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-JPS

JENNIFER KING VASSEL, *et al.*,

Defendant.

RELATOR'S MOTION _IN LIMINE_ Re: FALSE CLAIMS

Relator, Dr. Toby Tyler Watson, as to the determination of whether the prescriptions at issue in this matter presented to Medicaid are false claims, moves for an order limiting testimony and argument to whether the prescriptions are off-label, and if so, whether they are supported by one of the statutorily incorporated drug references known as "compendia."

Dated this 14th day of September, 2013.

LAW PROJECT FOR PSYCHIATRIC
RIGHTS, INC.

s/ James B. Gottstein
James B. Gottstein (Alaska Bar # 7811100)
Attorney for *relator* Dr. Toby Tyler Watson

James B. Gottstein
Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, AK 99501

Phone: (907) 274-7686
Fax: (907) 274-9493
e-mail: jim.gottstein@psychrights.org

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MEMORANDUM IN SUPPORT OF
***RELATOR'S* MOTION *IN LIMINE* Re: FALSE CLAIMS**

Relator, Dr. Toby Tyler Watson, as to the determination of whether the prescriptions at issue in this matter presented to Medicaid are false claims, has moved for an order limiting testimony and argument to whether the prescriptions are off-label, and if so, whether they are supported by one of the statutorily incorporated drug references known as "compendia."

Such a limiting order is necessary, as the Relator expects that the defendant will otherwise attempt to enter evidence regarding "standard of care" and how common off-label prescriptions are. While that evidence may be relevant in an action based upon malpractice, here it would just create confusion for the jury and is wholly irrelevant.

Only relevant evidence is admissible, FRE 402, and evidence is only relevant if "the fact is of consequence in determining the action." FRE 401. The gravamen of the Complaint in this action is that Dr. King-Vassel caused false claims by prescribing certain drugs off-label to N.B. because Medicaid outpatient drug coverage for off-label drug prescriptions is limited to

those whose use have support in at least one of the compendia.[1]

This Court agreed with this analysis at page 11 of its Order granting summary judgment, Docket No. 59:

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

In its remand opinion, at page 16, the Court of Appeals affirmed:

> Medicaid can only provide reimbursement for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r–8(a)(3). Covered drugs do not include any drugs "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r–8(k)(3). . . . Helpfully, "medically accepted indication" is a statutorily-defined term that refers to a prescription purpose approved by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., or "supported by" any of several identified "compendia," 42 U.S.C. § 1396r–8(k)(6), § 1396r–8(g)(1)(B)(i).

Thus, in evaluating whether the prescriptions presented to Medicaid at issue in this matter were false claims, the only relevant, proper inquiry is whether they were off-label and not supported by one of the compendia.[2]

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[1] As the Court of Appeals held in its remand at page 16, under 42 U.S.C. § 1396r–8(k)(6), § 1396r–8(g)(1)(B)(i), the statutorily incorporated compendia are the American Hospital Formulary Service Drug Information (AHFS), the United States Pharmacopeia–Drug Information (or its successor publications) (US Pharmacopeia), and the DRUGDEX Information System (DRUGDEX). After inquiry, it is believed that US Pharmacopeia is no longer published, leaving two compendia.

[2] With respect to the prescriptions identified in the Complaint, the sole question is whether there is support in the compendia because the parties agree their use was off-label, as acknowledged at page 16 of the Court of Appeals remand opinion:

> The prescriptions at issue are "off-label" and so the parties agree that the drugs were not prescribed for an indication covered under the FDCA.

Dr. King-Vassel undoubtedly issued many other off-label prescriptions to patients under the age of 18, which should be revealed in discovery. (There is a pending Local C.R. 7(h) expedited non-dispositive motion to reset the close of discovery. Docket # 101.)

This is essentially what the Court of Appeals held at pages 3-4 of its opinion remanding this case:

> Once a drug has been approved for one use . . . the FDA cannot prevent physicians from prescribing the drug for other uses. Indeed, off-label prescriptions by physicians are quite common. . . . The legality of the prescription, however, does not answer questions such as . . . whether the government is obligated to pay for a Medicaid patient's off-label prescriptions.

(citations omitted).

Similarly, whether or not psychiatrists commonly write off-label prescriptions for uses on children that do not have support in any of the compendia, i.e., which may make such use within the "standard of care," does not answer the question of whether the government is allowed to pay for the prescription. Such standard of care type of evidence is of no consequence in determining this action, and should be excluded.

For the foregoing reasons, *Relator's* Motion In *Limine* Re: False Claims, should be **GRANTED**.

Dated this 14th day of September, 2013.

LAW PROJECT FOR PSYCHIATRIC RIGHTS, INC.

s/ James B. Gottstein
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ORDER

At Docket # ___, *Relator*, Dr. Toby Watson has moved, as to the determination of whether the prescriptions at issue in this matter presented to Medicaid are false claims, for an order limiting testimony and argument as to whether the prescriptions are off-label,[1] and if so, whether they are supported by one of the statutorily incorporated drug references known as "compendia."

Inasmuch as the sole question to be determined in this case with respect to whether the prescriptions presented to Medicaid at issue in this case is whether the prescriptions are off-label, and if so, whether they are supported by one of the statutorily incorporated drug references known as compendia, **IT IS ORDERED** that *Relator's* Motion In *Limine* Re: False Claims at Docket # _____ is hereby **GRANTED.**

IT IS FURTHER ORDERED, that testimony and argument as to whether the prescriptions presented to Medicaid at issue in this action are false claims, are limited to

[1] "Off-label" means a prescription use that is not approved by the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq.

whether such prescriptions are off-label, and if so, whether they are supported by any of the compendia.

Dated at Milwaukee, Wisconsin, this _____ day of _____.

BY THE COURT:

_____

J.P. Stadtmueller
U.S. District Judge