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.

DEFENDANT JENNIFER KING VASSEL'S MOTION IN LIMINE TO PRECLUDE THE PLAINTIFF'S CLAIMS THAT DR. KING KNOWINGLY CAUSED TO BE SUBMITTED FALSE CLAIMS

Defendant Jennifer King Vassel (Dr. King), by her attorneys, Gutglass, Erickson, Bonville & Larson, S.C., respectfully submits the following motion in limine:

To preclude the plaintiff's claims as he lacks any evidence that Dr. King knowingly caused to be submitted any false claims to the Medicaid program.[1]

ARGUMENT

I. THE PLAINTIFF ADMITS THAT THE PRESCRIPTION MEDICATIONS AT ISSUE WERE REIMBURSED BY THE STATE PURSUANT TO ITS REGULATIONS.[2]

In order to establish liability under the federal False Claims Act, the plaintiff must establish

---

[1]The plaintiff acknowledged this question as one of two issues in this case. (Document 145, p. 7).

[2]Portions of this argument have been presented in opposition to the plaintiff's renewed motion in limine, and are being presented here in support of this motion. Dr. King does not intend to be redundant, but these arguments are important to support the motion. Dr. King also adopts the arguments presented in the opposition brief in support of Argument Section I here.

that (a) a false or fraudulent claim, (b) was presented, or was caused to be presented, by Dr. King to the United States for payment or approval, (c) with the knowledge that the claim was false or fraudulent. ***U.S. ex rel. Fowler v. Caremark Rx, LLC***, 496 F.3d 730, 740-41 (7th Cir. 2007), *overruled in part on other grounds,* ***Glaser v. Wound Care Consultants, Inc.***, 570 F.3d 907, 920 (7th Cir. 2009); 31 U.S.C. § 3729(a)(1)(A). The plaintiff only contends that Dr. King "caused to be presented" claims, as opposed to presenting a claim. *Complaint*, ¶ 26 (Document 1).

As to sub (c), "knowing" and "knowingly" mean a person:

> (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
> [. . . .]

31 U.S.C. § 3729 (b)(1)(A).

The plaintiff has admitted that "actual knowledge" is not at issue here: "[w]e understand that Dr. King did not actually know she was causing false claims when writing prescriptions to N.B." (Document 148-4). The plaintiff has also not presented any evidence that Dr. King acted in deliberate ignorance of the truth. Therefore the definition of knowledge turns to whether the plaintiff has presented any evidence that Dr. King acted in "reckless disregard" when allegedly causing prescription medications to be submitted to Medicaid. "Reckless disregard" is not negligence. ***Hindo v. University of Health Sciences***, 65 F.3d 608, 613 (7th Cir. 1995). "Reckless disregard" is either a failure "to make such inquiry as would be reasonable and prudent to conduct under the circumstances," or "when the actor knows or has reason to know of facts that would lead a reasonable person to realize" that harm is the likely result of the relevant act. ***United States v. King-Vassel***, 728 F.3d 707, 712-13 (7th Cir. 2013).

In November 2013, the plaintiff admitted that if a prescription medication was submitted in compliance with the applicable formulary, the prescription medication was legally reimbursable by the State Medicaid program.(Document 148-1, Number Four).

> REQUEST NO. 4: Admit that if a prescription medication was submitted in compliance with the applicable formulary described in Request No. 3[3], the prescription medication was legally reimbursable by a state Medicaid program.
> RESPONSE: **Denied as to federal funds used to pay for such prescriptions. Without sufficient information to admit or deny whether such prescriptions are legally reimbursable with state funds. It may be that it is allowable for a state Medicaid program to use state funds to pay for outpatient drug prescriptions that are not for a medically accepted indication as defined in 42 U.S.C. § 1396r-8(k)(6), § 1396r-8(g)(1)(B)(I); however, it is not legally reimbursable by federal funds**. As to using state funds, that is an open question which may or may not be resolved through discovery or briefing and decision, or both.

Id.

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 plaintiff also testified that he lacked the factual basis that the State did *not* pay for the prescription medications pursuant to its regulations. (Document 148-3, p. 42) (testifying that he did not recall or know whether BadgerCare has a different formulary than the three compendia listed in the complaint.)

Even before the plaintiff answered the second set of requests to admit, he admitted that he "does not dispute that Wisconsin has been reimbursing prescriptions that are not for a medically

[3]In request number three, the plaintiff was asked to admit "that the prescription medication written by Dr. King, as alleged in the complaint, were in compliance with the formulary, applicable for the period of time she treated N.B., used by the State of Wisconsin in compliance with 42 U.S.C. § 1396r-8 *et seq*." (Document 148-1, Number Three).

accepted indication when a doctor such as the defendant here ignores Congress' coverage restriction to medically accepted indications. Whether such prescriptions may be legally reimbursed is a *legal question*, not a factual one." *Plaintiff's Opposition to Dr. King's Motion for a HIPAA Qualified Protective Order* (Document 133, pp. 2-3)(emphasis added). Thus, the plaintiff acknowledges that he does not possess any factual knowledge of the basis for his claim that the prescriptions written were not supported by a formulary.

The admission of payment by the State pursuant to its criteria eviscerates Dr. King's liability for the state and federal claims. "[C]laims submitted to state Medicaid agencies are considered claims presented to the federal government and may serve as the basis for FCA liability." ***King-Vassel***, 728 F.3d at 711. "If a state knowingly chooses to reimburse for a drug, even for an off-label use, after a prior authorization review, liability would not attach because extensive government knowledge would 'negate the intent requirement under the FCA [False Claims Act] as a matter of law.' *See* ***Shaw v. AAA Eng'g & Drafting, Inc.***, 213 F. 3d 519, 534 (10th Cir. 2000)(explaining government knowledge defense.)" ***United States ex rel. Rost v. Pfizer, Inc.***, 253 F.R.D. 11, 16 (D. Mass. 2008). Accordingly, Dr. King cannot be held liable for knowingly causing to submit a false claim where the plaintiff admits that the state of Wisconsin reimburses medications prescribed for off-label use pursuant to its criteria.

II. THE PLAINTIFF CANNOT ESTABLISH KNOWLEDGE BASED ON DIFFERING INTERPRETATIONS OF THE MEDICAID REIMBURSEMENT STATUTES.

A. 42 U.S.C. § 1396r-8 Permits Reimbursement For Off-Label Use Not Supported By the Compendia.

Before beginning the analysis of the plaintiff's erroneous position, a review of the statute's background may provide some context. A state participating in Medicaid must submit a state

Medicaid plan for approval by the Centers for Medicaid and Medicare Services (CMS). 42 U.S.C. § 1396a; 42 C.F.R. § 430.15. Pursuant to 42 U.S.C. § 1396a(54), if a state's plan chooses to cover prescription medications, it must comply with the requirements of 42 U.S.C. § 1396r-8. 42 U.S.C. § 1396r-8 provides that if a manufacturer agrees to pay certain rebates to a state, the state's Medicaid program must cover the manufacturer's drugs. ***In Re Vioxx Liab. Litig.***, 2010 WL 2649513, at *10 (E.D. La. 2010) (all unpublished cases cited in this brief attached pursuant to local rule). This section permits a state the option of not covering certain limited categories of drugs. 42 U.S.C. § 1396r-8(d). A state, however, "may exclude or otherwise restrict coverage of a covered outpatient drug" if "the prescribed use is not for a medically accepted indication." 42 U.S.C. § 1396r-8(d)(1)(B)(I).

The plaintiff's interpretation ignores statutory construction and case law in interpreting section 1396r-8(g)(1)(B)(I).[4] First, it is significant that the plaintiff asserts that this is the statute that forms the basis of his argument. Sub (g) is part of the drug use review section in which drug review must consist of the compendia *and the peer-reviewed medical literature.* 42 U.S.C. § 1396r-8 (g)(1)(B)(ii). "It is a cardinal principle of statutory construction that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." ***TRW Inc. v. Andrews,*** 534 U.S. 19, 31 (2001).

The drug use review program, in assessing prospective drug review, "*shall* use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review." 42 U.S.C. § 1396r-8(g)(2)(A)(i)(emphasis added). The plaintiff's interpretation completely ignores the medical

[4]In an October 24, 2013 email, the plaintiff provided his interpretation of the Medicaid reimbursement statutes: "We are relying on the federal restriction of coverage to medically accepted indications as defined in 42 U.S.C. § 1396r-8(k)(6), § 1396r-8(g)(1)(B)(I)." *Affidavit of Bradley S. Foley, Exhibit A, Plaintiff's October 24, 2013 email.*

literature element that must comprise drug review and does not give effect to the actual statutory language. "Courts have a 'duty to construe statutes, not isolated provisions.'" ***Graham Cnty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson***, 559 U.S. 280, 290 (2010)(citation omitted).

The plaintiff also ignores how the drug review standards are to be applied.

> **(c) Application of Standards.**
> The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (**using the compendia and literature referred to in subsection** (1)(b) as the source of standards for assessment) including but not limited to monitoring for therapeutic appropriateness, [other standards listed] in order to improve the quality of care and to conserve program funds or personal expenditures.

42 U.S.C. § 1396r-8(g)(2)(C)(emphasis added). The plaintiff's interpretation forces medical science to wait for a whole year, until another book that comprises the compendia is published. *Affidavit of Bradley S. Foley, Exhibit B, AHFS Titles Issued Pursuant to Each Calendar Year.* Each introduction section of the yearly AHFS formulary, does not contemplate this: "The nature of drug information is that it is constantly evolving because of ongoing research and clinical experience and is often subject to interpretation and the uniqueness of each clinical situation and patient. [. . .] Because of the dynamic nature of drug information, readers are advised that decisions regarding drug therapy must be based on the independent judgment of the clinician, changing information about a drug (e.g., as reflected in the literature), and changing medical practices." (Document 148-8, p. 2).

Congress did not recognize such a restrictive interpretation, nor do Dr. King's experts, Mr. Olson and Dr. Diamond, both of whom serve or have served on formulary and drug utilization committees. (Document 145-1, p. 2; Document 145-2, p. 2). In other words, Congress understood that medicine is not static, and requested that the drug use review program be assessed on an ongoing basis as do physicians continuously do in the practice of medicine.

Another area of section 1396r-8 permits a state to exclude or otherwise restrict coverage of a covered outpatient drug for off-label uses not support by the compendia. 42 U.S.C. § 1396r-8(d)(1)(B)(i). Permissible restrictions for coverage of prescription medications are stated in 42 U.S.C. § 1396r-8(d).

> (d) Limitations on coverage of drugs
> (1) **Permissible** restrictions. [. . .]
> (B) A State **may** exclude or otherwise restrict coverage of a covered outpatient drug if –
> (i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(g) of this section);
> (ii) the drug is contained in the list referred to in paragraph (2); [. . .] **or**
> (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).

42 U.S.C. § 1396r-8(d) (emphasis added). Of significance, the limitations on coverage are not mandated, but are subject to the *discretion* of the State. "'May' is permissive." ***Directv, Inc. v. Barczewski***, 604 F.3d 1004, 1007 (7th Cir. 2010)(citation omitted).

The plaintiff has failed to present any evidence or legal basis as to whether the State of Wisconsin has restricted coverage for the medications at issue. The formulary, as noted in sub(iv) above, may be established by a state if it meets certain requirements. 42 U.S.C. § 1396r-8(d)(4). Among other requirements, the formulary must be developed by the state's drug use review board. 42 U.S.C. § 1396r-8(d)(4)(A). The establishment of a drug use review board is mandated by statute. 42 U.S.C. § 1396r-8(g)(3) ("Each State shall provide for the establishment of a drug use review board [. . .] either directly or through a contract with a private organization.")

The drug use review board reviews prescription medications to determine whether they are appropriate, medically necessary, and not likely to result in adverse medical results, using a number of sources and *not limited* to the compendia as contended by the plaintiff.

> (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**
> **(ii) the peer reviewed literature.**

42 U.S.C. § 1396r-8(g) (emphasis added).

The State of Wisconsin complied with this mandate and established a Drug Utilization Board. *See* Dr. Diamond's report and CV (Document 145-2, pp. 2 and 3). According to the bylaws of the State of Wisconsin Drug Utilization Review Board,

> Pursuant to the Omnibus Budget Reconciliation Act of 1990 (OBRA '90), federal rules require at 42 CFR § 456.716 that the state Medicaid agency establish a Drug Utilization Review (DUR) program. The DUR program is charged with developing procedures to assure drug use as appropriate, medically necessary and unlikely to result in adverse medical results.

(Document 110-2). Wisconsin regulations permit the reimbursement of prescription medications, as long as it is "medically necessary and cost-effective in treating the condition for which it is prescribed." Wis. Admin. Code DHS 107.10(3)(j).

In other words, states have the option to provide coverage for drugs for which the prescribed use is not for a medically accepted indication; the limitations on coverage are not mandated, but are subject to the *discretion* of the State. A formulary, as noted in sub(iv) above, may be established by a State or its contracted insurer if it meets certain requirements. 42 U.S.C. § 1396r-8(d)(4); *see* Wis. Admin. Code DHS 107.10(1)(covered drugs include legend and non-legend drugs and supplies listed in the Wisconsin medicaid drug index); *see also Affidavit of Bradley S. Foley*, *Exhibits C-E*, Managed Health Services Preferred Drug Lists. Of note, the administrative regulation does not

mention the compendia at all.

B. The Plaintiff's Interpretation of Medicaid Reimbursement Law Ignores Rules of Statutory Construction.

While the remainder of this section will discuss the plaintiff's flawed statutory interpretation, it is important to note that the foundation for the plaintiff's position that the compendia does not support the prescription of medications is without factual support. Risperdal, for example, is alleged in the complaint. (Document 1, ¶ 24(c). The American Hospital Formulary Service (AHFS) specifically states that it can be used for the treatment for children with autistic disorder, such as N.B. *Deposition of Christine Maxwell Meyer* (Document 148-5, pp. 36-37). "Risperdal: Autistic Disorder: Risperidone is used for the management of irritability associated with autistic disorder in children and adolescents [. . . .]" *Affidavit of Bradley S. Foley, Exhibit F*, *AHFS current on-line drug reference*; *See also Affidavit of Bradley S. Foley, Exhibit G, AHFS 2005 Drug Information* ("However, the drug has been used for the treatment of severe behavioral problems associated with autistic disorders in a limited number of children and adolescents 5-17 years of age without unusual side effects.")

Returning to the plaintiff's statutory analysis, the prescription of medication, however, is not solely governed by reference to the compendia. Rather than relying solely on the compendia to determine whether there is Medicaid coverage for prescription medications, Medicaid reimbursement law mandates that a panel of physicians, pharmacists, and other professionals consider not only the compendia, but also other medical information including medical literature.

C. The Centers for Medicare and Medicaid Services Does Not Support the Plaintiff's Restrictive Interpretation.

CMS does not disagree with the interpretation that the compendia is not the sole source for

determining whether a prescription medication is subject to Medicaid reimbursement. The plaintiff admitted that the State of Utah Attorney General's office on October 22, 2007 wrote to CMS requesting clarification as to whether CMS interpreted federal law to restrict federal financial participation for state Medicaid programs to uses of otherwise covered outpatient drugs that are either FDA approved or supported in the specified compendia, what the plaintiff contends here. (Document 31-3); (Document 31-6). In response to this letter, the CMS, in a letter dated December 6, 2007 stated that section 1927(d) of the Social Security Act (which became codified at 42 U.S.C. § 1396r-8) authorizes States to exclude or otherwise restrict coverage of a covered outpatient drug if the prescribed use is not for a medically accepted indication, ***however, it did not explicitly require them to do so.*** (Document 31-7).

The State of Utah then challenged CMS's assertion in a subsequent letter. (Document 31-8). In response, CMS reiterated that "our previous response to you is correct." (Document 31-9). CMS's interpretation must be afforded deference. "We have long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer, and the principle of deference to administrative interpretations has been consistently followed by this Court whenever decisions as to the meaning or reach of a statute has involved reconciling conflicting policies, and a full understanding of the force of the statutory policy in the given situation has depended upon more than ordinary knowledge respecting the matters subjected to agency regulations." ***Chevron, U.S.A., Inc. v. Natural Res. Def. Council, Inc.***, 467 U.S. 837, 844 (1984).

D. The Basis in Which Medicaid Was Established Does Not Support the Plaintiff's Interpretation.

The plaintiff's interpretation of the statutory scheme is not supported by the method in which

the Medicaid program operates. "Medicaid is not funded by a static block grant. Instead, the state seeks federal funding through quarterly requests, draws down from federal letters of credit as providers seek payment for Medicaid claims, and then submits reconciliations to the federal government which affect future funding. Under this funding scheme, in which false claims lead to direct draw downs from federal letters of credit, a provider who submits a false Medicaid claim to the state presents a false claim for payment or approval to the United States." ***United States ex re. Ven-A-Care v. Actavis Mid Atlantic, LLC***, 659 F.Supp.2d 262, 269 (D. Mass. 2009).

The plaintiff's position that essentially prohibits states from providing coverage for non-compendium uses of prescription medication, is contrary to the Medicaid program's "system of 'cooperative federalism'" that its federal laws established. ***Wisconsin Dept. of Health and Family Services v. Blumer***, 534 U.S. 473, 495 (2002). The Medicaid statute "gives the States substantial discretion to choose the proper mix, amount, scope, and duration of coverage, as long as care and services are provided 'in the best interest of the recipients.'" ***Alexander v. Choate***, 469 U.S. 287, 303 (1985), *citing* 42 U.S.C. § 1396a(a)(19).

Federal and state regulations follow echo this position. CMS provides the state Medicaid prescription medication reimbursement regulatory framework. 42 C.F.R. § 447.1 provides that "[t]his subpart prescribes State plan requirements, FFP limitations and procedures concerning payments made by State Medicaid agencies for Medicaid services." The following is one portion of the regulatory oversight involving State plans.

> State plan requirements, findings and assurances.
>
> (a) State plan. The State plan must describe comprehensively the agency's payment methodology for prescription drugs.
>
> (b) Findings and assurances. Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for

> multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:
>
> (1) Findings. The agency must make the following separate and distinct findings:
>
> (i) In the aggregate, its Medicaid expenditures for multiple source drugs are in accordance with the established upper limits.
>
> (ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.512 of this subpart.
>
> (2) Assurances. The agency must make assurances satisfactory to CMS that the requirements set forth in § 447.512 of this subpart concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.
>
> (c) Recordkeeping. The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

42 C.F.R. 447.518.

The Wisconsin administrative regulations do not prohibit reimbursement for the off-label use of a prescription medication. "(1) Covered Services. Drugs and drug products covered by MA [medical assistance] include legend [defined as any drug requiring a prescription under 21 U.S.C. § 353(b), pursuant to Wis. Admin. Code DHS 101.03 (94)] and non-legend drugs and supplies listed in the Wisconsin medicaid drug index which are prescribed by a physician [. . . .]" Wis. Admin. Code DHS § 107.10 Drugs. Nowhere in the code is there a restriction for use just to the FDA approval or the compendia. In fact a "drug produced by a manufacturer who does not meet the requirements of 42 U.S.C. 1396r-8 may be a covered service if the department determines that the drug is medically necessary and cost-effective in treating the condition for which it is prescribed." Wis. Admin. Code DHS 107.10(3)(j). The federal and state regulatory agencies do not support the plaintiff's position.

E. Cases Cited in Support of the Plaintiff's Position Are Distinguishable.

In the event the plaintiff relies on case law cited by the Court, the following is to note that those cases are distinguishable. The cases cited by the Court in its October 2, 2013 order that were presented as supporting the plaintiff's position are distinguishable. All three cases, ***U.S. ex rel. Bennett v. Medtronic, Inc.***, 747 F.Supp.2d 745, 754 (S.D. Tex. 2010), ***U.S. ex rel. Carpenter v. Abbott Labs., Inc.***, 723 F.Supp. 2d 395, 4009 (D. Mass. 2010), and ***U.S. v. Ortho-McNeil Pharm., Inc.***, 2007 WL 2091185 (N.D. Ill. 2007) are based on ***U.S. ex rel. Franklin v. Parke-Davis***, 147 F.Supp.2d 39 (D. Mass. 2001). *See* ***Bennett,*** F.Supp.2d at 754 n. 8; ***Carpenter***, 723 F.Supp.2d at 405, and ***Ortho-McNeil***, at *2. These decision all rely on the 2001 decision in ***Parke-Davis*** where the court put forth an interpretation of 42 U.S. § 1396r-8(g)(1)(B)(i) that ignores the fact that it is located in the drug use review section of the establishment of a State formulary. Moreover, the court's interpretation ignores "(ii): reference to peer-reviewed literature." 42 U.S.C. § 1396r-8(g)(1)(B)(ii).

Furthermore, the opinion is clear that it was postured as a motion to dismiss where the complaint is to be read broadly, and the defendant did not dispute the plaintiff's characterization of the law. ***Parke-Davis***, 147 F.Supp.2d at 51. *See also* ***U.S. ex rel. Franklin v. Parke-Davis***, 2003 WL 22048255, * 2 (D. Mass. 2003)("In the early phases of this litigation, 'Defendant d[id] not dispute that an off-label prescription submitted for reimbursement by Medicaid is a false claim within the meaning of the FCA.") In fact, now with the benefit of briefing, the 2003 ***Parke-Davis*** court noted the differing interpretations of Medicaid reimbursement (as presented in the case at bar as well) and stated the following:

> The debate may be immaterial. If the Medicaid statute gives states the discretion to cover off-label, non-compendium prescriptions, and a

> state exercised its discretion to cover such prescriptions, then an off-label Neurontin prescription in that state would not be a false claim. On the other hand, if the Medicaid statute does *not* give states the discretion to cover off-label, non-compendium prescriptions, but the state misconstrued the statute and authorized coverage of such prescriptions, an FCA action against Parke-Davis in that state would likely fail, as it would be difficult to establish Parke-Davis's scienter.

Parke-Davis, 2003 WL 22048255 at *3. The 2003 decision in ***Parke-Davis*** establishes that differing interpretation of the statutes do rise to liability under the False Claims Act.

F. Even if the Plaintiff's Interpretation of the Medicaid Reimbursement Statutes is Not Dismissed, the Differing Statutory Interpretations Do Not Rise to the Level that Dr. King Knowingly Caused to Be Submitted a False Claim.

The plaintiff cannot establish knowledge, as there is a dispute as to which interpretation of the Medicaid reimbursement statute is correct. This dispute, alone, does not rise to the level of reckless disregard, *i.e.*, that Dr. King failed to make a reasonable and prudent inquiry or has reason to know or knows of the fraud. The plaintiff's claim rests upon his interpretation of the Medicaid statutory scheme. Dr. King disputes this interpretation, an interpretation that is supported by the statutes, case law, and CMS. Dr. King cannot be held to have acted with "reckless disregard," when there are differing interpretations of complex Medicaid statutes and regulations, it is undisputed that the State reimbursed the prescription medications, and the State permits such reimbursement pursuant to its own regulations. The Seventh Circuit has held that knowledge cannot be established in the context of a false claim if legal theories are contested: "And imprecise statements or differences in interpretation growing out of a disputed legal question are similarly not false under the FCA." ***U.S. ex rel. Lamers v. City of Green Bay***, 168 F.3d 1013, 1018 (7th Cir. 1999).

Even if Dr. King's interpretation of the entire statutory scheme is rejected, the plaintiff still fails to meet the knowledge requirement of the False Claims Act. This is a dispute in the law which

does not rise to a reckless disregard of the law. *See* (Document 116, pp. 3-4)(where this Court acknowledged this legal dispute). A defendant who relies on a "good faith interpretation of a regulation is not subject to liability." ***U.S. ex rel. Oliver v. Parsons Co.***, 195 F.3d 457, 464 (9th Cir. 1999). This is correct "not because his or her interpretation was correct or 'reasonable' but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met." ***Id.***

In a decision issued this month, a judge of the Western District of Wisconsin concluded similarly that when there is a dispute about the interpretation of the law, knowledge under the False Claims Act cannot be established. "Indeed, numerous district courts have dismissed similar FCA claims at least in part because a debate surrounding the plaintiff's theory of falsity precludes any finding of knowledge." ***Thulin v. Shopko Stores Operating Co., LCC***, 2013 WL 5946503, *7 (W.D. Wis. 2013) (citing cases throughout the country in support of this view, including ***United States ex rel. Englund v. Los Angeles Cnty.***, 2006 WL 3097941, at *7 (E.D. Cal. 2006): "Claims are not 'false under the FCA when reasonable persons can disagree regarding whether the service was properly billed to the Government.'").

Here, the plaintiff is suing a psychiatrist on the theory that she is required to analyze complex statutes and regulations, whose reliance on the Medicaid or Medicaid HMO formularies is disputed, and reach a legal conclusion that rejects statutory construction and what Wisconsin administrative regulations mandate. Dr. King should not be held to a standard that "would transform every inaccurate claim into a false claim and consequently replace the Act's knowledge requirement with a strict liability standard." ***Fowler***, 496 F.3d at 743.

Even the plaintiff is not sure of the outcome of his interpretation of these statutes. "It may

be that it is allowable for a state Medicaid program to use state funds to pay for outpatient drug prescriptions that are not for a medically accepted indication as defined in 42 U.S.C. § 1396r-8(k)(6), § 1396r-8(g)(1)(B)(i); however, it is not legally reimbursable by federal funds. As to using state funds, that is an open question which may or may not be resolved through discovery or briefing and decision, or both." (Document 148-1, Number Four). If the plaintiff cannot determine whether he is presenting a question capable of resolution, then Dr. King cannot be held liable for allegedly knowingly causing the submission of a false claim. "The False Claims Act, even in its broadest application, was never intended to be used as a back-door regulatory regime to restrict practices that the relevant federal and state agencies have chosen not to prohibit through their regulatory authority." ***United States ex rel. Polansky v. Pfizer, Inc.***, 914 F.Supp.2d 259, 266 (E.D. N.Y. 2012).

CONCLUSION

Based on the foregoing arguments, defendant Jennifer King Vassel respectfully requests that the Court grant her motion.

Dated at Milwaukee, Wisconsin this 22nd 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

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