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,

Defendant.

CIVIL L.R. 7(h) EXPEDITED NON-DISPOSITIVE MOTION BY *RELATOR* TO COMPEL DR. KING-VASSEL TO PROVIDE PROPER RESPONSES TO DR. WATSON'S FIRST DISCOVERY REQUESTS and SUPPLEMENT DR. KING-VASSEL'S INITIAL DISCLOSURES

Relator, Dr. Toby Tyler Watson, moves for an order to compel defendant Dr. Jennifer King-Vassel, by November 7, 2013, to:

1. Provide non-evasive, complete responses to *Relator's* First Discovery Requests To Defendant Jennifer King-Vassel, and
2. Supplement her Initial Disclosures with respect to her defense that prescriptions presented to Medicaid that are not written for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) (off-label and not supported by any compendia), are not false claims under the False Claims Act, 31 U.S.C. § 3729, *et seq.*

Dated this 26th day of October, 2013.

LAW PROJECT FOR PSYCHIATRIC
RIGHTS, INC.

s/ James B. Gottstein
James B. Gottstein (Alaska Bar # 7811100)
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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA, and THE STATE OF WISCONSIN,

Plaintiffs,

ex rel. DR. TOBY TYLER WATSON,

Relator,

v.

JENNIFER KING VASSEL, *et al*.,
Defendant.

Case No. 11-CV-236-JPS

ORDER TO COMPEL DISCOVERY BY JENNIFER KING-VASSEL

Upon motion by *Relator*, Dr. Toby Tyler Watson (Dr. Watson), for an order to compel Defendant, Jennifer King-Vassel (Dr. King) to provide non-evasive, complete answers to Dr. Watson's First Discovery Requests and to supplement her Initial Disclosure, and good cause having been shown, the motion is **GRANTED**.

IT IS FURTHER ORDERED, that by November 7, 2013, Dr. King shall:

1. Serve non-evasive, complete answers to Dr. Watson's First Discovery Responses, including:

a. if she does not admit that the prescriptions identified in ¶ 24 of the Complaint in this matter, Docket No. 1, and Docket Nos. 46-1, 46-2, and 46-3 (Identified Prescriptions) were not prescribed for a use approved under approved under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (off-label), that she:

i. set forth in detail the facts upon which she bases, supports or justifies such denial or qualification, including the use and diagnosis or diagnoses for

which each of the prescriptions was issued,

ii. identify the specific document(s) and passage(s) that support or justify such denial or qualification, including any such document(s) and passage(s) that support such denial that the prescription was off-label,

iii. produce all documents relating to N.B's diagnoses for each of the Identified Prescriptions; and

iv. produce all documents relating to her contention that the prescription was for a use approved under the Food, Drug, and Cosmetic Act,

b. if she does not admit that the Identified Prescriptions were not issued for a use supported by (1) the American Hospital Formulary Service Drug Information (AHFS), (2) the United States Pharmacopeia–Drug Information (or its successor publications) (US Pharmacopeia), or (3) the DRUGDEX Information System (DRUGDEX), or (iv) any combination thereof, hereinafter referred to as "compendia," that she,

i. set forth in detail the facts upon which she bases, supports or justifies such denial or qualification, including the use and diagnosis or diagnoses for which each of the prescriptions was issued,

ii. identify the specific document(s) and passage(s) that support or justifies such denial or qualification, including any document(s) and passages that support her contention that the prescription was for a use supported by one or more of the compendia,

iii. to the extent not produced pursuant to 1.a.iii.,produce all documents relating to N.B.'s diagnosis or diagnoses for each of the prescriptions which she asserts was issued for a use supported by one or more of the compendia, and

iv. produce for each of the Identified Prescriptions that she contends is for a use supported by one or more of the compendia, all documents relating to such contention,

and

2. Supplement her Initial Disclosures by:

a. disclosing the name and, if known, the address and telephone number of each individual likely to have discoverable information she may use to support her defense that prescriptions not issued for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) (off-label and not supported by any compendia), are not false claims under the False Claims Act, 31 U.S.C. § 3729, *et seq.*; and

b. produce a copy of all documents, electronically stored information, and tangible things that she has in her possession, custody, or control and may use to support such defense.

Dated at Milwaukee, Wisconsin, this _____ day of _____, 2013.

BY THE COURT:

_____

J.P. Stadtmueller
U.S. District Judge

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,

Defendant.

**BRIEF IN SUPPORT OF
CIVIL L.R. 7(h) EXPEDITED NON-DISPOSITIVE
MOTION BY *RELATOR* TO COMPEL DR. KING-VASSEL TO
PROVIDE PROPER RESPONSES TO DR. WATSON'S
FIRST DISCOVERY REQUESTS
and
SUPPLEMENT DR. KING-VASSEL'S INITIAL
DISCLOSURES**

Relator, Dr. Toby Tyler Watson (Dr. Watson), has moved for an order to compel defendant Dr. Jennifer King-Vassel (Dr. King), by November 7, 2013, to:

1. Provide complete, non-evasive responses to *Relator's* First Discovery Requests To Defendant Jennifer King-Vassel (Discovery Requests), and
2. Supplement her Initial Disclosures with respect to her defense that prescriptions presented to Medicaid that were not issued for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) (off-label and not supported by any compendia), are not false claims under the False Claims Act, 31 U.S.C. § 3729, *et seq.*

A. Standards for Motions to Compel

Under Fed. R. Civ. P. 37(a)(3)(B)(iii) & (iv), a party seeking discovery may move for an order compelling an answer, production or inspection if (1) a party fails to answer an interrogatory submitted under Rule 33, and (2) a party fails produce documents as requested under Rule 34. Under Fed. R. Civ. P. 37(a)(3)(A), "If a party fails to make a disclosure required by Rule 26(a), any other party may move to compel disclosure and for appropriate sanctions."

For purposes of these provisions, an evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond. Fed. R. Civ. P. 37(a)(4).

B. *Relator's* First Discovery Requests

Relator's claims, on behalf of the United States Government and the State of Wisconsin, are quite simple: that prescriptions presented to Medicaid for payment that are not for a medically accepted indication are false claims within the meaning of the False Claims Act. This Court originally held that it was that simple 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, 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).

U.S.. v. King-Vassel, 728 F.3d 707, 715 (7th Cir. 2013).

Thus, through Request For Admission No. 1, Interrogatory No. 1, and Request for Production No. 1, of *Relator's* Discovery Requests,[1] Dr. King was asked to admit that the currently identified prescriptions were issued off-label, and if not, provide the basis for such denial, as follows:

> **REQUEST FOR ADMISSION NO. 1**. Please admit under F.R.C.P. 36 that each of the prescriptions identified
>
> 1. in ¶ 24 of the Complaint in this matter, Docket No. 1, and
> 2. Docket Nos. 46-1, 46-2, and 46-3,
>
> were not issued for a use approved under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (off-label).
>
> **INTERROGATORY NO. 1.** If the response to Request for Admission No. 1 is anything other than an unqualified admission, please (a) set forth in detail the facts upon which you base, support or justify your denial or qualification, including the use and diagnosis or diagnoses for which each of the prescriptions was issued, and (b) identify the specific document(s) and passage(s) that support or justify your denial or qualification, including any such document(s) and passages that support your denial that the prescription was off-label.
>
> **REQUEST FOR PRODUCTION NO. 1.** If the response to Request for Admission No. 1 is anything other than an unqualified admission, please produce:
>
> (a) all documents relating to N.B.'s diagnosis or diagnoses for each of the prescriptions; and
>
> (b) all documents identified in Interrogatory No. 1 or otherwise, relating to a contention that the prescription was for a use approved under the Food, Drug, and Cosmetic Act.

Exhibit 1, pp. 4-6. Frankly, Dr. King was expected to admit the prescriptions were off-label, because as the 7th Circuit noted:

> 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.

U.S. v. King-Vassel, 728 F.3d 707, 715 (7th Cir. 2013).

[1] Exhibit 1.

However, Dr. King denied it as follows:

> **Response to Request for Admission No.1:** Object to the form and foundation for the Request as it is multiple in form, ambiguous, and incomplete as to the factual and legal foundation. Subject to the objections, deny.

Exhibit 2, p. 2.

Later, Dr. King responded to Interrogatory No. 1 and Request for Production No. 1 as follows:

> **Response to Interrogatory No**. **1:** Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, incomplete as to the factual and legal foundation, and the request assumes that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment, and not paid for by a means other than through a Medicaid program.
>
> Subject to the objections, Dr. King wrote the prescriptions consistent with the formularies of the third party payors that paid for N.B. 's prescriptions, or for which Dr. King obtained prior authorization approval. Dr. King never submitted any prescription medications for reimbursement. Dr. King never was compensated for writing any prescriptions.
>
> **Response to Request for Production No. 1**: Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, incomplete as to the factual and legal foundation, and that the request assumes that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment, and not paid for by a means other than through a Medicaid program. Subject to the objections, see the response to Interrogatory No. 1. The plaintiff has already obtained records from Encompass. See forward to the applicable PDR.

Exhibit 3, pp. 1-2.

Through Request For Admission No. 2, Interrogatory No. 2, and Request for Production No. 2, *Relator* first sought Dr. King to admit the currently identified prescriptions were not supported by any of the compendia , and if this was denied, provide the basis for such denial, as follows:

> **REQUEST FOR ADMISSION NO. 2.** Please admit under F.R.C.P. 36 that each of the prescriptions identified
>
> (a) in ¶ 24 of the Complaint in this matter, Docket No. 1, and

(b) Docket Nos. 46-1, 46-2, and 46-3,

were not issued for a use supported by (i) the American Hospital Formulary Service Drug Information (AHFS), (ii) the United States Pharmacopeia–Drug Information (or its successor publications) (US Pharmacopeia), or (iii) the DRUGDEX Information System (DRUGDEX), or (iv) any combination thereof, hereinafter referred to as "compendia."

INTERROGATORY NO. 2. If the response to Request for Admission No. 2 is anything other than an unqualified admission, please (a) set forth in detail the facts upon which you base, support or justify your denial or qualification, including the use and diagnosis or diagnoses for which each of the prescriptions was issued, and (b) identify the specific document(s) and passage(s) that support or justify your denial or qualification, including any such document(s) and passages that support your contention that the prescription was for a use supported by one or more of the compendia.

REQUEST FOR PRODUCTION NO. 2. If the response to Request for Admission No. 2 is anything other than an unqualified admission, please produce:

(a) all documents relating to N.B.'s diagnosis or diagnoses for each of the prescriptions which you assert was issued for a use supported by one or more of the compendia; and

(b) for each and every prescription that you contend is for a use supported by one or more of the compendia, all documents identified in your response to Interrogatory No. 2, or otherwise, relating to your contention that the prescription was issued for a use supported by one or more of the compendia.

Exhibit 1, pp. 6-7.

Dr. King responded to these as follows:

Response to Request for Admission No.2: Object to the form and foundation for the Request as it is multiple in form, ambiguous, and incomplete as to the factual and legal foundation. Subject to the objections, deny.

Exhibit 2, p. 2.

Response to Interrogatory No.2: Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, incomplete as to the factual and legal foundation, the request assumes that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment, and not paid for by a means other than through a Medicaid program. Subject to the objections, see the response to Interrogatory No. 1.

> **Response to Request for Production No.2:** Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, incomplete as to the factual and legal foundation, and the request assumes that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment, and not paid for by a means other than through a Medicaid program. Subject to the objections, see response to Request for Production No. 1.

Exhibit 3, pp. 3 & 4.

The discovery requests are not ambiguous. They are very specific and precise, aimed exactly at *Relator's* claims. It is not believed they have to provide a factual and legal foundation; just seek relevant information, which is clearly the case. In any event the factual and legal foundation is clear. Dr. King's objection that the Discovery Requests are multiple in form is similarly not well taken. The discovery requests don't assume all prescriptions written to N.B. were submitted to a pharmacy for fulfillment, although it can be noted the 7th Circuit in *King-Vessel* held that can be presumed absent affirmative evidence to the contrary. 728 F.3d at 715. They are just asking for information about the prescriptions themselves. Their presentment to Medicaid is a different factual question. That "Dr. King wrote the prescriptions consistent with the formularies of the third party payors" (see Response to Interrogatory No. 1, which is incorporated by reference in Response to Interrogatory No. 2) is not a proper basis for failure to provide the requested discovery. It is Dr. King's theory of the case only.

It is respectfully suggested *Relator* is entitled to complete, non-evasive responses by Dr. King to the simple fact questions of whether the currently identified prescriptions were for off-label uses and whether there is any support in any of the compendia for such uses. This includes (1) the uses (diagnoses) for which the drugs were prescribed, (2) identifying exactly what documentary evidence supports the contention, and (3) producing such documents. That Dr. King has a defense theory contrary to the plain meaning of the statute, as this Court has

described it, does not mean she is not still obligated to respond to discovery directed at *Relator's* claims.

The Certification Regarding Discovery Discussions Between Watson and King-Vassel of even date describes undersigned counsel's futile efforts to obtain Dr. King-Vassel to respond properly.

C. Supplementation of Dr. King's Initial Disclosures

Dr. King's Discovery Responses object on the basis that the prescriptions were written "consistent with the formularies of the third party payors," presumably including Medicaid. In response to *Relator's* Motion *In Limine*[2] to restrict testimony and argument to whether prescriptions at issue were for a "medically accepted indication," as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i), Dr. King stated at page 6 of her brief in opposition,[3] that she "will present expert testimony regarding her off-label use of prescription medications and Wisconsin's formulary permitting reimbursement beyond the compendia."

In its October 2, 2013, Order denying the Motion *In Limine*, pending further discovery and the right to renew, this Court stated:

> [*Relator's* interpretation] is the plain reading of the statutory scheme, and many courts apply the scheme in precisely that cut-and-dry fashion without even considering that there is an alternative. Those courts interpreting this statutory scheme hold that there is no wiggle room: if a prescription was written for a non-FDCA-approved or non-compendia supported use, then it is a false claim.
>
> There is, however, another alternative: that states have the power to determine whether they wish to cover prescriptions for uses that are not approved by the FDCA and are not supported by the compendia (or that, perhaps, they lack that power, but nonetheless do so anyway) . . .

[2] Document No. 102.
[3] Document No. 109.

> Some courts have even gone further to explicitly find that states retain the control to determine whether they wish to reimburse for such prescriptions that fall outside of both the FDCA and compendia. . . .
>
> Perhaps Wisconsin is one of those states. Or, perhaps Wisconsin does not have the power to determine whether it will reimburse for non-FDCA, non-compendia prescriptions, but nonetheless has represented to physicians that it will reimburse the prescriptions, anyway. . . .
>
> The Court does not outright decide, at this point, that it will admit such evidence. Rather, the parties should engage in discovery on the topic, and, after they have identified the Wisconsin reimbursement process, they may submit such further arguments to the Court regarding the relevance of the discovered information. . . .
>
> Accordingly, the Court will deny Watson's motion *in limine* without prejudice subject to renewal, together with additional briefing, after the parties have had an opportunity to engage in further discovery.

Trial Scheduling Order, Document No. 116, pp. 3-5 (citations omitted). Thus, writing prescriptions consistent with a formulary is being interposed as a defense by Dr. King.

Under Fed. R. Civ. P. 26(e), Dr King, "must supplement or correct [her] disclosure or response:"

> (A) in a timely manner if the party learns that in some material respect the disclosure or response is incomplete or incorrect, and if the additional or corrective information has not otherwise been made known to the other parties during the discovery process or in writing; or
>
> (B) as ordered by the court.

With respect to this and any other defense(s), under Fed. R. Civ. P. 26(a)(1)(A)(i) & (ii), Dr. King is required to provide

> (i) the name and, if known, the address and telephone number of each individual likely to have discoverable information--along with the subjects of that information--that the disclosing party may use to support its claims or defenses, unless the use would be solely for impeachment;
>
> (ii) a copy--or a description by category and location--of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control and may use to support its claims or defenses, unless the use would be solely for impeachment;

Undersigned counsel has attempted to get Dr. King to recognize these obligations to no avail as set forth in Exhibit 3 to the Certification Regarding Discovery Discussions Between Watson and King-Vassel of even date.

D. Conclusion

For the foregoing reasons, *Relator* respectfully requests an order compelling Dr. King to provide by November 7, 2013,[4] complete, non-evasive answers, to Dr. Watson's First Discovery Requests and to supplement her Initial Disclosures with the information required under Fed. R. Civ. P. 26(a)(1)(A)(i) & (ii) with respect to any defense(s) she may have.

Dated this 26th day of October, 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

[4] Dr. King has been making her formulary argument at least since the 7th Circuit oral argument on April 25, 2013. By the time Dr. King's response to this motion is due, it will have been almost two months since the Trial Scheduling Order was issued and less than a month from the deadline for the Final Pretrial Report. Document No. 100, p. 2. To the extent Dr. King is not required to produce the information forthwith, *Relator* will be unfairly prejudiced.

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 FIRST DISCOVERY REQUESTS TO DEFENDANT JENNIFER KING-VASSEL

NOW COMES *Relator* Dr. Toby Tyler Watson, who requests that you produce for inspection and copying the material hereafter described and that you answer the following Requests for Admissions and written Interrogatories, and respond to the Requests for Production. Your answers to the Requests for Admissions, Interrogatories and Requests for Production must be served no later than thirty (30) days after the service of this pleading upon you.

The questions that follow are to be considered as continuing, and you are requested to provide by way of supplemental answers hereto such additional information as you or any person acting on your behalf may hereinafter learn which will augment or otherwise supplement or change your answers to the questions below. Such supplemental responses are to be served upon this party immediately upon receipt of such information.

Where knowledge, information, or documents are requested, such request encompasses knowledge, information or documents in your possession, custody or control, or in the possession, custody or control of your staff, agents, employees, representatives and, unless privileged, attorneys, or any other person who has possession, custody or control of your

proprietary knowledge, information or documents.

I. DEFINITIONS

Unless the question conclusively indicates otherwise, the following definitions apply to the words used in these interrogatories:

A. Person: The term "person" includes a corporation, partnership, other business association or entity, a natural person, and any government or government body, commission, board or agency.

B. Document or Record: The term "document" or "record" are defined to mean and include any and all graphic or physical representations, including without limitation all handwritten, typed or printed material, photographs, copies of all the foregoing, and material stored on tape. computer or any other electronic medium, including e-mail and sound recordings.

C. Identification of Documents: When you are requested to "identify" a document or record, you are requested to provide the following with regard to each document:

(1) A description of the document with sufficient particularity to enable the custodian of the document to respond to a request for production or subpoena *duces tecum* for the document;

(2) The name, business address, residence address, telephone number and occupation of the present custodian of the document;

(3) The date on which such document as first prepared; and

(4) The name, business address, residence address, telephone number and occupation of each person who prepared or signed the document.

D. Identification of Natural Person: When you are requested to "identify" a natural person. you are requested to provide the following with regard to each such person:

(1) The name of the person;

(2) person's date of birth;

(3) The residence address of the person;

(4) The business telephone number of the person;

(5) The residence telephone number of the person;

(6) The e-mail address of the person;

(7) The occupation of the person and the name of the employer of the person, if any.

E. Identification of Business Entity: When you are requested to "identify" any corporation, partnership, joint venture or other business entity, you are requested to provide the following with regard to each such entity:

(1) Whether the entity is a corporation, partnership, joint venture or other type of entity;

(2) If the entity is a partnership or joint venture:

(i) identify each partner or joint venturer;

(ii) state whether he or she is a limited or general partner; and

(iii) specify the date on which the partnership or joint venture was formed;

(3) If the entity is a corporation:

(i) identify each of the current officers of the corporation;

(ii) state the date of incorporation;

(iii) state the State in which the corporation is incorporated.

F. The words "you" and "your," refer to Jennifer King-Vassel, M.D., her employees and agents and anyone acting by, for or through Jennifer King-Vassel, M.D.

G. Relate: The words "relate" or "relating to" mean referring to, concerning, alluding to, responding to, connected with, commenting on, in respect of, about, regarding, discussing,

showing, describing, mentioning, reflecting, analyzing, constituting, evidencing, or pertaining to, directly or indirectly, in whole or in part.

II. CLAIMS OF PRIVILEGE:

(a) If the response to any Interrogatory is withheld on grounds of privilege, the basis for such claim shall be stated with particularity.

(b) If any document(s) or other item(s) identified or requested herein are withheld for any reasons under a claim of privilege or any other claim, the particular document or other item(s) withheld are to be described as follows:

(1) The date of the document or other item;

(2) The author or addressor of the document or other item;

(3) The recipient or addressee of the document or other item;

(4) The number of pages of the document;

(5) The general subject matter of the document or other item;

(6) Each person who sent, received and obtained copies of the document or other item;

(7) A general description of the document or other item (i.e., letter, report, memoranda, audio or video recording); and

(8) The basis of the privilege asserted with respect to the alleged grounds for non-production of the document or other item.

REQUEST FOR ADMISSION NO. 1.

Please admit under F.R.C.P. 36 that each of the prescriptions identified

1. in ¶ 24 of the Complaint in this matter, Docket No. 1, and
2. Docket Nos. 46-1, 46-2, and 46-3,

were not issued for a use approved under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (off-label).

RESPONSE

INTERROGATORY NO. 1.

If the response to Request for Admission No. 1 is anything other than an unqualified admission, please (a) set forth in detail the facts upon which you base, support or justify your denial or qualification, including the use and diagnosis or diagnoses for which each of the prescriptions was issued, and (b) identify the specific document(s) and passage(s) that support or justify your denial or qualification, including any such document(s) and passages that support your denial that the prescription was off-label.

RESPONSE

REQUEST FOR PRODUCTION NO. 1.

If the response to Request for Admission No. 1 is anything other than an unqualified admission, please produce:

(a) all documents relating to N.B.'s diagnosis or diagnoses for each of the prescriptions; and

(b) all documents identified in Interrogatory No. 1 or otherwise, relating to a contention that the prescription was for a use approved under the Food, Drug, and Cosmetic Act.

RESPONSE

REQUEST FOR ADMISSION NO. 2.

Please admit under F.R.C.P. 36 that each of the prescriptions identified

(a) in ¶ 24 of the Complaint in this matter, Docket No. 1, and

(b) Docket Nos. 46-1, 46-2, and 46-3,

were not issued for a use supported by (i) the American Hospital Formulary Service Drug Information (AHFS), (ii) the United States Pharmacopeia–Drug Information (or its successor publications) (US Pharmacopeia), or (iii) the DRUGDEX Information System (DRUGDEX), or (iv) any combination thereof, hereinafter referred to as "compendia."

RESPONSE

INTERROGATORY NO. 2.

If the response to Request for Admission No. 2 is anything other than an unqualified admission, please (a) set forth in detail the facts upon which you base, support or justify your denial or qualification, including the use and diagnosis or diagnoses for which each of the prescriptions was issued, and (b) identify the specific document(s) and passage(s) that support or justify your denial or qualification, including any such document(s) and passages that support your contention that the prescription was for a use supported by one or more of the compendia.

RESPONSE

REQUEST FOR PRODUCTION NO. 2.

If the response to Request for Admission No. 2 is anything other than an unqualified admission, please produce:

(a) all documents relating to N.B.'s diagnosis or diagnoses for each of the prescriptions which you assert was issued for a use supported by one or more of the compendia; and

(b) for each and every prescription that you contend is for a use supported by one or more of the compendia, all documents identified in your response to Interrogatory

No. 2, or otherwise, relating to your contention that the prescription was issued for a use supported by one or more of the compendia.

RESPONSE

REQUEST FOR ADMISSION NO. 3.

Please admit under F.R.C.P. 36 that you knew from your initial meeting with NB in 2004 that NB was a recipient of Medical Assistance/Medicaid.

RESPONSE

INTERROGATORY NO. 3.

If the response to Request for Admission No. 3, is anything other than an unqualified admission, please (a) set forth in detail the facts upon which you base, support or justify your denial or qualification in light of you billing Medicaid/Medical Assistance for your services, and (b) state when you first became aware that NB was a recipient of Medical Assistance / Medicaid.

RESPONSE

REQUEST FOR PRODUCTION NO. 3.

If the response to Request for Admission No. 3 is anything other than an unqualified admission, please produce all documents relating to such denial or qualification, including but not limited to copies of all records you submitted or caused to be submitted for billing the services you provided to NB.

RESPONSE

INTERROGATORY NO. 4.

Please identify every person who is a Medicaid recipient to whom you, since March 3, 2005, when the person was under 18 years of age, prescribed at least one of the drugs listed in the attached chart of Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications (Medically Accepted Indications Chart) where the row for the diagnosis for which the drug was prescribed does not have a white background in the Medically Accepted Indications Chart. For purposes of this Interrogatory, "identify" means to provide the person's (a) full name, (b) parent(s) or guardian(s), (c) date of birth, and (d) Medicaid Identification Number. It is acceptable that the person's full name and parent(s) or guardian(s) be omitted, PROVIDED the person's Medicaid Identification Number is provided.

RESPONSE

REQUEST FOR PRODUCTION NO. 4.

Please produce all mental health, prescription, and billing records for each person identified in Interrogatory No. 4. It is acceptable that the person's full name and parent(s) or guardian(s) be redacted so long as his or her date of birth and Medicaid Identification Number is included.

RESPONSE

INTERROGATORY NO. 5.

Identify by name, address and phone number every person who participated in responding to these Admissions, Interrogatories and Requests for Production, and identify what information each person provided.

Dated this 16th 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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VERIFICATION OF RESPONSES

I, Jennifer King-Vassel, M.D. swear or affirm that I have read the responses to the *Relator's* First Discovery Requests To Defendant Jennifer King-Vassel, M.D., and that they are true and correct to the best of my informed knowledge and belief.

Date: _____ _____

STATE OF WISCONSIN)
) ss:
_____ COUNTY)

Subscribed and sworn or affirmed to before me this ___ day of _____ 2013, by Jennifer King-Vassel, M.D.

_____
Clerk of Court, Notary Public or other
person authorized to administer oaths.

My Commission expires: _____

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications
by
The Law Project for Psychiatric Rights (PsychRights

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Key:	**White Background: Medically Accepted Indication**			
	Orange Background: Pediatric Indication cited, but not supported by DRUGDEX			
	Red Background: No Pediatric FDA Approval or DRUGDEX citation			
Abilify (Aripiprazole) - Antipsychotic				
	Autistic disorder-Psychomotor agitation	Yes (6-17)		
	Bipolar I Disorder - Adjunctive therapy with lithium or valproate for Acute Manic or Mixed Episodes	Yes (for 10 yrs old and up)		
	Bipolar I Disorder, monotherapy, Manic or Mixed Episodes	Yes (for 10-17 years old re acute therapy)		
	Schizophrenia	Yes (for 13-17 years old)		
Adderall (amphetamine/dextroamphetamine) - Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 3 years old and up re: [immediate-release] and 6 years old and up re: [extended-release] drug		
	Narcolepsy	Yes (for 6 years old and up (immediate release only)		
Ambien (zolipidem) - nonbartiturate Hypnotic				
	Insomnia, Short-term treatment	No		Class III
Anafranil (clomipramine) - Antidepressant; Antidepressant, Tricyclic; Central Nervous System Agent				
	Obsessive-Compulsive Disorder	Yes (for 10 years and up)		
	Depression	No		Class IIb
Ativan (lorazepam) - Antianxiety, Anticonvulsant, Benxodiazepine, Short or Intermediate Acting, Skeletal Muslgel Relaxant.				
	Anxiety	Yes, oral only, 12 years and older		
	Chemotherapy-induced nausea and vomiting; Prophylaxis	No	Class IIa	
	Insomnia, due to anxiety or situational stress	Yes		
	Seizure	No	Class IIa	
	Status epilepticus	No	Class IIa	
	Premedication for anesthetic procedure	No		Class IIb
	Sedation	No		Class IIb
	Seizure, drug-induced; Prophylaxis	No		Class IIb
Buspar (buspirone) - Antianxiety, Azaspirodeconedione				
	Anxiety	No		Class III
	Autistic disorder	No		Class IIb
	Behavioral syndrome	No		Class IIb
	Pervasive developmental disorder	No		Class IIb
Celexa (citalopram) - Antidepressant, Serotonin Reuptake Inhibitor				
	Depression	No		None
	Obsessive-compulsive disorder	No		Class IIb
	Panic disorder	No		Class IIb
	posttraumatic stress disorder	No		Class IIb

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications
by
The Law Project for Psychiatric Rights (PsychRights

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

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications
by
The Law Project for Psychiatric Rights (PsychRights

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

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications
by
The Law Project for Psychiatric Rights (PsychRights

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Mellaril (thioridazine) - Antipsychotic; Phenothiazine; Piperidine				
	Schizophrenia, Refractory	Yes		
	Behavioral Syndrome	No		Class III
Moban (molindone) - antipsychotic, Dihydroindolone				
	Schizophrenia	Yes, 12 years and older		
	Aggressive behavior, In children	No		Class IIb
Neurontin (gabapentin) anticonvulsant				
	Partial seizure; Adjunct	Yes (3- 12 years old)		
	Complex Regional Pain Syndrome, Type 1	No		Class IIb
	Neuropathic Pain	No		Class IIb
	Partial Seizure	No		Class IIb
	Partial Seizure, Refractory	No		Class III
	Phantom Limb Syndrome	No		Class IIb
Orap (pimozide) - Antipsychotic; Diphenylbutylpiperidine; Dopamine Antagonist				
	Gilles de la Tourette's syndrome	Yes (12 years and older)		
	Anorexia Nervosa	No		Class III
Paxil (paroxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Panic disorder	No		Class IIb
	Trichotillomania	No		Class IIb
Pristiq (desvenlafaxine) Antidepressant, Serotonin/Norepinephrine Reuptake Inhibitor				
Prozac (fluoxetine) - Antidepressant; Central Nervous System Agent; Serotonin Reuptake Inhibitor				
	Major Depressive Disorder	Yes (for 8 years old and up)		
	Obsessive-Compulsive Disorder	Yes (for 7 years old and up		
	Anxiety Disorder of Childhood	No		Class IIb
	Autistic disorder	No		None
	Bulimia nervosa	No		Class IIb
	Vasovagal syncope; Prophylaxis	No		Class III
Restoril (temazepam) - Antianxiety, Bensodiazepine, Short or Intermediate Acting, Hypnotic				
Ritalin (methylphenidate) - Amphetamine Related; Central Nervous System Agent; CNS Stimulant				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years to 12 years old)(exteded release)		
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)(immediate release)		
	Narcolepsy	Yes (for 6 years and up, and Ritalin(R) -SR only)		
	Autistic disorder	No		Class IIb
	Finding related to coordination / incoordination - Impaired cognition	No		Class IIb
	Schizophrenia	No		Class III
	Traumatic Brain Injury	No		Class IIb
Risperdal (risperidone) - Antipsychotic; Benzisoxazole				
	Autistic Disorder – Irritability	Yes (for 5 years old and up)		
	Bipolar I Disorder	Yes (for 10 years old and up)		
	Schizophrenia	Yes (for 13 years old and up, ORALLY)		
	Behavioral syndrome - Mental retardation	No		Class IIb
	Gilles de la Tourette's syndrome	No		Class IIb
	Pervasive developmental disorder	No		Class IIb

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications
by
The Law Project for Psychiatric Rights (PsychRights

Drug	Indication (diagnosis)	FDA Approval	DRUGDEX Support for Off-Label Use	DRUGDEX Recommendation Level
Rozerem (ramelteon) - Melatonin Receptor Agonist, Nanbarbiturate Hypnotic				
Seroquel (QUETIAPINE) - Antipsychotic; Dibenzothiazepine				
	Bipolar disorder, maintenance	Yes, 10-17 regular release only (12/4/09)		
	Manic bipolar I disorder	Yes, 10-17 regular release only (12/4/09)		
	Schizophrenia	Yes 13-17, regular release only (12/4/09)		
	Gilles de la Tourette's syndrome	No		Class IIb
Sinequan (doxepin) - Antianxiety Antidepressant; Antidepressant, Tricyclic; Antiulcer Dermatological Agent				
	Alcoholism - Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety – Depression	Yes (for 12 years old and up)		
	Anxiety - Depression - Psychoneurotic personality disorder	Yes (for 12 years old and up)		
	Pruritus (Moderate), Due to atopic dermatitis or lichen simplex chronicus	No		Class IIb
Sonata (zaleplon) - Nonbarbiturate Hypnotic				
Strattera (atomoxetine) - Central Nervous System Agent; Norepinephrine Reuptake Inhibitor				
	Attention Deficit Hyperactivity Disorder (ADHD)	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD) - Social phobia	No		Class IIb
Symbyax (fluoxetine hydrochloride/olanzapine) - Antidepressant; Antipsychotic				
Tegretol (carbamazepine) - Anticonvulsant; Antimanic; Dibenzazepine Carboxamide; Neuropathic Pain Agent				
	Epilepsy, Partial, Generalized, and Mixed types	Yes		
	Apraxia			None
	Chorea			Class IIb
	Migraine; Prophylaxis			Class IIb
	Myokymia			Class IIb
	Neuropathy, General			Class IIb
	Schwartz-Jampel syndrome			Class IIb
Tofranil (imipramine) - Antidepressant; Antidepressant, Tricyclic; Urinary Enuresis Agent				
	Nocturnal enuresis	Yes (for 6 years old and up)		
	Attention Deficit Hyperactivity Disorder (ADHD), Predominantly Inattentive Type	No		Class III
	Depression	No		Class IIb
	Schizophrenia, Adjunct	No		Class III
	Separation Anxiety Disorder of Childhood	No		Class III
	Trichotillomania	No		Class IIb
	Urinary incontinence	No		Class IIb
Topamax (topiramate) - anticonvulsant, Fructopyranose Sulfamate				
	Lennox-Gastaut syndrome; Adjunct	Yes, 2 years and older		
	Partial seizure, Initial monotherapy	Yes, 10 years and older		
	Partial seizure; Adjunct	Yes, 10 years and older		
	Tonic-clonic seizure, Primary generalized; Adjunct	Yes, 2 to 16 years old		
	Tonic-clonic seizure, Primary generalized (initial monotherapy)	Yes, 10 years and older		
	Angelman syndrome	No		Class IIb
	Migraine; Prophylaxis	No		Class IIb

Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications
by
The Law Project for Psychiatric Rights (PsychRights

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

DRUGDEX® Consults

RECOMMENDATION, EVIDENCE AND EFFICACY RATINGS

RESPONSE

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

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

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

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

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,

Defendant.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on this date I e-mailed *Relator's* First Discovery Requests To Defendant Jennifer King-Vassel, M.D., to Stacy C Gerber Ward at stacy.g.ward@usdoj.gov and snail mailed the same to:

Thomas L Storm
Wisconsin Department of Justice
Office of the Attorney General
PO Box7857
Madison, W153707-7857

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330 E Kilbourn Ave - 11th Fl
Milwaukee, WI 53202-6616

Dated this 16th day of September, 2013.

s/ James B. Gottstein
James B. Gottstein

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.

JENNIFER KING VASSEL,

Defendant.

Case No. 11-CV-236

DEFENDANT'S RESPONSE TO
PLAINTIFF'S FIRST SET OF REQUESTS TO ADMIT

Defendant Jennifer King Vassel, by her attorneys, Gutglass, Erickson, Bonville, & Larson, S.C., and as and for a response to the plaintiff's first set of requests to admit responds as follows:

Request for Admission No. 1: Please admit under F.R.C.P. 36 that each of the prescriptions identified

1. in ¶ 24 of the Complaint in this matter, Docket No. 1, and

2. Docket Nos. 46-1, 46-2, and 46-3,

were not issued for a use approved under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (off-label).

Response to Request for Admission No. 1: Object to the form and foundation for the Request as it is multiple in form, ambiguous, and incomplete as to the factual and legal foundation. Subject to the objections, deny.

Request for Admission No. 2: Please admit under F.R.C.P. 36 that each of the prescriptions identified

(a) in ¶ 24 of the Complaint in this matter, Docket No. 1, and

(b) Docket Nos. 46-1, 46-2, and 46-3,

were not issued for a use supported by (I) the American Hospital Formulary Service Drug Information (AHFS), (ii) the United States Pharmacopeia-Drug Information (or its successor publications) (US Pharmacopeia), or (iii) the DRUGDEX Information System (DRUGDEX), or (iv) any combination thereof, hereinafter referred to as "compendia."

Response to Request for Admission No. 2: Object to the form and foundation for the Request as it is multiple in form, ambiguous, and incomplete as to the factual and legal foundation. Subject to the objections, deny.

Request for Admission No. 3: Please admit under F.R.C.P. 36 that you knew from your initial meeting with NB in 2004 that NB was a recipient of Medical Assistance/Medicaid.

Response to Request for Admission No. 3: Object to the form and foundation for the Request as it is multiple in form, ambiguous, and incomplete as to the factual and legal foundation. Subject to the objections, deny.

Dated at Milwaukee, Wisconsin this 16th day of October, 2013.

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

Bradley S. Foley

Mark E. Larson (#1016423)
Bradley S. Foley (#1026871)
Attorneys for defendant Jennifer King Vassel

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v. Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

DEFENDANT'S RESPONSE TO PLAINTIFF'S FIRST SET OF INTERROGATORIES AND REQUEST FOR PRODUCTION OF DOCUMENTS

Defendant Jennifer King Vassel, by her attorneys, Gutglass, Erickson, Bonville, & Larson, S.C., and as and for a response to the plaintiff's first set of interrogatories and request for production of documents responds as follows:

Interrogatory No. 1: If the response to Request for Admission No. 1 is anything other than an unqualified admission, please (a) set forth in detail the facts upon which you base, support or justify your denial or qualification, including the use and diagnosis or diagnoses for which each of the prescriptions was issued, and (b) identify the specific document(s) and passage(s) that support or justify your denial or qualification, including any such document(s) and passages that support your denial that the prescription was off-label.

Response to Interrogatory No. 1: Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, incomplete as to the factual and legal

foundation, and the request assumes that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment, and not paid for by a means other than through a Medicaid program.

Subject to the objections, Dr. King wrote the prescriptions consistent with the formularies of the third party payors that paid for N.B.'s prescriptions, or for which Dr. King obtained prior authorization approval. Dr. King never submitted any prescription medications for reimbursement. Dr. King never was compensated for writing any prescriptions.

Request for Production No. 1: If the response to Request for Admission No. 1 is anything other than an unqualified admission, please produce:

(a) all documents relating to N.B.'s diagnosis or diagnoses for each of the prescriptions; and

(b) all documents identified in Interrogatory No. 1 or otherwise, relating to a contention that the prescription was for a use approved under the Food, Drug, and Cosmetic Act.

Response to Request for Production No. 1: Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, incomplete as to the factual and legal foundation, and that the request assumes that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment, and not paid for by a means other than through a Medicaid program. Subject to the objections, see the response to Interrogatory No. 1. The plaintiff has already obtained records from Encompass. See forward to the applicable PDR.

Interrogatory No. 2: If the response to Request for Admission No. 2 is anything other than an unqualified admission, please (a) set forth in detail the facts upon which you base, support or justify you denial or qualification, including the use and diagnosis or diagnoses for which each of the prescriptions was issued, and (b) identify the specific document(s) and passages that support your contention that the prescription was for a use supported by one or more of the compendia.

Response to Interrogatory No. 2: Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, incomplete as to the factual and legal foundation, the request assumes that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment, and not paid for by a means other than through a Medicaid program. Subject to the objections, see the response to Interrogatory No. 1.

Request for Production No. 2: If the response to Request for Admission No. 2 is anything other than an unqualified admission, please produce:

(a) all documents relating to N.B.'s diagnosis or diagnoses for each of the prescriptions which you assert was issued for a use supported by one or more of the compendia; and

(b) for each and every prescription that you contend is for a use supported by one or more of the compendia, all documents identified in your response to Interrogatory No. 2, or otherwise, relating to your contention that the prescription was issued for a use supported by one or more of the compendia.

Response to Request for Production No. 2: Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, incomplete as to the factual and legal foundation, and the request assumes that all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment, and not paid for by a means other than through a Medicaid program. Subject to the objections, see response to Request for Production No. 1.

Interrogatory No. 3: If the response to Request for Admission No. 3 is anything other than an unqualified admission, please (a) set forth in detail the facts upon which you base, support or justify your denial or qualification in light of you billing Medicaid/Medical Assistance for your services, and (b) state when you first became aware that NB was a recipient of Medical Assistance/Medicaid.

Response to Interrogatory No. 3: Object to the form and foundation for the interrogatory as it is multiple in form, ambiguous, and incomplete as to the factual and legal foundation. Subject to the objections, N. B. was covered by an HMO, Managed Health Services, that had its own distinct formulary. Dr. King prescribed medications that were either listed in the formulary or for which she received prior authorization from the managing entity. See the Encompass medical records and Managed Health Services formulary. Dr. King's diagnosis as well as N.B.'s age and history were fully disclosed to any third party payor. Dr. King never billed Medicaid/Medical Assistance.

Request for Production No. 3: If the response to Request for Admission No. 3 is anything other than an unqualified admission, please produce all documents relating to such denial or

qualification, including but not limited to copies of all records you submitted or caused to be submitted for billing the services you provided to NB.

Response to Request for Production No. 3: See response to Interrogatory No. 3.

Interrogatory No. 4: Please identify every person who is a Medicaid recipient to whom you, since March 3, 2005, when the person was under 18 years of age, prescribed at least one of the drugs listed in the attached chart of Medically Accepted Indications for Pediatric Use of Certain Psychotropic Medications (Medically Accepted Indications chart) where the row for the diagnosis for which the drug was prescribed does not have a white background in the Medically Accepted Indications Chart. For purposes of this Interrogatory, Identify means to provide the person's (a) full name, (b) parent(s) or guardian(s), (c) date of birth, and (d) Medicaid Identification Number. It is acceptable that the person's full name and parent(s) or guardian(s) be omitted, PROVIDED the person's Medicaid Identification Number is provided.

Response to Interrogatory No. 4: Objection, form, foundation, and the request does not comply with the restrictions imposed by the Court's October 2, 2013 protective order. Subject to those objections, Dr. King is not a records custodian for any such patients and thus does not have custody or control of medical records for such patients. When she provided services to N.B., she did not personally submit billing or receive reimbursement from any third party payor.

Moreover, Dr. King prescribed medications that were either listed in the applicable formulary or for which she received prior authorization from the third party payor. Dr. King's diagnosis as well as N.B.'s age and history were fully disclosed to the third party payor. Thus, the information requested cannot be provided.

Request for Production No. 4: Please produce all mental health, prescription, and billing records for each person identified in Interrogatory No. 4. It is acceptable that the person's full name and parent(s) or guardian(s) be redacted so long as his or her date of birth and Medicaid Identification Number is included.

Response to Request for Production No. 4: See response to Interrogatory No. 4.

Interrogatory No. 5: Identify by name, address and phone number every person who participated in responding to these Admissions, Interrogatories and Requests for Production, and identify what information each person provided.

Response to Interrogatory No. 5: Object to the Request as it improperly seeks attorney client communication and attorney work product.

As to the interrogatories:

Jennifer King, M.D.

Subscribed and sworn to before me
this 18th day of October, 2013.

Notary Public, State of Wisconsin
My Commission expires: is perm.

As to Objections to the Interrogatories and Responses to the Requests for Production of Documents:

Dated at Milwaukee, Wisconsin this 21st day of October, 2013.

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

Bradley S. Foley

Mark E. Larson (#1016423)
Bradley S. Foley (#1026871)
Attorneys for Defendant Jennifer King Vassel

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v. Case No. 11-CV-236-JPS

JENNIFER KING VASSEL,

Defendant.

CERTIFICATION REGARDING DISCOVERY DISCUSSIONS BETWEEN WATSON AND KING-VASSEL

Pursuant to Fed. R. Civ. P. 27(a), and this Court's September 11, 2013, Trial Scheduling Order, Docket No. 100, with respect to *Relator*, Dr. Toby Watson's Motion to Compel Proper Responses to His First Discovery Requests, Document No. 127, the undersigned counsel hereby certifies:

1. On October 22, 2013, at a little after noon in Alaska and 3:00 p.m. in Wisconsin, I e-mailed Brad Foley and Mark Larson, co-counsel for defendant Jennifer King-Vassel (Dr. King) about the inadequacies of their responses to *Relator's* First Discovery Requests To Defendant Jennifer King-Vassel (*Relator's* First Discovery Requests) received the previous day. The e-mail is attached hereto as Exhibit 1, Dr. King's responses to *Relator's* First Discovery Requests are Document Nos. 128-2 & 128-3.

2. At approximately 1:15 p.m. in Alaska and 4:15 p.m. in Wisconsin on October 22, 2013, I called Mr. Foley, and after the receptionist told me Mr. Foley was on the telephone, left voice mail to the effect that I would like to speak with him to see if we could work out the discovery issues.

3. At approximately 1:40 p.m. in Alaska and 4:40 p.m. in Wisconsin on October 22, 2013, I called Mr. Larson, and after the receptionist told me Mr. Larson was not in the office that day, left voice mail to the effect that I would like to speak with him to see if we could work out the discovery issues.

4. Just before 8:00 a.m., in Alaska and 11:00 a.m. in Wisconsin on October 23, 2013I called Mr. Foley and being unable to reach him left a voice mail that I had called.

5. At approximately 8:15 a.m., in Alaska and 11:15 a.m., in Wisconsin on October 23, 2013, Mr. Larson called and we spoke. Mr. Larson disputed that their responses were improper on the ground that "that's not way the process works in Wisconsin," which I understood to mean that whether or not a prescription is for a "medically accepted indication" as defined in the Medicaid statute is not determinative of whether Wisconsin Medicaid will reimburse. I informed Mr. Larson that I understood that is their position and agreed they can make that argument, but I was entitled to the discovery, especially as to the basis for their denial that the currently identified prescriptions were written for uses not approved under the Food, Drug and Cosmetic Act (off-label), and their denial that the prescriptions were for uses not supported by the compendia. Mr. Larson said he would take another look and asked that I give him until mid-afternoon Alaska time the following day, October 24, 2013. I agreed.

6. I followed this up with an e-mail at 12:02 p.m., in Alaska, 3:02 p.m., in Wisconsin in an attempt to further explain why Dr. King had to provide the diagnoses for which the currently identified prescriptions were written and the basis for a denial that that they were not supported by any of the compendia, including identifying the passages that supported the use, which resulted in a response by Mr. Larson, to which I responded, and in which Mr. Larson confirmed he would advise by mid-afternoon the next day, October 24, 2013, whether Dr. King would supplement her responses. Exhibit 2. hereto.

7. Later that day, October 23, 2013, at 4:38 p.m. in Alaska, I e-mailed Mr. Larson to try and obtain information sufficient for the *Relator* admit or deny Dr. King's Request for Admission No. 3. Mr. Larson replied without answering the questions at 5:55 a.m., Alaska time, 8:55 a.m., Wisconsin time on October 24, 2013. I responded to this e-mail with a further explanation of why the *Relator* needed this information in order to be able to either admit or deny Request for Admission No. 3 at 10:35 a.m. in Alaska, 2:35 p.m, in Wisconsin, and also pointing out that under Fed .R. Civ. P. 26, Dr. King was obligated to supplement her Initial Disclosures with the requested information. Mr. Larson responded at 11:07 a.m. in Alaska, 2:07 p.m., in Wisconsin, again refusing to provide the information and reneging on his agreement to advise me whether Dr. King would supplement her responses to the *Relator's* first set of discovery requests, to which I responded at 6:28 p.m., in Alaska, 9:28 p.m., in Wisconsin, noting at the end that I would call Mr. Larson in the morning. Exhibit 3, hereto.

On October 25, 2013, at approximately 7:45 a.m. in Alaska, 10:45 a.m. in Wisconsin I called Mr. Larson and being unable to reach him, left voice mail.

As of the filing of this certificate, Mr. Larson has not returned my call, nor has anyone else.

Dated this 26th day of October, 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

Jim Gottstein

From: Jim Gottstein <jim.gottstein@psychrights.org>
Sent: Tuesday, October 22, 2013 12:12 PM
To: Mark Larson; bradley.foley@gebsc.com
Cc: jim.gottstein@psychrights.org; Rebecca Gietman; Dr. Toby Watson
Subject: Inadequate Discovery Responses

Importance: High

Hi Brad and Mark,

Dr. King's responses to Dr. Watson's first discovery requests are inadequate and we need to talk about them. I will be calling shortly.

General

While I know you argue that prescribing from the formulary(ies) insulates Dr. King from False Claims Act liability, the 7th Circuit agreed with Dr. Watson that if Dr. King wrote prescriptions presented to Medicaid are off-label and not "supported" by one of the compendia they are false claims. Judge Stadtmueller has left open the possibility of you presenting evidence and making arguments pending further discovery with respect to whether Wisconsin has determined to cover prescriptions that are not for a medically accepted indication, but that doesn't mean you are free to ignore your obligations under the discovery rules.

The 7th Circuit also held that absent affirmative evidence that prescriptions written by Dr. King were not presented to Medicaid for payment, that it can be presumed, she knowingly caused claims to Medicaid for such prescriptions if she knew the patient was a Medicaid recipient.

The discovery requests were very focused on the elements to establish False Claims Act liability for causing presentment of claims to Medicaid prescriptions that were not for a medically accepted indication, i.e., for off-label uses that do not have compendia support.

Request for Admission No. 1.

Request for Admission No. 1 (RFA 1) simply asked Dr. King to admit the currently identified prescriptions were not issued for a use approved under the Food, Drug, and Cosmetic Act, 21 U.S.C. §301 et seq. (off-label). You responded:

> Object to the form and foundation for the Request as it is multiple in form, ambiguous, and incomplete as to the factual and legal foundation. Subject to the objections, deny.

RFA 1 is certainly not ambiguous and the denial is directly contrary to the admission of Dr. King that all of the currently identified prescriptions were off-label, as recited at page 16 of the 7th Circuit Opinion that, "the parties agree that the drugs were not prescribed for an indication covered under the FDCA." Thus, the denial appears to be in bad faith.

As to the objection that RFA 1 is multiple in form, F.R.C.P. 36(a)(2) merely requires that each matter must be separately stated. RFA 1 complies with this requirement. If you have any authority for the proposition that the form of RFA 1 is improper in the 7th Circuit because it is multiple in form, please provide it immediately. You

should have such authority at your fingertips to make such an objection. I didn't find any with a Westlaw search.

As to the objection that RFA 1 is incomplete as to the factual and legal foundation, I do not understand that to be a proper objection, but am willing to be convinced by citation to authority, which again, you should have at your fingertips before making such an objection. RFA 1 was to a simple fact: Were the currently identified prescriptions off-label? I believe the only proper objection along these lines would be that RFA 1 is irrelevant, which is clearly not the case.

Interrogatory No. 1

Similarly, Dr. King's Response to Interrogatory No. 1 (Int 1), is inadequate. Int 1 simply asks for the facts upon which anything but an admissiont to RFA 1 is based and identification of documents supporting the denial. Since Dr. King denied the prescriptions were for an off-label use the Interrogatory requires her to identify the use approved under the FDCA for each of the currently identified prescriptions. Dr. King should have these at her fingertips in light of her denial. I will note, however, that the denial is not only contrary to the admission in previous proceedings in this case as set forth above, it is contrary to Dr. King's records.

As to the objection that Int 1 is multiple in form, please provide authority for the proposition that she need not respond to an interrogatory because it is multiple in form or incomplete as to the factual and legal foundation. The interrogatory simply sought facts. I do not believe a factual or legal foundation needed to be set forth in the interrogatory. It is well established in the case. The interrogatory only needed to seek relevant evidence.

Request for Production No. 1

If the response to RFA 1 was anything but an admission, Request for Production No. 1 (RP 1) asks for all documents relating to N.B's diagnoses and all documents relating to a contention that the uses were for a use approved under the FDCA.

As she did with all of the discovery requests, you object that Request for Production No. 1 (RP 1) is multiple in form. Please provide authority that this is a proper objection for a request for production. F.R.C.P. 34(b)(1)(A) merely requires the request "must describe with reasonable particularity each item or category of items. RP 1 clearly does so.

Dr. King's objection that the request assumes all prescriptions written by Dr. King were submitted to a pharmacy for fulfillment is incorrect. That is a separate fact, which, not so incidentally, the 7th Circuit in its remand opinion held at 15 is established absent affirmative evidence to the contrary. The documents required by RP 1, are those relating to Dr. King's failure to admit that the currently identified prescriptions were off-label.

With respect to the objection that the plaintiff has already obtained records from Encompass this is not a proper objection unless the request is unreasonably cumulative or duplicative under F.R.C.P. 26(b)(2)(C)(i), which I do not believe it is. Any legible records already obtained from Encompass need not be produced again. I also note this response is inconsistent with your later assertion Dr. King does not have custody or control of any such records.

I am not sure I understand the response, "See forward to the applicable PDR." If by that Dr. King means the Forward to Physicians Desk Reference monographs for the drugs prescribed for the currently identified prescriptions or any other documents, RP 1 requires Dr. King to produce such documents. Int 1 requires Dr. King to identifiy the specific passages that support Dr. King's failure to admit that the currently identified

prescriptions were off-label. If that is not what Dr. King meant, please explain and you are required provide the required documents.

Interrogatory No. 2 and Request for Production No. 2

Interrogatory No. 2 (Int 2) requires Dr. King to provide the facts upon which Dr. King based her failure to admit the currently identified prescriptions were not suported by any of the compendia pursuant to Request for Admission No. 2 (RFA 2) including identifying the specific documents and passages constituting such support. Since Dr. King failed to admit the currently identified prescriptions are not supported by any of the compendia, she was required to provide the information sought by Int 2. You also made the same objections as in your response to Int 1, and my same demands apply. The same goes with respect to Request for Production No. 2 (RP 2). Dr. King is required to produce all documents relating N.B.'s diagnosis for each of the currently identified prescriptions relating to your contention that currently identified prescriptions are supported in any of the compendia. My responses and demands relating to your objections also apply.

Interrogatory No. 3 and Request for Production No. 3

Interrogatory No. 3 (Int 3) requires Dr. King to provide the facts upon which Dr. King based her failure to admit that Dr. King knew from her initial meeting with N.B. in 2004 that he was a Medicaid recipient. In addition to my responses and demands to your form response, I first note that your response appears to have a couple of deliberate misstatements or to be deliberately misleading. Managed Health Services' website states. "We provide most of the medical & mental health services available under BadgerCare Plus (Standard, Benchmark, Core) through the Medicaid program." (emphasis added). In addition, your statement that Dr. King never billed Medicaid is belied by Document 46-4 and is otherwise not credible in light of all of the Medication Management notes that were presumably paid for by Medicaid. In connection with this uncredible statement that Dr. King never billed Medicaid, Request for Production No. 3 (RP 3) requires you to provide copies of all records Dr. King submitted or caused to be submitted for billing the services she provided to NB. By its terms, RP 3 is not limited to billings Dr. King herself submitted to Medicaid.

Interrogatory No. 4.

Interrogatory No. 4 (Int 4) requires Dr. King to identify every of her Medicaid patients who was under 18 when she prescribed drugs listed on the Medically Accepted Indications Chart for a use which did not have a white background on the chart. You responded that Int 4 did not comply with the Court's October 2, 2013, protective order. This is true because the discovery requests were propounded prior to the protective order, but that does not relieve you of the responsibility of complying with the interrogatory to the extent allowed by the protective order.

You responded that Dr. King is not a records custodian for any such patients. Even if true, this does not relieve Dr. King of her responsibility to identify such patients. Who are such custodians in addition to Encompass? Are you including CAPS as such a custodian?

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

Law Project for Psychiatric Rights
406 G Street, Suite 206
Anchorage, Alaska 99501 USA
Phone: (907) 274-7686 Fax: (907) 274-9493
jim.gottstein@psychrights.org
http://psychrights.org/

The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging and electroshock. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Currently, due to massive growth in psychiatric drugging of children and youth and the current targeting of them for even more psychiatric drugging, PsychRights has made attacking this problem a priority. Children are virtually always forced to take these drugs because it is the adults in their lives who are making the decision. This is an unfolding national tragedy of immense proportions. Extensive information about all of this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

Jim Gottstein

From: Jim Gottstein <jim.gottstein@psychrights.org>
Sent: Wednesday, October 23, 2013 10:54 AM
To: 'Mark Larson'
Cc: 'Brad Foley'; 'Rebecca Gietman'; jim.gottstein@psychrights.org; Dr. Toby Watson
Subject: RE: Follow-Up

Hi Mark,

Thank you for your prompt response. Specific responses are in red, below.

From: Mark Larson [mailto:mark.larson@gebsc.com]
Sent: Wednesday, October 23, 2013 9:57 AM
To: Jim Gottstein
Cc: Brad Foley; Rebecca Gietman
Subject: RE: Follow-Up

Jim

As I indicated in our telephone discussion this afternoon, I will review the responses again but the problem is the imprecise way the interrogatories are worded. Your email underscores the ambiguity by using the phrase "medically accepted indication" which is not a phrase defined or limited by the compendia nor the FDA as the FDA expressly acknowledges, and is inconsistent with the medically accepted use of that phrase.

You are profoundly incorrect that the definition of "medically accepted indication" under the Medicaid statute is ambiguous. As explained by the Seventh Circuit:

> "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)

Furthermore, the Court of Appeals did not and could not reach the conclusion you assert since the only issue before it was whether SJ had been properly granted.

You are free to make your argument about what "medically accepted indication" means as applicable to this litigation in the face of the above quoted language from the remand opinion (subject to Rule 11), but to reiterate, that doesn't mean you don't have to provide the requested discovery.

I would also ask that you review the plaintiff's responses to the defendant's initial discovery and provide supplemental, non-evasive responses.

I don't believe Dr. Watson has provided evasive responses in the past and he won't going forward. We are reviewing whether supplemental responses to previous discovery are warranted and also expect to respond to your extant discovery requests in a timely manner.

As I further indicated, I will advise you as to whether we determine supplementation of defendant's responses are required tomorrow.

Thank you.

Sincerely yours,

Mark E. Larson
Gutglass, Erickson, Bonville & Larson, S.C.
735 North Water Street, Suite 1400
Milwaukee, WI 53202
direct phone: (414) 908-0226

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Wednesday, October 23, 2013 12:02 PM
To: Mark Larson
Cc: Brad Foley; jim.gottstein@psychrights.org; Rebecca Gietman; Dr. Toby Watson
Subject: Follow-Up

Hi Mark,

Here is my take on the situation. First, it doesn't seem to me that we should really fight over things over which there is no legitimate dispute. I understand you do not believe that the fact that a prescription was not written for what is defined in the statute as a "medically accepted indication," meaning a use approved under the Food, Drug and Cosmetic Act (FDCA), or supported by a compendia is not determinative of whether or not it is a false claim if presented to Medicaid.

You can make that argument and the District Court is allowing you to make at least some argument about that for now in spite of apparently clear language from the 7th Circuit to the contrary.

That being so, it seems to me that we just need not fight over whether the currently identified prescriptions were off-label and if so, whether there is support for their use in the compendia, if there is no real dispute over it. In other words, let's narrow the issue to your contention that whether or not the prescriptions were for a medically accepted indication is irrelevant if it was within the formulary (or whatever argument you might make about this).

If you do believe that any of the currently identified prescriptions were for a use approved under the FDCA or supported by the compendia, then just show us your basis for that as requested in our discovery. It is required.

I am happy to discuss this with you further and any other matters, especially settlement.

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

Psych Rights®
LAW PROJECT FOR PSYCHIATRIC RIGHTS

Law Project for Psychiatric Rights
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The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging and electroshock. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Currently, due to massive growth in psychiatric drugging of children and youth and the current targeting of them for even more psychiatric drugging, PsychRights has made attacking this problem a priority. Children are virtually always forced to take these drugs because it is the adults in their lives who are making the decision. This is an unfolding national tragedy of immense proportions. Extensive information about all of this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.

Jim Gottstein

From: Jim Gottstein <jim.gottstein@psychrights.org>
Sent: Thursday, October 24, 2013 6:28 PM
To: 'Mark Larson'
Cc: jim.gottstein@psychrights.org; Brad Foley; Rebecca Gietman; Dr. Toby Watson
Subject: RE: Request for Admission No 3

Hi Mark,

My responses are in red, below.

From: Mark Larson [mailto:mark.larson@gebsc.com]
Sent: Thursday, October 24, 2013 11:07 AM
To: Jim Gottstein
Cc: 'Dr. Toby Watson'; 'Rebecca Gietman'; Brad Foley
Subject: RE: Request for Admission No 3

Hi Jim

I disagree on Rule 26 impacting RFAs in the matter that you assert. In fact, if you answer the RFA accurately, there will be no need for any witness which is one of the purposes of using RFAs.

The problem is the Relator cannot admit or deny RFA 3, without knowing the facts involved. That is not going to help us narrow the issues.

They can be used to assert legal and factual propositions. We will certainly supplement our Rule 26 disclosures as warranted.

Since you are asserting this theory that the Wisconsin formulary somehow trumps federal law, under Civil Rule 26(a)(1)(A)(i) you are obligated to inform us of any individual you might call to support it and under Civil Rule 26(a)(1)(A)(ii) to provide "a copy--or a description by category and location--of all documents, electronically stored information, and tangible things that the disclosing party has in its possession, custody, or control and may use to support its claims or defenses."

Furthermore, since your claim alleges the prescriptions were not covered under Wisconsin's Medicaid program, you are asserting your knowledge and reliance on the applicable formularies.

We are not asserting any knowledge and reliance on the supposed applicable formularies. You are. 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). We are just trying to get you to disclose your theory.

Therefore if you are not aware of the contents of the formularies, then please indicate that in your response as to why you cannot admit or deny the response.

I can respond that the *Relator* is unable to admit or deny, but I am trying to avoid having to do that.

I would note that the plaintiff has never disclosed the compendia in a Rule 26 disclosure and therefore the plaintiff's RFAs are in the same situation as the defense RFAs.

I don't believe that is accurate. My understanding is the relevant DRUGDEX monographs were supplied as part of the *Relator's* Initial Disclosures, or thereabouts. My understanding is DRUGDEX is universally acknowledged as the most expansive of the compendia, so it was used.

Also, if you mean to imply the formularies can only be more restrictive in coverage than what is set forth in the compendia, you are incorrect based on a plain reading of the statute, Wisconsin administrative code, etc. But whether that is true or not does not relieve the plaintiff of its obligation to respond to the written discovery. Compliance is used here consistent with its usual meaning as contained in commonly used dictionaries.

As for supplementing our discovery responses, we are continuing to determine whether supplementation is required in light of our recent discussions and do so if we determine the current responses are insufficient. We are actively working on this issue.

Yesterday, you represented to me that you would give me an answer by mid-afternoon today, my time. Now, you seem to be putting this off indefinitely. I will call tomorrow morning to discuss this.

Jim Gottstein

Sincerely yours,

Mark E. Larson
Gutglass, Erickson, Bonville & Larson, S.C.
735 North Water Street, Suite 1400
Milwaukee, WI 53202
direct phone: (414) 908-0226

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Thursday, October 24, 2013 10:35 AM
To: Mark Larson
Cc: 'Dr. Toby Watson'; 'Rebecca Gietman'; jim.gottstein@psychrights.org; Brad Foley
Subject: RE: Request for Admission No 3

Hi Mark,

I know what the statute provides. However, you are asking the *Relator* to admit that the currently identified prescriptions were in compliance with the formulary. What "in compliance with" is ambiguous in this context so I asked what you mean by that. I also asked you to provide the formulary and what regulations and rules pertain to it so the *Relator* could either admit or deny the request. I understand your response to these questions to be that you will not do so. However, such information is required to be produced under F.R.C.P. 26(a)(1)(a)(ii) irrespective of Request for Admission No. 3. Also, under F.R.C.P. 26(a)(1)(a)(i) you are required to identify individuals likely to have discoverable information with respect to Request for Admission No. 3. Please provide the information required under F.R.C.P. 26(a)(1)(a)(i)&(ii) relating to Request for Admission No. 3. You must have it if you asked the *Relator* to admit to it.

I am not trying to be cute here. I am trying to understand your defense. Formularies under 42 U.S.C. §1396r-8(d)(4), by its terms, are used to further restrict coverage, not expand it. The *Relator* is entitled to discover the facts supporting this defense and you are required to provide the documents relating thereto and identify individuals who are likely to have information that you may use to support it. Please do so immediately. You must have it since you have asked the *Relator* to admit to it.

Jim

From: Mark Larson [mailto:mark.larson@gebsc.com]
Sent: Thursday, October 24, 2013 5:55 AM
To: Jim Gottstein; Brad Foley
Cc: Dr. Toby Watson; Rebecca Gietman
Subject: RE: Request for Admission No 3

Jim

The statute you claim Dr. King violated clearly provides that each state is to establish a formulary to apply to Medicaid drug coverage. The provisions clearly state that the compendia is only a factor that may be considered by the state board. If you do not have knowledge of the formularies and whether the prescriptions at issue fell within the applicable formulary for a the specific timeframe, that should be part of your response.

Sincerely yours,

Mark E. Larson
Gutglass, Erickson, Bonville & Larson, S.C.
735 North Water Street, Suite 1400
Milwaukee, WI 53202
direct phone: (414) 908-0226

From: Jim Gottstein [mailto:jim.gottstein@psychrights.org]
Sent: Wednesday, October 23, 2013 4:38 PM
To: Mark Larson; Brad Foley
Cc: jim.gottstein@psychrights.org; Dr. Toby Watson; Rebecca Gietman
Subject: Request for Admission No 3

Hi Mark and Brad,

I am working on our responses to your 2nd set of discovery requests and have some questions about Request for Admission No 3, which states:

> REQUEST NO. 3: Admit that the prescription medications 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.

What I would like to do is clarify exactly what is being asked so I don't need to respond with an objection and a series of different responses depending on the numerous possible meanings of the request.

My first question is what does "in compliance with the formulary" mean? A sub question to that is what is the formulary? **Please provide it**. Another subquestion is what does "in compliance with" mean in that context? In other words, does it mean that the prescriptions were of drugs that appear on the formulary? In that regard, **if there are any regulations or similar rules pertaining to "the formulary," that would inform a response please provide it**.

My second question is what does "the formulary . . . used by the State of Wisconsin in compliance with 42 U.S.C. § 1396r-8 et seq.," mean? First, leaving aside whether there actually is a formulary, it assumes that the formulary is in compliance with 42 U.S.C. § 1396r-8 et seq. I don't see how we can admit to that. Also, my copy of 42 U.S.C. §1396r-8 runs 28 pages. So, do you mean a formulary established under 42 U.S.C. §1396r-8(d)(4)?

We are very much in favor of narrowing the issues, so want to admit to anything that we can. However, we can't admit to anything that would suggest that prescriptions written for uses 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) are not false claims.

On the other hand, we may very well be able to admit to something like the prescriptions written were for drugs on the formulary, once we have a clear understanding of what the formulary is and any regulations or rules regarding it. This may very well be what you are looking for in Request for Admission No. 3. Of course, we think it is irrelevant, but the Court has left the door open for you to make your argument.

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The Law Project for Psychiatric Rights is a public interest law firm devoted to the defense of people facing the horrors of forced psychiatric drugging and electroshock. We are further dedicated to exposing the truth about these drugs and the courts being misled into ordering people to be drugged and subjected to other brain and body damaging interventions against their will. Currently, due to massive growth in psychiatric drugging of children and youth and the current targeting of them for even more psychiatric drugging, PsychRights has made attacking this problem a priority. Children are virtually always forced to take these drugs because it is the adults in their lives who are making the decision. This is an unfolding national tragedy of immense proportions. Extensive information about all of this is available on our web site, http://psychrights.org/. Please donate generously. Our work is fueled with your IRS 501(c) tax deductible donations. Thank you for your ongoing help and support.