Medicaid program by the State of Alaska under the direction and supervision of Defendant Hogan. In other words, Defendants Hogan and Streur are in charge of the administration of the Medicaid program by the State of Alaska.

Congress restricted reimbursement for outpatient drugs by the federal government under Medicaid to those that are "medically accepted indications," defined as indications approved by the Food and Drug Administration (FDA), or the use of which is supported by one or more citations included or approved for inclusion in (i) American Hospital

[1] "FFP" stands for "Federal Financial Participation," which means "the Federal Government's share of a State's expenditures under the Medicaid program." 42 CFR §400.203.

Formulary Service Drug Information, (ii) United States Pharmacopeia-Drug Information (or its successor publications), or (iii) DRUGDEX Information System (Covered Outpatient Drugs). 42 USC § 1396r-8(k)(3); 42 USC § 1396r-8(k)(6); 42 USC § 1396r-8(g)(1)(B)(i).

The parties sought to be enjoined continue to present claims or cause claims to be presented to Medicaid for payment of prescriptions to children and youth for psychiatric drugs that are not for a medically accepted indication. This motion thus seeks to preliminarily enjoin such continuing violation of federal law.

II. STANDARDS FOR PRELIMINARY INJUNCTIONS

In *California Pharmacists Ass'n v. Maxwell-Jolly*, 563 F.3d 847, 849 (9th Cir. 2009), citing to *Winter v. Natural Res. Def. Council, Inc*., --- U.S. ----, 129 S.Ct. 365, 376, 172 L.Ed.2d 249 (2008), the 9th Circuit, recently had occasion to state the standard for obtaining a preliminary injunction:

> Plaintiffs seeking a preliminary injunction in a case in which the public interest is involved must establish that they are likely to succeed on the merits, that they are likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in their favor, and that an injunction is in the public interest. .

These factors will be discussed in turn.

III. THE STANDARDS FOR ISSUANCE OF A PRELIMINARY INJUNCTION ARE MET HERE

A. PsychRights is Likely to Succeed on the Merits

(1) Medicaid Coverage for Outpatient Drugs is Limited to "Medically Accepted Indications

42 USC 1396R-8(k)(3) provides in pertinent part, "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.

(Compendia).

In sum, Medicaid is only permitted by Congress to reimburse the states for expenditures on outpatient drugs for "medically accepted indications," defined as indications approved by the FDA or "supported" by a citation in any of the three Compendia. This was recognized in *US ex rel Rost v. Pfizer*, 253 F.R.D. 11, 13-14 (D.Mass 2008) where the Court held:

> Medicaid can only pay for drugs that are used for a "medically accepted indication," meaning one that is either approved by the FDA or "supported by citations" in one of three drug compendia, including DRUGDEX. See 42 U.S.C. § 1396r8 (k)(3), (6); 42 U.S.C. § 1396r-8 (g)(1)(B)(I).

Similarly, in *U.S. ex rel. Franklin v. Parke-Davis*, 147 F.Supp. 2d 39, 44,45 (D.Mass 2001), the Court held:

> Whether a drug is FDA-approved for a particular use will largely determine whether a prescription for that use of the drug will be reimbursed under the federal Medicaid program. Reimbursement under Medicaid is, in most circumstances, available only for "covered outpatient drugs." 42 U.S.C. § 1396b(i)(10). Covered outpatient drugs do not include drugs that are "used for a medical indication which is not a medically accepted indication." Id. §1396r-8(k)(3). A medically accepted indication, in turn, includes a use "which is approved under the Federal Food Drug and Cosmetic Act" or which is included in specified drug compendia. Id. § 1396r-8(k)(6). See also id. § 1396r-8(g)(1)(B)(i) (identifying compendia to be consulted). Thus, 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.

(footnote omitted)

The Department of Justice concurs as shown by its news release announcing the $2.3 Billion settlement with Pfizer, in which it stated, "[Pfizer] 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." Exhibit A.

(2) Defendants Hogan and Streur Are Personally Liable for Presenting or Causing False Claims to be Presented to Medicaid.

Under *Stoner v. Santa Clara County Office of Education*, 502 F.3d 1116, 1124-5 (9th Cir. 2007), Defendants Hogan and Steur are personally liable for presenting or causing the presentment of false claims to Medicaid:

> The district court also held that Stoner failed to state an FCA [False Claims Act] claim against the individual defendants in their personal capacities because Stoner could not allege that the defendants' actions exceeded the scope of their official responsibilities. As explained below, this was an error. The plain language of the FCA subjects to liability "any person" who, among other things, knowingly submits a false claim or causes such a claim to be submitted to the United States. 31 U.S.C. § 3729. Although the FCA does not define the term "person," the Supreme Court has made clear that the term includes "natural persons." . . . Therefore, state employees sued in their personal capacities are "persons" who may be subject to liability for submitting a false claim to the United States. . . .
>
> To state a claim against Wilcox, Fimiani, and Wong in their personal capacities, Stoner need show only that the individual employees "knowingly present[ed], or cause[d] to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval."

(citations omitted).

(3) Defendants Hogan and Streur Are Flouting Medicaid Requirements By Presenting or Causing the Presentment of Claims for Prescriptions of Psychotropic Drugs to Children and Youth That Are Not For A Medically Accepted Indication

In *ex rel Rost*, 253 F.R.D. at 14 the district court noted, "Each prospective Medicaid provider must agree that he will comply with all Medicaid requirements." States must similarly agree to abide by Medicaid requirements as a condition of participation. Attached hereto as Exhibit B is a copy of the State of Alaska's agreement to comply with all Medicaid requirements.

Among these requirements, under 42 USC §1396r-8 (g)(1)(A), the State of Alaska is required to have a drug use review program (DUR) "designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud."

Under 42 CFR §456.703, the DUR is required to include "prospective drug review." 42 CFR §456.705 in turn provides in pertinent part:

> **42 CFR §456.705 Prospective drug review.**
>
> (a) General. Except as provided in Sec. Sec. 456.703 (b) and (c), the State plan must provide for a review of drug therapy before each prescription is filled or delivered to a recipient . . . . The State must provide pharmacies with detailed information as to what they must do to comply with prospective DUR requirements . . . . The pharmacies, in turn, must provide this information to their pharmacists.

In other words, through this prospective drug review, before each prescription is filled, the state Medicaid agency is required to review it to determine if it is eligible for reimbursement by Medicaid.

42 CFR §456.722 allows for this prospective review of prescriptions to occur through a computerized system:

> **42 CFR §456.722 Electronic claims management system.**
>
> (a) Point-of-sale system. Each Medicaid agency, at its option, may establish, as its principal (but not necessarily exclusive) means of processing claims for covered outpatient drugs, a point-of-sale electronic claims management (ECM) system to perform on-line, real-time (that is,

immediate) eligibility verifications, claims data capture, adjudication of claims, and to assist pharmacists and other authorized persons (including dispensing physicians) in applying for and receiving payment. . . . If the State exercises this option and wishes to receive FFP for its ECM system, the system must meet the functional and additional procurement and system requirements in paragraphs (b) and (c) of this section.

(b) Functional requirements. The ECM system developed by the State must include at least the on-line, real-time capabilities specified in paragraphs (b)(1) through (3) of this section. . . .

(2) Claims data capture, including the following: . . .

(iii) Minimum data set (as defined in Part 11 of the State Medicaid Manual).

(3) Claims adjudication, including the following:

(i) Performing all edits and audits contained in the State's Medicaid Management Information System (MMIS) applicable to prescription drugs.

(ii) Notifying the pharmacist (or other authorized person, such as the dispensing physician) about the claim status.

(iii) Taking steps up to, but not including, payment of the claim.

Included in the data set of Part 11 of the State Medicaid Manual[2] are:

*6. Recipient's Date of Birth:

The date of birth of the recipient. . .

*61. Principal Diagnosis Code:

a. The diagnosis code for the principal condition requiring medical attention. . . .

62. Other Diagnosis Code:

a. The diagnosis code of any condition other than the principal condition which requires supplementary medical treatment. . . .

88. Drug Code:

Codes identifying particular drugs; e.g., National Drug Code, drug tables.

89. Diagnosis Code:

A table of codes identifying medical conditions; i.e., ICD-9-CM.

[2] Exhibit C, downloaded from http://www.cms.hhs.gov/manuals/downloads/P45_11.zip on March 17, 2010.

90. Drug Name:
The generally accepted nomenclature for a particular drug.
91. Drug Classification:
The therapeutic group in to which a drug is categorized.
92. Minimum Days Supply of Drugs:
The minimum units of a drug prescription eligible for payment.
93. Maximum Days Supply of Drug:
The maximum units of a drug prescription eligible for a particular drug. . . .
95. Diagnosis Name:
The generally accepted nomenclature for a diagnosis. Name is required only if not encoded by provider. (See Data Element No. 61.)

These statutory and regulatory provisions require the State of Alaska to screen prescriptions for compliance with the requirement that it not seek federal Medicaid payment for outpatient prescriptions to children and youth for psychotropic drugs that are not for a medically accepted indication.

To summarize: 42 USC §1396r-8 (g)(1)(A) requires a DUR program, 42 CFR §456.703 requires the DUR program to include prospective drug review, and 42 CFR §456.705 requires such prospective review to verify eligibility before the prescription is filled. Under 42 CFR §456.722, the State's electronic claims management system is required to collect the minimum data specified in Part 11 of the State Medicaid Manual, relevant elements of which are set forth above. These elements can determine whether psychotropic drugs prescribed to children and youth are or are not for a medically accepted indication.

Under Defendants Hogan's and Steur's administration of Alaska's Medicaid program, these requirements are being flouted.

(4) Injunctive Relief is Available Against Defendants Hogan and Streur

Injunctive relief to enjoin a state official from violating a federal statute is proper and not barred by the 11th Amendment to the United States Constitution. *Armstrong v. Wilson*, 124 F.3d 1019 (9th Cir. 1997); *Independent Living Center of Southern*

California, Inc., v Maxwell-Jolly, 572 F.3d 644 (9th Cir. 2009). Where a district court has the power to issue a permanent injunction, it also has authority to issue preliminary injunctions. *F.T.C. v. H. N. Singer, Inc.*, 668 F.2d 1107, 1111 (9th Cir. 1982).

B. The Plaintiff Will Suffer Irreparable Harm Without the Preliminary Injunction

(1) To the Extent the 11th Amendment Prohibits a Monetary Judgment Against the State of Alaska for its Medicaid Fraud, Irreparable Harm is Established as a Matter of Law.

In *California Pharmacists, supra*., 563 at 852, the 9th Circuit held that to the extent the 11th Amendment prevents a federal court from awarding a damages remedy against a state, irreparable harm is established as a matter of law:

> Because the economic injury doctrine rests only on ordinary equity principles precluding injunctive relief where a remedy at law is adequate, it does not apply where, as here, the Hospital Plaintiffs can obtain no remedy in damages against the state because of the Eleventh Amendment.

(citation and footnote omitted).

In *Stoner*, as set forth above, the Ninth Circuit held that state employees are personally liable under the False Claims Act for Medicaid violations while acting within the scope of their official duties. However, it specifically held open the question of whether the 11th Amendment prevented the district court from awarding money damages against a state under the False Claims Act through its employees:

> With respect to the official capacity claims, the district court held that the individually named defendants could not be sued for damages in their official capacities because such a suit would, in effect, be against the state. . . . The parties do not challenge this ruling and we express no opinion on the merits of the district court's conclusion.

572 F.3d at 1123 (citation omitted).

California Pharmacists does not mention *Stoner*, and the two cases are certainly distinguishable, especially in that *California Pharmacists* is not a False Claims Act case

while *Stoner* is, but it can be read to suggest that even under the False Claims Act, the 11th Amendment bars a federal court from awarding monetary damages against a state.

If Defendants Hogan and Streur, who are being represented by the Alaska Department of Law as to both their individual and official capacities,[3] concede that the State of Alaska is subject to monetary damages by virtue of Defendants Hogan and Streur having been sued in their official capacities as well as individually, then irreparable harm will not have been established on the grounds that the 11th Amendment bars this Court from awarding monetary damages against the State of Alaska through Defendants Hogan and Streur. However, if the State of Alaska, through Defendants Hogan and Streur, does not concede the State is subject to monetary damages, and this Court concludes the State of Alaska is immune, under *California Pharmacists*, irreparable harm has been established as a matter of law.

As will be discussed in the next section, however, even if the Court concludes the State of Alaska through Defendants Hogan and Streur is subject to monetary damages in this case and therefore irreparable harm has not been established for that reason, irreparable harm is established as a matter of law because the continuing violation of a federal statute constitutes irreparable harm as a matter of law.

(2) The Continuing Violation of a Federal Statute is Irreparable Harm as a Matter of Law.

In *New Motor Vehicle Bd. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351, 98 S.Ct. 359, 363, 54 L.Ed.2d 439 (1977) (Rehnquist, J., in chambers), the U.S. Supreme Court held, "any time a State is enjoined by a court from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury." In *Coalition for Economic Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997), citing *New Vehicle*, the Ninth Circuit held, "it is clear that a state suffers irreparable injury whenever an enactment of its people or their representatives is enjoined." In *Independent Living*

[3] *See*, Docket Nos. 52 & 55.

Center, *supra*., 572 F.3d at 658, the Ninth Circuit clarified, that while that may be true, enforcing federal law pre-empts such irreparable harm suffered by a state, stating:

> As the cited authority suggests, a state may suffer an abstract form of harm whenever one of its acts is enjoined. To the extent that is true, however, it is not dispositive of the balance of harms analysis. If it were, then the rule requiring "balance" of "competing claims of injury," *Winter*, 129 S.Ct. at 376, would be eviscerated. Federal courts instead have the power to enjoin state actions, in part, because those actions sometimes offend federal law provisions, which, like state statutes, are themselves "enactment [s] of its people or their representatives,"

PsychRights respectfully suggests the Ninth Circuit has thus implicitly held that allowing continuing violation of federal law constitutes irreparable harm as a matter of law.

C. The Balance of Equities Tips in Favor of the Plaintiff and the Injunction is in the Public Interest as a Matter of Law

Under California Pharmacists, *supra*., 563 at 852-853, as a matter of law, the balance of equities tips in favor of the plaintiff and a prospective preliminary injunction is in the public interest if the requested preliminary injunction is to enjoin continuing violation of federal law ("it is clear that it would not be equitable or in the public's interest to allow the state to continue to violate the requirements of federal law"). Thus, these two factors are satisfied as a matter of law. Where, as here, the violation of law is clear, the court must not allow it to continue.

IV. SCOPE OF THE REQUESTED PRELIMINARY INJUNCTION

Whether a prescription for a psychotropic drug to a child or youth that is not for an FDA approved indication is nonetheless covered under Medicaid because it is a medically accepted indication, the American Hospital Formulary Service and DRUGDEX compendia citations must be consulted to be if such use is "supported."[4]

[4] It is PsychRights' understanding, after inquiry, that United States Pharmacopeia-Drug Information (or its successor publications), the other compendium specified in 42 U.S.C. 1396r-8(g)(1)(B)(i), is no longer being published.

Attached hereto as Exhibit D are the most recent citations in the American Hospital Formulary Service compendium, and Exhibit E the most recent citations in DRUGDEX[5] available to PsychRights,[6] for specific prescription psychotropic drugs often prescribed to children and youth. These establish the following with respect to medically accepted indications prescribed to children and youth for the specific psychotropic drugs:

1. The following psychotropic drugs have no medically accepted indication for anyone under 18 years of age and should be prohibited entirely:

   a. Clorazil (clozapine)
   b. Cymbalta (duloxetine)
   c. Desyrel (trazadone)
   d. Effexor (venlafaxine)
   e. Geodon (ziprasidone)
   f. Invega (paliperidone)
   g. Paxil (paroxetine)
   h. Symbyax (fluoxetine hydrochloride/olanzapine)

2. The only medically accepted indications for anyone under 18 years of age are as set forth below for the following psychotropic drugs and all other indications should be prohibited:

Drug	**Medically Accepted Indication**	**Notes**
Abilify (Aripiprazole)		
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	10 yrs old and up
	Bipolar I Disorder, monotherapy, Manic	10-17 years old for acute therapy

[5] Exhibit F is a copy of the DRUGDEX Recommendation, Evidence and Efficacy Ratings.

[6] PsychRights has requested Defendant Thomson Reuters (Healthcare), the publisher of DRUGDEX, for the most recent citations in DRUGDEX and to keep them current so that any additions to medically accepted indications may be reflected in the requested preliminary injunction. *See*, Exhibit G.

Drug	Medically Accepted Indication	Notes
	or Mixed Episodes	
	Schizophrenia	13-17 years old
Adderall (amphetamine/dextroamphetamine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	3 years old and up for immediate-release and 6 years old and up for extended-release
	Narcolepsy	6 years old and up for immediate release
Anafranil (clomipramine)		
	Obsessive-Compulsive Disorder	10 years and up
Concerta (methylphenidate)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old to 12 years old
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old and up for ConcertaR
Depakote (valproic acid)		
	Absence Seizure, Simple and Complex and/or Complex Partial Epileptic Seizure	10 years and older
Dexedrine (dextroamphetamine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release))
	Narcolepsy	6 years old and up
Focalin (dexmethylphenidate)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years and older
Haldol (haloperidol)		
	Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy	3 years old and up
	Problematic Behavior in Children (Severe), With failure to respond to non-antipsychotic medication or psychotherapy	3 years old and up
	Psychotic Disorder	3 years old and up but ORAL formulations only

Drug	Medically Accepted Indication	Notes
	Schizophrenia	3 years old and up but ORAL formulations only
Lamictal (lamotrigine)		
	Epilepsy, Refractory	
Lexapro (escitalopram)		
	Major Depressive Disorder	12 years old and up
Luvox (fluvoxamine)		
	Obsessive-Compulsive Disorder	8 years old and up and immediate release formula only
Mellaril (thioridazine)		
	Schizophrenia, Refractory	
Neurontin (gabapentin)		
	Partial Seizure; Adjunct	3-12 years old
Orap (pimozide)		
	Gilles de la Tourette's syndrome	12 years and older
Prozac (fluoxetine)		
	Major Depressive Disorder	8 years old and up
	Obsessive-Compulsive Disorder	7 years old and up
Ritalin (methylphenidate)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years to 12 years old (extended release)
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old and up (immediate release)
	Narcolepsy	6 years and up, and Ritalin(R) -SR only
Risperdal (risperidone)		
	Autistic Disorder – Irritability	5 years old and up
	Bipolar I Disorder	10 years old and up
	Schizophrenia	13 years old and up (Orally)
Seroquel (quetiapine)		
	Manic episodes associated with bipolar disorder	10 years old to 17 years old
	Schizophrenia	13 years old to 17 years old
Sinequan (doxepin)		
	Alcoholism - Anxiety – Depression	12 years old and up

Drug	Medically Accepted Indication	Notes
	Anxiety – Depression	12 years old and up
	Anxiety - Depression - Psychoneurotic personality disorder	12 years old and up
Strattera (atomoxetine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old and up
Tegretol (carbamazepine)		
	Epilepsy, Partial, Generalized, and Mixed types	
Tofranil (imipramine)		
	Nocturnal enuresis	6 years old and up
Trileptal (*oxcarbazepine*)		
	Partial Seizure, monotherapy	4 years old and up
	Partial seizure; Adjunct	2 years old and up
Vyvanse (lisdexamfetamine)		
	Attention Deficit Hyperactivity Disorder (ADHD)	6 years old to 12 years old
Zoloft (sertraline)		
	Obsessive-Compulsive Disorder	6 years old and up
Zyprexa (olanzapine)		
	Schizophrenia	13 years old to 17 years old
	manic or mixed episodes associated with bipolar I disorder	13 years old to 17 years old

For psychotropic drugs not listed, PsychRights respectfully suggests the parties sought to be enjoined should be prohibited from approving for payment or reimbursement by Medicaid of the United States Government's FFP share of outpatient prescriptions for psychiatric drugs to anyone under 18 unless (a) it is for an indication approved by the FDA, or (b) upon application to the Court with notice to the other parties to determine whether such use is for a medically accepted indication.

V. BOND

Under F.R.C.P. 65(c) the United States is not required to give security. Since the United States is the real party in interest in this action, *Stoner*, *supra*, 502 F.3d at 1126, no security is required.

VI. CONCLUSION

For the foregoing reasons PsychRights' motion for a preliminary injunction should be granted.

RESPECTFULLY SUBMITTED this 24th day of March, 2010.

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

By: /s/ James B. Gottstein
JAMES B. GOTTSTEIN
ABA #7811100

Attorney for *relator*, Law Project for Psychiatric Rights

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on March 24 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

Department of Justice

FOR IMMEDIATE RELEASE
Wednesday, September 2, 2009
WWW.USDOJ.GOV

AAG
(202) 514-2007
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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09-900

Revision: HCFA-PM-91-4 (BPD) OMB No. 0938-
AUGUST 1991

STATE PLAN UNDER TITLE XIX OF THE SOCIAL SECURITY ACT
MEDICAL ASSISTANCE PROGRAM

State/Territory: ALASKA

Citation

42 CFR
430.10

As a condition for receipt of Federal funds under title XIX of the Social Security Act, the

Department of Health and Social Services
(Single State Agency)

submits the following State plan for the medical assistance program, and hereby agrees to administer the program in accordance with the provisions of this State plan, the requirements of titles XI and XIX of the Act, and all applicable Federal regulations and other official issuances of the Department.

TN No. 91-13
Supersedes TN No. 76-31
Approval Date 4/10/92
Effective Date 10/1/91
HCFA ID: 7982E

11375 DATA REQUIREMENTS

The minimum data element file requirements for systems approval derive from State plan requirements and Federal reporting requirements. Data elements related to services not covered in the State plan need not be included.

Claim format and content varies depending upon the type of provider that submits a claim and individual State plan requirements.

NOTE: Subtitle F of Public Law 104-191 mandates that the Secretary of the Department of Health and Human Services adopt a wide range of national standards for the electronic exchange of health information. Standards are to be adopted for: 1) electronic transactions and data elements, 2) code sets, 3) unique health identifiers for individuals, providers, health plans, and employers, 4) security of health information, and 5) electronic signatures. The recommended standards for various types of standards mandated under Public Law 104-191 will be made available for public comment via Notices of Proposed Rulemaking in the Federal Register. Once standards are published as Final Rules in the Federal Register, States and all health related providers must implement standards within 2 years from the Federal Register publication date. The final standards will supersede any/all standards currently in place for electronic transactions and data elements.

The Uniform Hospital Discharge Data Set (UHDDS), developed through the National Committee on Vital and Health Statistics (NCVHS) and required by HHS departmental policy, effective January 1, 1975, and which meets current PRO requirements of §11205, contains, for hospital service only, discharge data as a file requirement and is identified in this section as:

* UHDDS as well as MMIS requirement
** UHDDS requirement only

The following data elements contained in the systems files are minimal and not exclusive requirements for source and use within the MMIS.

1. Recipient Identification Number:
   A number that uniquely identifies an individual eligible for Medicaid benefits.

*2. Recipient Social Security Number (SSN):
   The number used by SSA throughout a wage earner's lifetime to identify earnings under the Social Security program.

   For newborns and children not having a SSN but covered under Medicaid use No. 1 above to identify these eligibles.

3. Recipient Social Security Claim Number:
   The number assigned to an individual by the SSA under which monthly cash benefits (and Medicare benefits) are paid or eligibility is established.

4. Recipient's Name:
   The name of the recipient.

*5. Recipient's Address:
The address of the recipient.

*6. Recipient's Date of Birth:
The date of birth of the recipient.

7. Recipient's Race Code:
a. The racial origin of the recipient
** b. Race/Ethnic
White, Black, Hispanic, Asian/Pacific Islander, American/Indian/Alaska Native, and other

*8. Recipient's Sex Code:
The sex of the recipient.

9. Recipient's Aid Category:
The statutory category of public assistance, SSI or State supplementary payment under which a recipient is eligible for Medicaid benefits.

10. Gross Family Income:
The monthly gross income for the family of which this recipient is a member.

11. Family Size:
The number of persons in the family of which this recipient is a member.

12. Eligibility Beginning Date:
A date that begins a period in which a recipient was certified as eligible to receive Medicaid benefits.

13. Eligibility Ending Date:
A date concluding a period in which a recipient is eligible to receive Medicaid benefits.

14. Third Party Liability Code:
a. A code indicating availability to a recipient of potential third party resources.
** b. Expected Principal Source of Payment
(1) Self-pay
(2) Workmen's Compensation
(3) Medicare
(4) Medicaid
(5) Maternal and Child Health
(6) Other Government Payments
(7) Blue Cross
(8) Insurance Companies
(9) No charge (free, charity, special research, or teaching)
(10) Other

15. Buy-In Status Code:
The code indicating a recipient's status with respect to the Medicare Buy- In Program.

16. Recipient Exception Indicator:
A code indicating that all claims for a given recipient are to be manually reviewed prior to payment.

17. Money Payment Code:
A code indicating whether or not the recipient is currently receiving cash assistance.

18. Medicare Type Code:
A code indicating whether the recipient is covered by Medicare, and, if so, whether he/she has Hospital Insurance Benefits (Part A) and/or Supplementary Medical Insurance Benefits (Part B).

19. Buy-In Eligibility Date:
The date from which the recipient is eligible for the Medicare Buy-In Program.

20. Buy-In Premium Date:
The date associated with a Buy-In premium amount.

21. Buy-In Premium Amount:
The amount of money the State pays to HCFA each month per recipient for Buy-In coverage.

22. SSA-Information Exchange Code:
A code scheme consisting of various numerical codes which describe situations that can occur at SSA or at the State level.

23. Recipient's Eligibility Certification Date:
Date recipient was certified as eligible for public assistance, supplemental security income or State supplemental benefits.

24. Recipient's Location Code:
The geographic or geopolitical subdivision of a State in which the recipient resides.

25. Medicaid Premium Amount:
A recurring premium paid by medically needy individuals before they can receive Medicaid services. The amount of the fee is based upon the number of persons in the family and the gross family income.

26. Medicaid Enrollment Fee Amount:
A one-time enrollment fee paid by medically needy individuals before they can receive Medicaid services. The amount of the fee is based on the number of persons in the family and the gross family income.

27. Medicaid Deductible Amount:
The annual (or other period) amount which the recipient must pay toward the cost of medical services before Medicaid will begin to pay.

28. Date of Death:
The date of a recipient's death as indicated in the Social Services or SSI file after an official notice of death has been received.

29. Provider Number (State):
A unique number assigned by the State to each participating provider of services.

30. Provider Name:
The name of the provider of Medicaid services as used on official State records.

31. Provider Address:
The mailing address of the provider.

32. Provider Pay to Address:
The address to which Medicaid payments to a provider are sent.

33. Provider Type:
A code indicating the classification of the provider rendering health and medical services as approved under the State Medicaid plan.

34. Provider Beginning Date of Service:
A date beginning a period in which the provider was authorized to receive Medicaid payments.

35. Provider Ending Date of Service:
A date concluding a period in which the provider is authorized Medicaid payments for services rendered.

36. Provider Group Number:
The number assigned to the group practice of which an individual provider is a member.

37. Provider Type of Practice Organization:
A code identifying the organizational structure of a provider's practice.

38. Provider Employer Identification Number:
The number assigned to an employer by the Internal Revenue Service for tax reporting purposes.

39. Provider Social Security Number:
The number assigned to an individual by SSA.

*40. Medicare Provider Number:
The identification number assigned to a Medicare provider by HCFA (provider means any individual or entity furnishing Medicaid services under a provider agreement with the Medicaid agency (Reference 42 CFR 430.l).

41. Provider Year End Date:
The calendar date on which the provider's fiscal year ends.

42. Provider Specialty Code:
A code used to indicate the medical specialty of a physician.

43. Provider Exception Indicator:
A code indicating that all claims from a given provider are to be manually reviewed prior to payment.

44. Provider Credit Balance Amount:
The amount of money the Medicaid program owes a provider.

45. Provider Credit Balance Date:
The processing date on which the last amount was entered in the Provider Credit Balance amount.

46. Out-of-State Provider Code:
A code indicating that the provider is located out of State.

47. Per Diem Rate:
The payment amount for each day of care in an institution reimbursed on a per diem basis.

48. Percent-of-Charges Factor:
The percent of a provider's charges that constitutes payment for certain categories of service.

49. Rate Effective Date:
The effective date of the accompanying per diem rate or percent-of-charges factor.

50. Provider Location Code:
The geographic or geopolitical subdivision in which the provider's place of business is located.

51. Provider Enrollment Status Code:
A code indicating a provider's certification status with respect to the Medicaid program.

52. Provider Enrollment Status Date:
The effective date of the accompanying provider enrollment status code.

53. Provider Group Name and Address:
The name and mailing address of the provider group.

54. Transaction Control Number:
A unique number identifying each claim transaction received.

55. Category of Service:
A code defining the category of service rendered (e.g., general inpatient, pharmacy, physician, home health).

56. Laboratory, Medicare Certified Indicator:
A code indicating that a laboratory is approved as meeting the requirements for participation in Medicare.

57. Laboratory Service Authorized Code:
A code indicating the services/procedures that a laboratory which meets the requirements for participation in Medicare is authorized to perform.

*58. Physician Identification:
a. Attending Physician Number
The provider number of the physician attending an inpatient in a hospital, nursing home, or other institution.

This is the physician primarily responsible for the care of the patient from the beginning of this institutional episode.

**b. Operating Physician
This is the physician who performed the principal procedure. See Data Element No. 87 below, for definition of principal procedure.

59. Referring Physician Number:
The provider number of the physician referring a recipient to another practitioner or provider.

60. Prescribing Physician Number:
The provider number of the physician issuing a prescription.

*61. Principal Diagnosis Code:
a. The diagnosis code for the principal condition requiring medical attention.

**b. The condition established after study to be chiefly responsible for causing the patient's admission to the hospital for care for the current hospital stay. (HCFA requires the acceptance of ICD-9-CM coding.)

62. Other Diagnosis Code:
a. The diagnosis code of any condition other than the principal condition which requires supplementary medical treatment.

**b. Conditions (up to four) other than the principal condition that coexisted at the time of admission, or developed subsequently, which affected the treatment received and/or the length of stay. Exclude diagnoses that relate to an earlier episode which have no bearing on this hospital stay. (HCFA requires the acceptance of ICD-9-CM coding.)

*63. Admission Date:
The date a recipient was admitted to a medical institution.

64. Beginning Date of Service:
The date upon which the first service covered by a claim was rendered. If a claim is for one service only (e.g., a prescription), this is the only service date.

65. Ending Date of Service:
The date upon which the last service covered by a claim was rendered.

*66. Discharge Date:
The formal release of an inpatient from a hospital.

67. Place of Service:
A code indicating where a service was rendered by a provider.

*68. Patient Number:
Any number assigned by a provider to a recipient or claim for reference purposes, such as a medical record number.

69. Patient Status:
A code indicating the patient's status on the last date of service covered by an institutional claim.

70. Total Claim Charge:
The sum of all charges associated with an individual claim.

71. Units of Service:
A quantitative measure of the services rendered to, or for, a recipient (e.g., days, visits, miles, injections).

72. Third Party Payment Amount:
The amount of payment applied toward a claim by third party sources.

73. Medicare Cash Deductible Amount:
The unmet Medicare deductible subject to payment by Medicaid.

74. Medicare Blood Deductible Amount:
The unmet Medicare deductible for blood subject to payment by Medicaid.

75. Medicare Coinsurance Charge:
The Medicare coinsurance amount subject to payment by Medicaid.

76. Medicare Reasonable Charge:
Payment amount recognized as the reasonable charge for Medicare.

77. Medicaid Co-Payment Amount:
The portion of the claim charge which the recipient must pay, called coinsurance when expressed as a percentage of the payment amount.

78. Prior Authorization Control Number:
A number that uniquely identifies a particular instance of prior authorization.

79. Payment Amount:
The computed amount of payment due a provider for a claim transaction.

80. Date of Adjudication:
The date a claim is approved (or partially approved) or disallowed.

81. Error Code:
A code indicating the nature of an error condition associated with that claim transaction.

82. Date Entered Suspense:
The date a claim transaction was initially suspended.

83. Payment Date:
The date a payment instrument was generated for a claim transaction.

84. Allowable Procedure Payment:
The maximum allowed amount payable for a particular medical procedure, treatment, or service item.

85. Professional Fee:
The amount allowed to a dispenser of drugs as compensation for his professional services.

86. Prescription Number:
The number assigned by a pharmacist to a prescription at the time it is filled.

87. Procedure Codes:
Codes identifying medical procedures (i.e. accept and use exclusively the HCPCS in a physician or outpatient setting). (For an inpatient setting, ICD-9-CM Volume 3 is recommended).

**a. Principal Significant Procedures:
When more than one procedure is reported, designate the principal procedure. In determining which of several procedures is the principal, apply the following criteria:

(1) The principal procedure is the one which was performed for definitive treatment rather than performed for diagnostic or exploratory purposes, or was necessary to take care of a complication.

(2) The principal procedure is that procedure most closely related to the principal diagnosis.

**b. Other Significant Procedures:

(1) One which carries an operative or anesthetic risk, requires highly trained personnel, or requires special facilities or equipment.

(2) Up to four significant procedures can be reported.

(HCFA requires the acceptance of ICD-9-CM coding.)

88. Drug Code:
Codes identifying particular drugs; e.g., National Drug Code, drug tables.

89. Diagnosis Code:
A table of codes identifying medical conditions; i.e., ICD-9-CM.

90. Drug Name:
The generally accepted nomenclature for a particular drug.

91. Drug Classification:
The therapeutic group in to which a drug is categorized.

92. Minimum Days Supply of Drugs:
The minimum units of a drug prescription eligible for payment.

93. Maximum Days Supply of Drug:
The maximum units of a drug prescription eligible for a particular drug.

94. Procedures Names:
The generally accepted nomenclature for medical, surgical, dental, etc., procedure.

95. Diagnosis Name:
The generally accepted nomenclature for a diagnosis. Name is required only if not encoded by provider. (See Data Element No. 6l.)

96. Unit of Measure:
The unit in which a drug is dispensed (e.g., cc, capsule, tablet).

97. Drug Cancellation Date:
The date after which a particular drug is no longer covered under the State Medicaid program.

98. Medicaid Reasonable Charge:
Payment amount recognized as the reasonable charge for Medicaid.

*99. Discharged Patient's Destination:
A code indicating a recipient's destination upon discharge from a medical institution.

a. Discharged to home (routine discharge).
b. Left against medical advice.
c. Discharged to another short term hospital.
d. Discharged to a long term care institution.
e. Died.
f. Other.

100. Billing Date:
The date a provider indicates a claim was prepared.

101. Procedure Charge:
The charge for an individual procedure, treatment, or service item as submitted by the provider.

102. Drug Charge:
The charge submitted by a provider for a given drug prescription.

103. Adjustment Amount:
The amount (plus or minus) by which a provider's account is to be changed.

104. Date Claim Received:
The date on which a claim transaction is received by the claims processing agency.

105. Date of Surgery:
The date on which a surgical procedure(s) was performed on an inpatient.

106. Drug Wholesale Cost:
The generally accepted wholesale cost of a drug.

107. Maximum Allowed Price:
The maximum amount that will be paid for a procedure, treatment, or service item.

108. Valid Sex Indicator:
A code which indicates when a procedure or diagnosis is limited to one sex only.

109. Age Range Indicator:
A code which specifies an age range when a procedure or diagnosis is limited to a particular age group.

110. Budgeted Amount:
The planned expenditures for various Medicaid services over a given period of time.

111. Screening Results Code:
A code indicating the outcome of the various screening tests rendered.

112. Screening Referral Code:
A code indicating the nature of any referrals made as a result of screening.

113. Screening Related Treatment:
A code identifying procedures or services received as a result of screening.

114. Family Planning Code:
A code indicating whether any diagnosis, treatment, drugs, supplies, and devices, counseling service, or other billed services or materials are for the purposes of family planning.

115. Certification Review Indicator:
Indicator showing that review was made of certification of a recipient who has been admitted to institutional care including approval status.

116. Certification/Recertification Date:
The date of certification/recertification of a recipient who has been admitted to institutional care.

117. Certification Status:
An indication of initial certification status of a patient in an institution.

118. Number of Requests for Extension:
The number of times an extension of certification of stay was requested for a patient in an institution.

119. Days Certified Initially:
The number of days stay certified initially for a patient in an institution.

120. Total Days Certified:
The total number of days stay certified for a patient in an institution.

121. Date of Application:
The date that a recipient applied for eligibility status in the Medicaid program.

122. SSN of an Absent Parent:
See 42 CFR 433.138 for the conditions under which this piece of information must be captured.

DRUGDEX® Consults

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

RESPONSE

The Thomson Efficacy, Strength of Evidence and Strength of Recommendation definitions are outlined below:

Table 1. Strength Of Recommendation		
Class I	Recommended	The given test or treatment has been proven to be useful, and should be performed or administered.
Class IIa	Recommended, In Most Cases	The given test, or treatment is generally considered to be useful, and is indicated in most cases.
Class IIb	Recommended, In Some Cases	The given test, or treatment may be useful, and is indicated in some, but not most, cases.
Class III	Not Recommended	The given test, or treatment is not useful, and should be avoided.
Class Indeterminant	Evidence Inconclusive	

Table 2. Strength Of Evidence	
Category A	Category A evidence is based on data derived from: Meta-analyses of randomized controlled trials with homogeneity with regard to the directions and degrees of results between individual studies. Multiple, well-done randomized clinical trials involving large numbers of patients.
Category B	Category B evidence is based on data derived from: Meta-analyses of randomized controlled trials with conflicting conclusions with regard to the directions and degrees of results between individual studies. Randomized controlled trials that involved small numbers of patients or had significant methodological flaws (e.g., bias, drop-out rate, flawed analysis, etc.). Nonrandomized studies (e.g., cohort studies, case-control studies, observational studies).
Category C	Category C evidence is based on data derived from: Expert opinion or consensus, case reports or case series.
No Evidence	

Table 3. Efficacy		
Class I	Effective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is effective
Class IIa	Evidence Favors Efficacy	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion favors efficacy.
Class IIb	Evidence is Inconclusive	Evidence and/or expert opinion is conflicting as to whether a given drug treatment for a specific indication is effective, but the weight of evidence and/or expert opinion argues against efficacy.
Class III	Ineffective	Evidence and/or expert opinion suggests that a given drug treatment for a specific indication is ineffective.

Subject: RE: Updated DRUGDEX Monographs
From: "Torgerson, James E." <JETORGERSON@stoel.com>
Date: Sun, 14 Mar 2010 09:02:49 -0700
To: "Jim Gottstein" <jim.gottstein@psychrights.org>

Hi Jim:

I will pass your request on to my client and get back to you with its response as soon as I have it.

Regards,

Jim

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Saturday, March 13, 2010 12:24 PM
To: Torgerson, James E.
Cc: Jim Gottstein
Subject: Updated DRUGDEX Monographs

Hi Jim,

I am working on a motion for a preliminary injunction I expect to file shortly after everyone's responses to the complaint are in and in working through that it has become apparent the most recent DRUGDEX® monographs are extremely relevant. For example, the FDA approved Seroquel and Zyprexa for limited pediatric uses on December 4, 2009, which is not reflected in the DRUGDEX monographs I have. The injunction which I will be seeking would, of course, not prohibit causing or presenting claims to Medicaid for those newly approved indications. Additions to medically accepted indications as a result of new FDA approval is easy enough for me to pick up, but DRUGDEX also updates its monographs pertaining to indications that have not received FDA approval.

It seems likely the judge would order your client to provide them in the context of the motion for preliminary injunction and I can certainly subpoena them to a hearing (subject to your possible objection), but I would prefer not to have to go to the court. Therefore, I am writing to ask if your client would voluntarily provide me with copies of the most recent monographs, and updates as they occur, for the drugs included in the Medically Accepted Indications Chart, plus the following drugs which I intend to add to the chart:

- alprazolam (Xanax®)
- Clonazepam (Klonopin®)
- clorazepate (Tranxene®)
- diazepam (Valium®)
- flurazepam (Dalmane®)
- lorzepam (Ativan®)

- temazepam (Restoril®)
- zaleplon (Sonata®)
- Zolpidem (Ambien®)

Granting me access to DRUGDEX would certainly be acceptable to me and presumably easier for your client, but I know your client closely guards access to DRUGDEX. Perhaps your client can grant me access to just the drugs of interest. Again, these would be the drugs included in the Medically Accepted Indications Chart as well as those listed above.

Please let me know.
--

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

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PsychRights®
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Psychiatric Rights

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