No. 12-3671

In the UNITED STATES COURT OF APPEALS For the Seventh Circuit

UNITED STATES OF AMERICA, and STATE OF WISCONSIN, Plaintiffs, and

TOBY T. WATSON, Plaintiff-Appellant

v.

JENNIFER KING-VASSEL, Defendant – Appellee

Appeal from The U.S. District Court for The Eastern District Of Wisconsin, Milwaukee Division Case No. 11-CV-236-JPS
The Honorable J.P. Stadtmueller Presiding

OPENING BRIEF and SHORT APPENDIX OF PLAINTIFF-APPELLANT TOBY T. WATSON

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I. CIRCUIT RULE 26.1 DISCLOSURE STATEMENT

Appellate Court No: 12-3671

Short Caption: Toby T. Watson, et al v. Jennifer King-Vassel

To enable the judges to determine whether recusal is necessary or appropriate, an attorney for a non-governmental party or amicus curiae, or a private attorney representing a government party, must furnish a disclosure statement providing the following information in compliance with Circuit Rule 26.1 and Fed. R. App. P. 26.1.

The Court prefers that the disclosure statement be filed immediately following docketing; but, the disclosure statement must be filed within 21 days of docketing or upon the filing of a motion, response, petition, or answer in this court, whichever occurs first. Attorneys are required to file an amended statement to reflect any material changes in the required information. The text of the statement must also be included in front of the table of contents of the party's main brief. Counsel is required to complete the entire statement and to use N/A for any information that is not applicable if this form is used.

- [X] PLEASE CHECK HERE IF ANY INFORMATION ON THIS FORM IS NEW OR REVISED AND INDICATE WHICH INFORMATION IS NEW OR REVISED.
- (1) The full name of every party that the attorney represents in the case (if the party is a corporation, you must provide the corporate disclosure information required by Fed. R. App. P 26.1 by completing item #3):
 - (1) Toby Tyler Watson, PsyD., Plaintiff-Appellant

[REVISED INFORMATION] Rebecca Lynn Gietman was dismissed as an appellant by Document No. 18.

(2) The names of all law firms whose partners or associates have appeared for the party in the case (including proceedings in the district court or before an administrative agency) or are expected to appear for the party in this court:

Law Project for Psychiatric Rights

Gietman Law

- (3) If the party or amicus is a corporation:
 - i) Identify all its parent corporations, if any; and

N/A

ii) list any publicly held company that owns 10% or more of the party's or amicus' stock:

| | N/A | |
|---------|-----------------------------------------------------------------------------------------|--------------------------------------------|
| | Attorney's Signature: /s James B. Gottstein Attorney's Printed Name: James B. Gottstein | |
| Circuit | Please indicate if you are Counsel of Record Rule 3(d). Yes _X_ No | I for the above listed parties pursuant to |
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IV. JURISDICTIONAL STATEMENT Basis for District Court Jurisdiction

The District Court had subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and the False Claims Act, 31 U.S.C. §§ 3729, 3730 and 3732, and supplemental jurisdiction over Dr. Watson's claims under Wisconsin law pursuant to 28 U.S.C. § 1367.

Basis for Court of Appeals Jurisdiction

Appellate jurisdiction is conferred in this case by 28 U.S.C. §1291. Plaintiff-Appellant, Toby T. Watson, the *Relator* (Dr. Watson), properly filed his Notice of Appeal on November 23, 2012, following entry of a final judgment disposing of all claims against all parties on October 23, 2012, by the District Court. The Notice of Appeal is proper pursuant to 28 U.S.C. § 1294 in that the United States District Court for the District of Wisconsin is within the confines of the Seventh Circuit.

V. STATEMENT OF ISSUES PRESENTED FOR REVIEW

- 1. Whether expert testimony is required to explain that when a doctor prescribes a drug to a Medicaid recipient, the pharmacy filling the prescription will present a claim to Medicaid for payment of the prescription.
- 2. Whether expert testimony is required to establish that a drug was not prescribed for an indication approved under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (FDCA) or supported by any of the drug compendia set forth in 42 U.S.C. § 1396r-8(g)(1)(B)(i).

3. Whether, after determining that expert testimony was required on a question of first impression, the District Court should have allowed Dr. Watson an opportunity to present such expert testimony rather than dismiss the action on summary judgment.

VI. STATEMENT OF THE CASE

A. Nature of the Case

In this *qui tam* case under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, Dr. Watson seeks to recover damages and civil penalties for the United States and the State of Wisconsin against Defendant-Appellee Jennifer King-Vassel (Dr. King-Vassel) for causing claims to be presented to Medicaid for prescriptions to N.B. of:

- (1) Risperdal, starting when he was only 4 years old,
- (2) Clonidine, starting when he was only 4 years old,
- (3) Strattera, when he was only 5 years old,
- (4) Prozac, starting when he was only 6 years old,
- (5) Zoloft, starting when he was only 6 years old, and
- (6) Seroquel, starting when he was only 7 years old.

These prescriptions were not for an indication approved under the FDCA, 21 U.S.C. § 301 et seq., or supported by any of the compendia set forth in 42 U.S.C. 1396r-8(g)(1)(B)(i) ("Compendia"), and therefore not covered (legally reimbursable) under Medicaid.

Following Dr. Watson not naming any expert witness in discovery because he didn't believe such testimony was necessary, the District Court dismissed the action on summary judgment on the grounds that expert testimony was required to establish that:

- (a) when Dr. King-Vassel issued undoubted prescriptions to N.B., who she knew was a Medicaid recipient, she caused claims to be made to Medicaid for payment of the prescriptions, and
- (b) the prescriptions Dr. Watson identified as causing false claims were not for an indication approved under the FDCA or supported by any of the Compendia.

It is believed that whether expert testimony is required to establish these facts are questions of first impression.

Frankly, it is hard to understand the District Court's holding that an expert is required to explain that when a Medicaid patient receives a prescription, it is going to be taken to a pharmacy to be filled and the pharmacy is going to bill (present a claim to) Medicaid. It is simply common experience. In addition, Dr. Watson presented evidence that this is exactly what did happen.

Dr. Watson also believes that the District Court was incorrect in holding that an expert is required to establish whether a prescription was written for an indication approved under the FDCA or supported by any of the Compendia. The

Medicaid Statute defines an indication approved under the FDCA or supported by any of the Compendia as a "medically accepted indication." This sounds something like "standard of care" in a medical malpractice case, but it is not. It is a simple question, at least in this case, of whether an indication is one which is approved under the FDCA or supported by any of the Compendia for the particular drug.

However, even if an expert is required to testify on either of these issues, the District Court should not have imposed what is, in effect, the litigation-ending sanction of dismissal for failure to name an expert, especially where, as here, it is a question of first impression whether expert testimony is even required.

B. Course of Proceedings²

The Complaint was filed under seal as required by 31 U.S.C. § 3730(b)(2) on March 3, 2011. Dkt. 1. On September 2, 2011, Dkt. 8, the United States declined to intervene and on September 6, 2011, Dkt 13, the State of Wisconsin declined to intervene. On September 13, 2011, Dkt. 9, the case was unsealed and the defendants allowed to be served.

Dr. King-Vassel answered on January 10, 2012, Dkt. 14.

¹ 42 U.S.C. § 1396R-8(k)(3).

² There were additional proceedings and parties not involved in this appeal that are not recited here.

On February 15, 2012, Dkt. No. 21, a Trial Scheduling Order was entered, setting a trial date of December 17, 2012.

On February 29, 2012, Dkt. No. 24, the District Court entered a Scheduling Order regarding discovery, which among other things, set April 11, 2012, as the deadline for Dr. Watson to name expert witness(es) and August 13, 2012, as the deadline for Dr. King-Vassel to name expert witness(es).

On July 16, 2012, Dkt. 29, Dr. King-Vassel moved for summary judgment on the grounds (among others) that Dr. Watson had not identified an expert witness and that expert testimony was required.

On July 17, 2012, Dkt. No. 32, Dr. King-Vassel filed an expedited non-dispositive motion seeking to extend her deadline for naming experts until 30 days after the District Court decided the pending summary judgment motion.

On July 19, 2012, Dkt. No. 33, Encompass Effective Mental Health Services, Inc.,³ filed its own summary judgment motion and a joinder to Dr. King-Vassel's motion for summary judgment.

Dr. Watson opposed the summary judgment motions on August 15, 2012, Dkt. No. 42, and August 20, 2012, Dkt. No. 45, stating among other things that he had not named any experts because no expert testimony was necessary.

³ Encompass was later voluntarily dismissed upon Dr. Watson's August 29, 2012, motion, Dkt. No. 49.

C. <u>Disposition Below</u>

The District Court granted Dr. King-Vassel's motion for summary judgment on October 23, 2012, Dkt. No. 59, on the grounds that an expert was required to prove the plaintiff's case and that by failing to name an expert in discovery, Dr. Watson could not prevail at trial. The District Court issued a Judgment dismissing the action on the same date, Dkt. No. 60.

VII. STATEMENT OF FACTS

N.B. was born in 2000.⁴ Dr. King-Vassel who knew N.B. was a Medicaid recipient⁵ wrote prescriptions to N.B. for the following drugs that were not for indications approved under the FDCA or supported by any of the Compendia for a child of N.B.'s age:

- (1) Risperdal, starting when he was only 4 years old,
- (2) Clonidine, starting when he was only 4 years old,
- (3) Strattera, when he was only 5 years old,
- (4) Prozac, starting when he was only 6 years old,
- (5) Zoloft, starting when he was only 6 years old, and
- (6) Seroquel, starting when he was only 7 years old.⁶

⁴ Watson Short App., 29 & 40.

⁵ Watson Short App., 24, ¶4.

⁶ Complaint, ¶24, Watson Short App. 16-18; Watson Short App. 26-39.

N.B.'s mother had these prescriptions filled by Walmart pharmacies, which were presented to and paid by Medicaid.⁷

VIII. SUMMARY OF ARGUMENT

As the District Court held below:

A "false or fraudulent claim" occurs when Medicaid pays for drugs that are not used for an indication that is either approved by the Food, Drug, and Cosmetic Act (FDCA) or supported by a drug compendia.⁸

However, the District Court held that, "Without an expert to testify, there is a grand mystery between the time of the prescription and the claim being made to Medicaid."

This is both factually and legally incorrect. First, Dr. Watson submitted evidence that Dr. King-Vassel knew N.B. was a Medicaid recipient, ¹⁰ that she knew these prescriptions had been filled, ¹¹ and that she knew that Medicaid had paid for them. ¹² By writing the prescriptions to N.B. who Dr. King-Vassel knew was a Medicaid recipient, she caused claims to be presented to Medicaid for such prescriptions. It does not take an expert to explain that when a Medicaid recipient

⁷ Watson Short App. 24-39.

⁸ Watson Short App. 4.

⁹ Watson Short App. 5.

¹⁰ Watson Short App. 24.

¹¹ Watson Short App. 41. ("Compliant with medication?" Checked Yes).

¹² Watson Short App. 24-39.

receives a prescription, that prescription will be taken to a pharmacy to be filled and Medicaid will be presented with the bill. Dr. Watson provided direct evidence that this is exactly what happened – evidence more than sufficient to defeat summary judgment. This included the affidavit of N.B.'s mother as well as Medicaid and Walmart pharmacy records.¹³

The District Court also held that an expert was required to establish that the prescriptions were not for indications approved under the FDCA or supported by any of the Compendia, rejecting Dr. Watson's position that it was a simple matter of comparing the indication(s) for which the drugs were prescribed with the indications approved under the FDCA or supported by any of the Compendia. The District Court based this ruling on the idea that "medical documents typically are not readily understandable by the general public and would require an expert to explain their application to a particular set of circumstances." However, this is simply not true in this case.

Dr. King-Vassel either prescribed the drugs in question for indications approved under the FDCA or supported by any of the Compendia, or she did not. No expert is required, at least in the circumstances of this case, because N.B. was

¹³ Watson Short App. 23-41.

¹⁴ Watson Short App. 6.

¹⁵ *Id*.

not prescribed these drugs for any indications that were approved, or even listed (as opposed to "supported"), in any of the Compendia for a child of N.B.'s young age. This is not a determination beyond the ability of a jury.

Finally, having determined that Dr. Watson was required to present expert testimony, the District Court should have allowed him the opportunity to name an expert and proceed, rather than dismiss the case in what amounted to a litigation-ending sanction for not naming an expert. This is especially true here because whether expert testimony is required is a question of first impression.

IX. ARGUMENT

A. Standard of Review

This Court reviews a grant of summary judgment *de novo*, viewing the evidence in the light most favorable to the nonmoving party and affirming only when "there is no genuine issue as to any material fact and ... the movant is entitled to judgment as a matter of law." *Foskett v. Great Wolf Resorts, Inc.*, 518 F.3d 518, 522 (7th Cir. 2008).

B. The False Claims Act

The False Claims Act was enacted shortly after the Civil War to stop the frauds perpetrated by government contractors during that period. .

Congress created the Act in response to the widespread loss of federal funds through fraud during the Reconstruction era. As the Supreme Court has stressed many times, "(i)t seems quite clear that the objective of Congress was broadly to protect the funds and property of the Government from fraudulent claims "

U.S. v. Azzarelli Const. Co., 647 F.2d 757, 759-760 (7th Cir. 1981), citation omitted.

As this Court has described:

The False Claims Act establishes civil penalties for "[a]ny person" who, *inter alia*, "knowingly presents, or causes to be presented, to an officer or employee of the United States Government ... a false or fraudulent claim for payment or approval" . . . Such a person "is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person." The FCA may be enforced by the Attorney General, or by a private person, known as a *relator*, who brings a *qui tam* suit "for the person and for the United States Government . . . in the name of the Government". . . . If the suit is successful, the *relator* receives a portion of the Government's award.

U.S. ex rel. Chandler v. Cook County, Ill., 277 F.3d 969, 973 (7th Cir. 2002), citations omitted.

C. Expert Testimony Was Not Required to Establish That Dr. King-Vassel Knowingly Caused The Prescriptions to Be Presented to Medicaid for Payment.

Under 31 U.S.C. § 3729(a)(1) of the False Claims Act, "Any person who knowingly . . . causes to be presented, a false or fraudulent claim for payment . . . to the Government is liable to the United States Government . . ."

"Knowingly" is broadly defined in 31 U.S.C. § 3729(b)(1):

- (1) the terms "knowing" and "knowingly" --
 - (A) mean that a person, with respect to information--
 - (i) has actual knowledge of the information;

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

- (iii) acts in reckless disregard of the truth or falsity of the information; and
- (B) require no proof of specific intent to defraud;

In Heckler v. Cmty. Health Servs. of Crawford County, Inc., 467 U.S. 51, 63-64 (1984), the Supreme Court held:

Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law... As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements for cost reimbursement.

And as the District Court held below:

A "false or fraudulent claim" occurs when Medicaid pays for drugs that are not used for an indication that is either approved by the Food, Drug, and Cosmetic Act (FDCA) or supported by a drug compendia.¹⁶

Thus, Dr. King-Vassel is charged with knowing that Medicaid coverage for drug prescriptions is restricted to indications approved under the FDCA or supported by one of the Compendia.

However, the District Court held it cannot know that Dr. King-Vassel's undoubted prescriptions to N.B. caused claims to be made to Medicaid without expert testimony, because there is a mysterious "black-box" like process involved.¹⁷ This is both factually and legally incorrect. Expert testimony is

¹⁶ Watson Short App. 4.

¹⁷ Watson Short App. 5.

required only when an issue is "beyond the realm of the lay person to understand." *Musser v. Gentiva Health Services*, 356 F.3d 751, 760 (7th Cir. 2004).

Factually, Christine Maxwell Meyer, N.B.'s mother, affied that Dr. King-Vassel prescribed the drugs as set forth in the complaint; that all of N. B.'s medical expenses, including those for drug prescriptions, have been paid by Medicaid; that Dr. King-Vassel knew that N.B.'s care was being paid for by Medicaid; that the prescriptions were filled by Walmart Pharmacy using N.B.'s medical assistance (Medicaid) card; and that she saved some of N.B.'s empty prescription bottles.¹⁸

In addition, authenticated records from Walmart show that it filled the prescriptions and was paid by Medicaid for them. Wisconsin Medicaid records presented to the District Court also show that Medicaid paid for these drug prescriptions by Dr. King-Vassel, and that Dr. King-Vassel herself was paid by Medicaid for prescribing the drugs (i.e., "Medication Management") on February 5, 2007. Dr. King-Vassel's related record shows that she confirmed the prescriptions had been filled by noting that N.B. was "medication compliant."

¹⁸ Watson Short App. 23-24.

¹⁹ Watson Short App. 25-36.

²⁰ Watson Short App. 37-39.

²¹ Watson Short App. 40.

²² Watson Short App. 41.

Dr. Watson submitted more than sufficient evidence that Dr. King-Vassel, in fact, caused the presentment of the identified prescriptions to Medicaid. No expert was required to establish this. Even if Dr. Watson had not presented such evidence, a lay jury can certainly understand that when a Medicaid recipient is prescribed drugs, the pharmacy filling the prescription is going to bill Medicaid. The notion that Dr. King-Vassel somehow did not "know" within the meaning of 31 U.S.C. § 3729(b)(1) that Medicaid was going to pay for the prescriptions is simply untenable.

D. Expert Testimony Was Not Required to Establish That the Prescriptions Were Not For Indications Approved Under the FDCA or Supported By Any of the Compendia

The District Court also held that expert testimony was required to establish that a prescription was not for an indication approved under the FDCA or supported by any of the Compendia, which is statutorily defined as a "medically accepted indication" through 42 U.S.C. §§ 1396r-8(g)(1)(B)(i), (k)(2), (3) & (6). Relying only on the general proposition that, "medical documents typically are not readily understandable by the general public and would require an expert to explain their application to a particular set of circumstances," the District Court rejected Dr. Watson's position that demonstrating a prescription was not for an indication approved under the FDCA or supported by any Compendia in this case

²³Watson Short App. 6.

requires only a comparison of the indication for which the drug was prescribed with indications approved under the FDCA or supported by any Compendia.²⁴

The Court and Dr. King-Vassel appear to incorrectly equate "medically accepted indication" with "standard of care." In her reply, Dr. King-Vassel argued that an expert was required to opine on whether the prescriptions were reasonable, ²⁵ that the issues constitute questions of medical practice and the application of complicated prescription medication definitions and regulations to those medical practices, ²⁶ and that in order to hold Dr. King-Vassel liable Dr. Watson was required to show she failed in the requisite degree of care and skill. ²⁷ Such determinations pertain to medical malpractice cases where the issue is whether the doctor breached the "standard of care," but not here where the sole question is whether the prescriptions were for indications approved under the FDCA or supported by any of the Compendia.

The District Court apparently adopted Dr. King-Vassel's view equating "medically accepted indication," with "standard of care" when it is not. In effect, the District Court held that <u>every</u> fact pattern would require expert testimony, a proposition that does not even apply in medical malpractice cases. For example,

²⁴ Watson Short App. 6.

²⁵ Dkt. No. 47, p 10.

²⁶ Dkt. No. 47, p. 11.

²⁷ *Id*.

Indiana law recognizes a "common knowledge" exception to the expert testimony requirement in a medical malpractice case, such as a fire occurring during surgery where an instrument that emits a spark is used near a source of oxygen. *Musser* 356 F.3d at 760.

This case does not involve medical malpractice, however. While "medically accepted indication," sounds something like "standard of care," it is not. It is a statutorily defined term, with very specific criteria, to wit: indications approved under the FDCA or supported by any of the Compendia.

The following illustration with respect to Risperdal, which was prescribed to N.B., starting when he was only 4 years old, demonstrates that no expert testimony was required to prove that it was not for an indication approved under the FDCA or supported by any Compendia.²⁸

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²⁸ The following illustration is taken from the chart of Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications, which was filed at Docket No. 113-5 in *United States ex rel Law Project for Psychiatric Rights v. Matsutani, et al*, USDC-Alaska, Case No. 3:09-cv-00080-TMB. It is requested that the Court take judicial notice of this filing under *Green v. Warden*, 699 F.2d 364, 369 (7th Cir. 1983) (federal courts may take notice of proceedings in other courts if the proceedings have a direct relation to matters at issue). Dr. Watson is not requesting that the Court accept that these are the only uses approved under the FDCA or <u>listed</u>, as opposed to <u>supported</u>, in the Compendia, but merely to illustrate that all one has to do is compare the indication for which the drugs were prescribed with the indictions approved under the FDCA or supported by any of the Compendia. For the convenience of the Court, a copy of the chart for which judicial notice is requested follows the Watson Short Appendix, in a separate section titled Judicial Notice Appendix.

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| | | DRUGDEX |
|----------------------------------|--------------------------|----------------|
| Indication | FDA Approval? | Recommendation |
| | Yes (for 5 years old and | |
| Autistic Disorder – Irritability | up) | |
| | Yes (for 10 years old | |
| Bipolar I Disorder | and up) | |
| | Yes (for 13 years old | |
| Schizophrenia | and up, ORALLY) | |
| Behavioral syndrome - Mental | | |
| retardation | No | Class IIb |
| Gilles de la Tourette's syndrome | No | Class IIb |
| Pervasive developmental | | |
| disorder | No | Class IIb |

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Dr. Watson reviewed N.B.'s medical records and can testify as a matter of fact that N.B. was not prescribed Risperdal for any of these indications.²⁹ No expert witness is required.

The Law Project for Psychiatric Rights, which published the chart for which judicial notice has been sought, and filed it in a similar case in Alaska, takes the ------(footnote continued)

²⁹ Since N.B. was not yet 10 years old when Dr. King-Vassel issued the offending prescriptions, even a diagnosis of schizophrenia or Bipolar I Disorder would still have caused a false claim. If N.B. was prescribed Risperdal for Autistic Disorder—Irritability, then such prescriptions, once he turned 5, would not have been a false claim. However, Dr. Watson reviewed N.B.'s medical records and can testify as a matter of fact that N.B. was not diagnosed with Autistic Disorder--Irritability.

The shaded indications—Behavioral syndrome - Mental retardation, Gilles de la Tourette's syndrome, and Pervasive developmental disorder—are not approved under the FDCA, but they are "listed" in DRUGDEX. In such situations, the question is whether the indication is "supported" within the meaning of 42 U.S.C. § 1396R-8(k)(3). In this case, all three of the shaded indications carry "IIb" recommendations. A IIb recommendation means, "The given test, or treatment may be useful, and is indicated in some, but not most, cases." Judicial Notice Appendix 7.

In the facts of this case, whether N.B. was prescribed drugs for indications that were not approved under the FDCA or supported by any of the Compendia is, in the words of *Musser*, "not beyond the realm of the lay person to understand."

This is why Dr. Watson does not believe expert testimony is required.

E. <u>Granting Summary Judgment For Failure to Name an Expert</u> Witness Was Error

After concluding Dr. Watson needed expert testimony to prevail at trial, the District Court granted summary judgment against Dr. Watson because he failed to name such an expert(s) in discovery. As set forth above, Dr. Watson believes the District Court erred in deciding expert testimony was required, but even if it was, this is not a case where dismissal is proper.

Continued footnote)-----position in the chart that a IIb recommendation does not constitute "support."
There can be an argument over that, however. Logically, since a IIb recommendation means it is "indicated in some, but not most cases," one must show that the particular prescription is in the minority of cases for which it is indicated in order for such a prescription not to be a false claim. While what "support" means under meaning of 42 U.S.C. § 1396R-8(k)(3) is primarily one of statutory interpretation, an expert may be helpful, or even required, for that inquiry. However, this question does not arise in this case because N.B. was not prescribed the drugs in question for any indication in which that question arises.

³⁰ Watson Short App. 6.

The District Court phrased this as Dr. Watson having "failed to establish ample evidence." However, Dr. King-Vassel presented no evidence on this issue, so it was not a question of Dr. Watson failing to establish a genuine issue of fact by failing to present his own evidence. The decision was based strictly on the District Court's determination that expert testimony was required and therefore Dr. Watson could not prevail at trial without such testimony. 32

Lech v. St. Luke's Samaritan Hosp., 921 F.2d 714 (1991) upheld a grant of summary judgment for failure to name an expert witness in a medical malpractice case, but only after many opportunities to cure the deficiency and where it was well-established that expert testimony was required to prove violation of the standard of care. In Musser, 356 F.3d at 759, this Court cautioned, "In affirming this judgment, we are mindful of our warning that '[i]n the normal course of events, justice is dispensed by the hearing of cases on their merits."

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³¹ *Id*.

³² Watson Short App. 6.

District Court discovery determinations are reviewed under an abuse of discretion standard, *Musser*, 356 F.3d at 755, but this issue doesn't involve a discovery determination. Here, Dr. Watson did not believe an expert was required and the District Court, holding that without expert testimony he could not prevail, granted summary judgment against him in the same decision in which it held an expert was necessary. Counsel has not found any case stating the standard of review directly applicable to this situation, but suggests it is the abuse of discretion standard enunciated by this Court in *Salgado*, 150 F.3d at 739, cited with approval in *Musser*, 356 F.3d at 759, in which this Court held an abuse of discretion would --------(footnote continued)

Rather than dismiss Dr. Watson's complaint after determining expert testimony was required, the District Court should have allowed Dr. Watson the opportunity to list such expert(s) and proceed. In fact, Dr. King-Vassel requested additional time to list her expert(s) pending determination of summary judgment, including whether Dr. Watson was required to present expert testimony. Dkt. 32.

As this Court held in *Salgado by Salgado v. General Motors Corp.*, 150 F.3d 735, 740 (7th Cir. 1998), cited by this Court with approval in *Musser*:

The sanction of dismissal with prejudice must be infrequently resorted to by district courts in their attempts to control their dockets and extirpate nuisance suits.... In the normal course of events, justice is dispensed by the hearing of cases on their merits; only when the interests of justice are best served by dismissal can this harsh sanction be consonant with the role of courts.

The words of Judge Charles Clark of the Second Circuit in *Gill v*. *Stolow*, 240 F.2d 669 (2d Cir.1957), must be remembered whenever the sanction of dismissal is contemplated:

In final analysis, a court has the responsibility to do justice between man and man; and general principles cannot justify denial of a party's fair day in court except upon a serious showing of willful default.

(citations omitted).

Unlike the medical malpractice situation where it is clear expert testimony is normally required, it appears to be a question of first impression in any court

(Continued footnote)-----be found where the district court chose an option that was not among those from which this Court might expect a district court reasonably to choose.

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whether or not expert testimony is required in a False Claims Act case to establish

(a) that prescribing a drug to a Medicaid recipient causes a claim to be presented to

Medicaid for such prescription, and (b) that prescriptions were not for an indication

approved under the FDCA or supported by any of the Compendia. Having decided

in a case of first impression that expert testimony was required, the District Court

should have given Dr. Watson the opportunity to present it.

X. **CONCLUSION**

For the foregoing reasons, Plaintiff-Appellant, Toby T. Watson, requests that

the District Court's determination that expert testimony was required in this case be

reversed, the Order granting summary judgment and related judgment be **vacated**,

and this case be remanded. In the alternative, the grant of summary judgment and

related judgment should be vacated and this case remanded in order to allow Dr.

Watson to present expert testimony.

RESPECTFULLY SUBMITTED this 19th day of February, 2013.

By: /s/ James B. Gottstein

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XI. FRAP 32 CERTIFICATE OF COMPLIANCE

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface, Times New Roman, 14 point font, using Microsoft Word 2007.

By: /s/ James B. Gottstein
James B. Gottstein (COUNSEL OF RECORD

XII. CIRCUIT RULE 30 STATEMENT

Counsel of record for the Plaintiff-Appellant, Toby Watson, hereby certifies that all material required by Circuit Rule 30(a) & (b) is included in the attached Short Appendix.

By: /s/ James B. Gottstein
James B. Gottstein (COUNSEL OF RECORD

XIII. CERTIFICATE OF SERVICE

Certificate of Service When All Case Participants Are CM/ECF

Participants

I hereby certify that on February 19, 2013, I electronically filed the foregoing Brief and Required Short Appendix of Plaintiff-Appellant with the Clerk of the Court for the United States Court of Appeals for the Seventh Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

By: /s/ James B. Gottstein
James B. Gottstein (COUNSEL OF RECORD

XIV. ADDENDUM

31 U.S.C. § 3729(a)

- (a) Liability for certain acts.--
 - (1) In general.--Subject to paragraph (2), any person who--
 - (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
 - (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
 - (C) conspires to commit a violation of subparagraph (A), (B), (D), (E), (F), or (G);
 - (D) has possession, custody, or control of property or money used, or to be used, by the Government and knowingly de-livers, or causes to be delivered, less than all of that money or property;
 - (E) is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the infor-mation on the receipt is true;
 - (F) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge property; or
 - (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410,

plus 3 times the amount of damages which the Government sustains because of the act of that person.

- **(b) Definitions.**--For purposes of this section--
 - (1) the terms "knowing" and "knowingly" --
 - (A) mean that a person, with respect to information--
 - (i) has actual knowledge of the information;
 - (ii) acts in deliberate ignorance of the truth or falsity of the information; or
 - (iii) acts in reckless disregard of the truth or falsity of the information; and
 - (B) require no proof of specific intent to defraud;

42 U.S.C. § 1396r-8(g)(1)(B)(i)

- (g) Drug use review
- (1) In general
- **(B)** The program shall assess data on drug use against predetermined standards, consistent with the following:
- (i) compendia which shall consist of the following:
 - (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.

42 USC 1396r-8(k)(2)

(2) Covered outpatient drug

Subject to the exceptions in paragraph (3), the term "covered outpatient drug" means--

- (A) of those drugs which are treated as prescribed drugs for purposes of section 1396d(a)(12) of this title, a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and--
 - (i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355 or 357] or which is approved under section 505(j) of such Act [21 U.S.C.A. § 355(j)];
 - (ii) (I) which was commercially used or sold in the United States before October 10, 1962, or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug; and (II) which has not been the subject of a final determination by the Secretary that it is a "new drug" (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 321(p)]) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act [21 U.S.C.A. § 331, 332(a), or 334(a)] to enforce section 502(f) or 505(a) of such Act [21 U.S.C.A. § 352(f) or 355(a)]; or
 - (iii) (I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(e)] on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which--

- (i) may only be dispensed upon prescription,
- (ii) is licensed under section 262 of this title, and
- (iii) is produced at an establishment licensed under such section to produce such product; and
- (C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 356].

42 USC 1396r-8(k)(3)

(3) Limiting definition

The term "covered outpatient drug" does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this subchapter as part of payment for the following and not as direct reimbursement for the drug):

- (A) Inpatient hospital services.
- (B) Hospice services.
- (C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.
- (**D**) Physicians' services.
- (E) Outpatient hospital services.
- **(F)** Nursing facility services and services provided by an intermediate care facility for the mentally retarded.
- **(G)** Other laboratory and x-ray services.
- (H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best

price (as defined in subsection (c)(1)(C) of this section) for such drug, biological product, or insulin.

42 USC 1396r-8(k)(6)

(6) Medically accepted indication

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.

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No. 12-3671

In the UNITED STATES COURT OF APPEALS For the Seventh Circuit

UNITED STATES OF AMERICA, and STATE OF WISCONSIN, Plaintiffs, and

> TOBY T. WATSON, Plaintiff-Appellant

> > V.

JENNIFER KING-VASSEL, Defendant - Appellee

Appeal from The U.S. District Court for The Eastern District Of Wisconsin, Milwaukee Division Case No. 11-CV-236-JPS The Honorable J.P. Stadtmueller Presiding

SHORT APPENDIX OF PLAINTIFF-APPELLANT TOBY T. WATSON

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2012 WL 5272486 Only the Westlaw citation is currently available. United States District Court, E.D. Wisconsin.

UNITED STATES of America, and the State of Wisconsin, ex rel. Dr. Toby Tyler Watson, Plaintiffs,

V.

Jennifer KING-VASSEL, Caps Child & Adolescent Psychological Services, and Encompass Effective Mental Health Services, Inc., Defendants.

No. 11-CV-236-JPS. | Oct. 23, 2012.

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Opinion

ORDER

J.P. STADTMUELLER, District Judge.

*1 This qui tam action was initially filed by the relator, Dr. Toby Watson, on March 3, 2011. (Docket # 1). The complaint alleges that defendant Dr. Jennifer King-Vassel violated the Federal False Claims Act and Wisconsin False Claims Law by prescribing medications to a minor patient receiving Medicaid assistance for reasons that are not medically-accepted. (Compl.¶¶ 1, 26-29). The complaint also alleged that CAPS Child & Psychological Services (CAPS) Adolescent Effective Encompass Mental Health Services (Encompass) employed Dr. King-Vassel and were, therefore, liable under a theory of respondeat superior. (Compl.¶¶ 30-33). At the time of filing, this matter was sealed while the United States and the State of Wisconsin determined whether to intervene in the matter; after they declined to do so, the Court unsealed the matter, and summons were issued to the defendants. (Docket # 4, # 9, # 10, # 11, # 12). The parties appeared before the Court on February 15, 2012, after which time the Court scheduled relevant trial and discovery dates. (Docket # 21, # 22, # 24). After completing much of the discovery process, Dr. King–Vassel and CAPS jointly moved for summary judgment on July 16, 2012; Encompass joined in that motion and filed a separate brief on July 19, 2012. (Docket # 28, # 29, # 33, # 35). That motion is now fully briefed, and the Court takes it up along with other procedural matters that remain outstanding. (Docket # 32, # 38, # 40, # 42, # 45, # 47, # 49, # 50, # 51, # 52, # 54, # 55, # 56, # 57).

1. BACKGROUND

The factual background of this case is fairly straightforward, and the parties do not dispute the core facts. The case's history, on the other hand, is very detailed, and includes a multitude of motions and briefs filed by the parties. Therefore, the Court will discuss those two bodies of facts separately—it will first address the factual background of the case before detailing the case history.

1.1 Factual Background

The relator, Dr. Watson, secured the cooperation of N.B. in bringing this suit after meeting an attorney through the International Society for Ethical Psychology and Psychiatry, and doing further research into bringing a qui tam claim through the website PsychRights.org. (King-Vassel/CAPS PFF ¶¶ 3-4). After researching qui tam false claims actions, Dr. Watson placed an ad in a Sheboygan newspaper soliciting minor Medicaid patients medications. who had received certain (King-Vassel/CAPS PFF ¶ 5). N.B.'s mother responded to the advertisement, and Dr. Watson obtained N.B.'s release.1 medical records through a medical (King-Vassel/CAPS PFF ¶¶ 11–14).

Dr. Watson obtained these records through what might be described as a borderline-fraudulent medical release. (See King-Vassel/CAPS PFF ¶¶ 11-12). The release stated that the information to be released was for the "purpose of providing psychological services and for no other purpose what so ever." (King-Vassel/CAPS PFF ¶¶ 11–12). Dr. Watson never used those records in the treatment of N.B., and in reality obtained them only to bring the immediate suit. (King-Vassel/CAPS PFF Notwithstanding 13-14). the questionable—indeed unethical—manner in which the release was obtained, the fact is not ultimately relevant to the motion for summary judgment currently under consideration.

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Thereafter, based on those records, Dr. Watson filed this qui tam action alleging that defendant Dr. King-Vassel prescribed psychotropic drugs to N.B., a minor Medical recipient, from Assistance 2004 until (KingVassel/CAPS PFF ¶¶ 1–2; Encompass PFF ¶ 3). Dr. Watson alleges that those prescriptions were not for indications approved by the Food and Drug Administration (FDA) or otherwise supported by applicable sources, and that therefore the prescriptions were false claims when made to Medicaid for reimbursement and further that Dr. King-Vassel is responsible for the filing of those false claims. (King-Vassel/CAPS PFF ¶ 2; Encompass PFF ¶ 3).

*2 During the relevant time period, Dr. King-Vassel worked in conjunction with both CAPS and Encompass, and therefore Dr. Watson filed *respondeat superior* claims against both CAPS and Encompass, alleging that those parties employed Dr. King-Vassel. (King-Vassel/CAPS PFF ¶ 21; Encompass PFF ¶ 5-47).

1.2 Case History

After this case was filed, the United States and State of Wisconsin declined to intervene. (Docket # 8, # 13). Thereafter, the Court set a trial schedule and discovery began. (Docket # 21, # 22, # 24).

After several months of discovery, CAPS and Dr. King–Vassel filed a joint motion for summary judgment. (Docket # 28).² Encompass joined that motion and filed a separate brief, specifically addressing Encompass' role in this case, and arguing that *respondeat superior* could not apply to Encompass. (Docket # 33).

One day after filing their motion for summary judgment, CAPS and Dr. King-Vassel filed a motion to stay the Court's scheduling order pending resolution of the summary judgment motion. (Docket # 32). Dr. Watson never filed a response to the motion to stay, and the Court has not yet acted upon that motion. Because the Court grants summary judgment as to Dr. King-Vassel, below, that motion is now moot and the Court will deny it as such. (Docket # 32).

While the summary judgment motion was pending, however, it apparently became clear to Dr. Watson that Dr. King-Vassel was not an employee of either CAPS or Encompass, and therefore those parties could not be held liable under a *respondeat superior* claim. (Docket # 40, # 49, # 50). Accordingly, Dr. Watson filed a motion to

dismiss Encompass on August 12, 2012 (Docket # 40), and later filed an amended motion to dismiss Encompass (Docket # 49) and an additional motion to dismiss CAPS (Docket # 50).

The motion to dismiss Encompass apparently was not made quickly enough, though, and on August 29, 2012, Encompass filed a motion for sanctions against Dr. Watson for his failure to dismiss Encompass earlier in the litigation process. (Docket # 51).

That motion for sanctions is still outstanding, as is the motion for summary judgment. However, because the Court will grant Dr. Watson's motions to dismiss both Encompass and CAPS (Docket # 49, # 50), the Court need only address the summary judgment motion as it pertains to Dr. KingVassel.

The Court addresses the substance of both the motion for summary judgment and the motion for sanctions, below.

2. DISCUSSION

The Court must address two separate substantive issues: first, whether Dr. King-Vassel is entitled to summary judgment as to Dr. Watson's claims against her; and, second, whether Encompass is entitled to sanctions against Dr. Watson.

2.1 Summary Judgment

As mentioned above, the Court will dismiss defendants CAPS and Encompass, pursuant to Dr. Watson's motion. (Docket # 49, # 50).

Therefore, the outstanding summary judgment motion must be decided only insofar as it effects Dr. King-Vassel. (Docket # 28). The Court turns to that issue now, and determines that Dr. King-Vassel is not entitled to summary judgment.

2.1.1 Summary Judgment Standard

The Court should grant summary judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed.R.Civ.P. 56(c).

*3 The Court must construe all facts in a light most favorable to the nonmoving party and draw all reasonable

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inferences in that party's favor. *Anderson v. Liberty Lobby*, 477 U.S. 242, 249, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). Nonetheless, the nonmoving party must present "definite, competent evidence to rebut" the summary judgment motion in order to successfully oppose it. *EEOC v. Sears, Roebuck & Co.*, 233 F.3d 432, 437 (7th Cir.2000).

The purpose of the summary judgment motion is to determine "whether there is a genuine need for trial." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986).

2.1.2 Substantive Analysis

Dr. King-Vassel has raised two primary arguments for summary judgment. First, she argues that this action is jurisdictionally barred by 31 U.S.C. § 3730(e)(4). (King-Vassel/CAPS Br. in Supp. 5–15). And, second, she alleges that Dr. Watson failed to name any expert to establish that the relevant medications were prescribed for off-label uses or that the claims for those medications were ever officially submitted and payments received therefor. (King-Vassel/CAPS Br. in Supp. 15).

2.1.2.1 Jurisdictional Bar

The False Claims Act (FCA) prohibits false or fraudulent claims for payments to the United States. 31 U.S.C. § 3729(a). In order to remedy such fraud, the FCA allows private individuals to bring *qui tam* actions in the government's name against violators. 31 U.S.C. § 3720(b)). If the *qui tam* action is successful, then the relator of the action is entitled to receive a share of any proceeds in addition to attorney's fees and costs. 31 U.S.C. §§ 3730(d)(1)-(2)).

However, there are jurisdictional limits on the abilities of private individuals to bring suit. *See, e.g.,* 31 U.S.C. § 3730(e)(4); *United States v. Bank of Farmington,* 166 F.3d 853, 888 (7th Cir.1999); *Graham County Soil and Water Conservation District v. United States ex rel. Wilson,* — U.S. —, —, 130 S.Ct. 1396, 1407, 176 L.Ed.2d 225 (2010).

At specific issue here is one of those jurisdictional limits: the "public disclosure" bar. 31 U.S.C. § 3730(e)(4). Under that bar, the Court "shall dismiss" any claim based on allegations that had previously been publicly disclosed in: (1) Federal hearings in which the Government is a party; (2) Federal reports hearings, audits, or investigations; or (3) news media reports. 31 U.S.C. § 3730(e)(4)(a). However, even if there is a public

disclosure upon which a *qui tam* action is based, the Court may still hear the action if the relator is an "original source" of the information in the *qui tam* complaint and either brought the suit before public disclosure or has independent knowledge that materially adds to the public disclosure. 31 U.S.C. § 3730(e)(4)(B). As the Seventh Circuit stated the rule in *United States ex rel. Baltazar v. Warden*, this inquiry is a three-prong analysis:

first, the Court must determine whether there has been a public disclosure of the allegations in the qui tam complaint—and if there has not been a public disclosure, then 31 U.S.C. § 3730(e)(4) does not bar the suit:

*4 then, second, the Court must determine whether the suit at hand is based upon that public disclosure—and if the suit at hand is not based on such disclosure, then 31 U.S.C. § 3730(e)(4) does not bar the suit;

finally, **third**, the Court must determine whether the relator is an original source of the information upon which the suit is based—and if the relator is an original source, then 31 U.S.C. § 3730(e)(4) does not bar the suit.

United States ex rel. Baltazar v. Warden, 635 F.3d 866, 867 (7th Cir.2011) (citing 31 U.S.C. § 3730(e)(4).

Importantly—and perhaps lost on counsel for Dr. King–Vassel—if the relator, Dr. Watson, prevails on *any* of those three questions, then his suit is not barred by 31 U.S.C. § 3730(e)(4). *Baltazar*, 635 F.3d at 867.

Here, there has not been public disclosure of the relevant facts and, therefore, 31 U.S.C. § 3730(e)(4) does not bar Dr. Watson's suit. A public disclosure has occurred only when "the critical elements exposing the transaction as fraudulent are placed in the public domain." United States ex rel. Feingold v. AdminaStar Fed. ., Inc., 324 F.3d 492, 495 (7th Cir.2003) (citing United States ex rel. Rabushka v. Crane Co., 40 F.3d 1509, 1512 (8th Cir.1994); United States ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 654 (D.C.Cir.1994)). Even when there have been public reports of rampant fraud-such as half of information showing fraud by chiropractors—there has not been public disclosure. Baltazar, 635 F.3d at 867-68. Such a "very high level of generality" cannot establish public disclosure. U.S. ex rel. Goldberg v. Rush University Medical Center, 680 F.3d 933, 935 (7th Cir.2012). The important fact in Baltazar was that there had been no public disclosure of "a particular fraud by a particular chiropractor." Id. (citing Baltazar, 635 F.3d at 867-68). Rather, because the news accounts that formed the alleged public disclosures lacked

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particulars, they could not be used as the basis of litigation, and therefore did not trigger the public disclosure bar; quite to the contrary, in fact, the relator in *Baltazar* provided detailed and particular information not otherwise available to the government that enabled the government to seek reimbursement—the very goal of allowing *qui tam* actions. *See Baltazar*, 635 F.3d at 867–68; *Goldberg*, 680 F.3d at 935.

The situation in the case at hand is almost precisely analogous to that in Baltazar. Here, Dr. Watson has provided particular information relating to King-Vassel that was previously unknown to the government. Nonetheless, Dr. King-Vassel argues that there has been public disclosure as a result of previous news accounts of Medicaid fraud and similar lawsuits throughout the nation. (See King-Vassel/CAPS Br. in Supp. 10–15). But, just as in *Baltazar*, none of those news accounts or lawsuits touched upon the particular facts of this case—they did not deal particularly with Dr. KingVassel, with the places at which she practiced, or even with the geographic area in which she practiced. As such, exactly as was the case in Baltazar, the alleged public disclosures could not have formed the basis of this lawsuit, and, therefore, lack the particulars that the Court must look for to find the public disclosure bar triggered. See Baltazar, 635 F.3d 867-68. Had Dr. Watson not brought this suit, the government would not be aware of Dr. KingVassel's alleged fraud (despite any highly generalized awareness of ongoing Medicaid fraud by doctors prescribing medications to minors for off-label uses)—thus, just as in Baltazar, this qui tam action serves the precise purpose for which such actions were intended. Id. As such, the Court must determine that there has not been a public disclosure of the allegations in this action.

*5 Having determined that there has not been a public disclosure of the allegations in Dr. Watson's complaint, the Court is obliged to conclude that his action is not barred by 31 U.S.C. § 3730(e)(4). See, e.g., Goldberg, 680 F.3d at 935, Baltazar, 635 F.3d at 867, Feingold, 324 F.3d at 495. As stated above, the mere fact that Dr. Watson's complaint satisfied a single one of the three prongs of analysis under 31 U.S.C. § 3730(e)(4) is enough to overcome that bar. Thus, though it is very possible that the Court would conclude that the other two prongs were not satisfied, 3 the Court does not need to engage in that analysis. Baltazar, 635 F.3d at 867.

Dr. King–Vassel's brief extensively addresses the issue of whether Dr. Watson is an "original source" of information in his complaint, with "direct and independent knowledge of the information on which the allegations are based." (*See* King–Vassel/CAPS Br. in Supp. 5–10 (citing 31 U.S.C. § 3730(e)(4)(B);

KingVassel/CAPS Reply 5–6). And, while the Court agrees that there may be some question as to whether Dr. Watson is a direct source, that inquiry is wholly irrelevant to the Court's analysis. As the Court has mentioned throughout this Order, the public disclosure bar inquiry consists of three sequentially-posed prongs, the satisfaction of any one of which is sufficient to overcome the bar. In fact, courts do not reach the original source issue unless they first determine that the first two prongs are not satisfied. Thus, despite Dr. King–Vassel's extensive arguments to the contrary, the Court need not address the original source issue, because that issue is entirely irrelevant to the final analysis.

Dr. Watson's *qui tam* action is not barred by 31 U.S.C. § 3730(e)(4).

2.1.2.2 Failure to Name Expert Witness

Dr. King-Vassel's only other argument for summary judgment centers around Dr. Watson's failure to name an expert witness to testify. (King-Vassel/CAPS Br. in Supp. 15). On this point, Dr. King-Vassel argues that Dr. Watson cannot establish Medicaid fraud without an expert to provide details on two broad areas of fact: (1) the processing of Medicaid reimbursements and whether Dr. King-Vassel received such reimbursement; and (2) the off-label nature of the prescriptions made by Dr. King-Vassel to N.B. (King-Vassel/CAPS Br. in Supp. 15; King-Vassel/CAPS Reply 10–13). This is a confusing way of arguing that Dr. Watson has not made the requisite showing to establish an actual Medicaid fraud.

To prevail in a false claims action, a relator must establish that the defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A) (emphasis added). A "false or fraudulent claim" occurs when Medicaid pays for drugs that are not used for an indication that is either approved by the Food, Drug, and Cosmetic Act (FDCA) or supported by a drug compendia. See, e.g., U.S. ex rel. West v. Ortho-McNeil Pharmaceutical, Inc., 2007 WL 2091185, at *2 (N.D.III. July 20, 2007) ("Medicaid generally reimburses providers only for 'covered outpatient drugs," "which "do not include drugs 'used for a medical indication which is not a medically accepted indiction.' ")⁴ (citing 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3), 1396r-8(k)(3)); U.S. ex rel. Franklin v. Parke-Davis, 147 F.Supp.2d 39, 45 (D.Mass.2001)); 42 U.S.C. §§ 1396r-8(k)(2),(3), (6) (setting forth the definitions of "covered outpatient drug" and "medically accepted indication"; a "medically accepted indication" is

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present only when the use is approved by the Food, Drug, and Cosmetic Act (21 U.S.C.A. § 301, et seq.) or any drug compendia (as described in 42 U.S.C. §§ 1396r8(g)(1)(B)(I))).

Dr. King–Vassel takes issue with the use of *West*, alleging that the court in that case "expressly acknowledged that physicians can prescribe for off-label uses even though pharmaceutical companies are prohibited from marketing or promoting off-label uses." (King–Vassel/CAPS Reply 13 (citing *West*, 2007 WL 2091185 at *2)).

With that information in mind, the Court views the required showing to have two elements. The relator must not only show that there was, in fact, a false or fraudulent claim made to Medicaid through the submission of a prescription for a non-approved purpose, but also must show that the defendant knowingly caused that submission to be made. If the relator fails to show *either* of these elements, then his claim must fail.

*6 The Court will examine the "knowingly caused" requirement first. In order to establish that Dr. King-Vassel knowingly caused the submission of a false claim, Dr. Watson must establish proof that Dr. King-Vassel acted with "actual knowledge," "deliberate ignorance," or "reckless disregard," of the fact that a claim she caused to be submitted was fraudulent. 31 U.S.C. §§ 3729(a)(1)(A), (b). This requirement, itself, has two separate prongs: a knowledge prong, and a causation prong. That is, it is not enough that Dr. King-Vassel knew that a claim was fraudulent, she must also have knowingly caused the claim to have been made.

When the Court examines those two prongs of the "knowingly caused" requirement, it must conclude that Dr. Watson has not shown "definite, competent evidence to rebut" the summary judgment motion, and therefore the Court will grant Dr. King-Vassel's motion for summary judgment. See Sears, Roebuck & Co., 233 F.3d at 437. Dr. Watson admits that he, himself, is unaware of whether Dr. King-Vassel actually received any reimbursements through Medicaid or would be entitled to reimbursements absence of prescribing medication. (King-Vassel/CAPS PFF ¶ 8, and Response). Thus, while he argues that Dr. King-Vassel should have known that any prescriptions would have been presented to Medicaid purely as a result of her knowledge that N.B. otherwise used Medicaid services, it is clear that Dr. Watson himself lacks understanding of the reimbursement system, and, therefore, will not be able to establish that Dr. King-Vassel had any knowledge whatsoever of the likelihood of submission of a fraudulent claim. (Relator's

Resp. [Docket # 45], 3–4). Even if Dr. King–Vassel knew that N.B. received Medicaid, Dr. Watson has not presented any evidence to show that Medicaid would be responsible for covering the cost of N.B.'s prescriptions. He has acknowledged his lack of personal knowledge on the topic, and has also failed to list any expert to provide further testimony. In that way, his failure to name an expert is fatal to his case. The Medicaid reimbursement system is obviously confusing—Dr. Watson himself is not sure of its application to the very person he has sued. Given his personal lack of knowledge of the reimbursement system, Dr. Watson will not be able to testify as to the operation of the reimbursement system and its application to Dr. King-Vassel. And, without that testimony, he will be unable to establish that Dr. King-Vassel had any knowledge (actual or constructive) that N.B.'s claim would be submitted to Medicaid. Because Dr. Watson will not be able to make that showing, there is no way that he will be able to establish the required elements of Medicaid fraud. His failure to show any "definite, competent evidence" to rebut Dr. King-Vassel's motion is fatal to his case, and the Court must grant Dr. King-Vassel's motion for summary judgment. See Sears, Roebuck & Co., 233 F.3d at 437.

*7 Relatedly, without the testimony of an expert, the Court believes that Dr. Watson would be unable to establish causation. Without a doubt, Dr. King-Vassel prescribed N.B. certain medications. But her mere prescription of those medications would not, in and of itself, cause the submission of a false claim. Rather, N.B.'s mother would need to submit the claim to a pharmacy at which time she would also need to claim entitlement to Medicaid coverage. Furthermore, the pharmacy would need to check the Medicaid coverage for N.B., ensure the validity of the prescription, fill the prescription, and then submit the claim to Medicaid for reimbursement. And those steps are just the basics that would need to logically occur so that N.B. received his medication and the pharmacy received payment—without testimony of an expert, the Court cannot know what other intervening steps may have occurred between Dr. King-Vassel's signature of the prescription and the submission of a claim to Medicaid. Perhaps more accurately, the Court can describe this as a proximate-cause problem for Dr. Watson. Without an expert to testify, there is a grand mystery between the time of the prescription and the claim being made to Medicaid. In many ways, that mystery is like a black box—perhaps Dr. King-Vassel's signature on the prescription set off a series of reactions that on the other side of the box resulted in a false claim, but the churning mechanism on the inside is still a mystery. Without an expert to explain the workings of the in-between phase

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(the black box), the Court and an hypothetical jury cannot make any determination of whether Dr. King-Vassel actually caused the submission of a false claim.

Finally, without an expert, Dr. Watson also cannot establish the "fraudulent claim" element required to show a violation of the False Claims Act. See 31 U.S.C. § 3729(a)(1)(A). To make the fraudulent claim showing, Dr. Watson would need to establish that Dr. King-Vassel prescribed N.B. medications "for a medical indication which is not a medically accepted indication." West, 2007 WL 2091185, at *2. As mentioned above, medically accepted indications must be approved in either the FDCA or one of three drug compendia. Id.; 42 U.S.C. §§ 1396r-8(g)(1)(B)(I), (k)(2), (3), (6). Dr. Watson argues that this is an easy showing to satisfy, requiring only a comparison of the FDCA and drug compendia to N.B.'s noted indications. (Relator's Resp. [Docket # 42], 7–8). Despite that statement, though, Dr. Watson did not submit any pages of those documents to the Court that would show how easy it would be to make such an identification. And, in reality, medical documents typically are not readily understandable by the general public and would require an expert to explain their application to a particular set of circumstances. See Pamela H. Bucy, The Poor Fit of traditional Evidentiary Doctrine and Sophisticated Crime: An Empirical Analysis of Health Care Fraud Prosecutions, 63 FORDHAM L.REV. 383, 402-04 (1994) (parties will "need billing experts to guide fact finders through these various applicable regulations ... [and] the inapplicability of, or least confusion about, such regulations."). Dr. Watson has not named an expert who could establish the applicability or non-applicability of the drug compendia or FDCA to N.B.'s indications. Therefore, as with the other required showings noted above, Dr. Watson has failed to produce "definite, evidence" competent to rebut King-Vassel's motion for summary judgment on the issue of fraudulent claim requirement, and the Court must, therefore, grant Dr. King-Vassel's motion. See Sears, Roebuck & Co., 233 F.3d at 437.

*8 Having determined that Dr. Watson has failed to establish ample evidence to support either requirement to succeed in a false claim action, the Court is obliged to grant Dr. King-Vassel's motion for summary judgment and dismiss this action against her.

2.2 Sanctions

The only remaining issue is whether to grant Encompass' motion for sanctions against Dr. Watson for Dr. Watson's filing a complaint against Encompass for what Encompass alleges were unsubstantiated claims of

respondeat superior liability. (Encompass Reply 6-14).

Encompass alleges three separate bases upon which relief could be granted. First, Encompass argues that sanctions are appropriate under Rule 11 of the Federal Rules of Civil Procedure. (Encompass Reply 6–9). Under that rule, the Court may award sanctions if the non-moving party sustained an action without evidentiary support or based on frivolous legal contentions, even after 21 days of being notified by the moving party that it would seek sanctions if the nonmoving party did not dismiss the claim. Fed.R.Civ.P. 11(b)(2), (b)(3), (c)(2). Dr. Watson counters that his voluntary dismissal of Encompass occurred within the 21–day safe harbor period, due to the additional days granted by Rules 5(b)(2)(E) and 6(d) following email service. (Relator's Atty. Fees Resp. 2–3).

The Court agrees that the dismissal occurred within the safe harbor period and, therefore, Rule 11 sanctions are inappropriate.

But, that does not end the Court's sanctions analysis, as Encompass also requests sanctions pursuant to 28 U.S.C. § 1927. Under that provision, sanctions are appropriate where an "attorney ... multiplies the proceedings in any case unreasonably and vexatiously." 28 U.S.C. § 1927. Under that statute, Dr. Watson's attorney Ms. Gietman could be held liable if the Court determines she unreasonably and vexatiously multiplied the proceedings. Ms. Gietman (in a brief written for Dr. Watson) argues that sanctions are inappropriate under this term because it voluntarily "moved to dismiss the claims against Encompass once it determined that those claims were not likely to succeed." (Relator's Atty. Fees Resp. 4). But the question the Court must ask is not whether Ms. Gietman moved to dismiss the claims when she determined they were unlikely to succeed, but instead whether she acted in an "objectively unreasonable manner" and with a "serious and studied disregard for the orderly process of justice" in waiting to dismiss Encompass until she did. Jolly Group, Ltd. v. Medline Indus., Inc., 435 F.3d 717, 720 (7th Cir.2006) (quoting Pacific Dunlop Holdings, Inc. v. Barosh, 22 F.3d 113, 119 (7th Cir.1994)).

Here, the Court is left with the inescapable conclusion that Ms. Gietman acted in an objectively unreasonable manner and with a serious disregard for the order process of justice, and therefore sanctions against her are appropriate. 28 U.S.C. § 1927. As Encompass points out in its brief, its attorney provided Ms. Gietman with a copy of Encompass' contract with Dr. King–Vassel in February of 2012, and explained that under the contract (under which Dr. King–Vassel was an independent contractor) a respondeat superior claim could not lie. (Encompass

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Reply 7-8; Patrick Knight Aff., Ex. 3). Despite that disclosure, Ms. Gietman did not withdraw her claims against Encompass; rather, it was not until nearly six months later, after Encompass was required to participate in the discovery process and prepare and file a summary judgment brief, that those claims were dismissed. At the time of dismissal, there was no additional evidence that would support a respondeat superior claim against Encompass—the primary and controlling piece of evidence was the prior-disclosed contract. A reasonable attorney would have attempted to quickly ferret out any information to support a respondeat superior claim rather than waiting six months to dismiss such claim. And, while the Court would not suppose that Ms. Gietman should have dropped the claim immediately upon reading the relevant contract, the receipt of such contract should have tipped her off to a serious flaw in the respondeat superior claim. She then should have conducted an appropriate investigation into whether there was truly any employment relationship and, barring such relationship, quickly moved to dismiss Encompass. Instead, Encompass was forced to proceed through the entire discovery process and file an extensive summary judgment brief, all to combat a claim that could have been readily dismissed after a minor inquiry based on disclosures made to Ms. Gietman by Encompass. That is unreasonably vexatious and was based upon Ms. Gietman's serious disregard for the orderly administration of justice. The Court's and Encompass' resources would have been much better spent elsewhere, as opposed to dealing with Dr. Watson's frivolous suit against Encompass. And Ms. Gietman's decision to prolong Encompass' involvement in the matter exposes her to sanctions under 28 U.S.C. § 1927.

*9 Finally, Encompass urges the Court to impose sanctions upon Ms. Gietman and Dr. Watson under Chambers v. NASCO, Inc., 501 U.S. 32, 45, 111 S.Ct. 2123, 115 L.Ed.2d 27 (1991). Chambers calls for the imposition of sanctions under the court's "inherent powers" to address a full range of litigation abuses by individuals beyond those addressed by 28 U.S.C. § 1927 and Rule 11. Id. However, as Dr. Watson points out in his brief, the Court's use of its inherent powers should be limited to situations involving abuse of the judicial process or bad faith. (Relator's Atty Fees Resp. 6); see also Tucker v. Williams, 682 F.3d 654, 661-62 (7th Cir.2012) (citing Chambers, 501 U.S. at 55; Cleveland Hair Clinic, Inc. v. Puig, 200 F.3d 1063, 1066 (7th Cir.2000); Salmeron v. Enter. Recovery Sys., Inc., 579 F.3d 787, 793 (7th Cir.2009); Maynard v. Nygren, 332 F.3d 462, 470-71 (7th Cir.2003); Runfola & Assoc., Inc. v. Spectrum II, Inc., 88 F.3d 368, 375 (6th Cir.1996); Gillette Foods Inc. v. Bayernwald-Fruchteverwertung,

GmbH, 977 F.2d 809, 813–14 (3d Cir.1992); Schmude v. Sheahan, 420 F.3d 645, 650 (7th Cir.2005); Zapata Hermanos Sucesores, S.A. v. Hearthside Baking Co., Inc., 313 F.3d 385, 391 (7th Cir.2002)).

Here, an award of sanctions under the Court's inherent powers is appropriate. In bringing this case to trial, Ms. Gietman and Dr. Watson engaged in conduct that skirted the line of their respective professional responsibilities. As to Dr. Watson, he obtained N.B.'s medical records in a that could best be described manner borderline-fraudulent. He obtained a medical release for those records only after representing that he was going to treat N.B.—a total falsity. (See King-Vassel/CAPS PFF ¶¶ 11–12). And that does not even touch upon the fishing-expedition style of fact-gathering engaged in by Dr. Watson. His attack here on a single doctor's prescriptions to a single patient does not provide the government with substantial valuable information, as intended by the *qui tam* statutes. Instead of providing the government with valuable information, Dr. Watson seemingly sought only to cash in on a fellow doctor's attempts to best address a patient's needs. In return, Dr. King-Vassel was treated to a lawsuit, the proceeds of which would be split three ways between Dr. Watson, Ms. Gietman, and the parent of the patient Dr. King-Vassel was attempting to serve. As to Ms. Gietman, she should know much better than to have allowed Dr. Watson to obtain medical records in the manner described. The fact that those records were used in deciding whether to bring a case before any court shows a lack of judgment on Ms. Gietman's part-those records were not obtained in an appropriate manner, irrespective of whatever role, if any, Ms. Gietman may have played in the decision of how to them. Dr. Watson's borderline-fraudulent obtain acquisition of the documents, and Ms. Gietman's ommissive failure to stop that action, calls for an award of sanctions against both individuals.

*10 Having determined that an award of sanctions is appropriate against both Ms. Gietman and Dr. Watson, the Court now turns to the appropriate form of such sanctions. First, under 28 U.S.C. § 1927, the Court determines that Ms. Gietman should be monetarily sanctioned. Her failure to timely address Encompass' lack of involvement in this matter caused Encompass to incur substantial legal fees engaging in depositions and preparing a summary judgment motion. Therefore, the Court believes that she should be required to pay Encompass some amount of money to compensate for those fees wasted in responding to frivolous claims. The Court determines that Ms. Gietman should have determined that Encompass should not be subject to suit prior to Encompass' filing a motion for summary

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judgment—by the summary judgment phase, it should have been reasonably clear through the exercise of reasonable diligence, that a *respondeat superior* claim would not lie again Encompass. Therefore, the Court will impose upon Ms. Gietman a sanction of reasonable attorney's fees incurred by Encompass in researching, drafting, and filing its brief supporting motion for summary judgment (Docket # 34) and its subsequent reply (Docket # 52).

Finally, as to the sanctions under the Court's inherent powers, it will require Ms. Gietman and Dr. Watson to pay \$500.00 (\$250.00 to be paid by each individual) to Dr. King–Vassel and \$500.00 (\$250.00 to be paid by each individual) to Encompass. Those amounts should be substantial enough to penalize both Ms. Gietman and Dr. Watson for engaging in such unscrupulous tactics to gain access to N .B.'s medical records, while not being so draconian as to impose undue financial hardship upon either individual.

3. CONCLUSION

Having fully discussed the entirety of motions and briefs before it in this matter, the Court will now render judgment on each of those motions. In sum, this matter will be dismissed in full (as, after granting Dr. King–Vassel's motion for summary judgment, and otherwise granting Dr. Watson's motions to dismiss CAPS and Encompass, there are no parties left against which Dr. Watson can sustain a suit). Furthermore, the Court will impose appropriate sanctions upon Ms. Gietman and Dr. Watson. Accordingly,

IT IS ORDERED that Dr. Watson's amended motion to dismiss Encompass (Docket # 49) be and the same is hereby **GRANTED**;

IT IS FURTHER ORDERED that Dr. Watson's first motion to dismiss Encompass (Docket # 40) be and the same is hereby **DENIED** as moot, the Court having already granted Dr. Watson's superseding motion to dismiss Encompass;

IT IS FURTHER ORDERED that Encompass' motion for summary judgment and joinder (Docket # 33) be and the same is hereby DENIED as moot, the Court having already granted Dr. Watson's superseding motion to dismiss Encompass;

IT IS FURTHER ORDERED that Dr. Watson's motion to dismiss CAPS (Docket # 50) be and the same is hereby **GRANTED**;

IT IS FURTHER ORDERED that CAPS' and Dr. King-Vassel's motion for summary judgment (Docket # 28) be and the same is hereby **DENIED** in part as moot, as it relates to CAPS, the Court having already granted Dr. Watson's motion to dismiss CAPS, and **GRANTED** in part, as it relates to **Dr. King-Vassel**, for the reasons set forth above:

*11 IT IS FURTHER ORDERED that Encompass' motion for sanctions (Docket # 51) be and the same is hereby **DENIED** in part, as to Encompass' request for sanctions pursuant to Rule 11; and GRANTED in part, as to Encompass' request for sanctions pursuant to 28 U.S .C. § 1927, and accordingly Ms. Gietman shall pay Encompass' reasonable attorneys fees in preparation of Encompass' brief in support of its motion for summary judgment (Docket # 34) and reply brief regarding summary judgment (Docket # 51) pursuant to 28 U.S.C. § 1927, and Encompass shall submit documentation of its fees to the Court on or before November 8, 2012, and Ms. Gietman shall file any objections thereto on or before November 29, 2012; and GRANTED in part as to the Court's inherent powers as discussed in *Chambers v*. NASCO, Inc., 501 U.S. 32, 45, 111 S.Ct. 2123, 115 L.Ed.2d 27 (1991) and Ms. Gietman shall further pay \$250.00 to Dr. King-Vassel pursuant to the Court's inherent powers, and Ms. Gietman shall further pay \$250.00 to Encompass pursuant to the Court's inherent powers, and Dr. Watson shall pay \$250.00 to Dr. King-Vassel pursuant to the Court's inherent powers, and Dr. Watson shall further pay \$250.00 to Encompass pursuant to the Court's inherent powers;

IT IS FURTHER ORDERED that CAPS' and Dr. King–Vassel's motion for relief from the scheduling order (Docket # 32) be and the same is hereby DENIED as moot:

IT IS FURTHER ORDERED that the state of Wisconsin's motion to substitute its attorney (Docket # 55) be and the same is hereby **GRANTED**; and

IT IS FURTHER ORDERED that this Court having dismissed all claims against all defendants, this matter be and the same is hereby **DISMISSED** on its merits, together with costs as taxed by the Clerk of Court.

The Clerk of Court is directed to enter judgment accordingly.

Parallel Citations

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UNITED STATES DISTRICT COURT EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, and THE STATE OF WISCONSIN, ex rel. DR. TOBY TYLER WATSON,

Case No. 11 CV 236 JPS

v.

JENNIFER KING VASSEL, CAPS CHILD & ADOLESCENT PSYCHOLOGICAL SERVICES, and ENCOMPASS EFFECTIVE MENTAL HEALTH SERVICES, INC.,

JUDGMENT

Defendants.

Plaintiffs,

Decision by Court. This action came on for consideration before the Court and a decision has been rendered.

IT IS ORDERED that Dr. Watson's amended motion to dismiss Encompass (Docket #49) be and the same is hereby **GRANTED**;

IT IS FURTHER ORDERED that Dr. Watson's first motion to dismiss Encompass (Docket #40) be and the same is hereby **DENIED** as moot, the Court having already granted Dr. Watson's superseding motion to dismiss Encompass;

IT IS FURTHER ORDERED that Encompass' motion for summary judgment and joinder (Docket #33) be and the same is hereby **DENIED** as **moot**, the Court having already granted Dr. Watson's superseding motion to dismiss Encompass;

IT IS FURTHER ORDERED that Dr. Watson's motion to dismiss CAPS (Docket #50) be and the same is hereby **GRANTED**;

IT IS FURTHER ORDERED that CAPS' and Dr. King Vassel's motion for summary judgment (Docket #28) be and the same is hereby **DENIED in** part as moot, as it relates to CAPS, the Court having already granted Dr. Watson's motion to dismiss CAPS, and **GRANTED** in part, as it relates to Dr. King Vassel, for the reasons set forth above: Watson Short Appendix

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IT IS FURTHER ORDERED that Encompass' motion for sanctions (Docket #51) be and the same is hereby **DENIED** in part, as to Encompass' request for sanctions pursuant to Rule 11; and GRANTED in part, as to Encompass' request for sanctions pursuant to 28 U.S.C. § 1927, and accordingly Ms. Gietman shall pay Encompass' reasonable attorneys fees in preparation of Encompass' brief in support of its motion for summary judgment (Docket #34) and reply brief regarding summary judgment (Docket #51) pursuant to 28 U.S.C. § 1927, and Encompass shall submit documentation of its fees to the Court on or before **November 8, 2012**, and Ms. Gietman shall file any objections thereto on or before **November 29, 2012**; and **GRANTED** in part as to the Court's inherent powers as discussed in *Chambers v. NASCO*, *Inc.*, 501 U.S. 32, 45 (1991) and **Ms. Gietman shall further pay \$250.00 to Dr.** King-Vassel pursuant to the Court's inherent powers, and Ms. Gietman shall further pay \$250.00 to Encompass pursuant to the Court's inherent powers, and **Dr. Watson shall pay \$250.00 to Dr. King-Vassel** pursuant to the Court's inherent powers, and Dr. Watson shall further pay \$250.00 to Encompass pursuant to the Court's inherent powers;

IT IS FURTHER ORDERED that CAPS' and Dr. King Vassel's motion for relief from the scheduling order (Docket #32) be and the same is hereby **DENIED as moot**;

IT IS FURTHER ORDERED that the State of Wisconsin's motion to substitute its attorney (Docket #55) be and the same is hereby **GRANTED**; and,

IT IS FURTHER ORDERED that the Court having dismissed all claims against all defendants, this matter be and the same is hereby **DISMISSED** on **its merits**, together with costs as taxed by the Clerk of Court.

APPROVED:

.P. Stadtmueller

J.S. District Judge

JON W. SANFILIPPO Clerk of Court

s/Nancy A. Monzingo

By: Deputy Clerk

October 23, 2012
Date

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF WISCONSIN MILWAUKEE DIVISION

UNITED STATES OF AMERICA, and The STATE OF WISCONSIN,

Ex rel. Dr. Toby Tyler Watson,

Relator Plaintiff,

Civil Action No.:

FILED IN CAMERA AND

UNDER SEAL

FALSE CLAIMS ACT MEDICAID FRAUD

JURY TRIAL DEMANDED

v.

JENNIFER KING-VASSEL, CAPS CHILD & ADOLESCENT PSYCHIATRIC SERVICES, AND ENCOMPASS EFFECTIVE MENTAL HEALTH SERVICES, INC..

Defendants.

PLAINTIFFS' COMPLAINT PURSUANT TO
31 U.S.C. §§3729-3732 OF THE FEDERAL FALSE CLAIMS ACT AND
WISCONSIN STATUTE §20.931 FOR FALSE CLAIMS FOR MEDICAL ASSISTANCE

Relator-Plaintiff Dr. Toby Watson, through his undersigned counsel, brings this qui tam action on behalf of the United States of America and the State of Wisconsin, and for his Complaint against the Defendants alleges as follows:

INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America under 31 U.S.C. §3729, et seq, as amended ("Federal False Claims Act") and on behalf of the State of Wisconsin under the Wisconsin False Claims for Medical Assistance Law, Wis. Stat. §20.931, as amended ("Wisconsin False Claims Law"), arising from the Defendants' actions which caused claims for outpatient psychotropic medications prescribed to Medical

Assistance Recipient N.B. and other children that were not for medically accepted indications to be made to and paid by the Wisconsin Medical Assistance Program and Medicaid.

- 2. The Federal False Claims Act was enacted during the Civil War. Congress amended the Federal 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 Federal 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 Government's behalf. The Wisconsin False Claim Law was enacted to effectuate the same on the State's behalf.
- 3. The Federal False Claims Act provides that any person who knowingly submits, or causes the submission of, a false and fraudulent claim to the U.S. Government for payment 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.
- 4. The Wisconsin False Claim Law provides that any person who knowingly presents or causes to be presented a false claim for medical assistance is liable for a civil penalty of up to \$10,000 for each false claim, plus three times the amount of the damages sustained by this State.
- 5. The Federal False Claims 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.

- 6. Likewise, the Wisconsin False Claim Law allows any person having information about a false or fraudulent claim for medical assistance to bring an action for himself and the State, and to share in any recovery. The Law 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 State time to conduct its own investigation and to determine whether to join the suit.
- 7. Under Medicaid, (a) psychiatrists and other prescribers and (b) mental health agencies all have specific responsibilities to prevent false claims from being presented and are liable under the Federal False Claims Act for their role in the submission of false claims.

PARTIES

- 8. Relator Dr. Toby Tyler Watson is a citizen of the Eastern District of Wisconsin, who has personal knowledge of N.B.'s confidential and non-publically-disclosed mental health treatment history. N.B. is a Wisconsin Medical Assistance recipient whose date of birth is 2000.
- 9. During times relevant to this Complaint, Defendant Jennifer King-Vassel transacted business in the Eastern District of Wisconsin.
- 10. During times relevant to this Complaint, Defendant Child and Adolescent Psychiatric Services ("CAPS") transacted business in the Eastern District of Wisconsin with a principal place of business at 933 N. Mayfair Road, Suite 308, in Wauwatosa, Wisconsin 53226, and employed Defendant Jennifer King-Vassel.
- 11. Defendant ENCOMPASS Effective Mental Health Services, Inc. ("Encompass") is a Wisconsin Corporation with a principal place of business at 1011 North Mayfair Road, Suite 304

in Wauwatosa, Wisconsin 53226, and at times relevant to this complaint employed Defendant Jennifer King-Vassel.

JURISDICTION AND VENUE

- 12. This Court maintains subject matter jurisdiction over this action pursuant to 31 U.S.C §§3732(a) (Federal False Claims Act).
- 13. There have been no public disclosures of the allegations or transactions contained herein that bar jurisdiction under 31 U.S.C. §3730(e).
- 14. This Court has Supplemental Jurisdiction over the state law claims pursuant to 28 U.S.C. §1367.
- 15. Venue is proper in this Court pursuant to 31 U.S.C §§3732(a) because the Defendants transact business in this District and did so at all times relevant to this Complaint, and because the Defendants committed acts giving rise to this action within this District.

APPLICABLE LAW

A. Medicaid and Medical Assistance

- 16. 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.
- 17. Wisconsin's Medical Assistance program ("MA") supports the costs for individuals who meet specified financial and nonfinancial criteria. Wisconsin must administer MA in conformity with federal law and policy, as claims paid by MA are partially reimbursed to the State by Medicaid.
- 18. Federal reimbursement for prescription drugs under the Medicaid program is, as relevant, limited to "covered outpatient drugs." 42 U.S.C. §1396b(i)(10), 1396r-8(k)(2), (3).

19. 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:

- (a) American Hospital Formulary Service Drug Information,
- (b) United States Pharmacopeia-Drug Information (or its successor publications, or
- (c) DRUGDEX Information System,

(Covered Outpatient Drugs).

- 20. Every MA provider and every Medicaid provider must agree to comply with all Medicaid requirements.
 - B. False Claim Liability
- 21. Federal False Claim Act and Wisconsin False Claim Law liability attaches to any person who knowingly presents or causes to be presented a false or fraudulent claim for payment, or who makes, uses or causes to be made a false record or statement to get a false or fraudulent claim paid. 31 U.S.C. §3729(a)(1)&(2); Wis. Stat. 20.931(2)(a)&(b).
- 22. Under the Federal False Claims Act and the Wisconsin False Claim Law, "knowing" and "knowingly" mean that a person, with respect to information:
 - (a) has actual knowledge of the information;
 - (b) acts in deliberate ignorance of the truth or falsity of the information; or
 - (c) acts in reckless disregard of the truth of falsity of the information, and no proof of specific intent to defraud is required.
- 31 U.S.C. §3729(b); Wis. Stat. §20.931(1)(d).

ALLEGATIONS

23. The Federal False Claims Act and Wisconsin False Claim Law are 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 course of conduct that causes the government to pay a false or fraudulent claim for money.

- 24. On the following dates, Defendant Jennifer King-Vassel prescribed the following psychotropic drugs to Medical Assistance recipient N.B. that were not for an indication approved by the FDA or supported by one of more of the Compendia:
 - a. Clonidine
 - 1. November 29, 2004
 - 2. December 28, 2004
 - 3. January 27, 2005
 - 4. February 21, 2005
 - 5. July 21, 2005
 - 6. September 8, 2005
 - 7. November 3, 2005
 - 8. December 13, 2005
 - 9. February 7, 2006
 - 10. August 14, 2006
 - 11. September 18, 2006
 - 12. October 17, 2006
 - 13. November 15, 2006
 - 14. December 27, 2006

- 15. February 5, 2007
- 16. May 17, 2007
- 17. July 17, 2007
- 18. April 29, 2008
- b. Prozac
 - 1. July 10, 2006
 - 2. April 29, 2008
- c. Risperdal
 - 1. November 29, 2004
 - 2. December 28, 2004
 - 3. January 27, 2005
 - 4. February 23, 2005
 - 5. July 21, 2005
 - 6. September 8, 2005
 - 7. October 4, 2005
 - 8. November 3, 2005
 - 9. December 13, 2005
 - 10. February 7, 2006
 - 11. June 6, 2006
 - 12. June 6, 2006
 - 13. July 10, 2006
 - 14. August 14, 2006
 - 15. September 18, 2006

- 16. October 17, 2006
- 17. November 15, 2006
- 18. December 27, 2006
- 19. February 5, 2007
- 20. April 29, 2008
- d. Seroquel
 - 1. May 17, 2007
 - 2. April 29, 2008
- e. Strattera
 - 1. December 13, 2005
- f. Zoloft
 - 1. November 15, 2006
 - 2. December 27, 2006
 - 3. February 5, 2007
 - 4. May 17, 2007
 - 5. July 17, 2007
 - 6. April 29, 2008
- 25. On information and belief, Defendant Jennifer King-Vassel prescribed to other Medical Assistance recipients psychotropic drugs that were not for an indication approved by the FDA or supported by one or more of the Compendia.

CAUSES OF ACTION

Count 1: Psychiatrist Liability For Uncovered Drugs

Federal False Claims Act

- 26. Defendant Jennifer King-Vassel prescribed the psychotropic drugs to Medical Assistance recipient N.B. set forth above, and to other minors, 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 for reimbursement
 - (a) with actual knowledge;
 - (b) in deliberate ignorance; or
 - (c) in reckless disregard

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

- 27. Upon information and belief, Defendant Jennifer King-Vassel continues to prescribe psychotropic drugs to minors 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 for reimbursement
 - (a) with actual knowledge;
 - (b) in deliberate ignorance; or
 - (c) in reckless disregard

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

Count 2: Psychiatrist Liability For Uncovered Drugs

Wisconsin False Claims Law

- 28. Defendant Jennifer King-Vassel prescribed the psychotropic drugs to Medical Assistance recipient N.B. set forth above, and to other minors, 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 Medical Assistance for payment
 - (a) with actual knowledge;
 - (b) in deliberate ignorance; or
 - (c) in reckless disregard

that such claims are false, and is liable under the Wisconsin False Claims Law, therefor.

- 29. Upon information and belief, Defendant Jennifer King-Vassel continues to prescribe psychotropic drugs to minors 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 Medical Assistance for payment
 - (a) with actual knowledge;
 - (b) in deliberate ignorance; or
 - (c) in reckless disregard

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

Count 3: CAPS Liability for Uncovered Drugs

Federal False Claims Act

30. CAPS is liable for the actions of its agent and/or employee Jennifer King-Vassel under the doctrine of respondeat superior.

Count 4: CAPS Liability for Uncovered Drugs

Wisconsin False Claims Law

31. CAPS is liable for the actions of its agent and/or employee Jennifer King-Vassel under the doctrine of respondeat superior.

Count 5: Encompass Liability for Uncovered Drugs

Federal False Claims Act

32. Encompass is liable for the actions of its agent and/or employee Jennifer King-Vassel under the doctrine of respondeat superior.

Count 6: Encompass Liability for Uncovered Drugs.

Wisconsin False Claims Law

33. Encompass is liable for the actions of its agent and/or employee Jennifer King-Vassel under the doctrine of respondeat superior.

DEFENDANTS' LIABILITY

- 34. By virtue of the acts described above, defendants knowingly (a) submitted, and continue to submit, and/or (b) caused and/or continue cause to be submitted, false or fraudulent claims to the Wisconsin Medical Assistance program for payment and the United States Government for reimbursement of psychiatric drugs prescribed to Medical Assistance recipient N.B. and other minors that are not for an indication that is approved by the FDA or supported by one or more of the Compendia.
- 35. Wisconsin Medical Assistance and Medicaid paid and continues to pay such false claims.
- 36. By reason of the defendants' acts, the State of Wisconsin and the United States have been damaged, and continue to be damaged, in substantial amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, United States of America and State of Wisconsin, through Relator,

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 \$11,000for each violation of 31 U.S.C. §3729;

C. That this Court enter judgment against Defendants in an amount equal to three times the

amount of damages the State of Wisconsin has sustained because of defendants' actions, plus a

civil penalty of not less than \$5,000 and not more than \$10,000 for each violation of Wis. Stat.

§20.931.

D. That Relator be awarded the maximum amount allowed pursuant to §3730(d) of the

Federal False Claims Act and the maximum allowed pursuant to Wis. Stat. §20.931(11).

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

and

F. That Relator recover such other relief as the Court deems just and proper.

Dated: February 26, 2011

Relator Dr. Toby Tyler Watson, by

Gietman Law, LLC

Rebecca L. Gietman

WI Bar No.: 1052401

805 S. Madison St.

Chilton, WI 53014

920-737-3036

IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF WISCONSIN MILWAUKEE DIVISION

| UNITED STATES OF AMERICA, Ex rel. Dr. Toby Watson, | Civil Action No.: 11-C-0236 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------|
| Plaintiff, | |
| V. JENNIFER KING-VASSEL, Doing Business as CAPS CHILD & ADOLESCENT PSYCHIATRIC SERVICES, AND ENCOMPASS EFFECTIVE MENTAL HEALTH SERVICES, INC. Defendants. | FALSE CLAIMS ACT MEDICAID FRAUD |
| AFFIDAVIT OF CHRISTINE M. | AXWELL MEYER |

SHEBOYGAN COUNTY)

)) SS.

TATE OF WISCONSIN

CHRISTINE MAXWELL MEYER, being first duly sworn, on oath deposes and says:

- 1. I am the mother of N.B., the minor child to whom Dr. King prescribed the complained-about medications. I make this affidavit through personal information.
- 2. Since N.B.'s birth, N.B. has lived with me in Wisconsin. N.B. has been the recipient of medicaid since his birth.
- 3. Since N.B.'s birth, I have paid for none of N.B.'s mental health services, nor any of hie prescribed medications. All have been obtained by me using my medical assistance / BadgerCare / Managed Health Services / ForwardHealth card.

4. N.B. was treated by Dr. King from 2004 through 2008. Dr. King knew that N.B. was on Medicaid and knew that his care was being paid for by Medicaid. I provided to Dr. King N.B.'s medicaid information, and never paid out of my pocket for his visits with her. Dr. King never informed me or suggested that she had not billed Medicaid for her services to N.B..

- 5. Dr. King issued many prescriptions to N.B.. I had those prescriptions filled by Walmart Pharmacy each time Dr. King prescribed, within a few days of her doing so. I always used my medical assistance card to pay for N.B.'s medications, and never paid for N.B.'s prescriptions out of my own pocket.
- 6. Through the years, I have saved some but not all of N.B.'s empty prescription bottles. I have provided to Attorney Rebecca L. Gietman those bottles relevant to Dr. King.

Dated this 20th day of August, 2012.

_/s/ Christine Maxwell Meyer Christine Maxwell Meyer Subscribed and sworn to before me this 20th day of August, 2012.

/s/ Theresa L. Kussard
Name: Theresa L. Kussard
Notary Public, State of Wisconsin
My commission: 7-24-16



Legal

HIPAA Team

Store(s): 1650, 3497, 2658

Dates of Service: 01/01/1997-07/25/2012

CERTIFICATION OF RECORDS

Filed: 02/19/2013

Enclosed are the prescription records of N В (24 page(s)). We are producing the records purs in the a subpoenalauthorized release issued to Wal-Mart in the matter of N Please accept this document as certification of the records produced herewith. The records you have requested are maintained by the Pharmacy Division of Wal-Mart Stores, Inc. in various locations throughout the company. Upon receipt of your subpoena/authorized release by the Wal-Mart Stores, Inc. Legal Department, we requested of the appropriate location of Wal-Mart Pharmacy to provide all documents in their possession responsive to your subpoena/authorized release. The records produced herewith are accurate, complete, true and correct copies of all records received or retrieved by Legal pursuant to your request. I further certify that Wal-Mart Stores, Inc. is the custodian of record, that the records were kept in the regular course of business and that this is a regularly conducted business activity, that these records were made at or near the time the acts, events, conditions, opinions, or diagnoses occurred or within a reasonable time thereafter, that the charges were reasonable for similar services, necessary as payment for a prescription filled by our pharmacy pursuant to a doctor's orders and finally that these records were made by, or from information transmitted by, a person with knowledge of the acts, events, conditions, opinions or diagnoses stated therein.

Katie Breeden

HealthPort Release of Information Bentonville, AR 72716-0215

STATE OF ARKANSAS

COUNTY OF BENTON

The foregoing instrument was acknowledged before me this 25 day of July 2012

SS.

NOTAR Public

NO

Store #: 1650

Report Date: 07/25/2012 FROM 01/01/1997 TO 07/25/2012

Connexus Pharmacy System Wal-Mart Pharmacy 10-1650 HIPAA Designated Record Set

825 EAST GREEN BAY AVENUE SAUKVILLE WI-53080

Patient Information

Name Address

ADEL WI-53001

DOB SSN # Phone Emall

/2000

Allergies

Clinical HIPAA Notes

Insurance Information

| Card Status | Plan/Carrier | Card ID # | Group # | Dependent Code |
|-------------|---------------------------------|------------|---------|----------------|
| Inactive | NAV /BADGER RX GOLD - NAVITUS C | 7401440474 | 8 | 01 |
| Active | MWI /MEDICAID OF WISCONSIN G | 7401440474 | 464 | 1 |
| Inactive | NAV /BADGER RX GOLD - NAVITUS C | 3872199090 | 1 | 01 |
| Inactive | MWI /MEDICAID OF WISCONSIN G | 3872199090 | 184 | 1 |
| Active | MHS /MANAGED HLTH SERVICES WI G | 3872199090 | | 1 |
| nactive | PMK /PRO-MARK C | 3872199090 | | 1 |
| nactive | PAI /PAID PRESCRIPTIONS C | 3872199090 | 816 | 1 |

| Fill Date | Rx # Fill 1D | Drug Name Qty | SIG | Physician | Ins. | Price |
|-----------|-----------------|------------------|-----|-----------|------|-------|
|-----------|-----------------|------------------|-----|-----------|------|-------|

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Case: 12-3671

DOCUMONTO Pharmacy Sylectic 02/19/2013
Wel-Mart Pharmacy 10-1650 HIPAA Designated Record Set

Pages: 80

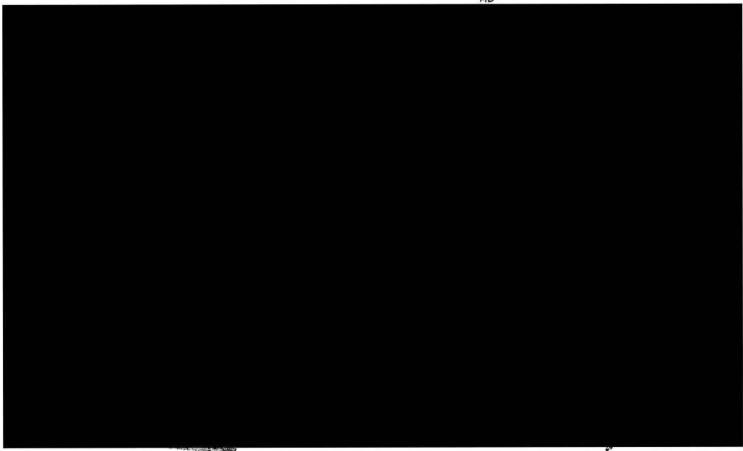
825 EAST GREEN BAY AVENUE SAUKVILLE WI-53080

Prescription Information

FROM 01/01/1997 TO 07/25/2012

Report Date: 07/25/2012

| Fili Date | Rx # FIII ID | Drug Name Qty | SIG | Physician | Ins. | Price |
|------------|--------------------|------------------------------------|-------------------------------------------------------------------------------------------------------------------|-----------------------------------|------|-----------------|
| 11/29/2004 | 7177146 2434559 | DEPAKOTE SPR 125MG CAP Qty: 90 | TAKE ONE CAPSULE BY MOUTH IN THE MORNING AND AT BEDTIME FOR 3 DAYS THEN TAKE ONE IN THE MORNING AND 2 AT BEDTIME. | KING- VASSEL,JENNIFER R MD | PMK | \$ 53.75 |
| 09/08/2005 | 2230879 2548006 | AMPHETA S/COMBO SMG TAB Qty: 30 | TAKE ONE- HALF TABLET IN THE MORNING MAY INCREASE TO TWICE DAILY AFTER ONE WEEK | KING- VASSEL, JENNIFER R MD | РМК | \$28.75 |
| 09/12/2005 | 7212634 2549262 | RISPERDAL 1MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL, JENNIFER R MD | PMK | \$313.01 |



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HIPAA Team

Store(s): 1650, 3497, 2658

Dates of Service: 01/01/1997-07/25/2012

CERTIFICATION OF RECORDS

Enclosed are the prescription records of N (24 page(s)). We are producing the records pursuant to a subpoenalauthorized release issued to Wal-Mart in the matter of N Please accept this document as certification of the records produced herewith. The records you have requested are maintained by the Pharmacy Division of Wal-Mart Stores, Inc. in various locations throughout the company. Upon receipt of your subpoena/authorized release by the Wal-Mart Stores, Inc. Legal Department, we requested of the appropriate location of Wal-Mart Pharmacy to provide all documents in their possession responsive to your subpoena/authorized release. The records produced herewith are accurate, complete, true and correct copies of all records received or retrieved by Legal pursuant to your request. I further certify that Wal-Mart Stores, Inc. is the custodian of record, that the records were kept in the regular course of business and that this is a regularly conducted business activity, that these records were made at or near the time the acts, events, conditions, opinions, or diagnoses occurred or within a reasonable time thereafter, that the charges were reasonable for similar services, necessary as payment for a prescription filled by our pharmacy pursuant to a doctor's orders and finally that these records were made by, or from information transmitted by, a person with knowledge of the acts, events, conditions, opinions or diagnoses stated therein.

Katie Breeden

HealthPort Release of Information Bentonville, AR 72716-0215

STATE OF ARKANSAS

COUNTY OF BENTON

SS.

The foregoing instrument was acknowledged before me this 25 day of July 2012

Notary Public

Short Appendix Page 28

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Case: 12-3671 Pages: 80 Document: 23 Filed: 02/19/2013

Store #: 3497

Connexus Pharmacy System Wal-Mart Pharmacy 10-3497 HIPAA Designated Record Set

428 WALTON DRIVE PLYMOUTH WI-53073

Patient Information

Report Date: 07/25/2012 FROM 01/01/1997 TO 07/25/2012

Name Address NO KNOWN DRUG ALLERGY

DOB 55N # Phone Email

/2000

Allergies

Clinical HIPAA Notes

Insurance Information

| Card Status | Plan/Carrier | Card ID # | Group # | Dependent Code |
|-------------|---------------------------------|------------|---------|----------------|
| | | | | |
| Active | MWI /MEDICAID OF WISCONSIN G | 3872199090 | 41 | 1 |
| Inactive | MHS /MANAGED HLTH SERVICES WI G | 3872199090 | | 1 |
| nactive | MER /MERCK MEDCO/PAID C | 3872199090 | 782 | 1 |
| Inactive | PAI /PAID PRESCRIPTIONS C | 3872199090 | 90 | 1 |

| 5000000 | 3201 | 282 | 200 | | F2 | |
|-----------|---------|-----------|-----|-----------|------|-------|
| Fili Date | Rx # | Drug Name | SIG | Physician | Ins. | Price |
| | FIII ID | Qty | | | | |



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02/26/2005

02/26/2005

03/14/2005

6636474

1099809

6636475

1099810

2202340

1101832

Case: 12-3671

DOCUMONIE 203 Pharmacy Sylvani 02/19/2013
Wal-Nart Pharmacy 10-3497
HIPAA Designated Record Set

Pages: 80 428 WALTON DRIVE PLYMOUTH WI-53073

Report Date: 07/25/2012 FROM 01/01/1997 TO 07/25/2012

Prescription Information FIII Date Rx # Drug Name SIG Physician Price Ins. FIII ID Qty TIMES DAILT 12/03/2004 0532643 RISPERDAL 0.5MG TAB TAKE ONE TABLET BY MOUTH KING-MHS \$191.53 1088563 VASSEL, JENNIFER Qty: 60 C'CC DAILY 6633824 12/31/2004 RISPERDAL 0.5MG TAB TAKE ONE TABLET BY MOUTH KING-MHS \$191.53 VASSEL, JENNIFER 1092289 TWICE DAILY Qty: 60 6633825 CLONIDINE 0.1MG TAB TAKE ONE TABLET BY MOUTH KING-12/31/2004 MHS \$6.20 1092290 Qty: 60 TWICE DAILY VASSEL, JENNIFER TAKE ONE & ONE-HALF 2202131 METHYLIN 10MG TAB 12/31/2004 KING-MHS \$27.47 TABLETS BY MOUTH IN THE 1092291 Qty: 120 VASSEL, JENNIFER MORNING , 1 TAB AT 11:00AM AND ONE & ONE -HALF TAB AT 3PM 01/30/2005 2202217 METHYLIN 10MG TAB TAKE ONE & ONE-HALF KING-MHS \$27.47 1096054 Qty: 120 TABLETS BY MOUTH IN THE VASSEL, JENNIFER MORNING, ONE TAB AT NOON, AND ONE & ONE-HALF TAB AT 3PM. RISPERDAL 0.5MG TAB \$286.29 01/30/2005 6635157 TAKE ONE TABLET BY MOUTH KING-MHS 1096055 Otv : 90 THREE TIMES DAILY VASSEL, JENNIFER 6635158 CLONIDINE 0.1MG TAB 01/30/2005 TAKE ONE TABLET BY MOUTH KING. MHS \$6.20 EVERY DAY AT 11:30 A.M. Qty: 60 VASSEL, JENNIFER 1096056 AND AT BEDTIME. TAKE ONE & ONE-HALF 2202297 METHYLIN 10MG TAB 02/26/2005 KING-MHS \$27.47 TABLETS BY MOUTH IN THE VASSEL, JENNIFER 1099808 Qty: 120 MORNING AND AT 3:30PM AND ONE AT 11:00AM EVERY

CLONIDINE 0.1MG TAB

RISPERDAL 0.5MG TAB

METHYLIN 10MG TAB

Qty: 90

Qty: 90

Qty: 130

MHS

MHS

MHS

VASSEL, JENNIFER

VASSEL, JENNIFER

VASSEL, JENNIFER

KING-

\$8.31

\$286.29

\$29.59

TAKE ONE TABLET BY MOUTH

TAKE ONE TABLET BY MOUTH KING-

IN THE MORNING TWO AT

TAKE 1 & 1/2 TABLETS BY

MOUTH 3 TIMES DAILY

THREE TIMES DAILY

BEDTIME

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Case: 12-3671

Documetonne (as Pharmacy 10-3497
Wal-Mart Pharmacy 10-3497
HIPAA Dasignated Record Set

Radio Marive PLYMOUTH WI-53073

Report Date: 07/25/2012 FROM 01/01/1997 TO 07/25/2012

| Fill Date | Rx # Fill 1D | Drug Name Qty | SIG | Physician | Ins. | Price |
|------------|-------------------------------|------------------------------------|-------------------------------------------------------------------------|----------------------------|------|------------------|
|)3/24/2005 | 6637641 1103334 | CLONIDINE 0.1MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH IN THE MORNING AND TWO AT BEDTIME | KING• VASSEL,JENNIFER | MHS | \$8.31 |
| 04/17/2005 | 6637641 1106489 | CLONIDINE 0.1MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH IN THE MORNING AND TWO AT BEDTIME | KING- VASSEL, JENNIFER | MHS | \$8.31 |
| 3/24/2005 | 6637642 | RISPERDAL 0.5MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL, JENNIFER | MHS | \$286.29 |
| 4/17/2005 | 1103335 6637642 1106490 | RISPERDAL 0.5MG TAB Qty : 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL, JENNIFER | MHS | \$286.29 |
| 04/14/2005 | 2202413 1106153 | METHYLIN 10MG TAB Qty: 135 | TAKE ONE & ONE-HALF TABLETS BY MOUTH THREE TIMES DAILY | KING- VASSEL,JENNIFER | MHS | \$30.65 |
| 05/11/2005 | 2202492 1109899 | METHYLIN 10MG TAB Qty: 135 | TAKE ONE & ONE-HALF TABLETS BY MOUTH THREE TIMES DAILY | KING- VASSEL,JENNIFER | MHS | \$30.6 5 |
| 05/23/2005 | 6640379 | CLONIDINE 0.1MG TAB | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL, JENNIFER | MHS | \$8.31 |
| 06/20/2005 | 1111443 6640379 | CLONIDINE 0.1MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL,JENNIFER | MHS | \$8.31 |
| 05/23/2005 | 1115022 6640380 1111444 | RISPERDAL 0.5MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL,JENNIFER | MHS | \$285.29 |
| 06/20/2005 | 6640380 1115023 | RISPERDAL 0.5MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL,JENNIFER | MHS | \$285.29 |
| 06/14/2005 | 6641360 1114306 | ABILIFY 5MG TAB Qty: 15 | TAKE ONE-HALF TABLET BY MOUTH AT BEDTIME | KING- VASSEL,JENNIFER | MHS | \$150.51 |
| 06/14/2005 | 2202578 1114307 | METHYLIN 10MG TAB Qty: 135 | TAKE ONE & ONE HALF TABLETS BY MOUTH THREE TIMES DAILY | KING- VASSEL,JENNIFER | MHS | \$3 0.65 |
| 07/08/2005 | 2202626 1117235 | METHYLIN 10MG TAB Qty : 135 | TAKE ONE & ONE-HALF TABLETS BY MOUTH THREE TIMES DAILY | KING- VASSEL,JENNIFER | MHS | \$ 30.65 |
| 07/15/2005 | 6642532 1117944 | CLONIDINE 0.1MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL,JENNIFER | MHS | \$8.31 |
| 07/15/2005 | 6642533 1117946 | RISPERDAL 0.5MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL, JENNIFER | MHS | \$ 286.29 |
| 07/26/2005 | 2202672 1119798 | METHYLIN 20MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | VASSEL, JENNIFER | MHS | \$ 45.20 |
| 07/27/2005 | 6643249 1120023 | CLONIDINE 0.1MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH IN THE AFTERNOON AND TWO TABS AT BEDTIME | KING- D VASSEL,JENNIFER | MHS | \$8.31 |
| 08/24/2005 | 6644450 1123801 | RISPERDAL 0.5MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL, JENNIFER | MHS | \$294.52 |
| 08/24/2005 | 6644451 1123802 | CLONIDINE 0.1MG TAB Qty: 60 | TAKE TWO TABLETS BY MOUTH AT BEDTIME | KING- VASSEL, JENNIFER | MHS | \$6.20 |
| 09/19/2005 | 6644451 1127300 | CLONIDINE 0.1MG TAB Qty: 60 | TAKE TWO TABLETS BY MOUTH AT BEDTIME | KING- VASSEL,JENNIFER | MHS | \$6.20 |
| 10/05/2005 | 2202854 1129720 | AMPHETA S/COMBO 10MGTAB Qty: 60 | TAKE ONE TABLET BY MOUTH IN THE MORNING AND ONE TAB AT NOON | 1 KING- VASSEL,JENNIFER | MHS | \$55.49 |
| 10/05/2005 | 6646282 1129728 | RISPERDAL 1MG TAB Qty : 90 | TAKE ONE TABLET BY MOUTH THREE TIMES DAILY | KING- VASSEL, JENNIFER | MHS | \$313.0 |

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Case: 12-3671

Documenties Pharmacy Sylectr 02/19/2013 Wal-Mart Pharmacy 10-3497 HIPAA Designated Record Set

Pages: 80 428 WALTON DRIVE PLYMOUTH WI-53073

Report Date: 07/25/2012 FROM 01/01/1997 TO 07/25/2012

| Fili Date | Rx # FIII ID | Drug Name Qty | SIG | Physician | Ind. | Price |
|------------|--------------------------------------|----------------------------------|----------------------------------------------------------------------------|---------------------------|------|----------|
| 11/10/2005 | 6647977 1134748 | CLONIDINE 0.1MG TAB | TAKE TWO TABLETS BY MOUTH AT BEDTIME | KING- VASSEL,JENNIFER | MHS | \$6.20 |
| 11/23/2005 | 6648577 1136717 | RISPERDAL 0.5MG TAB Qty: 90 | TAKE ONE TABLET BY MOUTH IN THE MORNING, ONE TAB AT NOON, ONE TAB AT | KING+ VASSEL,)ENNIFER | MHS | \$294.52 |
| | | | | | | |
| 12/26/2005 | 6650038 1141153 | CLONIDINE 0.1MG TAB Qty: 60 | TAKE TWO TABLETS BY MOUTH AT BEDTIME | KING- VASSEL,JENNIFER | MHS | \$6.20 |
| 02/02/2006 | 6650038 1146652 | CLONIDINE 0.1MG TAB Qty: 60 | TAKE TWO TABLETS BY MOUTH AT BEDTIME | KING- VASSEL, JENNIFER | MHS | \$6,20 |
| 12/26/2005 | 5650039 1141154 | RISPERDAL 0.25MG TAB Qty: 50 | TAKE ONE TABLET BY MOUTH IN THE MORNING ONE TAB AT BEDTIME | KING- | MHS | \$179.72 |
| 02/02/2006 | 6650039 1146653 | RISPERDAL 0.25MG TAB Qty: 60 | TAKE ONE TABLET BY MOUTH IN THE MORNING ONE TAB AT BEDTIME | | MHS | \$179.77 |
| 01/09/2006 | 6650466 1142553 | STRATTERA 25MG CAP | TAKE ONE CAPSULE BY MOUTH IN THE MORNING | KING- VASSELJENNIFER | MHS | \$102.84 |
| 02/10/2006 | 6652313 | STRATTERA 25MG CAP | TAKE ONE CAPSULE BY | KING- | MHS | \$102.84 |
| 03/20/2006 | 1147895 6652313 | Qty: 30 STRATTERA 25MG CAP | MOUTH IN THE MORNING TAKE ONE CAPSULE BY | VASSEL, JENNIFER KING- | MHS | \$107.19 |
| 82 SS | 1153398 | Qty: 30 | MOUTH IN THE MORNING | VASSEL, JENNIFER | MHS | |
| 03/05/2006 | 6652314 1151210 | RISPERDAL 0.25MG TAB Qty: 60 | TAKE ONE TABLET BY MOUTH TWICE DAILY | VASSEL, JENNIFER | MUZ | \$186.44 |
| 04/03/2006 | 6652314 1155313 | RISPERDAL 0.25MG TAB Qty : 60 | TAKE ONE TABLET BY MOUTH TWICE DAILY | KING- VASSEL,JENNIFER | MHS | \$186.44 |
| 02/22/2006 | 6652888 1149596 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | KING- VASSEL, JENNIFER | MHS | \$5.83 |
| 03/18/2006 | 665 288 8 1151 2 09 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | | MHS | \$4.91 |
| | | | | | | |
| 04/24/2006 | 6655815 1158427 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | KING- VASSEL, JENNIFER | MHS | \$4.91 |
| 05/22/2006 | 6655815 1162613 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | KING- VASSEL, JENNIFER | MHS | \$4.91 |
| 04/24/2006 | 6655816 1158428 | STRATTERA 25MG CAP Oty: 30 | TAKE ONE CAPSULE BY MOUTH IN THE MORNING | KING- VASSEL, JENNIFER | MHS | \$107.19 |
| 05/22/2006 | 6655817 1162615 | RISPERDAL 0.25MG TAB Qty: 60 | TAKE ONE TABLET BY MOUTH TWICE DAILY | | MHS | \$186.44 |

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Case: 12-3671

DOCUM Connexts Pharmacy System 02/19/2013 HIPAA Designated Record Set

428000 BONDBIVE PLYMOUTH WI-53073

FROM 01/01/1997 TO 07/25/2012

1186027

Qty: 120

Report Date: 07/25/2012

Prescription Information Price Physician Ing. SIG Drug Name FILI Date FIII ID Qty TAKE ONE TABLET BY MOUTH KING-MHS \$4.91 CLONIDINE 0.2MG TAB 6658101 06/15/2006 VASSEL, JENNIFER AT BEOTIME Qty: 30 1166141 KING-MHS \$5.05 TAKE ONE CAPSULE BY FLUOXETINE 10MG CAP 6658102 05/08/2006 VASSEL, JENNIFER MOUTH IN THE MORNING Qty: 30 1165178 MH5 \$5.00 KING-TAKE ONE CAPSULE BY 6658102 FLUOXETINE 10MG CAP VASSEL,JENNIFER 07/02/2006 MOUTH IN THE MORNING Qty: 30 1168545 \$185,44 MHS TAKE ONE TABLET BY MOUTH KING-6658103 RISPERDAL 0.25MG TAB 06/15/2006 VASSEL, JENNIFER IN THE MORNING AND ONE Qty: 60 1165183 TABLET AT BEDTIME \$292.23 MHS TAKE ONE TABLET BY MOUTH KING-RISPERDAL 0.25MG TAB 6660777 08/03/2006 VASSEL, JENNIFER IN THE MORNING AND TWO 1173375 Qty: 90 TABLETS EVERY DAY AT 1PM \$5.00 TAKE ONE CAPSULE BY MHS KING-FLUOXETINE 10MG CAP 6660778 08/03/2006 VASSEL, JENNIFER MOUTH IN THE MORNING Qty: 30 1173379 MHS \$4.91 KING-TAKE ONE TABLET BY MOUTH **CLONIDINE 0.2MG TAB** 6660779 08/03/2005 VASSEL, JENNIFER AT BEDTIME Qty: 30 1173380 MHS \$4.91 KING-TAKE ONE TABLET BY MOUTH CLONIDINE 0.2MG TAB 6660779 VASSEL, JENNIFER 05/10/2007 AT BEDTIME 1219243 Qty: 30 \$292.23 MHS KING-TAKE ONE TABLET BY MOUTH RISPERDAL D.25MG TAB 6661935 08/28/2006 IN THE MORNING AND TWO VASSEL, JENNIFER Qty: 90 1176957 TABLETS EVERY DAY AT 1PM \$292.23 MHS TAKE ONE TABLET BY MOUTH KING-RISPERDAL D.25MG TAB 6661935 09/25/2006 IN THE MORNING AND TWO VASSEL, JENNIFER Qty: 90 1181343 TABLETS EVERY DAY AT 1PM \$4.91 MHS TAKE ONE TABLET BY MOUTH KING-CLONIDINE 0.2MG TAB 6551936 08/28/2006 VASSEL, JENNIFER AT BEDTIME **Cty: 30** 1176958 \$4.91 KING MHS TAKE ONE TABLET BY MOUTH 6661935 CLONIDINE 0.2MG TAB 09/25/2006 VASSEL, JENNIFER AT BEDTIME Qty: 30 1181341 \$113.56 MHS TAKE ONE CAPSULE BY KING-STRATTERA 25MG CAP 5661937 09/01/2006 VASSEL, JENNIFER MOUTH EVERY DAY 1176959 Qty : 30 \$113.56 TAKE ONE CAPSULE BY KING-MHS STRATTERA 25MG CAP 6661937 09/27/2006 VASSEL, JENNIFER MOUTH EVERY DAY Qty: 30 1181342 MHS \$388.97 TAKE ONE TABLET BY MOUTH KING-RISPERDAL 0.25MG TAB 10/25/2006 6665041

IN THE MORNING AND 2 AT

NOON AND 1 AT 5PM

VASSEL, JENNIFER

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Case: 12-3671

Docume Wal-Mart Pharmacy 10-34972/19/2013 HIPAA Designated Record Set

Pages: 80 428 WALTON DRIVE PLYMOUTH WI-53073

Report Date: 07/25/2012 FROM 01/01/1997 TO 07/25/2012

| Fill Date | Rx # Fill ID | Drug Name Qty | SIG | Physician | Ins. | Price |
|------------|--------------------|----------------------------------|-----------------------------------------------------------------------------------------|---------------------------------------------|------|-----------------|
| 10/25/2006 | 6665039 1186028 | CLONIDINE 0.1MG TAB Qty: 30 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING AND SPM | KING- VASSEL,JENNIFER | MHS | \$4.90 |
| 10/25/2006 | 6665040 1186029 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | KING- VASSEL, JENNIFER | MHS | \$6.05 |
| 10/25/2006 | 6665042 1186030 | STRATTERA 25MG CAP Qty : 30 | TAKE ONE CAPSULE BY MOUTH EVERY DAY | KING- VASSEL, JENNIFER | MHS | \$113.56 |
| 11/20/2006 | 6666347 1189608 | STRATTERA 25MG CAP Qty : 30 | TAKE ONE CAPSULE BY MOUTH EVERY DAY | KING- VASSEL, JENNIFER | MHS | \$113.56 |
| 12/16/2006 | 6666347 1194304 | STRATTERA 25MG CAP Qty : 30 | TAKE ONE CAPSULE BY MOUTH EVERY DAY | KING- VASSEL, JENNIFER | MHS | \$113.56 |
| 11/19/2006 | 6666348 1189609 | RISPERDAL 0.25MG TAB Qty: 120 | TAKE ONE TABLET BY MOUTH IN THE MORNING, TWO TABS AT NOON, AND ONE TAB AT 4PM. | KING- | MHS | \$388.97 |
| 2/15/2006 | 6666348 1194307 | RISPERDAL 0.25MG TAB Qty: 120 | TAKE ONE TABLET BY MOUTH IN THE MORNING, TWO TABS AT NOON, AND ONE TAB AT 4PM. | KING- VASSEL, JENNIFER | MHS | \$388.97 |
| 1/19/2006 | 6666349 1189610 | CLONIDINE 0.1MG TAB Qty: 30 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING,AND ONE-HALF TAB AT NOON. | KING- VASSEL,JENNIFER | MHS | \$4,90 |
| 2/15/2006 | 6666349 1194305 | CLONIDINE 0.1MG TAB Qty: 30 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, AND ONE-HALF TAB AT NOON. | KING- VASSEL,JENNIFER | MHS | \$4.90 |
| 1/19/2006 | 6666350 1189612 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | KING- VASSEL,JENNIFER | MHS | \$6.05 |
| 2/15/2006 | 6666350 1194306 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | | MHS | \$ 6.05 |
| 1/17/2006 | 6666352 1189620 | SERTRALINE 25MG TAB Qty: 4 | TAKE ONE-HALF TABLET BY MOUTH EVERY MORNING FOR 7 DAYS. THEN UP TO 25 MG | KING- | MHS | \$10.15 |
| 1/17/2006 | 6666353 1189627 | SERTRALINE 50MG TAB Qty: 14 | TAKE ONE-HALF TABLET BY | KING- VASSEL,JENNIFER | MHS | \$30.51 |
| 2/18/2006 | 6666353 1194642 | SERTRALINE SOMG TAB Qty: 14 | TAKE ONE-HALF TABLET BY | KING- VASSEL, JENNIFER | MHS | \$30.51 |
| 1/11/2007 | 6668729 1196759 | STRATTERA 25MG CAP Qty : 30 | TAKE ONE CAPSULE BY | KING- VASSEL, JENNIFER | MWI | \$118.57 |
| 2/12/2007 | 6668729 1204013 | STRATTERA 25MG CAP Qty: 30 | TAKE ONE CAPSULE BY | KING- VASSEL, JENNIFER | MWI | \$118.57 |
| 3/05/2007 | 6668729 1207558 | STRATTERA 25MG CAP Qly: 30 | TAKE ONE CAPSULE BY | KING- | MWI | \$118.57 |
| /11/2007 | 6668732 1196760 | ZOLOFT 50MG TAB Qty: 15 | TAKE ONE-HALF TABLET BY | VASSEL, JENNIFER KING- | MWI | \$40.12 |
| /12/2007 | 6668732 1204017 | ZOLOFT 50MG TAB Qty: 15 | TAKE ONE-HALF TABLET BY | VASSEL,JENNIFER KING- VASSEL,JENNIFER | MWI | \$ 43.75 |

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Connexus Pharmacy System

Docume Walker Pharmacy 1303492/19/2013

HIPAA Designated Record Set

Page MALEON DRIVE PLYMOUTH WI-53073

Report Date: 07/25/2012 : 12-3671 FROM 01/01/1997 TO 07/25/2012

| Fili Date | Rx # F/II ID | Drug Name Qty | SIG | Physician | Ins. | Price |
|------------|--------------------|----------------------------------|-----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|----------------|
| 01/09/2007 | 6668730 1198269 | CLONIDINE 0.1MG TAB Qty: 45 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, AT NOON AND 5 PM | KING- VASSEL, JENNIFER | MWI | \$ 5.50 |
| 02/10/2007 | 5668730 1203819 | CLONIDINE 0.1MG TAB Qty: 45 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, AT NOON AND 5 PM | KING- VASSEL,JENNJFER | MWI | \$ 5.50 |
| 01/09/2007 | 6668731 1196762 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | KING- VASSEL, JENNIFER | MWI | \$3.50 |
| 01/09/2007 | 6668733 1196763 | RISPERDAL 0.25MG TAB Qty: 120 | TAKE ONE TABLET BY MOUTH IN THE MORNING, TWO TABLETS AT NOON AND ONE TABLET AT 4 PM. | THE RESERVE OF THE PROPERTY OF THE PARTY OF | MWI | \$400.4 |
| 02/12/2007 | 6658733 1204014 | RISPERDAL 0.25MG TAB Qty: 120 | TAKE ONE TABLET BY MOUTH IN THE MORNING, TWO TABLETS AT NOON AND ONE TABLET AT 4 PM. | KING- VASSEL, JENNIFER | MWI | \$400.40 |
| 03/05/2007 | 6668733 1207556 | RISPERDAL 0,25MG TAB Qty: 120 | TAKE ONE TABLET BY MOUTH IN THE MORNING, TWO TABLETS AT NOON AND ONE TABLET AT 4 PM. | KING- VASSEL, JENNIFER | MWI | \$400.46 |
| 3/05/2007 | 6671333 1207557 | SERTRALINE SOMG TAB Qty: 15 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING | KING- VASSEL, JENNIFER | MWI | \$8.88 |
| 14/06/2007 | 6671333 1213332 | SERTRALINE SOMG TAB Qty: 15 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING | KING- VASSEL, JENNIFER | MHS | \$32.55 |
| 5/20/2007 | 6671333 1220924 | SERTRALINE SOMG TAB Qty: 15 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING | KING- VASSEL, JENNIFER | MH5 | \$32.55 |
| 4/06/2007 | 6671335 1213330 | STRATTERA 25MG CAP Qty : 30 | TAKE ONE CAPSULE BY MOUTH EVERY DAY | KING- VASSEL JENNIFFR | MHS | \$113.56 |
| | | | | | | |
| 4/06/2007 | 6671334 1213331 | RISPERDAL 0.25MG TAB Qty: 120 | TAKE ONE TABLET BY MOUTH IN THE MORNING, TWO TABLETS AT NOON AND ONE TABLET AT 4 PM | KING- VASSEL, JENNIFER | MHS | \$388.97 |
| 3/05/2007 | 5671336 1207561 | CLONIDINE D.1MG TAB Qty: 45 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, AT NOON AND AT 5 PM. | KING- VASSEL,JENNIFER | MWI | \$5.50 |
| 4/06/2007 | 6671336 1213328 | CLONIDINE 0.1MG TAB Qty: 45 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, AT NOON AND AT 5 PM. | KING- VASSEL,JENNIFER | MHS | \$4.50 |
| 2/12/2007 | 6671337 1204011 | CLONIDINE 0.2MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | KING- VASSEL,JENNIFER | MW1 | \$3,50 |
| 3/05/2007 | 6671337 1207554 | CLONIDINE 0.2MG TAB Qty : 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | | MWI | \$3.50 |
| 4/06/2007 | 6671337 1213329 | CLONIDINE 0.2MG TAB Oty: 30 | TAKE ONE TABLET BY MOUTH | KING- VASSEL JENNIEER | MHS | \$4.91 |

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Case: 12-3671
Report Date: 07/25/2012

Docume Wal-Hait Pharmacy: System 2/19/2013
HIPAA Designated Record Set

Pages: 80 PLYMOUTH WI-53073

FROM 01/01/1997 TO 07/25/2012

| | Rx # Fill ID | Drug Name Qty | SIG | Physician | Ins. | Price |
|--------------------------------------------------|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------|------------|------------------------------|
| 04/21/2007 | 6675520 1215960 | SEROQUEL 100MG TAB Qty: 30 | TAKE ONE TABLET BY MOUTH AT BEDTIME | KING- VASSEL,JENNIFER | MHS | \$100.79 |
| 05/09/2007 | 6676576 1219116 | SEROQUEL 100MG TAB Qty : 60 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, AND ONE & ONE-HALF TABS AT BEDTIME | KING- VASSEL, JENNIFER | MHS | \$199.59 |
| 05/10/2007 | 6676612 1219235 | STRATTERA 25MG CAP Qty: 30 | TAKE ONE CAPSULE BY MOUTH IN THE MORNING | KING- VASSEL, JENNIFER | MHS | \$113.56 |
| 05/10/2007 | 6676613 1219250 | CLONIDINE 0.1MG TAB Qty: 40 | TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, ONE-QUARTER TABLET AT NOON AND ONE-HALF TABLET AT 5 PM. | KING- VASSEL, JENNIFER | MHS | \$4.22 |
| 06/20/2007 | 6679033 1226408 | STRATTERA 40MG CAP Qty: 30 | TAKE ONE CAPSULE BY MOUTH IN THE MORNING | KING- VASSEL, JENNIFER | MHS | \$129.19 |
| 07/16/2007 | 6679033 1231502 | STRATTERA 40MG CAP Qty: 30 | TAKE ONE CAPSULE BY MOUTH IN THE MORNING | KING- | MHS | \$129.19 |
| | | | | | | |
| | | | | | | |
| 7/19/2007 | 6680928 1232024 | CLONIDINE 0.1MG TAB | BACK COLL BALL SOLVER CARE DATE OF THE PARTY | KING- | MHS | \$4.50 |
| | 1232024 | Qty: 45 | MOUTH IN THE MORNING, NOON, AND 4PM | KING- VASSEL,JENNIFER | MHS | \$4.50 |
| 8/13/2007 | | | MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY | 1010177 | MHS | \$4.50 \$4.50 |
| 8/13/2007 7/19/2007 | 1232024 6580928 1236181 6680930 1232025 | Qty: 45 CLONIDINE 0.1MG TAB | MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY | VASSEL, JENNIFER KING- VASSEL, JENNIFER KING- | | |
| 8/13/2007 7/19/2007 8/15/2007 | 1232024 6580928 1236181 6680930 1232025 6680930 1236184 | Qty: 45 CLONIDINE 0.1MG TAB Qty: 45 SERTRALINE 50MG TAB Qty: 15 SERTRALINE 50MG TAB Qty: 15 | MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING TAKE ONE-HALF TABLET BY | VASSEL, JENNIFER KING- VASSEL, JENNIFER KING- VASSEL, JENNIFER KING- KING- | MHS | \$4.50 |
| 8/13/2007 7/19/2007 8/15/2007 7/19/2007 | 1232024 6580928 1236181 6680930 1232025 6680930 | Qty: 45 CLONIDINE 0.1MG TAB Qty: 45 SERTRALINE 50MG TAB Qty: 15 SERTRALINE 50MG TAB | MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING TAKE ONE TABLET BY MOUTH | VASSEL, JENNIFER KJNG- VASSEL, JENNIFER KING- VASSEL, JENNIFER KING- VASSEL, JENNIFER KING- VASSEL, JENNIFER KING- | MHS MHS | \$4.50 \$32.55 |
| 8/13/2007 7/19/2007 8/15/2007 | 1232024 6680928 1236181 6680930 1232025 6680930 1236184 6680929 | Qty: 45 CLONIDINE 0.1MG TAB Qty: 45 SERTRALINE 50MG TAB Qty: 15 SERTRALINE 50MG TAB Qty: 15 CLONIDINE 0.2MG TAB | MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING, NOON, AND 4PM TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING TAKE ONE-HALF TABLET BY MOUTH IN THE MORNING TAKE ONE TABLET BY MOUTH AT BEDTIME TAKE ONE TABLET BY MOUTH | VASSEL, JENNIFER KJNG- VASSEL, JENNIFER KING- VASSEL, JENNIFER KING- VASSEL, JENNIFER KING- VASSEL, JENNIFER | MHS MHS | \$4.50 \$32.55 \$32.55 |

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Wisconsin Forward Health Medicaid and Badger Care 19/2013 Pages: 80 Claims History Report

| Case PE | R NAME: E | ; , | | MEMBER ID: | | |
|---------------------|-----------|------------------------------|---------------|------------|-----------|--------|
| 000 | 9/11/2006 | | | | | |
| -00236-JPS | 9/11/2006 | • | | | | |
| 000 | 9/19/2006 | | | | | |
| 07 <u>T</u> | 1/9/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | | 1/14/2007 | 5.50 |
| 07 Filed 08/20/127 | 1/9/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | | 1/14/2007 | 3.50 |
| 070/ | 1/9/2007 | WAL-MART PHARMACY 10-3497 | RISPERDAL | | 1/14/2007 | 400.46 |
| 007 F | 1/11/2007 | WAL-MART PHARMACY 10-3497 | STRATTERA | | 1/14/2007 | 118.57 |
| Page | 1/11/2007 | WAL-MART PHARMACY 10-3497 | ZOLOFT | | 1/14/2007 | 40.12 |
| 0월 3 | 1/22/2007 | | | | | |
| 07 | 2/10/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | | 2/18/2007 | 5.50 |
| om. | 2/12/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | * | 2/18/2007 | 3.50 |
| ocument 4 | 2/12/2007 | | | | | |
| ဂ 07ယ | 2/12/2007 | WAL-MART PHARMACY 10-3497 | RISPERDAL | | 2/18/2007 | 400.46 |
| 07 | 2/12/2007 | WAL-MART PHARMACY 10-3497 | STRATTERA | | 2/18/2007 | 118.57 |
| 07 | 2/12/2007 | WAL-MART PHARMACY 10-3497 | ZOLOFT | | 2/18/2007 | 43.75 |

Watson Short Appendix

Page 37

Case: Wis2678in ForocardHeald3Medicafdland Badge2C42e Plusages: 80 Claims History Report

| MEMB) | ER NAME: | B , N | MEMBER | and: | |
|----------|----------|------------------------------|----------------|-----------|-------|
| 3/5/2007 | 3/5/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | 3/11/2007 | 3.5 |
| 3/5/2007 | 3/5/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | 3/11/2007 | 5.5 |
| 3/5/2007 | 3/5/2007 | Sill. | | | |
| 3/5/2007 | 3/5/2007 | WAL-MART PHARMACY 10-3497 | RISPERDAL | 3/11/2007 | 400.4 |
| 3/5/2007 | 3/5/2007 | WAL-MART PHARMACY 10-3497 | SERTRALINE HCL | 3/11/2007 | 8.8 |
| 3/5/2007 | 3/5/2007 | WAL-MART PHARMACY 10-3497 | STRATTERA | 3/11/2007 | 118.5 |
| 3/6/2007 | 3/6/2007 | | | | |
| 3/6/2007 | 3/6/2007 | 3 | | | |
| 3/6/2007 | 3/6/2007 | | | | |
| 3/6/2007 | 3/6/2007 | | | | |
| 3/6/2007 | 3/6/2007 | | | | |
| 3/6/2007 | 3/6/2007 | | | | |
| 3/6/2007 | 3/6/2007 | | | | |
| | | | | | |

Watson Short Appendix Page 6 of 47

Case: 1 wisconsin Forward Health Medicaid and Blagger Care Phages: 80 Claims History Report

| | R NAME: B | 9. | MEMBER ID: | |
|------------------------|-----------|------------------------------|------------------------------|---------------|
| 9/11/2006 | 9/11/2006 | MARCHI JAIME | PERIODIC ORAL EVALUATION | 9/17/2006 15 |
| 9/11/2006 | 9/11/2006 | MÂRCHI JAIME K DDS | TOPICAL APP FLUORIDE CHILD | 9/17/2006 12 |
| 9/19/2006 | 9/19/2006 | MARCHI JAIME K DDS | FIXED BILAT SPACE MAINTAINER | 10/8/2006 163 |
| 1/0/2007 | 1/9/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | 1/14/2007 5 |
| 1/9/2007 | 1/9/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINÉ HCL . | 1/14/2007 3 |
| 2 1/9/2007 | 1/9/2007 | WAL-MART PHARMACY 10-3497 | RISPERDAL | 1/14/2007 400 |
| 1/11/2007 | 1/11/2007 | WAL-MART PHARMACY 10-3497 | STRATTERA | 1/14/2007 118 |
| 2 2 1/11/2007 | 1/11/2007 | WAL-MART PHARMACY 10-3497 | ZOLOFT | 1/14/2007 40 |
| <u>9</u> 1/22/2007 | 1/22/2007 | WAL-MART PHARMACY 10-3497 | NYSTATIN | 1/26/2007 22 |
| 2/10/2007 | 2/10/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | 2/18/2007 5 |
| 2/12/2007 2/12/2007 | 2/12/2007 | WAL-MART PHARMACY 10-3497 | CLONIDINE HCL | 2/18/2007 3 |
| 2/12/2007 | 2/12/2007 | WAL-MART PHARMACY 10-3497 | NYSTATIN | 2/18/2007 22 |
| 2/12/2007 | 2/12/2007 | WAL-MART PHARMACY 10-3497 | RISPERDAL | 2/18/2007 400 |
| 2/12/2007 | 2/12/2007 | WAL-MART PHARMACY 10-3497 | STRATTERA | 2/18/2007 118 |
| 2/12/2007 | 2/12/2007 | WAL-MART PHARMACY 10-3497 | ZOLOFT | 2/18/2007 43 |

Watson Short Appendix

Case: 12-367 Viscopsin Forevard Sealth Medicaid and Budger Care Pluges: 80 Claims History Report

Date of Report: 07/16/2012

THIS IS NOT A BILL

| MEMBER NAME: B | IBER ID: |
|----------------|----------|
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CLAIMS SERVICE FROM: 02/01/2001 THROUGH 07/13/2012 DATE

DATE OF BIRTH: /2000

This is a report that you requested of your confidential health care services, such as mental health and family planning, processed by the State of Wisconsin. If you need additional information about this report or you see a service that you think you did not receive, please contact Member Services at 1-800-362-3002.

| Service From | Service To | Service Performed | Diagnosis Description | Date Paid | Detail Paid Amount |
|--------------|------------|-----------------------|---------------------------------|-----------|-----------------------|
| | | | | | |
| /5/2007 | 2/5/2007 | MEDICATION MANAGEMENT | ATTN DEFICIT W HYPERACTIVITY | 4/8/2007 | 63.36 |
| | | | | | |
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Case: 12-3671 Document: 23 Filed: 02/19/2013

Pages: 80

Medication Management:

| Patient: (First) | Date: 2-5-07 | |
|--------------------------------------------------------------------------------------------|--------------------------------------------------|------------------|
| Interim Data: pt sweet ho Los of an oring un le freil well how were note | Lee to show and a lee to the free free to have a | nee |
| Compliant with medication?: Weight | Min Com cats a | hes T |
| Any complaints of side effects?: No Yes | | |
| Any recent suicidal/homicidal ideation?: No Yes Significant mental status exam findings: | | |
| Assessment: olay belle | everele. | 0 4 ' |
| | | x 6+ |
| Plan: Pat Shotten 2 Clarice Property | 38 / po gu bix id men | -3 174 |
| Follow up: 1 mo. mo. 3 mo. | 25% regre 1 | al |
| annifor Vind Mo | | 0.0.0. |
| ennifer King-Vassel, MD | * | 020 |

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Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by

| Drug | Indication (diagnosis) | FDA Approval | DRUGDEX Support for Off-Label Use | DRUGDEX Recommendation Level | | | |
|---------------------|--------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------|--------------------------------------|------------------------------------|--|--|--|
| Key: | White Background: Medically Accepted Indication | | | | | | |
| <u> </u> | Orange Background: Pediatric Indicat | | orted by DRUGDE | X | | | |
| | Red Background: No Pediatric FDA Ap | | | | | | |
| | | • | | | | | |
| Abilify (Aripiprazo | ole) - Antipsychotic | | | | | | |
| <u> </u> | Autistic disorder-Psychomotor agitation | Yes (6-17) | | | | | |
| | Bipolar I Disorder - Adjunctive therapy with | 103 (0 11) | | | | | |
| | lithium or valproate for Acute Manic or Mixed | | | | | | |
| | Episodes | Yes (for 10 yrs old and up) | | | | | |
| | | Yes (for 10-17 years old re | | | | | |
| | Episodes | acute therapy) | | | | | |
| | Schizophrenia | Yes (for 13-17 years old) | | | | | |
| Adderall (ampheta | amine/dextroamphetamine) - Central Nervous System Agen | nt; CNS Stimulant | | | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 3 years old and up re: [immediate-release] and 6 years old and up re: [extended-release] drug | | | | | |
| | Narcolepsy | Yes (for 6 years old and up (immediate release only) | | | | | |
| Ambien (zolipiden | n) - nonbartiturate Hypnotic | | | | | | |
| | Insomnia, Short-term treatment | No | | Class III | | | |
| Anafranil (clomi | ipramine) - Antidepressant; Antidepressant, Tricyclic; Centr | | | | | | |
| (Cloud | | T. | | | | | |
| | Obsessive-Compulsive Disorder | Yes (for 10 years and up) | | CI TI | | | |
| A 4.* | Depression | | | Class IIb | | | |
| Auvan (lorazepam) |) - Antianxiety, Anticonvulsant, Benxodiazepine, Short or In | termediate Acting, Skeletal Mus | lgel Relaxant. | | | | |
| | Anxiety | Yes, oral only, 12 years and older | | | | | |
| | Chemotherapy-induced nausea and vomiting; Prophylaxis | No | Class IIa | | | | |
| | Insomnia, due to anxiety or situational stress | Yes | | | | | |
| | Seizure | No | Class IIa | | | | |
| | Status epilepticus | No | Class IIa | | | | |
| | Premedication for anesthetic procedure | No | | Class IIb | | | |
| | Sedation | No | | Class IIb | | | |
| | Seizure, drug-induced; Prophylaxis | No | | Class IIb | | | |
| Buspar (buspirone) |) - Antianxiety, Azaspirodeconedione | | | | | | |
| | Anxiety | No | | Class III | | | |
| | Autistic disorder | No | | Class IIb | | | |
| | Behavioral syndrome | No | | Class IIb | | | |
| | Pervasive developmental disorder | No | | Class IIb | | | |
| Celexa (citalopram |) - Antidepressant, Serotonin Reuptake Inhibitor | | | | | | |
| | Depression | No | | None | | | |
| | | No | | Class IIb | | | |
| | Obsessive-compulsive disorder | 1110 | | | | | |
| | Obsessive-compulsive disorder Panic disorder | No | | Class IIb | | | |

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by

| Drug | Indication (diagnosis) | FDA Approval | DRUGDEX Support for Off-Label Use | DRUGDEX Recommendation Level |
|-------------------------------|-----------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------|
| <u>Clozaril</u> (clozapine) – | Antipsychotic; Dibenzodiazepine | | | |
| | Bipolar I Disorder | No | | Class IIb |
| | | | | cited, with no |
| | Schizophrenia, Treatment Resistant | No | | recommendation level |
| Concerta (methylpher | nidate) - Amphetamine Related; Central Nervous System | n Agent; CNS Stimulant | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years old to 12 years old) | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years old and up) re ConcertaR | | |
| | Autistic Disorder | No | | Class IIb |
| | Impaired Cognition - inding related to | | | |
| | coordination/ in coordination | No | | Class IIb |
| | Schizophrenia | No | | Class IIII |
| Complete | Traumatic Brain Injury | No | | Class IIb |
| Cymbalta (duloxetine | e) - Antidepressant; Central Nervous System Agent; Net | ropathic Pain Agent; Serotonin/I | Norepinephrine Reuptake | Inhibitor |
| <u>Dalmane</u> (flurazepam) | - Benzodiazepine, Long Acting, Hypnotic | | | |
| | Insomnia | Yes, 15 years and older | | |
| Depakote/Depake | <u>ne</u> (valproate/valproic acid) – Anticonvulsant; Antimigra | aine; Valproic Acid (class) | | |
| | Absence Seizure, Simple and Complex | Yes (10 years and older) | | |
| | Complex Partial Epileptic Seizure | Yes (10 years and older) | | |
| | Seizure, Multiple sezure types; Adjunct | Yes (10 years and older) | | |
| | Bipolor I disorder, Maintenance | No | | Class IIb |
| | Bipolor II disorder, Maintenance | No | | Class IIb |
| | Chorea | No | | Class IIb |
| | Febrile Seizure Mania | No No | | Class IIb |
| | Manic bipolar I disorder | No | | Class IIII Class IIb |
| | Mental Disorder - Mood Disorder | No | | Class IIb |
| | Migraine; Prophylaxis | No | | Class IIb |
| | Status epilepticus | No | | Class IIb |
| | West syndrome | No | | Class IIb |
| <u>Desyrel</u> (trazodone) - | Antidepressant; Triazolopyridine | | | |
| | Migraine, Pediatric; Prophylaxis | No | | Class III |
| <u>Dexedrine</u> (dextroam | phetamine) - Amphetamine (class); CNS Stimulant | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 3 years to 16 years old (immediate-release) and age 6 years to 16 years old (sustained-release)) | | |
| | Narcolepsy | Yes (for 6 years old and up) | | |
| Effexor (venlafaxine) - | - Antidepressant; Antidepressant, Bicyclic; Phenethylan | nine (class); Serotonin/ Norepine | phrine Reuptake Inhibitor | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | No | | Class IIb |
| | Generalized Anxiety Disorder | No | | Class IIb |
| | Major Depressive Disorder | No | | Class IIb |
| | Social Phobia | No | | Class IIb |
| Focalin (dexmethylphe | enidate) - Amphetamine Related; CNS Stimulant | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years and older) | | |
| Geodon (ziprasidone) | - Antipsychotic; Benzisothiazoyl | | | |

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by

| Drug | Indication (diagnosis) | FDA Approval | DRUGDEX Support for Off-Label Use | DRUGDEX Recommendation Level |
|------------------------------|-------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------|-----------------------------------------------|------------------------------------|
| Haldol (haloperidol) - | Antipsychotic; Butyrophenone; Dopamine Antagonis | | | |
| | | | It does not ap | near the |
| | Gilles de la Tourette's syndrome | Yes (for 3 years old and up) | | |
| | Hyperactive Behavior, (Short-term treatment) after failure to respond to non-antipsychotic medication and psychotherapy | Yes (for 3 years old and up) | injectible form (decanoate) is approved for a | FDA |
| | Problematic Behavior in Children (Severe), With failure to respond non-antipsychotic medication or psychotherapy | Yes (for 3 years old and up) | use, nor is it s | upported by |
| | Psychotic Disorder | Yes (for 3 years old and up but ORAL formulations only) | | , |
| | Schizophrenia | Yes (for 3 years old and up but ORAL formulations only) | | |
| | Agitation | No | | Class IIb |
| | Migraine | No | | Class III |
| Invega (paliperidone) | - Antipsychotic; Benzisoxazole | | | |
| | n) -antianxiety, Anticonvulsant, Bensodiazepine, Short of | or Intermediate Acting | | |
| , K** | Seizure | Yes, upt to 10 years or up to 30 kg | | |
| | Gilles de la Tourette's syndrome | No | | Class IIb |
| | Hyperexplexia | No | | Class IIb |
| | Nocturnal epilepsy | No | | Class IIb |
| | Panic disorder | No | | Class IIb |
| | Status epilepticus | No | | Class IIb |
| Lamictal (lamotrigine | e) - Anticonvulsant; Phenyltriazine | | | |
| | Convulsions in the newborn, Intractable | No | Class IIa | |
| | Epilepsy, Refractory | No | Class IIa | |
| | Lennox-Gastaut syndrome; Adjunct | yes (2 years and older) | | |
| | Partial seizure, Adjunct or monotherapy | yes (13 years and older, extended-release only; 2 years and older, chewable dispersible | | |
| | Tonic-clonic seizure, Primary generalized; Adjunct | yes (2 years and older) | | |
| | Absence seizure; Adjunct | No | | Class IIb |
| | Bipolar Disorder, Depressed Phase | No | | Class IIb |
| | Infantile neuronal ceroid lipofuscinosis | No | | Class IIb |
| | Juvenile myoclonic epilepsy | No | | Class III |
| | Paroxysmal choreoathetosis, Paroxysmal | No | | Class IIb |
| | Rett's disorder | No | | Class IIb |
| | Status epilepticus West syndrome | No No | | Class IIb Class IIb |
| Lexapro (escitalopram) | - Antianxiety, Antidepressant, Serotonin Reuptake Inhib | | | Class III |
| | | Yes (for 12 years old and | | |
| T . 1 | Major Depressive Disorder | up) | | |
| | epoxide/amitriptyline) - Tricyclic Antidepressant/Benzoo | flazepine Combination | | |
| - | - Nonbarbiturate Hypnotic | | | |
| LUVOX (fluvoxamine) - | Antidepressant; Central Nervous System Agent; Serote | <u> </u> | | |
| | Obsessive-Compulsive Disorder | Yes (for 8 years old and up and immediate release formula only) | | |
| | IODSessive-Compulsive Disorder | | | |

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by

| Drug | Indication (diagnosis) | FDA Approval | DRUGDEX Support for Off-Label Use | DRUGDEX Recommendation Level |
|----------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|------------------------------------|
| | - Antipsychotic; Phenothiazine; Piperidine | 1 DA Approvai | 101 OII LUBEI 030 | Level |
| (* * * * * * * * * * * * * * * * * * * | Schizophrenia, Refractory | Yes | | |
| | Behavioral Syndrome | No | | Class III |
| Moban (molindone) - a | antipsychotic, Dihydroindolone | | | |
| <u> </u> | Schizophrenia | Yes, 12 years and older | | |
| | Aggressive behavior, In children | No | | Class IIb |
| Neurontin (gabapenti | | 110 | | Class 110 |
| (gabapenti | | \\ \(\O_1 \do 1 \O_2 \do 1 \ | | |
| | Partial seizure; Adjunct Complex Regional Pain Syndrome, Type 1 | Yes (3- 12 years old) | | Class IIb |
| | Neuropathic Pain | No | | Class IIb |
| | Partial Seizure | No | | Class IIb |
| | Partial Seizure, Refractory | No | | Class III |
| | Phantom Limb Syndrome | No | | Class IIb |
| Dean / Land | | | | - LADO 110 |
| <u>Jrap</u> (pimozide) - Ant | tipsychotic; Diphenylbutylpiperidine; Dopamine Antago | 1 | | |
| | Gilles de la Tourette's syndrome | Yes (12 years and older) | | |
| | Anorexia Nervosa | No | | Class III |
| Paxil (paroxetine) - Ar | ntidepressant; Central Nervous System Agent; Serotonir | Reuptake Inhibitor | | |
| | Panic disorder | No | | Class IIb |
| | Trichotillomania | No | | Class IIb |
| Prozac (fluoxetine) - A | Antidepressant; Central Nervous System Agent; Serotoni Major Depressive Disorder | rin Reuptake Inhibitor Yes (for 8 years old and up) | | |
| | Obsessive-Compulsive Disorder | Yes (for 7 years old and up | | |
| | Anxiety Disorder of Childhood | No | | Class IIb |
| | Autistic disorder | No | | None |
| | Bulimia nervosa | No | | Class IIb |
| | Vasovagal syncope; Prophylaxis | No | | Class III |
| Restoril (temazepam) - | - Antianxiety, Bensodiazepine, Short or Intermediate Ad | cting, Hypnotic | | |
| Ritalin (methylphenida | ate) - Amphetamine Related; Central Nervous System A | Agent; CNS Stimulant | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years to 12 years old)(exteded release) Yes (for 6 years old and | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | up)(immediate release) | | |
| | | Yes (for 6 years and up, | | |
| | Narcolepsy Autiotic disorder | and Ritalin(R) -SR only) | | Class III |
| | Autistic disorder | No | | Class IIb |
| | Finding related to coordination / incoordination - | | | |
| | Impaired cognition | No | | Class IIb |
| | Schizophrenia | No No | | Class III |
| Diamondal | Traumatic Brain Injury | No | | Class IIb |
| AISPETUAL (risperidon | e) - Antipsychotic; Benzisoxazole | | | |
| | Autistic Disorder – Irritability | Yes (for 5 years old and up) Yes (for 10 years old and | | |
| | Bipolar I Disorder | up) Yes (for 13 years old and | | |
| | I | up, ORALLY) | | |
| | Schizophrenia | up; 0:0:1=1) | | |
| | Schizophrenia Behavioral syndrome - Mental retardation | No No | | Class IIb |
| | | | | Class IIb Class IIb |

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by

| Drug | Indication (diagnosis) | FDA Approval | DRUGDEX Support for Off-Label Use | DRUGDEX Recommendation Level |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| $\underline{Rozerem}$ (ramelte | eon) - Melatonin Receptor Agonist, Nanbarbiturate Hypnotic | | | |
| Seroquel (QUET | TAPINE) - Antipsychotic; Dibenzothiazepine | | | |
| | Bipolar disorder, maintenance | Yes, 10-17 regular release only (12/4/09) | | |
| | Manic bipolar I disorder | Yes, 10-17 regular release only (12/4/09) | | |
| | Schizophrenia | Yes 13-17, regular release only (12/4/09) | | |
| | Gilles de la Tourette's syndrome | No | | Class IIb |
| Sinequan (doxep | in) - Antianxiety Antidepressant; Antidepressant, Tricyclic; | Antiulcer Dermatological Agent | | |
| | Alcoholism - Anxiety – Depression | Yes (for 12 years old and up) | | |
| | | Yes (for 12 years old and | | |
| | Anxiety - Depression Anxiety - Depression - Psychoneurotic | yes (for 12 years old and | | |
| | personality disorder Pruritus (Moderate), Due to atopic dermatitis or | up) | | |
| | lichen simplex chronicus | No | | Class IIb |
| Sonata (zalepl | on) - Nonbarbiturate Hypnotic | | | |
| Strattera (atomo | exetine) - Central Nervous System Agent; Norepinephrine Ro | euptake Inhibitor | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years old and up) | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) - Social phobia | No | | Class IIb |
| Symbyax (fluoxe | etine hydrochloride/olanzapine) - Antidepressant; Antipsycho | otic | | |
| Tegretol (carbar | nazepine) - Anticonvulsant; Antimanic; Dibenzazepine Carb | oxamide; Neuropathic Pain Agen | t | |
| | | 1 | | |
| | | | | |
| | Epilepsy, Partial, Generalized, and Mixed types | Yes | | |
| | Apraxia | Yes | | None |
| | Apraxia Chorea | Yes | | Class IIb |
| | Apraxia Chorea Migraine; Prophylaxis | Yes | | Class IIb Class IIb |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia | Yes | | Class IIb Class IIb Class IIb |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General | Yes | | Class IIb Class IIb Class IIb Class IIb |
| Tofranil (imines | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome | | | Class IIb Class IIb Class IIb |
| Tofranil (imipra | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I | Enuresis Agent | | Class IIb Class IIb Class IIb Class IIb |
| Tofranil (imipra | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I | | | Class IIb Class IIb Class IIb Class IIb |
| Tofranil (imipra | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), | Enuresis Agent Yes (for 6 years old and up) | | Class IIb Class IIb Class IIb Class IIb |
| Tofranil (imipra | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I | Enuresis Agent | | Class IIb Class IIb Class IIb Class IIb Class IIb |
| Tofranil (imipra | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct | Enuresis Agent Yes (for 6 years old and up) No | | Class IIb Class IIb Class IIb Class IIb Class IIb Class IIb Class III |
| Tofranil (imipra | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood | Yes (for 6 years old and up) No No No No No | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III Class III |
| Tofranil (imipra | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania | Yes (for 6 years old and up) No No No No No No | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania Urinary incontinence | Yes (for 6 years old and up) No No No No No | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III Class III Class III Class III Class III Class III |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania | Yes (for 6 years old and up) No No No No No No | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania Urinary incontinence | Yes (for 6 years old and up) No No No No No No | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania Urinary incontinence mate) - anticonvulsant, Fructopyranose Sulfamate Lennox-Gastaut syndrome; Adjunct Partial seizure, Initial monotherapy | Enuresis Agent Yes (for 6 years old and up) No No No No No No Ves, 2 years and older Yes, 10 years and older | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania Urinary incontinence mate) - anticonvulsant, Fructopyranose Sulfamate Lennox-Gastaut syndrome; Adjunct Partial seizure, Initial monotherapy Partial seizure; Adjunct Tonic-clonic seizure, Primary generalized; | Enuresis Agent Yes (for 6 years old and up) No No No No No No Yes, 2 years and older Yes, 10 years and older Yes, 10 years and older | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania Urinary incontinence mate) - anticonvulsant, Fructopyranose Sulfamate Lennox-Gastaut syndrome; Adjunct Partial seizure, Initial monotherapy Partial seizure; Adjunct Tonic-clonic seizure, Primary generalized; Adjunct | Enuresis Agent Yes (for 6 years old and up) No No No No No No Ves, 2 years and older Yes, 10 years and older | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania Urinary incontinence mate) - anticonvulsant, Fructopyranose Sulfamate Lennox-Gastaut syndrome; Adjunct Partial seizure, Initial monotherapy Partial seizure; Adjunct Tonic-clonic seizure, Primary generalized; | Enuresis Agent Yes (for 6 years old and up) No No No No No No Yes, 2 years and older Yes, 10 years and older Yes, 10 years and older | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III |
| | Apraxia Chorea Migraine; Prophylaxis Myokymia Neuropathy, General Schwartz-Jampel syndrome mine) - Antidepressant; Antidepressant, Tricyclic; Urinary I Nocturnal enuresis Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type Depression Schizophrenia, Adjunct Separation Anxiety Disorder of Childhood Trichotillomania Urinary incontinence mate) - anticonvulsant, Fructopyranose Sulfamate Lennox-Gastaut syndrome; Adjunct Partial seizure, Initial monotherapy Partial seizure; Adjunct Tonic-clonic seizure, Primary generalized; Adjunct Tonic-clonic seizure, Primary generalized (initial | Enuresis Agent Yes (for 6 years old and up) No No No No No No Ves, 2 years and older Yes, 10 years and older Yes, 10 years and older Yes, 2 to 16 years old | | Class IIb Class IIb Class IIb Class IIb Class IIb Class III |

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications by

| Drug | Indication (diagnosis) | FDA Approval | DRUGDEX Support for Off-Label Use | DRUGDEX Recommendation Level |
|-----------------------|-------------------------------------------------------------|-----------------------------------------------|-----------------------------------|------------------------------------|
| | Status epilepticus | No | | Class IIb |
| | West syndrome | No | | Class IIb |
| Tranxene (cloraze | epate) - Antianxiety, Anticonfulsant, Benzodiazepine, Long | Acting | | |
| | Partial seizure; Adjunct | Yes, 9 years and older | | |
| | Epilepsy | No | | Class IIb |
| Trileptal (oxcarba | azepine) - Anticonvulsant; Dibenzazepine Carboxamide | | | |
| | Partial Seizure, monotherapy | Yes (for 4 years old and up) | | |
| | Partial seizure; Adjunct | Yes (for 2 years old and up) | | |
| Vyvanse (lisdexan | nfetamine) - Amphetamine (class); CNS Stimulant | | | |
| | Attention Deficit Hyperactivity Disorder (ADHD) | Yes (for 6 years old to 12 years) | | |
| Wellbutrin (bupi | ropion) - Aminoketone, Antidepressant, Smoking Cessation | Agent | | |
| | Attention deficit hyperactivity disorder | No | | None |
| Xanax (alprazolam |) - Antianxiety, Benzodiazepine, Short or Intermediate Acti | ng | | |
| Zoloft (sertraline) - | Antidepressant; Central Nervous System Agent; Serotonin | Reuptake Inhibitor | | |
| | Obsessive-Compulsive Disorder | Yes (6 years old and up) | | |
| | Anorexia nervosa | No | | Class III |
| | Generalized Anxiety Disorder | No | | Class IIb |
| | Major Depressive Disorder | No | | Class IIb |
| Zyprexa (olanzapi | ine) - Antipsychotic; Thienobenzodiazepine | | | |
| | Bipolar 1, Disorder, Acute Mixed or Manic Episodes | Yes (ages 13-17), oral only, approved 12/4/09 | | |
| | Schizophrenia | Yes (ages 13-17), oral only, approved 12/4/09 | | |
| | Schizophrenia, Refractory | No | | Class IIb |
| | Pervasive Developmental Disorder | No | | Class IIb |

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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 | | | |
|-------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|--|
| Α | ategory A evidence is based on data derived from: Meta-analyses of randomized controlled als with homogeneity with regard to the directions and degrees of results between individual udies. Multiple, well-done randomized clinical trials involving large numbers of patients. | | |
| В | 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 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 Ila | | 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. | |
| | 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. | |

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