

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v.

Case No. 11-CV-236-JPS

JENNIFER KING VASSEL,

Defendant.

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**JOINT FINAL PRETRIAL REPORT**

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*Relator*, Dr. Toby Tyler Watson (Dr. Watson), by his attorneys, James B. Gottstein of the Law Project for Psychiatric Rights and Rebecca L. Gietman of Gietman Law, and Defendant Jennifer King-Vassel now known as Jennifer King (Dr. King), by her attorneys Bradley S. Foley and Mark E. Larson of Gutglass Erickson Bonville & Larson, SC, hereby submit the following Joint Final Pretrial Report pursuant to this Court's September 11, 2013, Trial Scheduling Order, Document No. 100, and Civil L.R. 16(c)(1).<sup>1</sup>

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<sup>1</sup> Note from James B. Gottstein: Both sides have worked very hard in good faith to complete this report in time, but there was some misunderstanding about the *voir dire* questions and those Exhibits have placeholders that it is expected will at least be e-filed filed in time. Because of the three hour time difference, I had a grave concern that this needed to be done on the 26th in Alaska or risk not getting it in in time. This seemed unacceptable, especially because the Court is going to be closed on Thanksgiving and the Friday after. So, I made the call to file this with the expectation that Dr. King may have to file some supplementary material to complete this report (in addition to the *voir dire* questions). I have removed the e-signatures of Dr. King's attorneys because they haven't approved this in its final form, but they may decide to "ink" it for the Court's paper copy. I will have to supply my "inked" signature after the hard copy is filed.

**A. SUMMARY OF FACTS, CLAIMS, AND DEFENSES;**

This is an action under the False Claims Act, 31 U.S.C. §3729, *et seq.*, brought by Dr. Watson against Dr. King, on behalf of the United States Government<sup>2</sup> as *Relator*, on the grounds that Dr. King caused the presentment of false claims under 31 U.S.C. §3729(a)(1)(A) by writing psychotropic drug prescriptions to patients under the age of 18 that were not for a medically accepted indication as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) to wit: "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, 21, U.S.C. §301 *et seq.*, or the use of which is supported by one or more citations included or approved for inclusion in [the American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information (or its successor publications); and the DRUGDEX Information System]."<sup>3</sup>

Under 31 U.S.C. §3729(a)(1)(G) the damages to the United States includes a civil penalty of not less than \$5,500 and not more than \$11,000 for each prescription constituting a false claim,<sup>4</sup> plus 3 times the amount of damages which the United States sustained.

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<sup>2</sup> Because an attorney for the State of Wisconsin has executed an affidavit that such prescriptions are not false claims as to Wisconsin, Dr. Watson's claims on its behalf will not be pursued.

<sup>3</sup> United States Pharmacopeia-Drug Information ceased publication sometime after 2005 and there are no successor publications. *See*, Document No. 157, Paragraphs 12-22.

<sup>4</sup> Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099 47103 (1999), the FCA civil penalties were adjusted to \$5,500 to \$11,000 per false claim for violations occurring on or after September 29, 1999.

Dr. Watson claims Dr. King caused false claims by writing:

1. 20 Risperdal prescriptions to N.B. in 2005 through 2007 that were not for a medically accepted indication as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i).

2. 1,111 prescriptions for Risperdal since this Court's October 23, 2012, Order, Document No. 59, concluding that prescriptions not written for a medically accepted indication as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) constituted false claims.

3. 139 prescriptions for Geodon from March 3, 2005 to November 1, 2013, for which there are no medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) for people under 18 and therefore constituted false claims.

**Summary Of Facts, Claims, And Defenses By Dr. King**

Defendant Jennifer King Vassel (Dr. King) denies that she caused to be submitted any prescription medication claims to Medicaid that were fraudulent. The prescriptions she wrote were in compliance with Medicaid HMO or Medicaid formularies in effect at the time, or were approved pursuant to a prior authorization process utilized by those entities.

Further, Dr. King lacked the requisite knowledge to cause to submit a false claim, within the context of the federal False Claims Act. The plaintiff admitted that the State is legally permitted to reimburse prescriptions pursuant to its criteria and that he does not have any evidence that the State did not pay for the prescription medication. The admission of payment by the State pursuant to its criteria eviscerates Dr. King's liability for the state and federal claims. Moreover, the plaintiff cannot establish knowledge based on differing interpretations of the Medicaid reimbursement statutes. The plaintiff's position is that the reimbursement of prescription medication should be limited to FDA approved uses, but neither the documents that comprise the compendia nor the FDA agree with the plaintiff's position. In short, off-label

prescriptions of FDA medication by a physician is legal and widely accepted, and is also reimbursable under Medicaid as widely recognized by multiple groups, including the State of Wisconsin.

Within the last week, the plaintiff drastically changed the actual medications on which he bases his fraudulent claims. The plaintiff's theory of liability now focuses on the prescription of Risperdal to minor patient N.B. and Dr. King's alleged prescription of Geodon to minor patients, but not to N.B., as he was never prescribed that medication by Dr. King.

As to Risperdal, the plaintiff has admitted that he cannot pursue claims prior to March 3, 2005 based on the expiration of the statute of limitations. The plaintiff claims Dr. King prescribed Risperdal between July 21, 2005 and April 29, 2005, a total of 20 times, in fact there are 15 times, as four are listed prior to the expiration of the statute of limitations, and one is listed twice. The total amount of damages has not been listed in the plaintiff's trial exhibits.

The plaintiff also claims damages for the prescription of Risperdal after the issuance of this Court's October 23, 2012 decision granting Dr. King's motion for summary judgment, which dismissed this case. Dr. King contends that there has never been a final decision on the merits, and in fact both the Seventh Circuit and this Court have specifically stated as such.

The plaintiff is now claiming that Dr. King's alleged prescription of Geodon for minors is Medicaid fraud. This is an entirely new claim being presented at the eleventh hour in a lawsuit pending for over two and a half years. This new claim does not pertain to N.B., the patient named in the complaint, but instead refers to discovery produced by the State of Wisconsin approximately 20 days ago.

**B. STATEMENT OF THE ISSUES;**

**Dr. Watson**

Dr. Watson believes the only issues to be decided by the jury are the following:

1. Whether Dr. King wrote all or some of the prescriptions described above and whether they were not for a medically accepted indication as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i).

2. In the event any such prescriptions are found to be false claim, what is the amount of the civil penalty for each false claim, between \$5,500 and \$11,000, to be assessed under 31 U.S.C. §3729(a)(1)(G).

3. What is the amount of the cost for such prescriptions paid by the United States Government to be trebled at 47.57% of the amount paid for the prescription.

4. In addition, to the extent the Court holds that whether Dr. King "knowingly" caused the presentment such false claims under 31 U.S.C. §3729(b)(1) is not, under the facts in this case, established as a matter of law, whether Dr. King "knowingly" caused the presentment of such false claims under 31 U.S.C. §3729(b)(1).

**Dr. King**

Dr. King believes other issues to be decided are the following:

5. Were the FDA prescriptions Dr. King wrote in compliance with Medicaid HMO or Medicaid formularies in effect at the time, or were they approved pursuant to a prior authorization process utilized by those entities?

6. Did Dr. King lack the requisite knowledge to cause to submit a false claim?

7. Is off-label prescription of FDA medication by a physician reimbursable under Medicaid?

**C. NAMES AND ADDRESSES OF ALL WITNESSES EXPECTED TO TESTIFY.**

**1. Plaintiff's Witnesses**

**Toby Tyler Watson, Psy.D.**  
2808 Kohler Memorial Drive  
Sheboygan, WI 53801

**Christine Maxwell Meyer**  
W6929 S. Country Road A  
Adell, WI 53001

**Matthew Joy**  
4166 Apollo  
Anchorage, AK 99504

**Jennifer King, M.D.**  
N52 W21717 Taylors Woods Drive  
Menomonee Falls, WI 53051

**Kimberly Smithers**  
1 West Wilson St, Rm 350  
PO Box 309  
Madison, WI 53701

**Monica Yeazel, RPh<sup>5</sup>**  
6406 Bridge Road  
Monona, WI 53713

**2. Defendant's Lay Witnesses**

**Jennifer King, M.D.**  
N52 W21717 Taylors Woods Drive  
Menomonee Falls, WI 53051

**Martha L. (Molli) Rolli, M.D.<sup>6</sup>**  
4322 Rolla Lane  
Madison, WI 53711

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<sup>5</sup> Ms. Yeazel is not expected to be called as a witness if Plaintiff's pending Renewed Motion *In Limine*, Document No. 144, is granted.

<sup>6</sup>There is a pending motion to exclude the testimony Dr. Rolli. *Relator's* Renewed Motion *In Limine*, Document No. 144.

### 3. Defendant's Expert Witnesses<sup>7</sup>

Jacob J. Olson, Pharm.D.  
9000 W Wisconsin Ave., #211  
Wauwatosa, WI 53226

Ronald J. Diamond, M.D.  
6001 Research Park Boulevard  
Madison, WI 53719-1176

#### **D. STATEMENT OF THE BACKGROUND OF ALL EXPERT WITNESSES LISTED;**

**Ronald J. Diamond, M.D.** Dr. Diamond is a board certified psychiatrist that has been a member of the faculty of the University of Wisconsin Medical School since 1978 and is a professor at the school. He has provided treatment to psychiatric patients for nearly 40 years. Dr. Diamond has been a member of the state Medicaid formulary committee since 2004, and a member of the state Medicaid Mental Health Drug Advisory Group since 2006.

**Jacob Olson, Pharm. D., RPh.,** is a registered pharmacist and President/CEO of Skywalk Pharmacy, located at Children's Hospital of Wisconsin. Mr. Olson was a member of the Pharmacy and Therapeutics committee of Medicaid HMO Managed Health Services from 2006 to 2008, and has been a member of the state Medicaid Drug Utilization Board since September 2010. Mr. Olson is also a member of the adjunct faculty of four Midwestern colleges of pharmacy.

#### **E. LIST OF EXHIBITS**

A list of exhibits to be offered at trial by Dr. Watson, sequentially numbered according to General L.R. 26 is attached to this Joint Final Pretrial Report as Exhibit A. A list of exhibits to be

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<sup>7</sup> There is a pending motion to exclude the testimony of Dr. Olson and Dr. Diamond. *Relator's Renewed Motion In Limine*, Document No. 144.

offered at trial by Dr. King, sequentially numbered according to General L.R. 26 is attached to this Joint Final Pretrial Report as Exhibit B.<sup>8</sup>

**F. DESIGNATION OF DEPOSITIONS TO BE USED AT TRIAL AS SUBSTANTIVE EVIDENCE.**

None.

**G. ESTIMATE OF THE TIME NEEDED TO TRY THE CASE;**

The parties currently anticipate that three days will be needed to try the case unless Dr. King disputes the reports extracting Geodon prescriptions for the entire period, Trial Exhibit No. 15, and Risperdal prescriptions since October 23, 2012, Trial Exhibit 16 accurately reflect the contents of the State's electronic records. In such event, and the electronic records are gone through prescription by prescription and recipient by recipient, the trial could take two weeks or more.

**H. JURY TRIAL MATTERS**

**i. Proposed *Voir Dire* Questions**

The proposed questions that the parties would jointly like the Court to ask on *voir dire* are attached to this Joint Final Pretrial Report as Exhibit C. The additional proposed questions Dr. Watson would like the Court to ask on *voir dire* are attached to this Joint Final Pretrial Report as Exhibit C-1.<sup>9</sup>

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<sup>8</sup> Dr. Watson has not yet received a copy or many of the exhibits listed nor were many of them identified before Exhibit B was provided Dr. Watson in connection with the preparation of this Joint Final Pretrial Report at about 5:45 p.m. Wisconsin time, November 26, 2013 . This includes Exhibits 1006, 1013, 1014, 1015, 1017, except for the cover and a couple of introductory pages, 1018 except for the cover and a couple of introductory pages, maybe not all of 1019, and 1038.

<sup>9</sup> Placeholders had to be used for these two exhibits as explained in footnote 1.



**ii. Proposed Instructions On Substantive Issues**

The proposed instructions that the parties agree they would like the Court to present to the jury on substantive issues are attached to this Joint Final Pretrial Report as Exhibit D.

The proposed instructions that Dr, Watson would like the Court to present to the jury on substantive issues are attached to this Joint Final Pretrial Report as Exhibit E.

The proposed instructions that Dr. King would like the Court to present to the jury on substantive issues are attached to this Joint Final Pretrial Report as Exhibit F.

**iii. Proposed Verdict Form**

The proposed verdict form instructions Dr. Watson would like the Court to present to the jury are attached to this Joint Final Pretrial Report as Exhibit G.

The proposed verdict form instructions Dr. King would like the Court to present to the jury are attached to this Joint Final Pretrial Report as Exhibit H.

**I. PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**

Not applicable.

**J. RELATOR'S MEMORANDUM REGARDING DISPUTED ISSUES, JURY INSTRUCTIONS AND VERDICT FORMS**

Relator's Memorandum Regarding Disputed Issues, Jury Instructions And Verdict Forms is attached to this Joint Final Pretrial Report as Exhibit I.

Dated: November 26, 2013

s/ James B. Gottstein  
James B. Gottstein (Alaska Bar # 7811100)  
Law Project for Psychiatric Rights  
406 G Street, Suite 206  
Anchorage, AK 99501  
(907) 274-7686  
jim.gottstein@psychrights.org

Dated: November 27, 2013

s/ Rebecca L. Gietman  
Rebecca L Gietman  
Gietman Law

805 S. Madison St.  
Chilton, WI 53014  
414.841.7173  
GietmanLaw@gmail.com

Attorneys for Relator, Dr. Toby Tyler Watson

Dated: \_\_\_\_\_

\_\_\_\_\_  
Bradley S. Foley (#1026871)  
bradley.foley@gebosc.com

Dated: \_\_\_\_\_

\_\_\_\_\_  
Mark E. Larson (#1016423)  
mark.larson@gebosc.com

Gutglass, Erickson, Bonville, & Larson, S.C.  
P.O. Address  
735 N. Water St., Ste. 1400  
Milwaukee, WI 53202  
(414) 273-1144

Attorneys for Defendant Jennifer King Vassel

## **EXHIBITS**

- A. Dr. Watson's Exhibit List
- B. Dr. King's Exhibit List
- C. Requested *Voire Dire* Questions
- C-1 Dr. Watson's Additional Requested *Voire Dire* Questions
- D. Joint Proposed Jury Instructions
- E. Dr. Watson's Proposed Jury Instructions
- F. Dr. King's Proposed Jury Instructions
- G. Dr. Watson's Proposed Jury Interrogatories and Verdict Form
- H. Dr. King's Proposed Jury Verdict Form
- I. *Relator's* Memorandum Regarding Disputed Issues, Jury Instructions And Verdict Forms

## DR. WATSON'S EXHIBIT LIST

<u>Exhibit No.</u>	<u>Description</u>
1.	Fraudulent Scheme Demonstrative Exhibit
2.	September 2, 2009, Department of Justice News Release: <i>Justice Department Announces Largest Health Care Fraud Settlement in Its History</i>
3.	April 20, 2010 BusinessWeek story, updated April 22, 2010, <i>Pfizer's Geodon Trial Had 'Significant Violations' (Update 2)</i>
4.	November 4, 2013, Department of Justice News Release: <i>Johnson &amp; Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations</i>
5.	November 4, 2013, New York Attorney General News Release: <i>A.G. Schneiderman Announces \$1.6 Billion Settlement With Johnson &amp; Johnson And Janssen Pharmaceuticals For Illegal Marketing Of Drugs</i>
6.	June 17, 2007, Boston Globe story: <i>Backlash on bipolar diagnoses in children MGH psychiatrist's work stirs debate</i>
7.	November 20, 2013, article in The Chronicle of Higher Education: <i>Major Fraud Plea Has University Scientists Regretting Journal Article</i>
8.	Certified Walmart prescription records for N.B.
9.	Portion of Certified Encompass records for N.B.
10.	N.B. Prescription Bottles
11.	Certified Electronic Records from the State of Wisconsin
12.	Walmart Receipts for NB Prescriptions
13.	Information about Matt Joy
14.	Access Database Coding for extracting prescription information from Wisconsin Electronic Records
15.	Compilation of Geodon Prescriptions from Wisconsin Electronic Records
16.	Compilation of Risperdal Prescription not for a Medically Accepted Indication from October 23, 2012, to November 1, 2013, from Wisconsin Electronic Records

**Exhibit**

**A**

17. Federal Financial Participation Rates from Fiscal Year 2005 through Fiscal Year 2014
18. March 20, 2009, New York Times article, *Drug Maker Told Studies Would Aid it, Papers say*.
19. February 5, 2002, e-mails regarding Janssen-MGH Child and Adolescent Bipolar Center - Dr Joe Biederman
20. DRUGDEX Ratings, 1974-2008
21. DRUGDEX Ratings September, 2013
22. Risperdal "Label," revised 8/20/2010
23. 2010 Risperdal DRUGDEX Listing
24. 2009 Risperdal American Hospital Formulary Service Listing
25. Risperdal DRUGDEX Listing as of November 20, 2013
26. Risperdal AHFS 2013 Listing
27. Geodon "Label"
28. Geodon DRUGDEX listing
29. Geodon American Hospital Formulary Service Drug Listing

# UNITED STATES DISTRICT COURT

EASTERN

DISTRICT OF

WISCONSIN

USA ex rel. Dr. Toby T. Watson

DEFENDANT'S  
**EXHIBIT AND WITNESS LIST**

V.

Jennifer King-Vassel

Case Number: 11-CV-236

PRESIDING JUDGE					PLAINTIFF'S ATTORNEY	DEFENDANT'S ATTORNEY
J.P. Stadtmueller					James Gottstein/Rebecca Gietman	Mark Larson/Bradley Foley
TRIAL DATE (S)					COURT REPORTER	COURTROOM DEPUTY
12/9/2012 - 12/12/2013						
PLF. NO.	DEF. NO.	DATE OFFERED	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS* AND WITNESSES	
	1001				CV - Jacob J. Olson, Pharm. D., RPh.	
	1002				Report of Jacob J. Olson, Pharm. D., RPh.	
	1003				CV - Ronald J. Diamond, M.D.	
	1004				Report of Ronald J. Diamond, M.D.	
	1005				CV - Martha L. (Molli) Rolli, M.D.	
	1006				CV - Jennifer King, M.D.	
	1007				Certified medical records (name redacted) of Encompass for 10/25/04 - 4/29/08.	
	1008				FDA Regulatory Information re "Off-Label" and Investigational Use of Marketed Drugs, etc.	
	1009				2005 AHFS book	
	1010				2006 AHFS book	
	1011				2007 AHFS book	
	1012				2008 AHFS book	
	1013				2005 PDR	
	1014				2006 PDR	
	1015				2007 PDR	
	1016				2008 PDR	
	1017				USP DI 1997, Vol. III, Advice for the Patient	
	1018				USP DI, 2005, Vol. I, Drug Information for the Health Care Professional	
	1019				Micromedex Gateway information re Drugdex and electronic access to medication information	
	1020				FDA Drug Bulletin, April 1982, Vol. 12 No. 1, "Use of Approved Drugs for Unlabeled Indications."	
	1021				ASHP Statement on the Use of Medications for Unlabeled Uses, Copyright 1992, ASHP, Inc.	
	1022				Managed Health Services' Preferred Drug List for 2003-2004	

\* Include a notation as to the location of any exhibit not held with the case file or not available

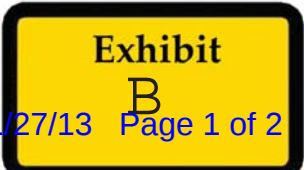


EXHIBIT AND WITNESS LIST – CONTINUATION

United States ex rel. Watson vs. Jennifer King-Vassel					CASE NO. 11-CV-236
PLF. NO.	DEF. NO.	DATE OFFERED	MARKED	ADMITTED	DESCRIPTION OF EXHIBITS AND WITNESSES
	1023				Managed Health Services' Preferred Drug List for 2006.
	1024				Managed Health Services' Preferred Drug List dated 1/2007.
	1025				State of Wisconsin/Department of Health Services Bylaws of Drug Utilization Board.
	1026				Letter, 10/22/2007, David R. Stallard, CPA to Steven E. Phurrough, MD, Medicare & Medicaid.
	1027				Letter, 12/6/2007, Dennis G. Smith, Medicaid, to David R. Stallard, CPA.
	1028				Letter, 12/17/2007, David R. Stallard, CPA to Dennis G. Smith, Medicaid.
	1029				Letter, 1/30/2008, Gale P. Arden of Medicare/Medicaid Services to David R. Stallard, CPA.
	1030				Authorization signed by Christine Maxwell Meyer allowing release of records to Dr. Watson.
	1031				Affidavit of Christine Maxwell Meyer dated 8/20/2012.
	1032				Relator's Response to Defendants' First Set of Interrogatories and Request for Production.
	1033				Deposition of Dr. Toby T. Watson dated 5/4/2012 with Exhibits 1 and 2.
	1034				Deposition of Jennifer King, M.D., dated 11/11/2013 with Exhibits 1-5.
	1035				Deposition of Christine Maxwell Meyer dated 11/11/2013 with Exhibits 1-5.
	1036				Relator's Response to Defendants' First Set of Requests to Admit dated April 3, 2012.
	1037				Relator's Responses to Defendants' Second Set of Requests to Admit dated November 5, 2013.
	1038				Medicaid formulary for meds Clonidine, Risperdal, Zoloft, Seroquel and Prozac for 2007-2008.

# Place Holder





# Place Holder

**Exhibit  
C-1**

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v.

Case No. 11-CV-236-JPS

JENNIFER KING VASSEL, *et al.*,

Defendant.

---

**JOINT PROPOSED JURY INSTRUCTIONS**

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*Relator*, Dr. Toby Tyler Watson (Dr. Watson), by his attorneys, James B. Gottstein of the Law Project for Psychiatric Rights and Rebecca L. Gietman of Gietman Law, and Defendant Jennifer King-Vassel now known as Jennifer King (Dr. King), by her attorneys Bradley S. Foley and Mark E. Larson of Gutglass Erickson Bonville & Larson, SC, hereby jointly propose the attached jury instructions.

Dated: November 26, 2013

s/ James B. Gottstein

James B. Gottstein (Alaska Bar # 7811100)  
Law Project for Psychiatric Rights  
406 G Street, Suite 206  
Anchorage, AK 99501  
(907) 274-7686  
jim.gottstein@psychrights.org

Dated: November 26, 2013

s/ Rebecca L. Gietman

Rebecca L Gietman  
Gietman Law  
805 S. Madison St.  
Chilton, WI 53014  
414.841.7173  
GietmanLaw@gmail.com

Attorneys for Relator, Dr. Toby Tyler Watson

**Exhibit**

**D**

Dated: November 26, 2013

s/Bradley S. Foley

Bradley S. Foley (#1026871)  
bradley.foley@gebosc.com

Dated: November 26, 2013

s/ Mark E. Larson

Mark E. Larson (#1016423)  
mark.larson@gebosc.com

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P.O. Address  
735 N. Water St., Ste. 1400  
Milwaukee, WI 53202  
(414) 273-1144

Attorneys for Defendant Jennifer King Vassel

### **Definitions--Claim<sup>1</sup>**

A "claim" includes any request or demand, whether under a contract or otherwise, for money or property that is made to a contractor, grantee or other recipient if the United States Government provides any portion of the money or property that is requested or demanded.

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<sup>1</sup> Joint Jury Instruction No. 1.

Source: § 178.33 O'Malley's Federal Jury Practice and Instructions.

### **Damages--Civil penalties<sup>1</sup>**

If you find that false claims were caused to be submitted by Dr. King, in determining the amount of the civil penalty of at least \$5,500 and not more than \$11,000 per false claim, you may consider factors such as the loss to the government and whether defendant Dr. King has shown any mitigating circumstances.

Each separate prescription constitutes a separate claim and thus a separate penalty.

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<sup>1</sup> Joint Jury Instruction No. 2

Source: Adapted from § 178.61 O'Malley's Federal Jury Practice and Instructions.

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v.

Case No. 11-CV-236-JPS

JENNIFER KING VASSEL,

Defendant.

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***RELATOR'S PROPOSED JURY INSTRUCTIONS***

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*Relator*, Dr. Toby Tyler Watson (Dr. Watson), by his attorneys, James B. Gottstein of the Law Project for Psychiatric Rights and Rebecca L. Gietman of Gietman Law hereby proposes the substantive jury instructions attached hereto. Dr. Watson reserves the right to supplement or alter these instructions, based on the evidence presented at trial and/or rulings made by the Court.

Dated: November 26, 2013

s/ James B. Gottstein

James B. Gottstein (Alaska Bar # 7811100)  
Law Project for Psychiatric Rights  
406 G Street, Suite 206  
Anchorage, AK 99501  
(907) 274-7686  
jim.gottstein@psychrights.org

Dated: November 26, 2013

s/ Rebecca L. Gietman

Rebecca L Gietman  
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805 S. Madison St.  
Chilton, WI 53014  
414.841.7173  
GietmanLaw@gmail.com

Attorneys for Relator, Dr. Toby Tyler Watson

**Exhibit  
E**

### **Generally--Nature Of The Action<sup>1</sup>**

Plaintiff United States of America, through Relator Dr. Toby Watson, alleges that from March 3, 2005, through November 1, 2013, defendant Jennifer King, formerly known as Dr. Jennifer King-Vassel, caused claims to be presented against the Wisconsin Medicaid Program, which is funded in part by the United States government, by writing prescriptions to minor patients that were not for a medically accepted indication as defined under the Medicaid statute when defendant Dr. King, knew, was deliberately ignorant, or recklessly disregarded that the defendant's claim was false or fraudulent.

Defendant Dr. King denies these allegations.

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<sup>1</sup> *Relator's Proposed Jury Instruction No. 1.*

## **Statutes--Generally<sup>1</sup>**

Under the False Claims Act, any person who knowingly causes a false claim to be presented to the United States Government for payment or approval is liable to the United States Government for a civil penalty plus damages sustained by the Government.

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<sup>1</sup> *Relator's* Proposed Jury Instruction No. 2.



### **Essential Elements of Plaintiff's Claim -- Generally<sup>1</sup>**

In order to sustain plaintiff's burden of proof for the charge of knowingly causing false claims to the United States, the *relator* must prove the following five essential elements by a preponderance of the evidence:

One: Defendant caused claims to be presented to Wisconsin Medicaid;

Two: Wisconsin Medicaid received reimbursements from the United States Government for at least some portion of the cost of the claims:

Three: The claims presented were false at the time they were caused;

Four: Defendant knew as defined under the False Claims Act that the claims were false;  
and

Five: The Defendant caused the false claims for the purpose of getting the false claims paid by the Government.

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<sup>1</sup> *Relator's* Jury Instruction No. 3.

**Essential Elements of the Plaintiff's Claim--Authorization to  
violate law<sup>1</sup>**

A government officer or agent cannot authorize a Medicaid provider to violate federal  
law.

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<sup>1</sup> *Relator's* Jury Instruction No. 4

## **Providers' Obligation to Know Law<sup>1</sup>**

Medicaid providers such as Dr. King are expected to know the law and may not rely on the conduct of Government agents contrary to law.

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<sup>1</sup> *Relator's* Jury Instruction No. 5

### **Definitions--Knowing and knowingly<sup>1</sup>**

The terms “knowing” and “knowingly” mean that a person (a) has actual knowledge of the true information, or (b) acts with deliberate ignorance of the truth or falsity of the information, or (c) acts in reckless disregard of the truth or falsity of the information.

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<sup>1</sup> *Relator's* Jury Instruction No. 6

**Prescriptions to Wisconsin Medicaid Are Claims Against the  
United States Government<sup>1</sup>**

Because the federal government pays for part of the cost, claims submitted to the Wisconsin Medicaid programs are also considered claims submitted to the federal government and may serve as the basis for False Claims Act liability.

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<sup>1</sup> *Relator's* Jury Instruction No. 7

## **Causation--Generally<sup>1</sup>**

Plaintiff Dr. Watson has the burden of proving each and every element of plaintiff's claims by a preponderance of the evidence. If you find that plaintiff Dr. Watson has not proved any one of the elements by a preponderance of the evidence, you must return a verdict for defendant Dr. King.

Defendant Dr. King has the burden of proving each element of defendant's affirmative defenses by a preponderance of the evidence.

---

<sup>1</sup> *Relator's* Jury Instruction No. 8

### **Causation Preponderance of the evidence<sup>1</sup>**

To “establish by the preponderance of the evidence” means to prove that something is more likely so than it is not so. In other words, a preponderance of the evidence in the case means such evidence as, when considered and compared to that opposed to it, has more convincing force, and produces in your mind a belief that what is sought to be proved is more likely true than not true.

In determining whether any fact in issue has been proved by a preponderance of the evidence in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

---

<sup>1</sup> *Relator's* Jury Instruction No. 9

### **Medically Accepted Indication<sup>1</sup>**

The federal government can only provide reimbursement for what the Medicaid statute defines as "covered outpatient drugs." Covered drugs do not include any drugs "used for a medical indication which is not a medically accepted indication." The term "medically accepted indication" is a statutorily-defined to mean a prescription purpose approved by the Food and Drug Administration ("FDA") or "supported by" either compendia.

If a prescription is written for a purpose that is not approved by the FDA, it is commonly called "off-label." Once a drug has been approved for one use, the FDA cannot prevent physicians from prescribing the drug for other uses. The legality of the prescription, however, does not mean the federal government may lawfully pay for a Medicaid patient's off-label prescriptions. Under the laws governing Medicaid, medication prescriptions submitted to Medicaid for payment that are for purposes not approved by the FDA or "supported" by either of two pharmaceutical reference books, called "compendia" cause false claims. The two compendia are the American Hospital Formulary Service Drug Information, and the DRUGDEX Information System.

A claim made to Medicaid for a prescription that is not for a medically accepted indication is false. Or, another way to put it is that a claim made to Medicaid for an "off-label" prescription is a false claim unless it is supported by either or both of the compendia.

---

<sup>1</sup> *Relator's* Jury Instruction No. 10



### **Geodon Medically Accepted Indications<sup>1</sup>**

There are no medically accepted indications as defined in the Medicaid Statute for Geodon, also known as ziprasidone, for anyone under the age of 18.

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<sup>1</sup> *Relator's* Jury Instruction No. 11.

### **Risperdal Medically Accepted Indications<sup>1</sup>**

Prescriptions of Risperdal, also known as risperidone to patients under 18 presented in this case that are not written for:

- (1) Treatment of Schizophrenia for ages 13-17 years,
- (2) Treatment of acute mania or mixed episodes associated with Bipolar I Disorder for ages 10 to 17 years,
- (3) Treatment of irritability associated with autistic, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods for ages 5 to 17 years,
- (4) Behavioral syndrome - Mental Retardation,
- (5) Pervasive developmental disorder, or
- (6) Gilles de la Tourette's syndrome,

and have been paid for by Medicaid, if any, are not for a medically accepted indication under the Medicaid Statute and therefore false claims.

---

<sup>1</sup> *Relator's* Jury Instruction No. 12.

**Deliberate Ignorance Knowledge—Submission of Prescriptions  
for Payment to United States Government<sup>1</sup>**

In order to establish that Dr. King was deliberately ignorant that she was causing false claims by writing prescriptions that were not for a medically accepted indication Dr. Watson must show that Dr. King had a strong suspicion that things were not what they seemed, yet shut her eyes for fear of what she would learn.

Under the facts of this case, if you decide that Dr. King did in fact cause a false claim or claims by writing prescriptions that were not for a medically accepted indication as defined under the Medicaid statute, you may conclude that she shut her eyes to this fact after (1) the Complaint was served on December 21, 2011, (2) this Court held such prescriptions were false claims on October 23, 2012, or (3) when the Court of Appeals also held such prescriptions were false claims on October 28, 2013, or both (2) and (3).

---

*Relator's Proposed Jury Instruction No. 13*

## **Recklessly Indifferent Knowledge—Submission of Prescriptions for Payment to United States Government<sup>1</sup>**

In order to establish that Dr. King recklessly disregarded that she was causing false claims by writing prescriptions that were not for a medically accepted indication Dr. Watson need only show that Dr. King had reason to know of facts that would lead a reasonable person to realize that she was causing the submission of a false claim or that Dr. King failed to make a reasonable and prudent inquiry into that possibility.

Under the facts of this case, Dr. Watson has established this essential element with respect to prescriptions written after October 23, 2012, the date on which this Court held that prescriptions that are not for a medically accepted indication submitted to Medicaid are false claims. This applies to any prescriptions identified in Plaintiff's Exhibit No. 16, which are prescriptions for Risperdal, also known as risperidone not written for a medically accepted indication that the jury finds were submitted to Medicaid. This also applies to any prescriptions identified in Plaintiff's Exhibit No. 15, which are prescriptions for Geodon, also known as ziprasidone, written after October 23, 2012. The only questions you must answer pertaining to these prescriptions are whether they were (1) written by Dr. King, (2) submitted to Medicaid for payment, and (3) were not for a medically accepted indication as defined in the Medicaid statute (off-label and without support in a compendia).

Dr. Watson has also established this element for writing prescriptions that are not for a medically accepted indication after she was served with the Complaint in this matter on December 21 2011. This applies to any prescriptions for Geodon also known as ziprasidone, identified in Plaintiff's Exhibit No. 15, written between December 21, 2011, and October 23, 2012.

With respect to prescriptions that were written prior to Dr. King being served with the Complaint in this action that were not for a medically accepted indication, Dr. King may not rely on any government action or statements suggesting such prescriptions do not cause false claims. This applies to the prescriptions written to "N.B.," and prescriptions for Geodon also known as ziprasidone, identified in Plaintiff's Exhibit No. 15, written before December 21, 2011. With respect to these prescriptions, in addition to answering the questions whether they were (1) written by Dr. King, (2) submitted to Medicaid for payment, and (3) were not for a medically accepted indication as defined in the Medicaid statute (off-label and without support in a compendia), you must answer a fourth question, (4), whether Dr. King had reason to know of facts that would lead a reasonable person to realize that she was causing the submission of false claims by writing these prescriptions that were not for a medically accepted indication as defined in the Medicaid Statute, or that Dr. King failed to make a reasonable and prudent inquiry into that possibility.

---

*Relator's* Jury Instruction No. 14.

### **Defenses--Generally<sup>1</sup>**

If you find that plaintiff Dr. Watson has proved each of the elements that plaintiff Dr. Watson must establish in support of plaintiff's claim, you must then consider defendant's defense as to which defendant Dr. King has the burden of proof by a preponderance of the evidence.

Defendant Dr. King claims that she did not know within the meaning of the False Claims Act, that the claims were false.

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<sup>1</sup> *Relator's* Jury Instruction No. 15

## **Damages--Generally<sup>1</sup>**

The measure of the government's damages is the amount that it paid out by reason of the false claims over and above what it would have paid if the claims would have been proper.

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<sup>1</sup> *Relator's* Jury Instruction No. 16

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v.

Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

---

**DEFENDANT JENNIFER KING VASSEL'S PROPOSED  
SUBSTANTIVE JURY INSTRUCTIONS**

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Defendant Jennifer King Vassel (Dr. King), by her attorneys, Gutglass, Erickson, Bonville & Larson, S.C., hereby proposes the following substantive jury instructions. Dr. King reserves the right to supplement or alter these instructions, based on the evidence presented at trial.

- Nature of the Action
- Definition of False
- Definition of Knowing and Knowingly
- Essential Elements that the Plaintiff Must Prove
- Causation
- Preponderance of the Evidence
- Defenses - Generally
- Damages - Generally

Dated at Milwaukee, Wisconsin this 26th day of November, 2013.

**GUTGLASS, ERICKSON,  
BONVILLE & LARSON, S.C.**

s/ Bradley S. Foley

Mark E. Larson (#1016423)

Bradley S. Foley (#1026871)

Attorneys for defendant Jennifer King Vassel

**Exhibit**

**F**

P.O. ADDRESS:

735 North Water Street, Suite 1400  
Milwaukee, Wisconsin 53202-4267  
Telephone: (414) 273-1144  
mark.larson@gebsc.com  
bradley.foley@gebsc.com



## NATURE OF THE ACTION

The plaintiff Toby Watson alleges between July 21, 2005 and April 29, 2008, defendant Dr. Jennifer King knowingly caused fraudulent claims to be presented to the federal and state governments by writing prescriptions for patients that were submitted by third parties for reimbursement under Wisconsin's Medicaid program.

Dr. King denies these allegations, asserting that she prescribed medications for medically accepted uses to her patients, that she did not submit the prescriptions for reimbursement and received no benefit from prescribing of such medications. In addition, Dr. King asserts that the Medicaid statutes permit reimbursement of these prescriptions pursuant to federal and state law, as the medications were either on a pre-approved list established by the state or its contracted HMO(s) or were approved by those entities via a patient specific process, both avenues pursuant to federal law.

*O'Malley's Federal Jury Practice*, § 178.01.

**DEFINITION OF FALSE**

A claim is “false” if it is an assertion that is untrue when made or when used.

*O'Malley's Federal Jury Practice*, § 178.30.

### **DEFINITION OF KNOWING AND KNOWINGLY**

The terms “knowing” and “knowingly” mean that a person (a) has actual knowledge of the true information, or (b) acts with deliberate ignorance of the truth or falsity of the information, or (c) acts in reckless disregard of the truth or falsity of the information.

Defendant Jennifer King Vassel must have made false statements for the purpose of getting the false or fraudulent claims paid or approved by the Government.

*O'Malley's Federal Jury Practice*, § 178.32.

### ESSENTIAL ELEMENTS THAT THE PLAINTIFF MUST PROVE

In order to sustain the plaintiff's burden of proof for the charge of knowingly submitting a false or fraudulent claim to the United States, the plaintiff must provide the following four essential elements by a preponderance of the evidence:

One: Defendant Dr. King caused to be presented to the state Medicaid program claims against the United States;

Two: At the time that the claim was caused to be presented, the state had established a program for covering expenses utilizing federal Medicaid funds;

Three: The claims presented was fraudulent in that the prescriptions were written for non-recognized medical uses;

Four: Defendant Dr. King knew that the claims were fraudulent; and,

Five: Defendant Dr. King made false statements for the purpose of getting the false or fraudulent claims paid or approved by the state Medicaid program.

*O'Malley's Federal Jury Practice*, § 178.20.

## CAUSATION

The plaintiff has the burden of proving each and every element of plaintiff's claim by a preponderance of the evidence. If you find that the plaintiff has not proved any one of the elements by a preponderance of the evidence, you must return a verdict for defendant Jennifer King, M.D.

*O'Malley's Federal Jury Practice*, § 178.40.

## PREPONDERANCE OF THE EVIDENCE

To “establish by the preponderance of the evidence” means to prove that something is more likely so than it is not so. In other words, a preponderance of the evidence in the case means such evidence as, when considered and compared to that opposed to it, has more convincing force, and produces in your mind a belief that what is sought to be provided is more likely true than not true.

In determining whether any fact in issue has been provided by a preponderance of the evidence in the case, you may, unless otherwise instructed, consider the testimony of all witnesses, regardless of who may have called them, and all exhibits received in evidence, regardless of who may have produced them.

*O'Malley's Federal Jury Practice*, § 178.41.

## DEFENSES - GENERALLY

If you find that plaintiff Dr. Watson has proved each of the elements that he must establish in support of the plaintiff's claim, you must then consider defendant Dr. King's defense as to whether she has the burden of proof by a preponderance of the evidence.

Dr. King asserts that she prescribed medications for medically accepted uses to her patients, that she did not submit the prescriptions for reimbursement, and received no benefit from prescribing of such medications. In addition, Dr. King asserts that the Medicaid statutes permit reimbursement of the prescriptions pursuant to federal and state law.

*O'Malley's Federal Jury Practice*, § 178.50.

## **DAMAGES - GENERALLY**

The measure of the government's damages is the amount that it paid out by reason of the false submissions over and above what it would have paid if the prescription medication claims would have been truthful.

*O'Malley's Federal Jury Practice*, § 178.60.



UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v.

Case No. 11-CV-236-JPS

JENNIFER KING VASSEL,

Defendant.

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***RELATOR'S PROPOSED VERDICT FORMS***

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*Relator*, Dr. Toby Tyler Watson (Dr. Watson), by his attorneys, James B. Gottstein of the Law Project for Psychiatric Rights and Rebecca L. Gietman of Gietman Law hereby proposes the verdict forms attached hereto.

Dated: November 26, 2013

s/ James B. Gottstein

James B. Gottstein (Alaska Bar # 7811100)  
Law Project for Psychiatric Rights  
406 G Street, Suite 206  
Anchorage, AK 99501  
(907) 274-7686  
jim.gottstein@psychrights.org

Dated: November 26, 2013

s/ Rebecca L. Gietman

Rebecca L Gietman  
Gietman Law  
805 S. Madison St.  
Chilton, WI 53014  
414.841.7173  
GietmanLaw@gmail.com

Attorneys for Relator, Dr. Toby Tyler Watson

**Exhibit  
G**

### **Jury Interrogatories**

1. Do you find that Dr. King wrote prescriptions of Risperdal and Geodon to Medicaid patients under the age of 18 that were not for a medically accepted indication as defined by the Medicaid Statute and submitted to Medicaid?

\_\_\_\_\_ YES \_\_\_\_\_ NO

If the answer to Interrogatory No. 1 is "Yes," please answer Interrogatories 2,3, 4, and 5.

If the answer to Interrogatory No. 1 is "no," please stop.

2. If the answer to Interrogatory No. 1 is "Yes," please state the number of false claims that you find defendant caused to be submitted to the government. \_\_\_\_\_

3. If the answer to Interrogatory No 1 is "Yes," please state the amount of damages that the government sustained as a result. \$\_\_\_\_\_.

4. If the answer to Interrogatory No. 1 is "Yes," please state the amount, not less than \$5,500 and not more than \$11,000, at which the civil penalty should be assessed for each false claim submitted. \$\_\_\_\_\_.

**Verdict form**

On the claim of plaintiff Dr. Toby Tyler Watson for violation of the False Claims Act (31 U.S.C.A. § 3729), we, the jury in the above-entitled action, unanimously find in favor of:

Plaintiff Dr Watson, or

Defendant Jennifer King-Vassel

Complete the following only if the above finding is in favor of plaintiff Dr. Watson

We, the jury in the above-entitled action, unanimously assess the plaintiff's actual or compensatory damages in the sum of \$\_\_\_\_\_.

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

---

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

Plaintiffs,

v.

Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

---

**SPECIAL VERDICT**

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We, the jury in the above-entitled action, unanimously find as follows:

1. Were the prescriptions for medications written by defendant Jennifer King Vassel false or fraudulent?

\_\_\_\_\_ Yes \_\_\_\_\_ No

2. Did defendant Jennifer King Vassel cause to present false or fraudulent prescription medications to the state Medicaid program?

\_\_\_\_\_ Yes \_\_\_\_\_ No

3. Did defendant Jennifer King Vassel know that the prescription medication claims were fraudulent?

\_\_\_\_\_ Yes \_\_\_\_\_ No

4. Did defendant Jennifer King Vassel cause to submit the false or fraudulent prescription medication for the purpose of getting the false or fraudulent prescription medication paid or approved by the state Medicaid program?

\_\_\_\_\_ Yes \_\_\_\_\_ No

If your answers to Questions Nos. 1, 2, 3, and 4 are “Yes,” then please answer the following questions:

**Exhibit  
H**

Re: Case No. 11-CV-236

5. Please state the number of false claims that you find defendant Jennifer King Vassel caused to be submitted to the state Medicaid program:

\_\_\_\_\_.

6. Please state the amount of damages that the government sustained as a result:

\$\_\_\_\_\_.

7. Please state the amount of any credit defendant Jennifer King Vassel is entitled to receive:

\$\_\_\_\_\_.

8. Please state the amount, not less than \$5,500 and not more than \$11,000, at which the civil penalty should be assessed for each false claim submitted:

\$\_\_\_\_\_.

Dated this \_\_\_\_\_ day of December, 2013 at Milwaukee, Wisconsin.

\_\_\_\_\_  
Foreperson

*O'Malley's Federal Jury Practice*, § 178.71

UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF WISCONSIN

Exhibit  
I

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

Plaintiffs,

v.

Case No. 11-CV-236-JPS

JENNIFER KING VASSEL, *et al.*,

Defendant.

---

**RELATOR'S MEMORANDUM REGARDING DISPUTED  
ISSUES, JURY INSTRUCTIONS AND VERDICT FORMS**

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*Relator*, Dr. Toby Tyler Watson (Dr. Watson), through counsel James B. Gottstein of the Law Project for Psychiatric Rights, and Rebecca L. Gietman of Gietman Law hereby submits his Memorandum Regarding Disputed Issues, Jury Instructions and Verdict Forms.

**A. Summary**

There is a fundamental disagreement over the law applicable to this case, specifically whether an outpatient drug prescription presented to Medicaid that is not for a medically accepted indication as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) constitutes a false claim. Dr. Watson believes this has already been settled in this case as a result of this Court's Order granting summary judgment, Document No. 59, p. 11., and the Court of Appeals decision in *United States v. King-Vassel*, 728 F.3d 707 (7th Cir. 2013). The Court did leave the door open in its October 2, 2013, Order, Document No. 116, by allowing further discovery on whether Wisconsin has determined to pay for drug prescriptions that are not for a medically accepted indication as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i). In Dr. Watson's view, this can only affect the knowledge requirement under the

False Claims Act, 31 U.S.C. §3729 and the Court at least came pretty close to holding this at Document 116, page 5.

Last Friday, the affidavit of an attorney for the State of Wisconsin, Department of Health Services (DHS) was filed wherein he states Wisconsin does pay for such prescriptions and disagreeing with the position that coverage of outpatient drugs is limited to medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i). As a result, Dr. Watson will not be pursuing false claims on behalf of the State of Wisconsin. Of course, Wisconsin cannot nullify federal law and Dr. Watson continues to pursue his claims on behalf of the federal government. Dr. Watson believes he has sufficiently briefed the issue of Medicaid outpatient drug coverage being limited to medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) and won't further brief this issue here. *See*, Document Numbers 103, 112, 145, and 158.

Dr. Watson similarly believes he has sufficiently briefed the knowledge or *scienter* issue under 31 U.S.C. §3729 and won't be briefing that further here, except as it relates to jury instructions and interrogatories. In addition to these, this Memorandum will address the issue of what are the medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) for patients under the age of 18 for the two drugs on which Dr. Watson intends to present evidence; Geodon, also known as ziprasidone, and Risperdal, also known as risperidone.

In other cases, whether prescriptions were written for a medically accepted indication as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) could be a factual one, but, for the facts in this case, what uses are for a medically accepted indication is a question of law.

## **B. Medically Accepted Indications**

### **1. Geodon (ziprasidone)**

There are no medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) for Geodon for use on patients under the age of 18. Document Numbers 157-1 is the current Food and Drug Administration (FDA) "label" for Geodon, Document No. 157-2 is the current DRUGDEX entry for Geodon, and Document No. 157-3 is the 2013 American Hospital Service Formulary Drug Information (AHFS) entry for Geodon.<sup>1</sup>

#### **(a) The Geodon Label**

Starting with the label, the highlighted portion on page 1 of Document 157-1, states, "*Pediatric Use*: Safety and effectiveness for pediatric patients has not been established. (8.4)" Thus, there are no uses approved under the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* This is also confirmed in the "Indications and Usage" section on the upper left, just below the "black box" warning of increased mortality in elderly patients with dementia related psychosis, which lists "indications and usage" only for adults. Section 8.4, which is under 8. Use in Specific Populations, at page 15, states:

#### **8.4. Pediatric Use**

The safety and effectiveness of ziprasidone in pediatric patients have not been established.

That is it, there is nothing else about pediatric use.<sup>2</sup> Thus, there is no use approved under the FDCA for patients under the age of 18.

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<sup>1</sup> Document No. 157-13 is the 2013 DrugPoints entry for Geodon, but Dr. Watson is confident DrugPoints is not the successor to United States Pharmacopeia-Drug Information.

<sup>2</sup> A word search on "pediatric" will only reveal the additional table of contents entry on page 2.



**(b) Geodon In DRUGDEX**

Document 157-2 is the DRUGDEX entry for Geodon. The last line on page 1, under Dosing Information is "2) Pediatric (highlighted), and the next page begins with:

a) safety and effectiveness in pediatric patients have not been established (Prod Info GEODON(R) oral suspension, 2009; Prod Info GEODON oral capsules, IM injection, 2009)

The next section, also in page 2 and highlighted, is for the injectable form of Geodon, Ziprasidone Mesylate, and states:

2) Pediatric  
a) safety and effectiveness in pediatric patients have not been established (Prod Info GEODON oral capsules, IM injection, 2009).

At page 6, under Pediatric Dosage, it is also stated that the safety and effectiveness in pediatric patients have not been established.

At page 114, for the indication or use of "Bipolar 1 disorder, Acute manic or mixed episodes, monotherapy," it is noted that there is no FDA approval for this use. The same is true on the next page for "Bipolar I disorder, to lithium or valproate; Adjunct," and "Schizoaffective disorder." On the page following that, 116, the same is true for "Schizophrenia." On the page after that, 118, the same is true for the use "Agitation, acute – Schizophrenia.

Thus, there is no support for any use of Geodon in patients under the age of 18 in DRUGDEX.

**(c) Geodon in AHFS**

The AHFS entry for Geodon is at Document 157-3. In contrast to DRUGDEX's 145 page entry for Geodon, AHFS has 12 pages. At page 9, it is stated for Pediatric Use, that "Safety and efficacy not established in children younger than 18 years of age." That is it.

Thus, as a matter of law, keeping in mind that the compendia "were specifically incorporated by Congress into the statutory standard for a 'medically accepted indication,' "<sup>3</sup> there is no medically accepted indication as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) for Geodon for patients under the age of 18.

Trial Exhibit 15, is a listing of the Geodon prescriptions written by Dr. King during the applicable period to patients under 18, paid for by Medicaid, in the electronic production by the State of Wisconsin pursuant to this Court's October 2, 2013, orders, Documents 116 & 117, as amended by this Court's November 5, 2013 orders, Documents 137 & 138, and Dr. Watson's request for production from the State of Wisconsin.<sup>4</sup>

Thus, the only questions for the jury with respect to whether the Geodon prescriptions identified in Trial Exhibit 15 are false claims is that Trial Exhibit 15 accurately reflects the contents of Wisconsin's electronic production and that that is sufficient to establish the prescriptions were presented to Medicaid for payment.

## **2. Risperdal (risperidone)**

Risperdal is somewhat more complicated because there are three medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i), and another that it could be argued is such a medically accepted indication. More specifically, the three medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) are:

1. Treatment of Schizophrenia for ages 13-17 years.

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<sup>3</sup> *U.S. v. King-Vassel*, 728 F.3d at 716.

<sup>4</sup> Trial Exhibit 14 is a printout of the computer programming that extracts this data from the electronic production. Trial Exhibit 11 is the certification of this production under Fed. R. Evid. 803(6) and 902(11).

2. Treatment of acute mania or mixed episodes associated with Bipolar I Disorder for ages 10 to 17 years.
3. Treatment of irritability associated with autistic, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods for ages 5 to 17 years.

Document 157-4, page 3.

*See*, also the DRUGDEX entries, Document No. 157-7, pp 2, 152, 161, 176; Document No. 157-5, pp. 2, 94, 100, 117, and the AHFS entries, Document No. 157-6, pp 2, 6; Document 157-8, p. 19.<sup>5</sup>

The additional uses that could be argued are medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i) are:

4. Behavioral syndrome – Mental Retardation. *See*, Document No. 157-7, p. 157; Document No. 157-5, p 97, p. 114.
5. Pervasive developmental disorder, Document No. 157-7, p. 172; Document No. 157-5, p. 114.
6. Gilles de la Tourette's syndrome. Document No. 157-5, p. 111.

These appear in DRUGDEX<sup>6</sup> with a Recommendation of IIb, which means "The given test, or treatment may be useful, and is indicated in some, but not most, cases." Document 157-9 and 157-10. Dr. Watson's position is that this does not constitute support or, at most, only if the prescription qualifies as having been written for a use in the "some" category, as opposed to the

---

<sup>5</sup> It is noted that AHFS states, "The manufacturer states that safety and effectiveness of risperidone in children with schizophrenia or acute mania associated with bipolar I disorder have not been established." Document 157-6, p. 6; Document 157-8, p. 19.

<sup>6</sup> It is noted that Gilles de la Tourette's syndrome is not listed in the current DRUGDEX entry, Document No. 157-7.

"most" category when it is not indicated does it have "support" in DRUGDEX.

With one exception, this issue does not come up in this case. Trial Exhibit 16 is a report of Risperdal prescriptions written to patients under 18, paid by Medicaid, that were not diagnosed with any of the 6 uses identified above. The one exception is I.B., who was diagnosed with Tourette's syndrome to whom Dr. King wrote 14 Risperdal prescriptions. It is not known by Dr. Watson, however, for what use those prescriptions were written. If any or all of them were written to treat Tourette's syndrome it could be argued they were written for a medically accepted indications as defined under 42 U.S.C. § 1396r-8(k)(6), §1396r-8(g)(1)(B)(i). *See*, Trial Exhibit 16, pp 305-310. Dr. Watson is not going to pursue these 14 prescriptions and the totals for I.B. on page 310 of Trial Exhibit 16 can come out of the grand totals on the last page of Trial Exhibit 16.

So, in this case, for Risperdal, as a matter of law, prescriptions that were not written for:

- (1) Treatment of Schizophrenia for ages 13-17 years,
- (2) Treatment of acute mania or mixed episodes associated with Bipolar I Disorder for ages 10 to 17 years,
- (3) Treatment of irritability associated with autistic, including symptoms of aggression towards others, deliberate self-injuriousness, temper tantrums, and quickly changing moods for ages 5 to 17 years,
- (4) Behavioral syndrome - Mental Retardation,
- (5) Pervasive developmental disorder, or
- (6) Gilles de la Tourette's syndrome,

are false claims.

Trial Exhibit 16 is a compilation of such prescriptions and calculation of damages from the electronically stored records produced by the State of Wisconsin, Trial Exhibit 11.<sup>7</sup>

*Relator's* jury instructions flow naturally from this.

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<sup>7</sup> Trial Exhibit 16 uses 57.47% as the federal amount to be trebled under 31 U.S.C. §3729(b)(1). It is the lowest federal share for all of the applicable periods. *See*, Trial Exhibit

### **C. Relator's Proposed Jury Instructions**

The following are the sources, bases and offers of proof in support of the *Relator's* proposed jury instructions, Exhibit E to the Joint Final Pretrial Report.

#### **1. Generally--Nature Of The Action**

*Relator's* Proposed Jury Instruction No. 1 adapts §178.01 of O'Malley's Federal Jury Practice and Instructions to the facts of this case.

#### **2. Statutes--Generally**

*Relator's* Proposed Jury Instruction No. 2 adapts §178.10 of O'Malley's Federal Jury Practice and Instructions to the facts of this case.

#### **3. Essential Elements of Plaintiff's Claim -- Generally**

*Relator's* Proposed Jury Instruction No. 3 adapts §178.20 of O'Malley's Federal Jury Practice and Instructions to the facts of this case.

#### **4. Essential Elements of the Plaintiff's Claim--Authorization to violate law**

*Relator's* Proposed Jury Instruction No. 4 adapts §178.23 of O'Malley's Federal Jury Practice and Instructions to the facts of this case. See, also *Heckler v. Community Health Services*, 467 U.S. 51, 63, 104 S.Ct. 2218, 2225 (1984), and discussion at Document No. 158, pp 2-3.

#### **5. Providers' Obligation to Know Law**

*Relator's* Proposed Jury Instruction No. 5 relies on *Heckler v. Community Health Services*, 467 U.S. 51, 63, 104 S.Ct. 2218, 2225 (1984), and discussion at Document No. 158, pp 2-3.

#### **3. Definitions--Knowing and knowingly**

*Relator's* Proposed Jury Instruction No. 6 is taken from §178.32 of O'Malley's Federal Jury Practice.

**4. Prescriptions to Wisconsin Medicaid Are Claims Against the United States Government**

*Relator's* Proposed Jury Instruction No. 7 relies on *United States v. King-Vassel*, 728 F.3d 707, 711 (7th Cir. 2013).

**5. Causation--Generally**

*Relator's* Proposed Jury Instruction No. 8 is taken from § 178.40 O'Malley's Federal Jury Practice and Instructions, incorporating the parties' names.

**6. Causation Preponderance of the evidence**

*Relator's* Proposed Jury Instruction No. 9 is taken from § 178.41 O'Malley's Federal Jury Practice and Instructions.

**7. Medically Accepted Indication**

*Relator's* Proposed Jury Instruction No. 10 relies on *United States v. King-Vassel*, 728 F.3d 707, 715 (7th Cir. 2013).

**8. Geodon Medically Accepted Indications**

The grounds for *Relator's* Proposed Jury Instruction No. 11 is set forth in Section B. 1., above, and is an offer of proof.

**9. Risperdal Medically Accepted Indications**

The grounds for *Relator's* Proposed Jury Instruction No. 12 is set forth in Section B. 2., above, and is an offer of proof.

**10. Deliberate Ignorance Knowledge—Submission of Prescriptions for Payment to United States Government**

The grounds for *Relator's* Proposed Jury Instruction No. 12 is set forth in Document 158, pp 4- 5, and the cited portions of the transcript of Dr. King therein, and is an offer of proof. The language comes from the "Ostrich" instruction regarding deliberate ignorance in criminal cases in *U.S. v. Carrillo*, 435 F.3d 767, 779 (7th Cir. 2006).

## **11. Recklessly Indifferent Knowledge—Submission of Prescriptions for Payment to United States Government<sup>1</sup>**

*Relator's* Proposed Jury Instruction No. 14 is based on the facts in this case regarding the medically accepted indications for Geodon and Risperdal as set forth in Section B., above, Document 158, pp 4- 5, and the cited portions of the transcript of Dr. King therein, all of which constitute an offer of proof, and the discussion of the reckless indifferent standard in *United States v. King-Vassel*, 728 F.3d 707, 713 (7th Cir. 2013).

## **12. Defenses--Generally**

*Relator's* Proposed Jury Instruction No. 15 is adapted from § 178.50 O'Malley's Federal Jury Practice and Instructions, using the word "claim" instead of "statement" because this is a false claim case under 31 U.S.C. §3729(a)(1)(A), not a false statement case under 31 U.S.C. §3729(a)(1)(A).

## **13. Damages--Generally**

*Relator's* Proposed Jury Instruction No. 16 is adapted from § 178.60 O'Malley's Federal Jury Practice and Instructions, using the word "claim" instead of "statement" because this is a false claim case under 31 U.S.C. §3729(a)(1)(A), not a false statement case under 31 U.S.C. §3729(a)(1)(A).

## **D. *Relator's* Jury Verdict Interrogatories and Verdict**

The Jury interrogatories proposed by *Relator* were adapted from § 178.71 O'Malley's Federal Jury Practice and Instructions to fit the facts in this case and the Verdict Form uses § 178.70 O'Malley's Federal Jury Practice and Instructions with the names of the parties included.

## **E. Dr. King's Proposed Jury Instructions**

Dr. Watson offers the following objections to Dr. King's proposed jury instructions, Exhibit F, to the Joint Final Pretrial Report.

**(1) Nature Of The Action**

Dr. King's proposed Nature of the Action instruction should not be given because:

- (a) Relator is no longer asserting State claims,
- (b) Dr. King uses the term "medically accepted uses," rather than the relevant term, "medically accepted indications as defined under the Medicaid statute,"
- (c) Relator does not allege Dr. King submitted the prescriptions, but rather that she caused the submission of the prescriptions constituting false claims,
- (d) it is asking the jury to decide a question of law, specifically that federal and state law permit reimbursement for the prescriptions at issue.

**(2) Definition Of False**

Dr. King's proposed Definition of False instruction should not be given because this is a false claim case under 31 U.S.C. §3729(a)(1)(A), not a false statement case under 31 U.S.C. §3729(a)(1)(A).

**(3) Definition Of Knowing And Knowingly**

Dr. King's proposed Definition of Knowing and Knowingly instruction should not be given because this is a false claim case under 31 U.S.C. §3729(a)(1)(A), not a false statement case under 31 U.S.C. §3729(a)(1)(A).

**(4) ESSENTIAL ELEMENTS THAT THE PLAINTIFF MUST PROVE**

Dr. King's proposed Essential Elements That the Plaintiff Must Prove instruction should not be given because:

- (a) With respect to Elements One and Two, the Court of Appeals has held that a claim presented to a state Medicaid program is also a claim presented to the federal government, *United States v. King-Vassel*, 728 F.3d 707, 711 (7th Cir. 2013),



- (b) With respect to Element Three Dr. King uses the term "non-recognized medical uses," rather than the correct term of medically accepted indication as defined under the Medicaid statute,
- (c) With respect to Element Four Dr. King uses the word "fraudulent," rather than "false,"
- (d) With respect to Element Five, Dr. King uses the term false statement rather than false claim which it should be because this is a false claim case under 31 U.S.C. §3729(a)(1)(A), not a false statement case under 31 U.S.C. §3729(a)(1)(A).

**(5) CAUSATION**

Dr. King's proposed instruction on Causation should not be given because it omits that "Defendant Dr. King has the burden of proving each element of defendant's affirmative defenses by a preponderance of the evidence." which is in the referenced form, O'Malley's Federal Jury Practice, § 178.40, to be included if any affirmative defenses are asserted.

**(6) PREPONDERANCE OF THE EVIDENCE**

With respect to Dr. King's proposed instruction on Preponderance of the Evidence, other than the two typographical errors ("provided" rather than "proved"), Dr. Watson accepts the proposed instruction. Counsel for Dr. Watson apologizes to the Court for not realizing it was acceptable in time to include it in the joint proposed instructions (corrected, of course).

**(7) DEFENSES-GENERALLY**

Dr. King's proposed Defenses-Generally instruction should not be given because:

- (a) Dr. King uses the term "medically accepted uses," rather than the proper term of "medically accepted indication, as defined under the Medicaid statute,"
- (b) Dr. Watson is not claiming Dr. King submitted the prescriptions for reimbursement; and
- (c) It asks the jury to decide a question of law, to wit: that the Medicaid statutes permit reimbursement.

**(8) DAMAGES-GENERALLY**

Dr. King's proposed Damages-Generally instruction should not be given because this is a false claims case under 31 U.S.C. §3729(a)(1)(A), not a false statement case under 31 U.S.C. §3729(a)(1)(A).

**F. Dr. King's Proposed Special Verdict Form**

Dr. King's Proposed Special Verdict form should not be used for the following reasons:

1. Question No. 1 uses the word "fraudulent," where it should, at a minimum, use the term "false claim." Much preferable is using the term "not for a medically accepted indication as defined by the Medicaid statute."
2. Question No. 2 is misstated in some manner. "Cause to present" is not correct. Ignoring that, it also uses "fraudulent" when only false should be used. Most importantly, it states "to the state Medicaid program" which is very confusing since the jury might misunderstand that the correct question is whether prescriptions not for a medically accepted indication as defined under the Medicaid statute were presented to the federal government by being presented to the state Medicaid program. In other words Dr. King's proposed instruction is likely to cause the jury to not understand that

- a claim that might not be false as to Wisconsin is false as to the federal government.
3. Question 3 implies actual knowledge is required, when deliberate ignorance and reckless disregard also satisfy the knowing or *scienter* requirement under 31 U.S.C. §3729(b)(1). *See, United States v. King-Vassel*, 728 F.3d 707, 713 (7th Cir. 2013). Also "false" should be used instead of fraudulent.
  4. Question 4 has the same "cause to submit" problem, as well as using the term "fraudulent".
  5. Question 5 has the same problem as Question 2 in likely causing the jury to not understand that a claim that might not be false as to Wisconsin is false as to the federal government.
  6. Question 6 is okay.
  7. Question 7 assumes there should be a credit, but there is no instruction on such a concept in Dr. King's proposed jury instructions.
  8. Question 8 is okay and is essentially the same as Question 4 in Dr. Watson's Jury Interrogatories.

Dated: November 26, 2013

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Dated: November 27, 2013

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