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 RENEWED MOTION _IN LIMINE_ Re: FALSE CLAIMS

Pursuant to this Court's October 2, 2013, and November 5, 2013 Orders, Document Numbers 116 and 137, respectively, *Relator*, Dr. Toby Tyler Watson, as to the determination of whether the prescriptions at issue in this matter presented to Medicaid are false claims,

(a) renews his motion to limit testimony and argument to whether the prescriptions are for medically accepted indications as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i),

and, in connection therewith,

(b) moves specifically to exclude the expert testimony of Jacob J. Olson, Pharm. D., and Ronald J. Diamond, M.D., and the lay testimony of Martha Rolli, M.D.

Dated this 18th day of November, 2013.

LAW PROJECT FOR PSYCHIATRIC
RIGHTS, INC.

s/ James B. Gottstein
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UNITED STATES DISTRICT COURT
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UNITED STATES OF AMERICA, and
THE STATE OF WISCONSIN,
ex rel. DR. TOBY TYLER WATSON,

Plaintiffs,

v.

JENNIFER KING VASSEL, *et al*.,

Defendant.

Case No. 11-CV-236-JPS

Proposed
ORDER

At Docket # ___, *Relator*, Dr. Toby Watson has moved, as to the determination of whether the prescriptions at issue in this matter presented to Medicaid are false claims, for an order limiting testimony and argument to whether the prescriptions were written for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i), including specifically to exclude the expert testimony of Jacob J. Olson, Pharm.D., and Ronald J. Diamond, M.D., and the testimony of Martha Rolli, M.D., as to the application of the phrase medically indicated in medicine.

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) (listing as approved "compendia" the American Hospital Formulary Service Drug

Information, the United States Pharmacopeia–Drug Information (or its successor publications), and the DRUGDEX Information System). *U.S. v. King Vassel*, 728 F.3d 707, 715 (7th Cir. 2013).

Inasmuch as the sole question to be determined with respect to whether the prescriptions presented to Medicaid at issue in this case are false claims is whether the prescriptions written by Dr. King-Vassel were for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i),

IT IS ORDERED that Dr. Watson's Renewed Motion In *Limine* Re: False Claims at Docket # _____ be and the same is hereby **GRANTED.**

IT IS FURTHER ORDERED, that Dr. Watson's motion that testimony and argument as to whether the prescriptions presented to Medicaid at issue in this action are false claims be limited to whether such prescriptions are for 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) be and the same is hereby **GRANTED**; and

IT IS FURTHER ORDERED that Dr. Watson's motion to exclude the expert testimony of Jacob J. Olson, Pharm.D., and Ronald J. Diamond, M.D., and the lay testimony of Martha Rolli, M.D., be and the same is hereby **GRANTED**.

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, *et al.*,

Defendant.

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

Pursuant to this Court's October 2, 2013, and November 5, 2013, Orders, Document Numbers 116 and 137, respectively, *Relator*, Dr. Toby Tyler Watson (Dr. Watson), as to the determination of whether the prescriptions at issue in this matter presented to Medicaid are false claims, has

(a) renewed his motion to limit testimony and argument to whether the prescriptions are for medically accepted indications as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i),

and, in connection therewith,

(b) moved specifically to exclude the expert testimony of Jacob J. Olson, Pharm. D., and Ronald J. Diamond, M.D., and the lay testimony of Martha Rolli, M.D.

I. PREVIOUS MOTION & ORDERS

On September 14, 2013, through Document No. 102, Dr. Watson filed a motion *in limine* to restrict testimony on the question of whether the prescriptions at issue in this matter are false

claims to whether they are for medically accepted indications as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i).[1]

In its October 2, 2013, Order, Document No. 116, p. 5, this Court deferred a decision pending further discovery and briefing on whether Wisconsin has determined to reimburse prescriptions that are not for medically accepted indications as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i). In its November 5, 2013, Order concerning three discovery motions, Document No. 137, this Court noted:

> The court left open the question of whether Wisconsin can or does take steps to allow reimbursement for off-label prescriptions, which the Court noted is an open question. Without more evidence and argument—which the Court anticipates will likely come in the form of motions in limine prior to trial, once the parties' discovery efforts are nearing an end—

This is such a motion.

II. FURTHER DISCOVERY

Since this Court's October 2, 2013, Order, Document No. 116, the Defendant, Dr. Jennifer King-Vassel (Dr. King) has conducted no formal discovery on the issue of whether Wisconsin has determined to reimburse prescriptions that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i), i.e., for uses not approved under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (FDCA), or supported by any of the compendia. However Dr. King has named two experts, Jacob J. Olson, Pharm.D., and Ronald J. Diamond, M.D., and a lay witness, Martha Rolli, M.D., and provided

[1] In that motion Dr. Watson phrased it as whether the prescriptions were "off-label, and if so, whether they are supported by one of the statutorily incorporated drug references known as "compendia." "Off-label" was defined as a use not supported under the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 et seq. However, in light of the way the term off label has not always been used in that specific way in this litigation, in this renewed motion, it seems best to just use the statutory language of "medically accepted indication," as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i).

documents which it asserts supports its position. Since this Court's November 5, 2013, Order, Document No. 137, Dr. Watson has deposed Dr. King, has received the State of Wisconsin's electronic discovery response, and is seeking further discovery from records custodians as allowed in this Court's November 5, 2013, Orders, Document Nos. 137 & 138.

A. Dr. King's Named Experts

1. Jacob Olson, Pharm.D.

The entirety of Dr. Olson's proffered expert report, Exhibit 1, is as follows:

> I have reviewed the complaint in this case, the Encompass Effective Mental Health Services, Inc. records for patient N.B., and Dr. King's brief in support of summary judgment, filed in July 2012. I have also reviewed formularies for Managed Health Services for the period of time alleged in the complaint, and am familiar with the formularies of Medicaid and Managed Health Services based on my service on the pharmacy and therapeutics committee of MHS and the Medicaid drug utilization board. My opinions are also based on my education and experience practicing in Wisconsin.
>
> The compendia is not used in writing prescriptions, as reimbursement for prescription medication is done pursuant to formularies and pre-authorizations. Reimbursement for prescription medication is not defined by the compendia. The writing of a prescription for medication for minors does not cause Medicaid coverage of fraudulent billing.
>
> A copy of my CV is attached. I have not previously testified as an expert at trial or in a deposition. My publication list is attached. I charge $200 an hour.
>
> The opinions expressed in this report are provided to a reasonable degree of pharmaceutical probability.

2. Ronald J. Diamond M.D.

The entirety of Dr. Diamond's expert report, Exhibit 2, is as follows:

> I have reviewed the complaint in this case, the Encompass Effective Mental Health Services, Inc records for patient N.B. and Dr. King's brief in support of summary judgment filed in July 2012. I have been a practicing physician in Wisconsin for more than 36 years. For a number of years I was staff consultant to the Medicaid Drug Utilization board, and then joined the board as a voting member in 2004.

> Medication decisions are made in the best interest of the patient, and are not limited to any specific formulary. The Medicaid formulary is referred to only in so far as prescribing medications listed in formulary does not require a prior authorization be filled out. Wisconsin, and many other states, specifically allow for medications to be filled off of formulary restrictions through the use of a prior authorization form. This is considered a regular part of medical practice.
>
> Medications are regularly and routinely used outside of FDA indications. Within Medicaid and the other commonly used pharmacy benefit management systems, diagnosis and indications are not even collected. Many of the medications that are considered "first line" by expert consensus guidelines are recommended outside of FDA indications. It is generally understood that pharmaceutical companies apply for specific FDA indications for business rather than medical or scientific reasons.
>
> Physicians are compensated for using their best medical judgment. They are not compensated for writing a specific prescription. I am equally compensated if my best medical judgment is to recommend a medication that is off a particular formulary, or is over-the-counter and not prescription at all, or is to not use a medication at all.
>
> The opinion expressed I (sic) this report is provided to a reasonable degree of medical certainty. I normally charge $425 an hour as expert witness, but am waiving my fee for the first 20 hours. A copy of my CV is attached.

B. Martha L (Molli) Rolli, MD

Dr. King also identified Martha L. (Molli) Rolli, M.D., as a lay witness who "may be called to testify as to the application of the phrase medically indicated in medicine." Exhibit 3.

C. Defendant's Response to November 5, 2013, Order, Document No. 137

At Document No. 127, among other things, Dr. Watson moved for an order to compel defendant Dr. King, by November 7, 2013, to:

> . . . 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.

At Document 137, p. 10, this Court granted Dr. Watson's motion "in this regard." No supplementation of Dr. King's Initial Disclosures was made before the November 7, 2013,

deadline,[2] but the defendant did bring to her November 11, 2013, deposition documents she asserts support her defense that prescriptions not written for a medically accepted indication are not false claims. Exhibit 4, pp 32-33; Exhibit 6, pp 1-16.

D. Dr. King Deposition

At her November 11, 2013, deposition, Dr. King did not bring any documents responsive to the subpoena commanding her to bring:

> 2. All documents, references, or other information, or any combination, she relied upon since March 2, 2005 through present before writing a prescription for a Medicaid recipient to determine whether such prescription was covered for purposes of reimbursement, i.e., properly paid by Medicaid.

Exhibit 5, p 1; Exhibit 4, pp. 14-15. Dr. King also did not bring any documents responsive to the subpoena commanding her to bring:

> 5. Any and all documents, references, or other information, or written communications with any person, entity, or governmental agency, other than counsel, from the time she was licensed to practice medicine in Wisconsin to date, regarding Medicaid drug coverage.

Exhibit 5, p. 2; Exhibit 4, p. 17.

In fact, the only documents Dr. King brought to her deposition were (1) the above described documents to support her argument that because doctors can legally prescribe drugs for any use once the Food and Drug Administration (FDA) has approved it for a particular use(s), prescriptions to Medicaid patients that are not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) do not constitute false claims, and (2) a summary of prescriptions from the year 2005. Exhibit 6. Dr. King testified that only within the previous month did she first see these documents she produced to support her

[2] The Court did not explicitly state the deadline was November 7th in its Order, but it did "grant Watson's motion in this regard." Document No. 137, p. 10.

argument that because doctors can legally prescribe drugs for any use once the Food and Drug Administration (FDA) has approved it for a particular use(s), prescriptions to Medicaid patients that are not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) do not constitute false claims. Exhibit 4, pp. 52-53.

At her deposition, Dr. King also testified that she assumed if a drug was on the formulary, a prescription for any use was proper unless it was subject to specific limitations on age or diagnosis (requiring prior authorization). Exhibit 4, p. 45.

Additional testimony of Dr. King at her deposition is discussed below in connection with the knowingly element of liability under the False Claims Act.

III. ANALYSIS

A. Overview

Through its Order granting summary judgment, Docket No. 59, page 11,this Court held:

> 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 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).

Because of this, in Dr. Watson's view, there are just two factual issues in this case:

1. Were specific prescriptions written by Dr. King to pediatric Medicaid patients not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i), and therefore false claims? [3]

and

2. Did Dr. King know, within the meaning of the False Claims Act, 31 U.S.C. §3729(a)(1)(A), and §3729(b) that such prescriptions were false claims because they were not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i)?

Dr. Watson's original Motion *In Limine*, Document No. 102, which this motion renews, also sought to limit testimony regarding whether prescriptions written by Dr. King and presented to Medicaid were false claims to whether they were for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i).

In its October 2, 2013, Order, Document No. 116, pp 3-5, regarding the Motion *In Limine*, however, this Court left open the possibility that the State of Wisconsin might be allowed to reimburse for prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i), or even if it is not allowed to reimburse for such prescriptions, if Wisconsin represented to physicians that it will reimburse the prescriptions anyway, such information would be relevant to determining whether Dr. King had the required

[3] Dr. King may rely on "prior authorizations" for certain prescriptions to convert prescriptions that were issued for a use that is not a medically accepted indication from a false claim to a prescription that was properly reimbursed, but prior authorizations under 42 U.S.C. § 1396r-8(d)(1)(A) only operate to restrict reimbursement for otherwise "covered outpatient drugs," which by definition do not include prescriptions for an indication that is not a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i). However, such prior authorizations could impact whether Dr. King had the required level of knowledge to be found liable under the False Claims Act for having caused a false claim.

level of knowledge to be found liable for having submitted a false claim. This Court then indicated the parties should engage in discovery on the topic, and denied Dr. 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. This was reiterated in this Court's November 5, 2013, Order, Document No. 137, p. 4.

Heretofore, the State of Wisconsin has declined to take a position on whether it has determined to cover prescriptions that are not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i). Perhaps a request from the Court to do so will yield a position. However, Dr. Watson respectfully suggests that a response by Wisconsin, or a conclusion by this Court, that Wisconsin has determined to cover prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) can only apply to Dr. Watson's claims on behalf of the State of Wisconsin, not Dr. Watson's claims on behalf of the United States.

B. Dr. King's Knowledge Under the False Claims Act

Under 31 U.S.C. §3729(b)(1):

(1) the terms "knowing" and "knowingly" --

(A) mean that a person, with respect to information--

(i) has actual knowledge of the information;

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

(iii) acts in reckless disregard of the truth or falsity of the information; and

(B) require no proof of specific intent to defraud;

First, the United States Supreme Court has held government agent representations do not negate knowledge, i.e., do not create an *estoppel*:

> Protection of the public fisc requires that those who seek public funds act with scrupulous regard for the requirements of law; respondent could expect no less than to be held to the most demanding standards in its quest for public funds. This is consistent with the general rule that *those who deal with the Government are expected to know the law and may not rely on the conduct of Government agents contrary to law*.

Heckler v. Community Health Services, 467 U.S. 51, 63, 104 S.Ct. 2218, 2225 (1984), emphasis added.

Citing to *Heckler*, in *Edgewater Hospital v. Bowen*, 857 F.2d 1123, 1138 (7th Cir. 1988), amended at 866 F.2d 228, the Seventh Circuit recognized a limited exception:

> The Supreme Court has questioned whether "*estoppel* can ever be appropriately applied against the Government." The general rule is that reliance on misinformation provided by a government employee (or agent) does not provide a basis for *estoppel*. However, various circuits have invoked the doctrine against the government in narrowly defined circumstances. This court set forth its standard for applying *estoppel* against a government agency in *Portmann v. United States*, 674 F.2d 1155 (7th Cir.1982):
>
> > First, the party to be *estopped* must know the facts. Second, this party must intend that his conduct shall be acted upon, or must so act that the party asserting *estoppel* has a right to believe it is so intended. Third, the party asserting *estoppel* must have been ignorant of the facts. Finally, the party asserting *estoppel* must reasonably rely on the other's conduct to his substantial injury.
>
> 674 F.2d at 1167. In addition to these traditional private law elements of the *estoppel* doctrine, we require that the party asserting *estoppel* establish that the government's action amounted to affirmative misconduct. Although the Supreme Court has not yet addressed the appropriateness of this additional element, many circuits have required it.
>
> The party claiming *estoppel* has the burden of demonstrating the elements.

(emphasis added, some citations and footnotes omitted).

Also citing to Heckler, in *Hagood v.Sonoma County Water Agency*, 929 F. 2d 1416 (9th Cir. 1991), the Ninth Circuit held that United States government officials' approval of a contract

based on an erroneous interpretation of law did not defeat a False Claims Act cause of action, and reversed the district court's dismissal under Fed. R. Civ. Proc. 12(b)(6).

It is upon this body of law that Dr. Watson relies to establish the knowledge element for the prescriptions written to N.B. Dr. Watson acknowledges this Court's Order of October 2, 2013, Document No. 116, casts doubt on whether this Court will apply to the facts in this case the principle that *estoppel* will not lie against the government. Even if this Court does not apply the principle that *estoppel* against the government does not apply in this case, Dr. King must still affirmatively prove the representation and that she relied upon it. General expert testimony regarding prescribing practices and the reimbursement process do not establish this.

However, even if she can establish an *estoppel* for the prescriptions identified in the Complaint, prescriptions written after

(a) Dr. King was served with the Complaint in this matter,

(b) this Court held prescriptions that were not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) constitute false claims, Document No. 59, p. 11, and

(c) the Court of Appeals affirmed this on appeal, 728 F.3d at 715,

are a different matter.

In its opinion, the Court of Appeals held the reckless disregard standard is met when the person "failed 'to make such inquiry as would be reasonable and prudent to conduct under the circumstances,' " or "when the actor knows or has reason to know of facts that would lead a reasonable person to realize." 785 F.3d at713. Dr. King was certainly put on notice that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) constituted false claims when she was served with the Complaint in this

matter. By this Court's Order on October 23, 2012, Dr. King was not only put on notice, there was a judicial ruling that such prescriptions constituted false claims. And on August 28, 2013, the Court of Appeals affirmed that such prescriptions constituted false claims.

In her deposition, Dr. King testified:

(1) that she did not change her practice with respect to what prescriptions she would write to a Medicaid patient after being served with the Complaint, Exhibit 4, pp 45-46;

(2) that she doesn't recall if she read this Court's October 23, 2012, decision that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) presented to Medicaid constitute false claims, Document No. 59, and that she did not change anything in how she prescribed medication to Medicaid patients, Exhibit 4, pp 46 & 48; and

(3) even if she had read the Court of Appeal's Opinion in this case where it affirmed that prescriptions not for a medically accepted indication as defined under 42 U.S.C. § 1396r–8(k)(6), §1396r–8(g)(1)(B)(i) presented to Medicaid constitute false claims she wouldn't have changed her practice because she doesn't base her prescribing habits on statutes, Exhibit 4, p. 48.

This certainly satisfies the reckless disregard standard for "knowingly" under the False Claims Act as a matter of law, and probably the deliberate ignorance standard as well.

Thus, Dr. Watson respectfully suggests the only relevant fact inquiry with respect to prescriptions written after this Court's October 23, 2012, Decision, Document No. 59, is whether they were written for a medically accepted indication as defined under 42 U.S.C. §1396r–

8(k)(6), §1396r–8(g)(1)(B)(i). As a matter of law, Dr. King knowingly caused false claims within the meaning of the False Claims Act as to prescriptions written to Medicaid patients that were not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i) after this Court's Order of October 23, 2012, Document 59. Any representations by Wisconsin state officials or anyone else cannot negate the knowingly element in the face of court decisions in this case holding prescriptions written to Medicaid patients that were not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i) constitute false claims.

It is within the context of this overview that Dr. Watson respectfully submits this renewed motion *in limine* should be considered.

C. The Proffered Expert Reports Are Insufficient

First, the expert reports proffered by Dr. King do not meet the standard of Fed. R. Civ. Proc. 26(a)(2)(B) on their face. Fed. R. Civ. Proc. 26(a)(2)(B) requires that at the time a retained expert is disclosed a written report prepared and signed by the proffered expert must be included and the report must contain,

> (i) a complete statement of all opinions the witness will express and the basis and reasons for them;
> (ii) the facts or data considered by the witness in forming them;

Neither the expert report submitted by Dr. Olson, Exhibit 1, nor Dr. Diamond, Exhibit 2, the entirety of which are also set forth above, express the basis and reasons for their opinions or the facts or data considered by them in forming their expressed opinions.

1. Dr. Olson's Expert Report Is Insufficient and Irrelevant

With respect to Dr. Olson, his expert report, Exhibit 1, states his opinions are based on his "service on the pharmacy and thereapeutics committee of MHS and the Medicaid drug

utilization board," and his "education and experience practicing in Wisconsin." This is not sufficient under Fed. R. Civ. Proc. 26(a)(2)(B).

The only facts or data identified are (1) the Complaint in this case, (2) Dr. King's brief in support of summary judgment, and (3) the formularies for Managed Health Services for the period of time alleged in the complaint. None of these have anything to do with the opinions expressed in his report. More specifically, the opinions expressed by Dr. Olson in their entirety are:

> The compendia is not used in writing prescriptions, as reimbursement for prescription medication is done pursuant to formularies and pre-authorizations. Reimbursement for prescription medication is not defined by the compendia. The writing of a prescription for medication for minors does not cause Medicaid coverage of fraudulent billing.

The facts and data identified do not relate to any of these opinions. Most importantly, Dr. Olson did not review, nor did he base his opinions on, federal coverage of outpatient drugs being limited by its terms to medically accepted indications as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i). Neither did he review or base his opinions on this Court's or the Court of Appeal's holdings to this effect in this case. Nor did he review this Court's October 2, 2013, Order, Document No. 116, in which this Court identified what question was relevant.

The opinion that "The compendia is not used in writing prescriptions, as reimbursement for prescription medication is done pursuant to formularies and pre-authorizations," has two parts. With respect to "the compendia is not used in writing prescriptions," there is no basis stated for that opinion unless "service on the pharmacy and thereapeutics committee of MHS and the Medicaid drug utilization board," and his "education and experience practicing in Wisconsin" is considered the basis. If so, it is insufficient under Fed. R. Civ. Proc. 26(a)(2)(B). There are no facts or data identified in support of this opinion. It is also clear the compendia

should be used in writing prescriptions to Medicaid patients that are not for a use approved under the FDCA in order to avoid causing false claims.

With respect to, "as reimbursement for prescription medication is done pursuant to formularies and pre-authorizations," there is similarly no basis stated unless "service on the pharmacy and thereapeutics committee of MHS and the Medicaid drug utilization board," and his "education and experience practicing in Wisconsin" is considered the basis. However, this is insufficient under Fed. R. Civ. Proc. 26(a)(2)(B). There are no facts or data to support this stated opinion. To the extent it is a legal conclusion, Dr. Olson has no stated expertise upon which to opine and it is inconsistent with the holdings of both this Court and the Court of Appeals in this case. Moreover, legal questions are to be decided by the court after citation to legal authority, not subject to expert opinion, let alone where the basis for the legal conclusion is not stated.

With respect to "Reimbursement for prescription medication is not defined by the compendia," there is similarly no basis stated unless "service on the pharmacy and thereapeutics committee of MHS and the Medicaid drug utilization board," and his "education and experience practicing in Wisconsin" is considered the basis. If so, it is insufficient under Fed. R. Civ. Proc. 26(a)(2)(B). There are no facts and data to support this opinion. To the extent it is also a legal conclusion, Dr. Olson has no stated expertise upon which to opine and it is inconsistent with the holdings of both this Court and the Court of Appeals in this case. Opinions as to legal questions at issue in the case are not resolved through expert testimony, but through citation to legal authority and a decision by the court(s).

The opinion that, "The writing of a prescription for medication for minors does not cause Medicaid coverage of fraudulent billing," is similarly a legal conclusion which Dr. Olson has no stated expertise upon which to opine and are inconsistent with the holdings of both this Court and the Court of Appeals in this case. Again, opinions as to legal questions at issue in the case are not resolved through expert testimony, but through citation to legal authority and a decision by the court(s).

2. Dr. Diamond's Expert Report Is Insufficient and Irrelevant

With respect to Dr. Diamond's expert report, no basis is stated at all, unless Dr. Diamond having "been a practicing physician in Wisconsin for more than 36 years" and being a staff consultant to the Medicaid Drug Utilization Board, and then joining the board as a voting member in 2004, are considered bases. If so, they are insufficient under Fed. R. Civ. Proc. 26(a)(2)(B). No facts or data are included. The only items Dr. Diamond reviewed for his expert report are (1) the Complaint in this case, (2) the patient records of N.B., and (3) Dr. King's brief in support of summary judgment filed in July of 2012.

Like Dr. Olson, Dr. Diamond did not even review or consider the federal statute providing that coverage of outpatient is limited by its terms to medically accepted indications as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i); or this Court's or the Court of Appeal's holdings to this effect in this case; or this Court's October 2, 2013, Order, Document No. 116, in which this Court identified what question was relevant.

Instead of addressing the question identified by the Court in its Court's October 2, 2013, Order, Document No. 116, as to whether Wisconsin has determined to cover outpatient drugs that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6),

§1396r–8(g)(1)(B)(i), Dr. Diamond gives his unsupported opinion on prescribing practices, and Medicaid reimbursement practice in Wisconsin.

These opinions are not relevant to the Court's question regarding whether Wisconsin has determined to cover drugs that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i). Dr. Watson does not dispute that such prescriptions have been paid for; indeed that is why they are false claims, at least as to the federal share.

These opinions are also not relevant to whether Dr. King had the requisite knowledge under the False Claims Act. Whether she had the requisite knowledge for liability under the False Claims Act depends on what Dr. King knew, was in deliberate ignorance of, or recklessly disregarded.

The proffered expert testimony of Dr. Olson and Dr. Diamond should not be allowed.

D. Dr. Rolli

Dr. Martha Rolli was identified as a lay witness who may testify "as to the application of the phrase medically indicated in medicine." Leaving aside that this appears to be an attempt to present expert testimony without following the rules for expert testimony disclosure, the application of the phrase medically indicated in medicine is irrelevant to this case. The question isn't the practice of medicine, but Medicaid coverage of outpatient drugs. Dr. Rolli should be excluded from testifying.

E. Testimony As to Whether Prescriptions Written By Dr. King to Pediatric Medicaid Patients Caused False Claims Should be Limited to Whether They Were for A Medically Accepted Indication.

In its October 2, 2013, Order, Document No. 116, this Court left the door open for Dr. King to conduct discovery and then further brief the issue as to whether Wisconsin has

determined to cover prescriptions that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i). In its November 5, 2013, Order, concerning three discovery motions, Document No. 137, p 4, this Court reminded the parties:

> The court left open the question of whether Wisconsin can or does take steps to allow reimbursement for off-label prescriptions, which the Court noted is an open question. Without more evidence and argument—which the Court anticipates will likely come in the form of motions in limine prior to trial, once the parties' discovery efforts are nearing an end— the Court is not prepared to rule on that issue at this juncture.

At page 6, this Court stated:

> To begin, the Court must reiterate the statutory scheme that this issue is a part of. Medicaid may only be used to provide reimbursement for "covered outpatient drugs." 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(3). The definition of such covered drugs explicitly excludes any drug that is "used for a medical indication which is not a medically accepted indication." 42 U.S.C. § 1396r-8(k)(3). A "medically accepted indication" is limited to a purpose that is either approved by the FDCA or "supported by" one of three medical compendia (the American Hospital Formulary Service Drug Information, the United States Pharmacopeia–Drug Information, and the DRUGDEX Information System). 42 U.S.C. §§ 1396r-8(g)(1)(B)(i), 1396r-8(k)(6).

Dr. King has failed to discover or disclose any evidence that Wisconsin has determined to cover outpatient drugs that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i). The most that can be said is that Wisconsin is paying for such prescriptions.

Moreover, even if Wisconsin has determined to pay for outpatient drugs that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i), the most that can flow from that is that such prescriptions are not false as to Wisconsin. Wisconsin cannot override the federal statute with respect to the federal share.

Should the State of Wisconsin, in its capacity as one of the parties for whom Dr. Watson is pursuing this action, advise this Court that it has determined to pay for outpatient drug

prescriptions that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i), Dr. Watson will dismiss the state claims. In order to streamline this case, he may very well do so even if the State of Wisconsin does not so advise the Court. On the other hand, if the State of Wisconsin takes the position that prescriptions not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i) also constitute false claims under state law, the state claims will remain.

Only relevant evidence is admissible, FRE 402, and evidence is only relevant if "the fact is of consequence in determining the action." FRE 401. The gravamen of the Complaint in this action is that Dr. King caused false claims by writing certain prescriptions that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i). That it is not illegal under the FDCA is irrelevant;[4] it causes a false claim.

This is what the Court of Appeals held in its opinion remanding this case:

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

(728 F. 3d at 709, citations omitted).

Similarly, whether or not psychiatrists commonly write prescriptions for uses on children that are not for a medically accepted indication as defined under 42 U.S.C. §1396r–8(k)(6), §1396r–8(g)(1)(B)(i), i.e., as opined by Drs Olson and Diamond, or as may be testified to by Dr. Rolli, does not answer the question of whether the government is allowed to pay for the

[4] Exhibit 6 pp 1-16, of the documents produced by Dr. King at her deposition only (a) state it is legal to prescribe drugs for uses not approved under the FDCA, and (b) exhort third party payors, of which Medicaid is one, to cover such prescriptions, thus implying that they often do not.

prescription. Such evidence is of no consequence in determining this action, and should be excluded.

IV. CONCLUSION

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

Dated this 18th day of November, 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

V. EXHIBITS

1. Dr. Jacob J. Olson Expert Report
2. Dr. Ronald J. Diamond Expert Report
3. Identification of Dr. Martha Rolli as a lay witness
4. Transcript of Dr. King's November 11, 2013, deposition
5. Notice of Subpoena to Testify at a Deposition and Produce Records to Dr. Jennifer King.
6. Documents produced at Dr. King's November 11, 2013, deposition.

Gutglass
Erickson
Bonville&Larson s.c.
A LIMITED LIABILITY ORGANIZATION

BRADLEY S. FOLEY
bradley.foley@gebsc.com

writer's direct: 414-908-0240

October 30, 2013

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

Re: Watson v. King-Vassel
Case No: 11-CV-236
Our File No: 911.19

Dear Mr. Gottstein:

Please find enclosed a copy of the report of an expert named on behalf of Dr. King, Jacob Olson, a copy of his Curriculum Vitae, and his publication list. Thank you.

Very truly yours,

Bradley S. Foley

Bradley S. Foley

BSF\cgw
Enclosures

cc:(w/encls.)(via email only): Attorney Rebecca L. Gietman

Exhibit 1 to Renewed Motion in Limine

Skywalk Rx PHARMACY

Located in Children's Hospital of Wisconsin
Clinics Building
9000 W Wisconsin Ave #211
Wauwatosa, WI 53226
Phone #414-266-1893 Fax #414-266-1894
e-mail info@skywalkpharmacy.com
www.skywalkpharmacy.com

October 30, 2013

Mr. Mark Larson
Gutglass, Erickson, Bonville & Larson, S.C.
735 N Water St Ste 1400
Milwaukee, WI 53202

Re. Watson v. King

Dear Mr. Larson:

I have reviewed the complaint in this case, the Encompass Effective Mental Health Services, Inc. records for patient N.B., and Dr. King's brief in support of summary judgment, filed in July 2012. I have also reviewed formularies for Managed Health Services for the period of time alleged in the complaint, and am familiar with the formularies of Medicaid and Managed Health Services based on my service on the pharmacy and therapeutics committee of MHS and the Medicaid drug utilization board. My opinions are also based on my education and experience practicing in Wisconsin.

The compendia is not used in writing prescriptions, as reimbursement for prescription medication is done pursuant to formularies and pre-authorizations. Reimbursement for prescription medication is not defined by the compendia. The writing of a prescription for medication for minors does not cause Medicaid coverage of fraudulent billings.

A copy of my CV is attached. I have not previously testified as an expert at trial or in a deposition. My publication list is attached. I charge $200 an hour.

The opinions expressed in this report are provided to a reasonable degree of pharmaceutical probability.

Very truly yours,

Jacob J. Olson, Pharm.D.

Curriculum Vitae

W170 N5353 Ridgewood Dr
Menomonee Falls, WI 53051
Phone: 262-754-0647
e-mail:jake@skywalkpharmacy.com

Jacob J. Olson, Pharm.D., RPh.

Professional Experience	**President/CEO**	**Skywalk Pharmacy** Located in the Children's Hospital of Wisconsin	**Dec. 2002 - Present**
	DUR Board Member	Wisconsin Medicaid	Sept. 2010 - Present
	P&T Committee	Managed Health Services (Wisconsin T-19 HMO)	July 2006 – January 2008
	Managing Diabetes for Life	Joint project with Independent Care (Wisconsin T-19 HMO) and Ye Olde Pharmacy	Oct. 2001 – Dec. 2002
	Clinical Director	Ye Olde Pharmacy	Dec. 2000 – Dec. 2002
	Junior Commissioned Officer Student Training Externship Program (JRCOSTEP)	Public Health Service Bureau of Prisons U.S.P. Leavenworth, KS	June 1997 – August 1997
Postdoctoral Residency	**First ASHP/APhA Accredited Community Pharmacy Practice Residency** Family PharmaCare Center, Inc. & Purdue University		July 1999 – July 2000
University Experience	Adjunct Faculty & Clinical Rotation Student Preceptor	Concordia University of Wisconsin	2010 - present
		St. Louis College of Pharmacy	2010 - present
		Creighton University	2006 - present
		Midwestern University	2004 – present
Professional Presentations & Exhibitions	"Topical Treatment of Pain Associated with Remodulin Therapy," United Therapeutics Investigator Meeting, July 27, 2002, Deer Valley, UT.		
Professional Associations	Pharmacy Society of Wisconsin (PSW)	Member	2001 - present
	Profession Compounding Centers of America (PCCA)	Member	1999 - present
	International Academy of Compounding Pharmacists (IACP)	Member	1999 – present
	American Pharmaceutical Association (APhA)	Member	1997 – present

Professional Education	University of Iowa Iowa City, IA	Doctor of Pharmacy	May 1999

Licensure State of Wisconsin #13224-040

State of Indiana #26020025

References Available Upon Request

PUBLICATION LIST

Kate, *et al.*, "Quality-Control Analytical Methods: Aqua Pura: Water Purification Systems and United States Pharmacopeia Waters for the Compounding Pharmacy, Part 3: Testimonials and Comparisons," International Journal of Pharmaceutical Compounding, Volume 15, Number 5 (September/October 2011).

Gutglass
Erickson
Bonville&Larson s.c.
A LIMITED LIABILITY ORGANIZATION

BRADLEY S. FOLEY
bradley.foley@gebsc.com

writer's direct: 414-908-0240

November 5, 2013

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

Re: Watson v. King-Vassel
Case No: 11-CV-236
Our File No: 911.19

Dear Mr. Gottstein:

Please find enclosed a copy of the report of an expert named on behalf of Dr. King, Ronald J. Diamond, M.D., a copy of his Curriculum Vitae, and his testimony list. Thank you.

Very truly yours,

Bradley S. Foley

Bradley S. Foley

BSF\cgw
Enclosures

cc:(w/encls.)(via U.S. mail): Attorney Rebecca L. Gietman

Exhibit 2 to Renewed Motion In Limine

School of Medicine
and Public Health
UNIVERSITY OF WISCONSIN-MADISON

Department of Psychiatry

November 5, 2013

Mr Mark Larson
Gutglass, Erickson, Bonville & Larson, S.C.
735 N Water St Ste 1400
Milwaukee, WI 53202

RE: Watson v. King

Dear Mr. Larson:

I have reviewed the complaint in this case, the Encompass Effective Mental Health Services, Inc records for patient N.B. and Dr. King's brief in support of summary judgment filed in July 2012. I have been a practicing physician in Wisconsin for more than 36 years. For a number of years I was staff consultant to the Medicaid Drug Utilization board, and then joined the board as a voting member in 2004.

Medication decisions are made in the best interest of the patient, and are not limited to any specific formulary. The Medicaid formulary is referred to only in so far as prescribing medications listed in formulary does not require a prior authorization be filled out. Wisconsin, and many other states, specifically allow for medications to be filled off of formulary restrictions through the use of a prior authorization form. This is considered a regular part of medical practice.

Medications are regularly and routinely used outside of FDA indications. Within Medicaid and the other commonly used pharmacy benefit management systems, diagnosis and indications are not even collected. Many of the medications that are considered "first line" by expert consensus guidelines are recommended outside of FDA indications. It is generally understood that pharmaceutical companies apply for specific FDA indications for business rather than medical or scientific reasons.

Physicians are compensated for using their best medical judgment. They are not compensated for writing a specific prescription. I am equally compensated if my best medical judgment is to recommend a medication that is off a particular formulary, or is over-the-counter and not prescription at all, or is to not use a medication at all.

The opinion expressed I this report is provided to a reasonable degree of medical certainty. I normally charge $425 an hour as expert witness, but am waiving my fee for the first 20 hours. A copy of my CV is attached.

Very truly yours,

Ronald J Diamond M.D.

Enclosures

CURRICULUM VITA

Ronald J Diamond

ADDRESS: Office: Department of Psychiatry
6001 Research Park Blvd
Madison, WI 53719

Home: 3324 River Birch Lane
Middleton, Wisconsin 53562

TELEPHONE: Office: 608-263-6098
Home: 608-836-6424

EMAIL diamond@wisc.edu

SOCIAL SECURITY #: 185-36-5762

DATE OF BIRTH: August 25, 1946

POSITIONS HELD:

1978-85	Assistant Professor, Department of Psychiatry, University of Wisconsin
1985–1995	Associate Professor, Department of Psychiatry, University of Wisconsin
1995-	Professor, Department of Psychiatry, University of Wisconsin
1977–1987	Staff Psychiatrist, Mental Health Center of Dane County
1977-83	Medical Director, Support Network Program of the Mental Health Center of Dane County
1980-87	Medical Director, Mobile Community Treatment Program of the Mental Health Center of Dane County
1987–2013	Medical Director, Mental Health Center of Dane County
1983–2000	Director, Acute Psychiatric Service, University of Wisconsin Crisis Service
1981–	Clinical Consultant to the University of Wisconsin Department of Psychology Assistant Consultant, 1981-1984 Associate Consultant, 1984-
1983–1992	Associate Director of the National Community Support Program Training Resource Center, Madison, WI
1986-87	Area Consultant for Prince of Wales Hospital, University of New South Wales, Australia
1995–	Consultant, Wisconsin Bureau of Mental Health and Substance Abuse

2001-2004	Board, Center for the Study of Cultural Diversity in Healthcare

EDUCATION:

1968	B.A., Swarthmore College, Swarthmore, Pennsylvania - Major in psychology, minor in anthropology and philosophy
1973	M.S., University of Pennsylvania Department of Psychology. Area of concentration: cognitive psychology. Research area: patterns of cognitive deficits in brain damage with particular interest in organic amnesia and aphasia
1973	M.D., University of Pennsylvania School of Medicine 1973-74 R-6 Internship at Presbyterian University of Pennsylvania Medical Center
1973-77	Resident in Psychiatry at Stanford Medical Center
1976-77	Stanford Chief Resident in Psychiatry at Santa Clara Valley Medical Center (Community Psychiatry)
1977-78	Postdoctoral Fellow for Research in the Social Sciences, Department of Psychiatry, University of Wisconsin-Madison

HONORS:
Graduated with Honors from Swarthmore College
Physician of the Year Award, 1981--Allen Hall Residential Facility: Madison, WI
Professional Recognition Award, Dane County Alliance for the Mentally Ill, 1988
Exemplary Psychiatrist Award, 1992, 1993 and 1997, National Alliance for the Mentally Ill
Elected by his peers for inclusion in Best Doctors in America from 1994 to 2012

PROFESSIONAL LICENSURE & CERTIFICATION:
Wisconsin Medical License
Board certified in Psychiatry by the American Board of Psychiatry and Neurology

PROFESSIONAL ORGANIZATIONS:
American Psychiatric Association
American Association of Community Psychiatry

COMMUNITY ACTIVITIES:

1980-86	Advisory Board of Off the Square Club (psychological drop-in center for the chronically mentally ill)
1982-83	Board Member, Mental Health Association of Dane County
1984-89	Board Member, Madison Jewish Social Services
1986-93	Medical Consultant, Wisconsin Department of Transportation (volunteer position)
1994-2000	Board Member, Housing Initiative Inc

1998- Director of MEDIC, volunteer psychiatry service for homeless shelter

ADMINISTRATION:

Departmental

1990–2010 Director of Training, Community Psychiatry

U.W. Hospital

1992–2001 University of Wisconsin Hospital Ethics Committee
2000- University of Wisconsin Department of Psychiatry Quality Assurance Committed (chairman)
2011- UW Hospital Credential Committee
2012- University of Wisconsin Tenure Track Promotions Committee, Division of Biological Science

State of Wisconsin

2006- Mental Health Drug Advisory Group: advisory to Prior Authorization (Medicaid) committee
2004- Wisconsin Prior Authorization Committee (Medicaid Formulary Committee)

OTHER PROFESSIONAL ACTIVITIES:

Journal Reviewer

Editorial Advisory Board, Community Mental Health Journal 1993-2005
Regular reviewer for *J of Hosp & Comm Psych*, 1984-2006

Consultant/Expert Witness for Class Action Litigation

Consultant/expert witness for Mental Health Law Project, Washington, D.C., 1982, 1985
Consultant/expert witness for Project on Justice and Equality. Gary, Indiana, 1981
Consultant/expert witness for Western Center on Law and Poverty and Los Angeles Mental Health Association, Los Angeles, California, 1984
Expert Witness/consultant, Arizona Center for Law in the Public Interest, 1990
Expert Witness/Consultant-Greater Boston Legal Services, 1992
Consultant and expert witness for the Wisconsin Coalition for Advocacy in the class action litigation of Joan S. et al. v. Gudeman et. al.
Consultant and Expert witness for Maine Department of Mental Health, 1994-
Consultant, Illinois Department of Mental Health and Developmental Disabilities, 1994-
Consultant, Maine Department of Mental Health and Mental Retardation 1999

TEACHING:

University of Wisconsin

Medical Student Teaching

1981-1999 Faculty for medical student Summer Fellowship Program in Psychiatry
1985- Faculty for second year medical student didactic psychiatry course
1991– Organizer and supervisor for community psychiatry 4th year medical student elective

Department of Psychiatry Teaching

1978-2009	Supervisor, community psychiatry
1978-2010	Co-teach community psychiatry seminar for PGY-2 psychiatry residents
1980-	Emergency psychiatry seminar
1981-2004	"Best of Call," advanced emergency psychiatry seminar/supervision for second year psychiatry residents

UW Madison (outside of Medical School)

Spring 2011 Psychopharmacology: School of Educational Psychology

Guest Lectures in:
- School of Social Work
- Counseling and Guidance
- Occupational Therapy
- School of Nursing

INVITED INTERNATIONAL PRESENTATIONS

Dec 1988	"The Role of the Psychiatrist in a Community Mental Health Center" invited paper at the International Congress of Community Mental Health, Lisbon, Portugal
Jan 1992	"The Roles, Preparation and Training for Professional in New Services". Invited workshop at Community Mental Health Care International Perspectives in Making it Happen, King College, London England.
Jan. to Feb. 1993	Invited series of lectures and workshops in Townsville, Brisbane, Adelaide and Sydney, Australia. Culminated in a three day workshop in Sydney with participants from throughout Australia.
Oct 1993	Community Care-the USA Experience. Invited address to the Scottish Conference on Mental Health, Glasgow Scotland
July 1994	Becker M and Diamond, RJ "Quality of Life and Mental Health" presentation at the XIIth World Congress of Sociology, Bielefeld, Germany
April 1995	"Issues for the Training and Development of Mental Health Professionals", invited presentation to conference "People with Mental Illness in a Modern Caring Society: A better situation for the 21st Century" , Prague, Czech Republic. sponsored by the International Mental Health Network, Ltd.
Nov-Dec 1995	Invited series of lectures and workshops in Townsville, Brisbane and Sydney Australia
May 1996	"What makes mental health services work" Invited workshop for the German Society for Social Psychiatry. Bremen, German

March 1997	"Characteristics of an ideal system for people with schizophrenia" Invited workshop as part of international conference: Evidence from Experience sponsored by Janssen-Cilag and Organon. Lisbon, Portugal
October 1997	"Schizophrenia, Antipsychotics and Quality of Life" Invited lecture to the United Kingdom Psychiatric Pharmacy Group International Conference, London UK
July 1998	"What is Required for Effective Community Based Care for Persons with Serious Psychiatric Disability" Invited keynote for the National Sainsbury Conference, York England
January 1999	Series of invited lectures in Brisbane, Alice Springs, Canberra and Sydney Australia. Keynote address to the National Mental Health Themhs Conference, January 1999, Sydney Australia "Should Mental Health Services Try to be Everything to Everyone? Point of view of the clinician, the society, the funder and the consumer"
March 2001	Crisis Intervention in a Community Based Mental Health System: Invited workshop: Chief Officers National Conference, Birmingham, England
Feb 2004	"Drinking, Drugging and Borderline Personality Disorder" and "Prescribing Medication for People who Abuse Drugs": Invited keynote address to the National Mental Health Themhs conference, Sydney Australia: Double Trouble: Comorbidity, drugs, alcohol and mental health.
Feb 2004	"Developing Collaboration in the Context of Involuntary Treatment" Lecture and Workshop at The Park Hospital, University of Queenland, Wacol Queensland
March 2004	Drugs, Alcohol and Mental Health, What is an Effective Response?" sponsored by Bundaberg Integrated Health Services, Queensland Australia
March 2004	Key Steps toward developing Recovery-orientated Mental Health Services.: Cairns Integrated Mental Health Program, Queensland Australia
April 2007	"The Role of Medication in Dealing with Social Suffering" Conference on Psychotropes, as an answer to suffering: Forum on Self-Management of Psychiatric Medication: sponsored by the Quebec Social Research Council, Montreal, Quebec
Feb 2011	Recovery Oriented Treatment: Making it Real: Conference Sponsored by Metro South Hospitals, Brisbane Queensland Australia
Feb 2011	Working with Angry People Borderline Personality Disorder and Aggression Agitated Patient in the Emergency Department Invited Set of Talks Keynoting the Summer Themes Conference, Sydney Australia

October 2011 George Witte Remembrance Symposium: Thoughts on Meaning of Recovery: Leiden Holland

PRESENTATIONS AT NATIONAL MEETINGS: INVITED OR REFERRED (partial list)

October 1991 Warner, R., Brand, A.L., Diamond, R.J., and Godard, S.L. "Power and Responsibility in Public Mental Health: Psychiatrists Roles". Symposium at Institute for Hospital and Community Psychiatry, Los Angeles, California

October 1991 Kanter, J.S., Balancio, F., Diamond, R.J., and Subert, R.W. "Case Management of Long-Term Patients: A Clinical Case Conference". Symposium at Institute for Hospital and Community Psychiatry, Los Angeles, California

October 1991 Diamond, R. J. "Working with Treatment Resistant Clients". Lecture at Institute of Hospital and Community Psychiatry, Los Angeles, California

October 1991 Lindy, D.C., Diamond, R.J., Pessin, N., and Puckett, J.A. "Models of Mobile Crisis Service Delivery". Symposium at Institute for Hospital and Community Psychiatry, Los Angeles, California

July 1992 Becker, M., Sainfort, F., Diamond, R. "Cost Effectiveness Evaluation of Clozaril: The Place of Quality of Life and Patient Values." Presented at 9th Annual Meeting of the Association of Health Services Research, Chicago, Illinois.

October 1993 Rosen, A., Diamond, R. and Miller, V. "Becoming Real: How to Go From a Model Program to an Enduring System." Symposium Presented at the Institute for Hospital and Community Psychiatry, Baltimore, MD

October 1993 Pollack, Diamond, Stastny, Fisher, and Glazer. "Controversial Issues in the Use of Psychotropic Medication,"--Symposium sponsored by the American Association of Community Psychiatrists, Presented at the Institute for Hospital and Community Psychiatry, Baltimore, MD

October 1993 Diamond, Morgan, McElroy and Rogers: "What do Patients Want to Know About Their Medications?" Symposium Presented at the Institute for Hospital and Community Psychiatry, Baltimore, MD

October, 1993 "Coercion and Aggressive Treatment in the Community" Invited Presentation to the John D and Catherine T MacArther Foundation Research Network on Mental Health and the Law. Seattle, Washington

July 1995 Alternatives to Involuntary Treatment: Invited Address to the National Alliance for the Mentally Ill, Washington D.C.

October, 1995	"The Use of Quality of Life Outcomes in Clinical Practice" Presented as part of a symposium on "Quality of Life in Mental Health: Different Views of the Elephant", APA Institute on Psychiatric Services, Boston
October 1996	"How can we use Quality of Life to guide clinical work?" Presented as part of symposium on "Quality of Life as a Focus for Clinical Work", Institute on Psychiatric Services, Chicago
October 1996	"Employment: What are Realistic Goals?" Presented as part of a symposium on "Dilemmas in Schizophrenia: Managing Obstacles to Recovery, Institute on Psychiatric Services, Chicago
October 1999	"Quality of Life: What do Clients Tell Us?" Psychiatric Services, Los Angeles California
July 1998	"Coercion and its alternatives": Keynote for the National Alliance for the Mentally Ill National Meeting, Washington D.C.
June 1999	"Challenges of Integrated Delivery Systems" invited talk to the 48th National Conference on Mental Health Statistics, Washington D.C.
Oct 1999	"What does recovery really mean for someone with a psychiatric disability:" invited William Rondeau Memorial Lecture: Portland Oregon
Oct 1999	"Schizophrenia, Antipsychotic Medications and Quality of Life: Oregon Health Sciences University, Portland Oregon
Oct 1999	"Psychiatric Rehabilitation and Recovery" NASMHPD Medical Directors Best Practices Symposium , New Orleans
Oct 1999	"How to Work with White Patients: Cultural Competence as Part of Clinical Competence" Psychiatric Services, New Orleans
Oct 1999	"Using Power and Coercion in Compliance" Psychiatric Services, New Orleans
Dec 2002	"What Makes Mental Health Services Work" invited presentation to the Presidents Freedom Commission on Mental Health, Washington D.C.
April 2003	"Coercion and Power in Mental Health Treatment" paper presented at "The Liberal State and Its Mental Health Power", sponsored by University of Wisconsin project on Law and the Humanities
Oct 2005	"Recovery Oriented ACT: Changing the pardigm" paper presented as part of a symposium at the Institute on Psychiatric Services, San Diego
Oct 2005	"Schizophrenia, Antipsychotic Medication, and Quality of Life" paper presented as part of a symposium at the Institute on Psychiatric Services, San Diego

May 2006	Diamond RJ and Lucht B "The use of Consumer Staff in a Mobile Crisis Unit" Paper presented as part of a Symposium at the American Psychiatric Assoc Meeting, Toronto, CA
May 2007	Diamond RJ, Mergener M and Collins T "Changes in Prescribing When Antidepressants Become Generic" presented as part of a Symposium at Amertican Psyciatric Assoc Meeting, San Diego, CA
Oct 2009	Diamond RJ "Working with Angry People" lecture at 61st Institute on Psychiatric Services N.Y.
Oct 2009	"Instant Psychopharmacology: An overview for the non-medical mental health clinician" Immersion course offered as part of Institute on Psychiatric Services, N.Y.
Oct 2010	From bad-mouthing to good-mouthing the customers: How we use words to separate us from our clients" Symposium at Institute on Psychiatric Services, Boston
Oct 2010	The Psychiatrist's Role in a Recovery Based Treatment Team: " Symposium at Institute on Psychiatric Services, Boston
Oct 2012	Recovery Oriented Prescribing: Invited lecture at Institute on Psychiatric Services, N.Y.

INVITED PRESENTATIONS: OUT OF STATE (partial list, last 10 years)

Jan 2000	"Recovery: What do we really mean and what are we really trying to do" invited workshop for New York Behavioral Health Partnership conference
April 2000	"The evolution of ACT: Considerations for the New Millenium" Invited presentation 1st Annual Illinois Statewide ACT Conference, Chicago, Ill
Aug 2000	"ACT within a continuum of care" Invited masterclass for American Association of Behavioral Healthcare, San Antonio, TX
"	
Oct 2000	Recovery from Serious Mental Illness" Invited opening keynote for NY state NAMI meeting, White Plains, NY
Oct 2000	"Effective Treatment of People with Borderline Personality Disorder" All Day Workshop sponsored by Southwestern MN Adult Mental Health Consortium, Wilmar MN
Oct 2000	"Recovery from a Psychiatrist's Point of View" invited lecture for Psychiatric Services, Philadelphia, Pa.

Dec 2000	Ensuring Consumer-centric Outcome Measurement in Behavioral Health, 7th Annual Florida Conference on Behavioral Healthcare Evaluation, Orlando, FL
April 2001	"Dialogue on Recovery" Pathways to Recovery Conference: Maine Department of Mental Health, Lewiston, Maine
May 2001	"Developing Effective Community Outreach Services: A Team Approach", Intensive Coummunity Outreach Forum, Bowling Green, KY
May 2001	Working with People Diagnosed with Borderline Personality Disorder, Wright State University, Dayton Ohio
May 2002	"Recovery: what is it and how do we make it real" Grand Rounds and workshop, University of Alabama
Jan 2003	"Some thoughts on Recovery for People with Serious Mental Illness" Grand Rounds at University of New Mexico, Albuquerque, NM
Feb 2003	"Recovery from a Psychiatrist's Point of View" Invited presentation to the Virginia state Psychiatric Association meeting, Charlottesville, VA
April 2004	"Effective Community Treatment for People with Schizophrenia" International Congress for Schizophrenia Research , Chicago Il
May 2004	Effective Community Recovery: Blue Earth County Mental Health Conference, Mankato, MN
June 2004	Recovery from a Psychiatrist's Point of View: Mayo Clinic, Rochester MN
June 2004	Washington Community Mental Health Council: Evidence Based Mental Health Treatment, Wenatchee, Washington
Jan, Feb, and March, 2005	Invited series of workshops on Best Practice in Mental Health on Social and Psychological Aspects of Prescribing and Taking Psychiatric Medication, New York City, N.Y.
Sept 2006	Welcoming People to the Mental Health System: Invited Keynote for the Minnesota Community Mental Health Annual Conference
Feb 2007	Effective Community Treatment for People with Serious Mental Illness Lutheran General Hospital Grand Rounds, Chicago, Ill
June 2007	Principles of Effective Community Treatment (morning workshop) Working with People with Borderline Personality Disorder (afternoon) Ozark Center, Joplin, MO
Oct 2007	Recovery Oriented Psychopharmacology Presentation at cience, Service and Recovery conference, Chicago Il

Oct 2008	Redefining the treatment goals in Schizophrenia Thresholds Annual Conference, Chicago Il
March 2009	Working with Angry People: Grand Rounds at SUNY Downstate, Brooklyn N.Y.
March 2009	Recovery from a Psychiatrist's Point of View: Recovery Training for Psychiatrists organized by University of Maryland Dept of Psychiatry
March 2009	Recovery Oriented Prescribing Thresholds Chicago Il
October 2010	Update on Bipolar Depression: Vista Health System, Waukegan Ill
December 2010	CBT with Psychotic Symptoms: Vista Health System Waukegan Ill
Feb 2011	Schizophrenia: Recovery Based Treatment: Full Day Conference for Mental Health Centers of Central Illinois, Springfield Illinois
March 2011	Social Aspects of Prescribing Medication: University of Massachusetts
June 2011	Practical Strategies for Treatment of People with Schizophrenia: Grand Rounds at Meharry School of Medicine, Nashville, TN
June 2011	June 2011 The Future of Community Psychiatry: Keynote address for annual conference of the Center for Public Service Psychiatry, Western Psychiatric Institute and Clinic
Oct 2012	Invited Lecture: Recovery Based Prescribing: At Psychiatric Services Meeting, N.Y.
Oct 2012	All Day Course: Psychopharmacology for Primary Care Prescribers Psychiatric Services Meeting, N.Y.
May 2012	Grand Rounds for N.Y. State Hospital System: Recovery Oriented Prescribing, Albany N.Y.
June 2013	Re-Visioning Recovery Services in a Newly Organized Health System: What Helps? Day-Long conference Mental Health Association of West Chester New York

REGIONAL PRESENTATIONS: (partial list, last 10 years)

Feb 2001	Working with Difficult Patients in Primary Care Sauk County Hospital
April 2001	Recovery From a Psychiatrist's Point of View, Wisconsin State Meeting, National Alliance for the Mentally Ill"

May 2002	"Ethics and Boundaries" workshop at the Wisconsin state Community Support Conference, Madison, Wisc
Sept 2002	"Chronic Crisis Patients" workshop at the 6th annual Wisconsin Crisis Intervention Conference, Waukesha, Wisc
Oct 2002	"Instant Psychopharmacology" Day-long workshop for non-medical mental health professionals, Waukesha, Wisconsin sponsored by WAFCA (Wisconsin Association of Family and Children
Sept 2003	Medical Illness that Presents as Psychiatric Problem: Workshop for the Wisconsin Crisis Intervention Crisis
Sept-Nov 2003	Course organizer: Medical Problems that Present as Psychiatric Illness: course for non-medical mental health professionals, Co-sponsored by the UW Department of Psychiatry and the Mental Health Center of Dane County
Sept 2005	Working with Angry People: Walsorth, WI
Sept 2006	A Collaborative Approach to Crisis Resolution Keynote for the Wisconsin 10th Annual Crisis Conference, Baraboo, Wisconsin,
Nov 2008	Overview of Psychopharmacology: all day course for non-medical mental health professionals Richland Center, WI
Feb 2009	Role of Psychiatric Medication in Co-Occurring Disorders: Wisconsin Co-Occurring Conference, Waukesha, WI
Feb 2009	Role of Social Workers in Medication Monitoring: NASW State Conference, Madison Wisconsin
April 2009	Recovery Principles in Treatment Planning: Sheboygan, WI
April 2009	Chronic Crisis Patients: Green Bay, WI
April 2009	Working with People who Drive You Crazy: workshop for primary care physicians working in ERs: Menomonie, WI
May 2009	Working with People with Borderline Disorder, Wausau, WI
Sept 2009	Practical Tips for Residential Services Staff: Working with People with Mental Illness in Residential Settings: Madison, WI
July 2010	Shared Decision Making: Making it Real: Ashland Wisconsin
Aug 2010	Ethics and Boundaries for Work in the Community: Door County Wisconsin
Sept 2010	Cognitive Behavioral Therapy for Psychotic Symptoms: Workshop for the Wisconsin Crisis Conference, Wisconsin Dells WI

Oct 2010	Police CIT training: Overview of Mental Illness for Police Officers
Oct 2010	Crisis Intervention with People with Borderline Personality Disorder: La Crosse, Wisconsin
Nov 2010	Suicide Assessment and Intervention: La Crosse, Wisconsin
Nov 2010	Decreasing the need for Coercion: Workshop in Green Bay, Wisconsin
March 2011	Mental Health Training for Police: St Croix, Wisconsin
April 2011	Working with People with Personality Disorders: Wausau Wisconsin

Impact of Mental Illness on Court Mandated Behavior
Wisconsin Association of Treatment Court Professionals

GRANT SUPPORT:

1992-1993 NIMH Multidisciplinary Training grant in community psychiatry (jointly submitted with School of Nursing)

PUBLICATIONS:

Books

Diamond RJ *Instant Psychopharmacology: A Guide for the Nonmedical Mental Health Professional* WW Norton & Co, New York 1998

Weiden, PJ, Scheifler, PL, Diamond RJ and Ross *R Breakthroughs in Antipsychotic Medications* National Alliance for the Mentally Ill and WW Norton & Co, New York 1999

Diamond RJ *Instant Psychopharmacolog 2nd edition: A Guide for the Nonmedical Mental Health Professional* WW Norton & Co, New York 2nd edition 2002
Spanish Translation published in Chile, April 2004

Diamond RJ and Scheifler PL: *Treatment collaboration in mental health: Improving the therapist, prescriber client relationship* WW Norton & Co, New York 2007

Diamond RJ *Instant Psychopharmacolog 3rd edition: A Guide for the Nonmedical Mental Health Professional* WW Norton & Co, New York 3rd edition 2009

Diamond RJ The Medication Question: Weighing Your Mental Health Treatment Options For Patients and Their Families WW Norton & Co, New York 2011

Papers

Essex, Estroff, Kane, McLanahan, Robbins, Dresser, and Diamond, R.J. "On Weinstein's Patient Attitudes Toward Mental Hospitalization: A Review of Quantitative Research." *J Health Soc Behav*, 21(4), 393-396, December 1980.

Diamond, R.J., Brooner, R.K., and Lowe, D. "The Use of Minor Tranquilizers With Jail Inmates." *Hosp Community Psychiatry*, 32(1), 40-43, January 1981.

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Diamond, R.J. "Outpatient Use of a Double-Blind Medication Trial as a Clinical Tool--A Case Report." *J Clinical Psychiatry*, 44(8), 304-305, April 1983.

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Stein, L.I. and Diamond, R.J. "The Chronic Mentally Ill and the Criminal Justice System: When to Call The Police." *Hosp Community Psychiatry*, 36(3), 271-274, March 1985.

Diamond, R.J., Alexander, A.A., and Marshall, J.R. "Economic Grand Rounds: A Chronic Patient in an HMO." *Hosp Community Psychiatry*, 36(3), 239-241, March 1985.

Wilson, W.H., Diamond, R.J., and Factor, R.M. "An Approach to Group Therapy with Severely Disturbed Patients." *Yale J Biol Med*, 58:363-372, 1985.

Diamond, R.J. "Antipsychotic Drugs and the Quality of Life: The Patient's Point of View." *J Clinical Psychiatry*, 46(5), (Sec. 2), 29-35, 1985.

Diamond, R.J. "Strategies for Medication Compliance with Resistant Patients." *Psychiatric Annals*, 16(11), 644-666, November 1986.

Diamond, R.J. "Community Treatment in Madison, Wisconsin." *Community Mental Health in New Zealand*, 3(2), 99-106, October 1987.

Diamond, R.J. "The Changing Role of the Community Psychiatrist" in *Community Psychiatrist*, 3 (1), pg. 12, June 1988.

Factor, R., Stein, L, Diamond, R. "A Model Community Psychiatry Curriculum for Psychiatric Residents." *Community Mental Health Journal*, 24 (4),310-326, Winter, 1988.

Wilson, W., Diamond, R., Factor, R. "Clinical Care Update: The Chronically Mentally Ill Group Treatment for Individuals with Schizophrenia." *Community Mental Health Journal*, 26(4), 361-372, August 1990.

Diamond, R.J., Stein, L.I., and Susser. E. "Essential and Nonessential Roles for Psychiatrists in Community Mental Health Centers." Hospital and Community Psychiatry, 43(2), 187-189, February, 1991.

Wolff, N., Helminiak, T., Diamond, R.J. "Sharing Responsibilities for the Mentally Disordered: A Legal System and Mental Health Center Cost Profile." *Mental Health Research Center Papers* No 15, December 1991.

Diamond, R.J. "Helping Treatment-Resistant Schizophrenic Patient Improve Their Quality of Life." *Relapse*, 1(15), 1991.

Nehl, N., Diamond, R.J. "Developing a Systems Approach to Caring for Persons with Borderline Personality Disorders." *Community Mental Health Journal*. Vol. 29 (2) 1993 161-172

Diamond, R.J. "The Psychiatric 's Role in Supported Housing." *Hosp and Community Psychiatry* 44 (5) 461-464, May 1993 .

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Becker, M, Diamond R and Sainfort, F. "Factors Affecting Quality of Life Among People with Severe and Persistent Mental Illness. Research Paper Series No 33, Mental Health Research Center, 1994

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Diamond, RJ, Goldfinger S, Pollack D and Silver M "The Role of Psychiatrists in Community Mental Health Centers: A Survey of Job Descriptions" (1995), *Community Mental Health Journal*

Wolff, N., Helminiak, T., Diamond, R.J. "Estimated Societal Costs of Assertive Community Mental Health Care" *Psychiatric Services* (1995) 46(9) 898-906

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Weiden, PJ, Scheifler PL and Diamond RJ "My Patient is Better: Now What? Managing Psycholgical Reactions" J Prac Psych and Behav Health May 1998 pp 175-181

Diamond RJ and Becker, M "Using the Wisconsin Quality of Life Index: A Multidimensional Model for Measureing Quality of Life" J Clin Psychiat 1998:59 (in press)

Scheifler PL, Weiden, PJ, and Diamond RJ "My Patient is Better: Now What? Part II. Dealing with Interpersonal Relationships" J Prac Psych and Behav Health Sept 1998 pp 1-7

Diamond R and Becker M "The Wisconsin Quality of Life Index: A Multidimensional Model for Measuring Quality of Life" J Clin Psychiatry 1999;60 (suppl 3) pp 29-31

Stein L.I., Diamond R.J. Commentary: A "Systems" - Based Alternative to Mandatory Outpatient Treatment. The Journal of the American Academy of Psychiatry and the Law. Volume 28, Number 2, 159-164, June 2000

Kushner, K, Diamond R , Beasley, JW, Mundt M, Plane MB and Robbins, K "Primary Care Physicians Experience with Mental Health Consultation" Psych Services 52(6) June 2001 838-840

Diamond R.J. *What Primary Care Physicians Need to Know about People with Schizophrenia.* Wisconsin Medical Journal 103 (6) 2004 pp 29-33

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Edwards NC, Locklear JC, Rupnow MF and Diamond RJ "Cost Effectiveness of Long-acting Risperidone Injection versus Alternative Antipsychotic Agents in Patients with Schizophrenia in the USA" PharmacoEconomics 23 supple 1, 2005: 75-89

Diamond, RJ *Recovery From Mental Illness: a Psychiatrist's Point of View*, Post Graduate Medicine Special Report: New Directions in Schizophrenia: August 2006 54-62

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Becker MA, Young SM, Ochshorn E and Diamond RJ *The Effects of Antipsychotic Medication Type on Service Use and Paid Employment: Outcomes for Florida Medicaid Beneficiaries Diagnosied with Schizophrenia* submitted for review to Schizophrenia Bulletin 2007

Lim LF, Diamond RJ, Chang JB, Primm AB and Lu FG *Using Non-Feature Films to Teach Diversity, Cultural Competence, and the DSM-IV-TR Outline for Cultural Formulation: Academic Psychiat 32:4 July-August 2008 291-298*

Becker M, Brown L, Ochshorn E, Diamond R. *Risk for Suicide among Medicaid Beneficiaries. Suicide Life Threat Behav.* 2009 Apr; 39(2):172-81.

Diamond RJ *Five Things a Psychiatrist Can Do to Support Recovery for People with Mental Illness* Psychiatric Services Taking Issue Column: Psych Services Sept 2009 60(9)

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Diamond, R.J. "The Role of the Hospital in Treating Chronically Disabled." In Stein, L. (Ed.), *New Directions in Mental Health Services*. Jossey-Bass, Inc., pp. 45-55, 1979. Reprinted in OHMA Journal - State of Michigan Office of Health and Medical Affairs, Vol. 2 & 3, Summer 1980.

Howell, Diamond, R.J. and Wikler. "Is There a Case for Voluntary Commitment?" In Beauchamp & Walters (eds.), *Contemporary Issues in Bioethics*, 2nd edition. Belmont, California: Wadsworth Publishing Company, 1982.

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Gilman, S. and Diamond, R.J. "Economic Analysis in Community Treatment of the Chronically Mentally Ill." In Stein, L.I. and Test, M.A. (Eds.), *The Training in Community Living Model - A Decade of Experience*. San Francisco: Jossey-Bass, New Directions for Mental Health Services, Chapter 8, 77-84, 1985.

Stein, L.I. and Diamond, R.J. "A Program for Difficult to Treat Patients." In Stein, L.I. and Test, M.A. (Eds.), *The Training in Community Living Model - A Decade of Experience*. San Francisco: Jossey-Bass, New Directions for Mental Health Services, Chapter 3, 29-39, 1985.

Washington, P. and Diamond, R.J. "Prevalence of Mental Illness Among Women Incarcerated in Five California County Jails. *Research in Community and Mental Health*, Volume 5, pp. 33-41. Greenwich, Connecticut: JAI Press, 1985.

Howell, T. and Diamond, R.J. "The Use of Psychotropic Drugs in Elderly Patients with Chronic Mental Illness." In Abramson, Quam, and Wasaw,(Eds), *The Elderly and Chronic Mental Illness*: New Directions for Mental Health Services, pp. 47-58, 1986.

Stein, L.I., Factor, R.M., and Diamond, R.J. "Training Psychiatrists In The Treatment of Chronically Disabled Patients." In Meyerson, A.T. and Fine, T. (Eds.), *Psychiatric Disability: Clinical, Legal and Administrative Dimensions*, pp. 271-283, 1987.

Stein, L.I., Diamond, R.J., and Factor, R.M. "A System Approach to the Care of Persons with Schizophrenia." *Handbook of Schizophrenia*, Volume 4, Marvin Herz, ed., pp. 213-246, 1990.

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Diamond R.J. "Community Care-The USA Experience" *A Slow Train Coming: Bringing the Mental Health Revolution to Scotland* Christine Dean and Tim Davison (Eds). Greater Glasgow Community and Mental Health Services NHS Trust 1994

Diamond RJ "Coercion in the Community: Issues for Mature Systems" in Hollingsworth and Stein (ed) , *New Directions for Mental Health Services*, San Francisco: Jossey-Bass, 1995

Diamond, R.J., Stein, L.I., and Schneider-Braus, K "The Psychiatrist's Role in Mental Health Center Administration pp 87-102 in W. Breakey ed., *Modern Community Psychiatry*, Oxford University Press. 1996

Diamond RJ "Coercion and Tenacous Treatment in the Community: Applications to the Real World" pp *Coercion and Aggrssive Community Treatment: A New Frontier in Mental Health Law*, pp 51-72, D Dennis and J Monahan (ed) Plenum Press, 1996. Reprinted in R.E. Drake et. al. ed *Readings in Dual Diagnosis,* Interntaional Associaton of Psychosocial Rehabilitation Services, Columbia MD 1998

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Factor, R.M. and Diamond, R.J. "Emergency Psychiatry and Crisis Resolution in *Community Psychiatry, a Practitioner's Manual*. Vacarro and Clark, ed., APA Press. 1996

Curtis, LC and Diamond, RJ. "Power & Coercion in Mental Health Practice " chapter 5, 97-122 in *Treatment Compliance and the Therapeutic Alliance* Barry Blackwell, ed., Harwood Academic Publishers, Amsterdam 1997

Rosen A, Diamond RJ, Miller V and Stein LI "Becoming Real: From Model Programs to Implemented Service" pp 27-41 in *Dissemination of Innovative Programs* , Hollingsworth (ed), *New Directions for Mental Health Services*, San Francisco: Jossey-Bass, No 74 Summer 1997

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Becker, M and Diamond, R "La qualita di vita in psichiatria: Definizione, misurazione, e implicazioni cliniche. II Pensier Schitifico Editore (119-148) Chichester England, John Wiley and Sons (1999)

Becker, M and Diamond, R "Wisconsin Quality of Life Index (W-QLI" 141-142 in *Handbook of Psychiatric Measures*, Rush J, et. Al APA Press, Washington D.C. 2000

Becker, M and Diamond, R "Qualify of Life Measurement in Persons with Schizophrenia: Are we Measuring What's Important?" *Quality of Life in Mental Disorder 2nd ed. s*, Katschnig H, Freeman H (Eds). John Wiley & Sons, Chichester England (2005)

Diamond R. "Engaging the Crisis Patient Around Medication": *Emergency Psychiatry: Principles and Practice*, edited by Rachel Lipson Glick, M.D., Jon S. Berlin, M.D., Avrim Fishkind, M.D., and Scott Zeller, M.D. Lippincott Williams & Wilkins, 2008

Diamond R " Psychopharmacology and Medication Adherence" *The American Association of Community Psychiatrists Handbook of Community Psychiatry*. (Ed) McQuistion H, Feldman JM,, Ranz J and Sowers W. 2012

Abstracts:

Becker, M and Diamond, R Quality of Life and Mental Health *Sociological Abstracts* (1994)

Becker, M and Diamond R "Quality of Life Measurement in Mental Health: What do the Data Tell Us? Abstracts 4th Annual Conference of ISOQOL, Quality of Life Research vol 6, 1997 p 621

Letters to the Editor

Marshall M, Bond G, Stein LI, Shepherd G, McGrew J, Hoult J, Rosen A, Huxley P, Diamond RJ, Warner R, Olsen M, Latimer E, Goering P, Craig TK, Meisler N, Test MA. "PRiSM Psychosis Study. Design limitations, questionable conclusions". Br J Psychiatry. 1999 Dec;175:501-3.

Posters:

Edwards, NC, Rupnow, FT, Diamond RJ and Poshos CL "Benefits of Compliance with Long-Acting Risperidone in Schizopahrenia" APA Institute on Psychiatric Services, Boston 2003

Edwards, NC, Rupnow, FT, Pashos CL, Botteman, MF Locklear , J and Diamond R. "Cost-Effectiveness of Long-Acting Risperidone Injection" APA annual meeting, 2004 New York

Hufnage E, Locklear J, Caruso R, Doyle J and Diamond R. "Treatment Goal Expectations of Physicians and Patients with Schizophrenia" APA Institute on Psychiatric Services, Atlanta 2004

Edwards, NC, Rupnow, FT, Pashos CL, Botteman, MF Locklear , J and Diamond R. "Cost-Effectiveness of Long-Acting Risperidone Injection" ISPORT 10th Annual Meeting, Washington D.C. 2005

Edwards, NC, Locklear , J Rupnow, FT, and Diamond R. "Cost-Effectiveness Evaluation of Long-Acting Risperidone" Institute of Psychiatric Services , 2005 San Diego, Calif

Diamond RJ "Striving Towards Recovery: Setting New Expectations in Schizophrenia" NAMI National Conference, Washington D.C. July 2006

Book Reviews

Serban, G. "Adjustment of Schizophrenics in the Community." *J Hosp Psychiatry*, November, 1981.

Sarban, T.R. and Mancuso, J.C. "Schizophrenia, Medical Diagnoses or Moral Verdict." *J Contemporary Psychiatry*, 2(2), 129-130, June 1983.

Cutler, D.L. (Ed.) "Effective Aftercare for the 1980's." In *New Directions in Mental Health* monograph - contemporary psychiatry, 3(3), 234-235, September 1984.

Allen, C.K. "Occupational Therapy for Psychiatric Diseases: Measurement and Management of Cognitive Disabilities." *J Clinical Psychiatry*, July 1985.

Kanter, J.S. (Ed.) "Clinical Issues in Treating the Chronic Mentally Ill." In *New Directions in Mental Health* monograph, reviewed for *Psychiatry*, 1986.

Bernheim, K.F. and Lehman, A.F. "Working with Families of the Mentally Ill" Reviewed for *Family Process*, 1986.

Letters and Newsletter Articles.

Jefferson, J., Greist, J., Marcetich, and Diamond, R. "Lithium and Hair Loss." *Therapy Newsletter*, 14:23-23, 1979.

Cummins, T.K., Diamond, R.J. "Letters to the Editors: Intranasal Buspirone", *J. Clin Psychopharmacology*, 10(4), 297-298, August 1990.

Diamond, R. J., & Factor, R. M. Training residents to care for the chronically ill, in Psychiatric News, Vol. 27, No. 1, Pg. 18. 1992

Diamond, RJ and Factor, R.M. "Don't Make Continuing Treatment More Difficult: A Discussion in Opposition to the Proposed Fifth Standard For Civil Commitment" in Wisconsin Psychiatrist 32(2): 14-19, 1991

Diamond, R.J. and Factor, R.M.. Training Residents to Care for the Chronically Ill (letter). *Psychiatric News* 1992, 27 (1), 18

Diamond, RJ "Excerpts from Instant Psychopharmacology: A Guide for the Nonmedical Mental Health Professional" *Mental Health Special Interest Section Newsletter* 18(2) June 1995 1-4. Published by the American Occupational Therapy Association

Diamond, RJ "Excerpts from Instant Psychopharmacology part II: A Guide for the Nonmedical Mental Health Professional" *Mental Health Special Interest Section Newsletter* 18(4) Dec 1995 3-4. Published by the American Occupational Therapy Association

Diamond, RJ "Excerpts from Instant Psychopharmacology part III: A Guide for the Nonmedical Mental Health Professional" *Mental Health Special Interest Section Newsletter* 19(3) September 1996. Published by the American Occupational Therapy Association

Marshall, M; Bond, G; Stein, LI; Shephert, G; McGrew, J; Hoult, J;, Rosen, A; Huxley, P; Diamond RJ; et al. "PRISM Psychosis Study: Design Limitations, Questionable Conclusions" Brit J of Psychiatry (1999) 175, 501-503

Unpublished Papers and Projects:
Curriculum developed for the New York Hospital Corporation Best Practice Training Series: The Psychopharmacology Dialogue Project: A curriculum to train mental health staff how to collaborate with clients on medication decision: 2006

Revised 10/13

School of Medicine
and Public Health
UNIVERSITY OF WISCONSIN-MADISON

Department of Psychiatry

10/30/13

Bradley S. Foley
Gutglass, Erickson, Bonville & Larson, S.C.
735 North Water Street, Suite 1400
Milwaukee, WI 53202

You asked that I send you information about legal cases where I have either been deposed or testified. While I have consulted with attorneys on a number of cases and written reports, I have only been deposed as expert in one malpractice case, Lorelli Vs Giannini in Ohio in 2003

I have testified as expert witness in two patent law cases involving antipsychotic medications.

Lilly v Zenith Goldline, trial held in Indiana in 2003
And
Novopharm v Lilly, trial held in Ottawa Canada in 2010

I have attached a copy of my CV.

Sincerely

Ronald J Diamond
Wisconsin Psychiatric Institute and Clinics
University of Wisconsin
6001 Research Park Blvd
Madison, Wisc 53719

Gutglass
Erickson
Bonville&Larson s.c.
A LIMITED LIABILITY ORGANIZATION

BRADLEY S. FOLEY
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writer's direct: 414-908-0240

November 8, 2013

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

Re: Watson v. King-Vassel
Case No: 11-CV-236
Our File No: 911.19

Dear Mr. Gottstein:

We name Martha Rolli, M.D. as a lay witness. A copy of her CV is enclosed. She may be called to testify as to the application of the phrase medically indicated in medicine.

Very truly yours,

Bradley S. Foley

Bradley S. Foley

BSF\cgw
Enclosure

cc:(w/encl.)(via email): Attorney Rebecca L. Gietman

Exhibit 3 to Renewed Motion in Limine

Martha L. (Molli) Rolli MD

State of Wisconsin
Department of Health Services
Mendota Mental Health Institute

PERSONAL DATA:

Office Address: Mendota Mental Health Institute
301 Troy Drive
Madison, Wisconsin 53704
Phone: (608) 301-1044

Home Address: 4322 Rolla Lane
Madison, Wisconsin 53711
Phone: (608) 218-8998
Cell: (608) 235-5368

Birth date/Place: 06/24/1961/St. Paul, Minnesota

EDUCATION:

1984 - 1987 B.S., Major: Psychology, Minors: Chemistry and Biology
Mankato State University
Mankato, Minnesota

GRADUATE:

1988 - 1992 M.D., Mayo Medical School
Rochester, Minnesota.

RESIDENCY:

1992 - 1996 Resident, Department of Psychiatry, University of Wisconsin
Madison, Wisconsin

1995 - 1996 Chief Resident, Department of Psychiatry
University of Wisconsin, Madison, Wisconsin

PRESENT APPOINTMENT:

Medical Director
Mendota Mental Health Institute
State of Wisconsin

CERTIFICATION AND LICENSURE:

American Board of Psychiatry and Neurology, 1997 – recertified 2008
Additional Qualifications in Forensic Psychiatry, 1998
Narcotics Registration Number: BR3742168
State Medical License: Wisconsin #34559-020

PROFESSIONAL APPOINTMENTS:

2008-2010	Psychiatry Director Wisconsin Department of Corrections.
2008- Present	Associate Professor, Clinical Faculty, Department of Psychiatry University of Wisconsin Medical School, Madison, Wisconsin
2011-Present	Medical Consultant Prest & Associates Inc An independent review organization Madison WI
2008	Associate Professor, Department of Psychiatry University of Wisconsin Medical School, Madison, Wisconsin
2000 - 2008	Assistant Professor, Department of Psychiatry University of Wisconsin Medical School, Madison, Wisconsin
2000 - 2008	Active Staff University of Wisconsin Hospitals & Clinics, Madison, Wisconsin
2000 - 2008	Director of Inpatient Psychiatry University of Wisconsin Hospitals & Clinics, Madison, Wisconsin
2000 - Present	Forensic Practice Wisconsin Psychiatric Institute and Clinic Focus: NGI evaluations, Malpractice and Disability Madison, Wisconsin
2000 - 2003	Director of Consultation Liaison Psychiatric Services University of Wisconsin Hospitals & Clinics, Madison, Wisconsin
2000 - 2003	Director of Psychiatric Emergency Services University of Wisconsin Hospitals & Clinics, Madison, Wisconsin
1996 - 1999	Assistant Clinical Professor, Department of Psychiatry University of Wisconsin Medical School, Madison, Wisconsin
1996 - 2000	Staff Psychiatrist Mendota Mental Health Institute, Madison, Wisconsin
1996 - 2000	Medical Director TRAC Program Mendota Mental Health Institute, Madison, Wisconsin
1996 - 2000	Medical Director

Cornerstone Community Support Program
Mental Health Center of Dane County
Madison, Wisconsin

1994 - 1996 Staff Psychiatrist, Emergency Services Unit
Mental Health Center of Dane County, Madison, Wisconsin

1994 - 1996 OBRA Evaluator
Comprehensive Assessments, Madison, Wisconsin

1994 - 1996 Staff Psychiatrist, Department of Veteran's Affairs
Compensation and Pension Evaluator, Madison, Wisconsin

PROFESSIONAL SOCIETY MEMBERSHIPS:

American Psychiatric Association
Offices held:
Assembly Representative, 2007 – to present

Wisconsin Psychiatric Association
Offices held:
President 2003 - 2005
Southern Chapter President 2002 - 2003
Nominations Committee 2002 - 2005
Membership Committee 2003 - present
Legislative Committee 2002 - present

Wisconsin Medical Society
Offices held:
Vice Chair: Board if Directors -2010-present
Member – Board of Directors 2008 - present
Chair, Council on Ethics and Judicial Affairs 2006 - 2010
Member Council on Ethics and Judicial Affairs 2002 - present
Member, Legislative Council 2007 - 2009
Alternate, Legislative Council 2004 - 2007
Chair, Nominating Committee 2006
Member, Nominating Committee 2006 - 2010
Member, House of Delegates, Reference Committee A- Health Insurance Coverage and Access, 2007
Delegate, House of Delegates 2005, 2006, 2007, 2008, 2009
Bioterrorism and Emergency Preparedness Advisory Committee 2002

Dane County Medical Society
Offices held:
President 2008-2009
President Elect 2007-2008
Vice President 2006 - 2007
Member, Board of Trustees 2005 - present

HONORS AND AWARDS:
Exceptional Performance Award, DHFS 1997

TEACHING:

Faculty, third year Psychiatry Clerkship for medical students 2000-2008
University of Wisconsin School of Medicine and Public Health
Duties include: Supervising medical students during a four week clinical rotation
Lectures on Psychiatry and the Law
General Review Sessions
Course Chair, Forensics and Ethics, PGY-3 Psychiatry Residents 2000-present
Instructor, Bipolar Disorder, PGY-1 Lecture Series 2000-2008
Resident Supervision, PGY-1, Inpatient Psychiatry Rotation 2000-2008
Resident Supervision, PGY-2-4, individual general supervision 2000-present
Faculty advisor, Forensic Clinical Rotation for PGY-3 residents 2000-present

RESEARCH INTERESTS:

Member, Deep Brain Stimulation work group, to look at feasibility of establishing a program for treatment resistant depression 2000-2008
Participant in ongoing Vagal Nerve Stimulation dosing study 2005-2008

SERVICE ACTIVITIES:

National:
Editorial reviewer for Academic Psychiatry, 2005 - 2008
Representative to the American Psychiatric Association from the Wisconsin Psychiatric Association, Legislative Advocacy Day, 2005
Representative for Wisconsin to the Annual American Medical Association, Advocacy Conference, 2004

Regional:
Consultant, Wisconsin Department of Regulation and Licensing
Member, Mental Health Drug Advisory Group, Department of Health and Family Services, State of Wisconsin, 2005 - 2006
Member, Medicaid Pharmacy Comprehensive Neuroscience Stakeholder Advisory Committee, Department of Health and Family Services, State of Wisconsin, 2005 - 2007

University:
Member, Health Sciences Institutional Review Board, 2003 - 2008

Medical School:
Vice Chair, Student Promotions Committee 2006 - 2008, (member since 2003)
Psychiatry Student Interest Group, Faculty Advisor, 2005 - 2208
Member, Mentoring Committee, Brian Bell, Neuropsychology, 2005 - 2008

Hospital:
Member, Medical Ethics Committee, University of Wisconsin Hospitals and Clinics, Reappointed as a community representative on the committee in 2010.
Member, Medical Ethics Committee, University of Wisconsin Hospitals and Clinics, 2000 – 2008

Member, Corrective Action Peer Review Committee, 2008
Chair, Residency Disciplinary Committee, University of Wisconsin Department of Psychiatry, 2007 – 2008, member since 2005
Quality Evaluation and Review Committee, University of Wisconsin Hospitals and Clinics, 2000 - 2004
Quality Assurance Committee, University of Wisconsin Hospitals and Clinics, 2000 - 2003
Disaster Preparedness Committee, University of Wisconsin Hospitals and Clinics, 2000 - 2002
Chair, Aggregate Root Cause Analysis, Sentinel Event Peer Review Subcommittee (SEPRS), Prevention of elopement, 2005

Community:
Member, Dane County Health Council 2009-present
President, Medical Staff Association, Mendota Mental Health Institute, 1998 - 2000
Member, Medical Executive Committee, Mendota Mental Health Institute, 1997 - 2000
Member, Performance Improvement Committee, Mendota Mental Health Institute, 1997 - 2000
Member, Quality Counsel, Mendota Mental Health Institute, 1997 - 2000

PUBLICATIONS:

1. "Contractile Dynamics of Rat Skeletal Myocytes Detected by High Speed Digital Imaging Microscopy." Poster presentation, Biophysical Society meeting 1988.
2. "Microscopic Motion Analysis: Laplacian-of Gaussian Masks for sub-pixel edge detection." Poster presentation, IEEE Tenth Annual Conference, 1988.
3. "Clozapine and Pulmonary Embolus." Am J of Psychiatry, 158(3):499-500, Mar 2001.
4. "Defining Ourselves." Wisconsin Psychiatrist, Fall 2003.
5. "What are You, Some Kind of Therapist?" Wisconsin Psychiatrist, Winter 2004.
6. "Resetting Our Lobbying Priorities." Wisconsin Psychiatrist, Spring 2004.
7. "A Fond Farewell." Wisconsin Psychiatrist, Winter/Spring 2005.
8. "Volunteerism." Wisconsin Psychiatrist, Fall 2006.

INVITED PRESENTATIONS:

Delerium, Dementia and Psychosis
16th Annual Jail Health Care Conference
Wisconsin Dells, 2010

Chapter 51, How Standard is it?
10th Annual Crisis Conference
Wisconsin Dells 2009

Suicide Assessment
Social Work Seminar Series
University of Wisconsin Hospitals and Clinics, 2007

Biological Issues in Psychiatry
Conference Chair

Wisconsin Psychiatric Association
Annual Meeting, Spring 2006

Navigating Medicare Part D
Department of Psychiatry Grand Rounds
Wisconsin Psychiatric Institutes and Clinics, 2006

Antisocial Personality Disorder and Crisis Intervention
The Many Faces of Crisis, 9th Annual Crisis Intervention Conference
Middleton, Wisconsin, 2005

Pharmacy, Management and Formularies - Impact on the Psychiatrist
Psychiatrists, Medications and the Companies that Produce Them
Wisconsin Psychiatric Association
Spring Conference, 2005

Hallucinations
Department Case Conference
Wisconsin Psychiatric Institute and Clinics
Madison, Wisconsin, 2003

Depression: Advances in Treatment
University Club, "A Dose of Medicine" Luncheon Series
University of Wisconsin, Madison, Wisconsin, 2003

Borderline Etiology
Sixth Annual Crisis Intervention Conference, Wisconsin, 2002

Neuroleptic Malignant Syndrome - A Complex Case With Legal Implications
Department Case Conference, 2001

The Hospital in the Continuum of Care
Fifth Annual Crisis Intervention Conference
Wisconsin, 2001

Pharmacologic Treatment of Personality Disorders
Grand Rounds
Mendota Mental Health Institute, Madison, Wisconsin, 2001

Pharmacologic Treatment of Personality Disorders
Grand Rounds
Winnebago Mental Health Institute, Winnebago, Wisconsin 2001

What's New in Psychiatric Treatment
Fourth Annual Crisis Intervention Conference, Wisconsin 2000

Effective Intervention Strategies with Chronically Suicidal Patients
Third Annual Wisconsin State Crisis Intervention Conference
Wisconsin, 1999

Sexuality and Mental Illness
National Alliance for the Mentally Ill
Wisconsin State Conference, 1999

Sexual Side Effects of Psychiatric Medications
Statewide Teleconference for Community Mental Health Providers
Wisconsin Department of Health and Family Services, 1999

Cognitive Behavioral Interventions for Crisis Personnel
Second Annual Wisconsin State Crisis Intervention Conference
Wisconsin, 1998

Treatment of Borderline Personality Disorder Parts I and II
Statewide Teleconference for Community Mental Health Providers
Wisconsin Department of Health and Family Services, 1998

Psychopharmacology for Psychologists
Edgewood College
Madison, Wisconsin, 1998

Delirium and Dementia
Mental Health Center of Dane County, brown bag lunch series
Madison, Wisconsin, 1996

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

vs. Case No. 11-CV-236

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

Defendants.

Deposition of JENNIFER KING, M.D.

Monday, November 11th, 2013

9:15 a.m.

at

GUTGLASS, ERICKSON, BONVILLE & LARSON, S.C.
735 North Water Street
Milwaukee, Wisconsin

Reported by Rosanne E. Pezze, RPR/CRR

Deposition of JENNIFER KING, M.D., a witness in the above-entitled action, taken at the instance of the Plaintiffs, pursuant to Chapter 804 of the Wisconsin Statutes, pursuant to Notice, before Rosanne E. Pezze, RPR/CRR, Certified Realtime Reporter and Notary Public, State of Wisconsin, at 735 North Water Street, Milwaukee, Wisconsin, on the 11th day of November, 2013, commencing at 9:15 a.m. and concluding at 12:49 p.m.

A P P E A R A N C E S:

OFFICE OF REBECCA L. GIETMAN, by
Ms. Rebecca L. Gietman
805 South Madison Street
Chilton, Wisconsin 53014-1535
-and-
PSYCH RIGHTS, by
Mr. Jim Gottstein
406 G. Street, Suite 206
Anchorage, Alaska 99501
Appeared on behalf of the Plaintiffs.

GUTGLASS, ERICKSON, BONVILLE & LARSON, S.C., by
Mr. Mark E. Larson
735 North Water Street, Suite 1400
Milwaukee, Wisconsin 53202
Appeared on behalf of the Defendant Jennifer King.

ALSO PRESENT: Dr. Toby Tyler Watson

I N D E X

E X H I B I T S

(Original exhibits attached to Original transcript. Copies of exhibits are attached to copies.)

R E Q U E S T S

(None.)

TRANSCRIPT OF PROCEEDINGS

JENNIFER KING, M.D., having been first duly sworn on oath, was examined and testified as follows:

E X A M I N A T I O N

BY MS. GIETMAN:

Q Can you state and spell your name, please.

A It's Jennifer King, K-I-N-G.

Q Not Vassel anymore?

A No.

Q And, Ms. King, where do you reside?

A My home address?

Q Yes.

A N52 W21717 Taylors Woods Drive, Menomonee Falls, Wisconsin.

Q Who do you reside there with?

A Myself and currently two out of the three of our kids.

Q I'm sorry. Dr. King.

A That's okay.

Q I apologize. You're currently working?

A Yes.

Q Where do you work now?

A I work as an independent contractor for Milwaukee Health Services and 16th Street Community Health.

Q Milwaukee Health Services?

A Um-hmm.
Q What is that?
A It's a community health center.
Q And then there was another place called --
A 16th Street Community Health Center.
Q How long have you been working through Milwaukee Health Services?
A I believe May of 2008.
Q How long have you been working at 16th Street Community Health?
A Around -- I think I started February of 2008.
Q Before working for or at Milwaukee Health Services or 16th Street Community Health, where did you work?
A I've always been pretty well, at least the last ten plus years, an independent contractor, so I was working out of Encompass Mental Health.
Q So other than Milwaukee Health Services, 16th Street Community Health, and Encompass, have you worked anywhere else in the past ten years?
A And prior to Encompass I had my own private office for about a year and a half, maybe.
Q And that was CAPS?
A Correct. Technically it's all still CAPS. That's just me, because I'm not employed by any of those places.

Q And CAPS is just a sole proprietorship?
A Yes.
Q So at Milwaukee Health Services who does your appointment billing there?
A The billing department.
Q And how about at 16th Street Community Health?
A The billing department.
Q At Encompass who did your billing?
A The office manager.
Q Did you ever submit claims directly to Medical Assistance for your time that you were seeing a Medicaid patient?
A Did I do the actual billing?
Q Um-hmm.
A No.
Q How about for CAPS, who does --
A The office manager.
Q Who's your office manager?
A Well, now it's at the individual places. It's the billing department. When I had my own office, I had an office manager.
Q You said that you were still -- that was still all CAPS?
A Well, I'm saying because I'm an independent contractor. If I gave a business name it would still

be CAPS. It's not a location.
Q But CAPS doesn't currently submit any billing?
A No.
Q So at Milwaukee Health Services who's in charge of the medical records there?
A The medical records department.
Q And 16th Street Community Health?
A The medical records department.
Q And Encompass, who's in charge of the records there?
A They don't have a separate medical records department, but the office manager.
Q And your records from CAPS, where are those records?
A Those are in a locked office at my house.
Q So you have control of those?
A Right. Except for -- not all of them, because when I moved from seeing patients in CAPS to Encompass, a lot of the patients transferred over. So the patients that transferred over, Encompass took over those records, so I don't have those.
Q At Milwaukee Health Services who schedules appointments for your clients to see you?
A There's a -- I don't know what her official title is, but there is the front desk registration person.
Q Do you pay for that service?
A No, I don't pay for any services there.

Q So they schedule your appointments at Milwaukee Health Service. Do they at 16th Street Community Health?
A Yes.
Q And when you worked at Encompass did they schedule your appointments?
A Yes.
Q At Milwaukee Health Services, what are your duties there?
A I mean I'm a child and adolescent psychiatrist, so I see and evaluate patients, I consult with, you know, the therapist and the other people in the office. There is primary healthcare as well, so I may, you know, if they have questions or whatever, consult with them.
Q Do you oversee other counselors?
A No.
Q At 16th Street Community Health what are your duties there?
A They're the same.
Q Do you oversee any counselors there?
A No.
Q At Encompass, what were your duties there?
A To see and evaluate patients.
Q And you oversaw other counselors there?

A No.
Q It wasn't your duty to review prescriptions that other doctors were writing?
A No.
Q When did you stop billing for CAPS?
A I never directly billed for CAPS. The office manager billed for CAPS, but that stopped when the office closed.
Q When did the office close?
A The end of 2005.
Q And you were the sole owner of CAPS, correct?
A Yes.
Q At Milwaukee Health Services do you participate in meetings there with other than your patients?
A Yeah, business meetings or, you know, office meetings, yes.
Q And how frequently do you have those at Milwaukee Health Services?
A There's a provider meeting which is for clinic-wide, all the physicians.
Q It's for clinical --
A No, clinic-wide. Not just the behavioral health department. We meet, on average, once a month.
Q And that's a mandatory meeting?
A Well, it's expected. It's not mandatory. I'm not an

employee. I'm an independent contractor.
Q So what happens if you don't go to one of those meetings?
A I just wouldn't bill for the time and I wouldn't get paid.
Q Have you ever missed one?
A If I wasn't at work, yes.
Q Has there been one where you haven't been at work?
A I mean I can't recall off the top of my head.
MR. LARSON: Object to foundation to a degree, but go ahead, if you know.
THE WITNESS: I don't know. I can't recall exactly but --
BY MS. GIETMAN:
Q Do they give you notice ahead of time if they're going to have a meeting?
A It's -- yeah, it's usually the first -- the second Monday of every month.
Q So other than those second Monday of every month meetings, are there other meetings that you participate in at work?
A There's a behavioral health department meeting about three out of four Mondays a month for an hour to discuss office matters.
Q And who all participates in that?

A Any physicians, therapists, office manager, the social worker from the behavioral health department.
Q And that's a meeting you are required to go to?
A I'm not technically required to go to any meeting because I'm not an employee. So if I don't go, I don't bill for the time.
Q And has there been a time where you haven't gone?
A I can't recall an exact date, but probably.
Q How about at Encompass, were there meetings that you were to participate in there?
A No.
Q At Milwaukee Health Services how are you paid?
A I'm paid by the hour for my time.
Q And you're paid by Milwaukee Health Services?
A Correct.
Q Do you ever receive payment directly from insurance companies?
A No.
Q How about at 6th (sic) Street Community Health?
A 16th Street Community Health?
Q Sorry.
A Same thing; I'm paid on an hourly rate.
Q From 16th Street?
A From 16th Street.
Q And in 2012 did you get a 1099 from Milwaukee Health

Services?
A Yes.
Q Did you get one from 16th Street?
A Yes.
Q Have you ever gotten other than a 1099 from Milwaukee Health Services, 16th Street, or Encompass?
A No.
Q You're here because of a Notice of Deposition, correct?
A Yes.
Q And you were asked to bring in a number of records. First of all, you were asked to bring all notes, reports and/or records related to NB's care from March 2nd, 2005 to the present including but not limited to medical records, billing records and pre-authorizations.
A I don't have -- NB's chart is at Encompass.
Q Did you make any effort to get his records, reports, notes from Encompass?
A Well, I know that there --
MR. LARSON: Let me just object. That has been a matter of litigation process that the doctor has not been -- she hasn't been required to be necessarily involved with. And I thought it was made very clear at the very inception of the case where

the records were. So I mean you've had as much access through them as we have through the litigation process. Encompass was originally a party to this action, so I don't know how that question is an appropriate question with regard to what her efforts are. She's made the statement they're not hers.

BY MS. GIETMAN:

Q Okay. Since getting this Notice of Deposition, did you make any effort at all to get notes, reports or records related to NB's care?

MR. LARSON: Well, if you're talking about them from Encompass, we've already discussed that. To the extent that you're talking about attorney-client communication, that's not appropriate so she's not going to answer that.

BY MS. GIETMAN:

Q Other than attorney-client documents, did you make any effort at all to get notes, reports or records related to NB's care since getting this Notice of Deposition?

A I guess I have the same copies that you guys have that Encompass sent.

Q Dr. King, since getting this Notice of Deposition did you make any effort to get notes, reports or records related to NB's care?

MR. LARSON: Let me just object to the foundation of that question, because since we don't have an authorization from NB, she couldn't possibly make such an effort.

MS. GIETMAN: I'm asking a simple question; she can answer yes or no. I'm making no determination about what she should have done.

MR. LARSON: Whether she should have? Whether it was legal for her?

MS. GIETMAN: I'm asking if she made any effort to --

MR. LARSON: With that clarification, you can answer the question.

THE WITNESS: Since getting notice on Wednesday night of last week that you guys wanted these records, no, I have not.

BY MS. GIETMAN:

Q Do you have in your personal files or under your care any notes, reports or records related to NB's care other than your communications with your attorney?

A No.

Q You were asked to bring all documents, references or other information or any combination you relied upon since March 2nd, 2005 through the present before writing a prescription for a Medicaid recipient to

determine whether such prescription was covered for purposes of reimbursement, i.e. properly paid by Medicaid. Did you bring any responsive documents?

A No.

Q Since getting this Notice of Deposition did you make any effort to get together those documents?

A I don't have any documents.

MR. LARSON: I just want to object to the foundation for the request.

BY MS. GIETMAN:

Q You were asked to bring all documents, references or other information or any combination you relied upon in prescribing medications to NB. Did you bring those records?

A I don't have records to bring.

Q You rely on no document, reference or other information in prescribing medication to NB?

A I rely on my training, my clinical experience, the knowledge base that I've gained over the years.

Q And what is that knowledge base?

A What do you mean?

Q You said you rely on the knowledge base you've gained over the years.

A Right.

Q What is that knowledge base?

A Through my experience, through practice, through -- I mean if I read things over the years, I don't save them.
Q Do you know what you've read through the years?
A No, I can't recall that.
Q Do you have a subscription to any medical journals?
A The American Academy of Child and Adolescent Psychiatry.
Q Do you save those?
A No, I do not.
Q You were asked to bring any and all written communications with any person, entity or government agency other than counsel regarding this litigation. Did you bring any responsive documents?
A I don't have any documents.
Q Have you ever had any written communication with any person, entity or government agency other than your counsel regarding this litigation?
A No, I have not.
Q Any and all documents, references or other information or written communications with any person, entity or governmental agency other than counsel from the time you were licensed to practice medicine in Wisconsin to date regarding Medicaid drug coverage. You were asked to bring those records.

Did you bring any responsive documents?
A Can you read that over?
Q Any and all documents, references or other information or written communication with any person, entity or governmental agency other than counsel from the time you were licensed to practice medicine in Wisconsin to date regarding Medicaid drug coverage.

MR. LARSON: I'm just going to object to that. The question was overly broad, unduly burdensome, not reasonably calculated to lead to the discovery of admissible evidence. But go ahead and answer the question.

THE WITNESS: No, I did not.

BY MS. GIETMAN:
Q Have you -- do you have any documents, references, information or written communication with any person other than counsel from the time you were licensed to practice in Wisconsin to date regarding Medicaid drug coverage?
A I may have a copy of a formulary.
Q But you didn't bring that?
A It's a current formulary, so no. I mean it's available online. It's available -- I don't know if I do. I just said I may. I can't say it's not in my office, but --

Q Did you make any effort to look through your documents, your e-mail, your computer, to find responsive documents to this request?
A I know there's none in there, so no.
Q But you said you may have some?
A Yeah, maybe like in an office drawer.
Q Did you make any effort since receiving this Notice of Deposition to gather any of those records?
A No, because I have not been at that office since I got this notice.
Q And what office is that?
A I mean if it's anywhere, and I don't even know if it is, the only thing I'm talking about would be a current Medicaid formulary. It would be at the Managed Health Services.
Q Where is --
A I mean Milwaukee Health Services. I'm sorry.
Q So you believe you may have a current formulary there. What is your process for dealing with formularies? You get one and put it in a drawer? Do you review it?
A I see hundreds of patients every year, so a lot of this information is just in my head. After a while I know what medications are on formulary and what aren't. So I don't constantly pull out a document to

look at. It's what I do day to day. So...
Q What changes have there been since last year's formulary to this year's formulary?
A In terms of what?
Q Medications that are approved to be prescribed or can be reimbursed.
MR. LARSON: Object to the form and the foundation for that question.
BY MS. GIETMAN:
Q Well, what changes have been made since last year to this year's formulary?
A In terms of which medications? I don't prescribe medication for every indication. I don't prescribe medication, you know, for cancer patients or for -- so can you be more specific?
Q You have said that you know, it's in your head, what's on the formulary so you don't review it. And I'm asking you, what changes have been made since last year's formulary to this one?
MR. LARSON: Let me object to the form and foundation for the question. Go ahead.
THE WITNESS: So in terms of the medications that I commonly prescribe, in the last 12 months I don't know specifically of any. In the last couple years, you know, Kapvay -- Intuniv, I'm sorry,

has been added to the formulary.
BY MS. GIETMAN:
Q So did you have a formulary for 2005?
A What do you mean did I have a formulary?
Q Did you have a state-issued formulary for 2005?
A There's always a formulary. I may not have it in hard copy, but I have access to a formulary.
Q So is this a document that you reviewed in 2005?
MR. LARSON: Object to foundation. If you remember.
THE WITNESS: Probably.
BY MS. GIETMAN:
Q Would you -- do you use a formulary?
A I have to use the formulary otherwise I won't be reimbursed. I only prescribe medications either that are on formulary or that I fill out a prior authorization form for.
Q So in 2005 were you prescribing medications that you were concerned about their reimbursement so you would have looked at the formulary?
A Most likely, but I probably knew what was on the formulary.
Q And do you have copies of the 2005 formulary?
A No.
Q Did you at any point have a copy of the 2005

formulary?
A Most likely, yes.
Q And where would that have been kept?
A That was eight years ago, so I don't recall where it would be kept.
Q And when you say "the formulary," what is the formulary?
A I said a formulary.
Q When you say "a formulary," what is a formulary?
A It depends on who's ever the insurance carrier. So if it was United Health Services, it would be United Health Services' formulary. If it was Network Health, it would be Network Health formulary. If it was straight Title 19, it would be straight Title 19 formulary.
Q So there are a number of different formularies?
A Correct.
Q For 2013 do you have a number of different formularies in your possession?
A No.
Q Why not?
A Because there has not been lots of new medications added to the formulary, and I'm fairly familiar with what medication I've prescribed and whether or not they're on formulary, one. And two, I don't know the

exact date, but a few years ago the HMOs and straight Title 19 all started using the same formulary.

Q And what is the formulary that they all use now?

A What do you mean?

Q You said they all use the same formulary.

A It's just the formulary. It doesn't have an official name. It's just their formulary. It's just a list of medications that they cover without having to do a prior authorization.

Q And do you have a copy of that?

A No.

Q You were asked to bring all notes, reports and/or records related to your current minor Medicaid patients, including but not limited to medical records, billing records and pre-authorizations produced in compliance with the Court's qualified protective order. Did you bring any responsive documents?

A I don't have any. Those records are not mine, so I don't have access to bring those.

Q Since being given Notice of this deposition, did you make any steps -- take any steps to get records of your current Medicaid patients?

MR. LARSON: Well, again, object to the form and the foundation. She doesn't have the legal

ability to do that. And, plus, there is the other avenues that you have sought through the Court with those entities. So I -- I think there's a lack of foundation for that question.

BY MS. GIETMAN:

Q Since getting Notice of this deposition did you go to anyone at Milwaukee Health Services and request copies of your current minor Medicaid patients' records?

A No, because those are their records and not mine.

Q But you made no effort to request them?

MR. LARSON: Object to the insinuation and the form of the question.

MS. GIETMAN: She can answer a yes or no.

MR. LARSON: Yeah. I'm objecting to the form. I have the right to do that.

MS. GIETMAN: Certainly, and please answer.

THE WITNESS: Those records are not mine, so no.

BY MS. GIETMAN:

Q Did you go to 16th Street Community Health and request access to your current minor Medicaid patients' records?

MR. LARSON: Same objections, but you can answer.

THE WITNESS: What do you mean access?

MS. GIETMAN: Access so that you could respond to this Notice of Deposition.

THE WITNESS: Okay. I can't legally print off those documents and take them outside of their agency. I can look it up on the computer, but I can't print it off because it belongs to the agency and not myself.

BY MS. GIETMAN:

Q Since getting this Notice of Deposition did you go to 16th Street Community Health and request copies of the file so that you could respond to this deposition Notice?

A No.

MR. LARSON: Same objections that I had for that request.

MS. GIETMAN: And the answer?

THE WITNESS: I said no.

BY MS. GIETMAN:

Q Do you have access to the records when you're seeing the patient?

A Yes.

Q You were asked to bring all documents -- excuse me just a moment. Do you have any personal notes, reports or records related to your current minor

Medicaid patients?
A No.
Q You were asked to bring all documents, references or other information, if any, you relied upon in determining whether uses for drugs are approved under the Food, Drug & Cosmetic Act for March 2nd, 2005 to date. Did you bring any records responsive to that?
A I'm sorry.
MR. LARSON: Let me object, because that's a misstatement of the Act. And I will tell you that we're producing today a number of documents, today, that in fact clarify that that's a misstatement.
So, in essence, she has produced today records responsive to that because it addresses why that's not an accurate -- it's hard to respond to something that's not accurate, and that's in fact what we've produced as documents today explaining why that's not accurate. So there are documents here today.
BY MS. GIETMAN:
Q And your documents here today are to explain why uses aren't approved under the Food, Drug & Cosmetic Act rather than any --
MR. LARSON: I think it's quite clear. You can take a look starting with the FDA Drug Bulletin.

It says -- that's not what the FD&C Act does. It doesn't approve physician uses. So --

MR. GOTTSTEIN: That wasn't the question.

MR. LARSON: It is. So you're -- implicit in the request was documents that talk about the FD&C approving uses, and the FDA says that's not what the FD&C does.

MR. GOTTSTEIN: Yeah, it does. It says any use and approved drug.

THE WITNESS: Okay. Any drug is approved if it has -- if the labeling is separate from approval. So if a drug is on market and the FDA has said it's safe to use in humans, as a physician, I'm authorized to use it. And that's what this document says.

MR. LARSON: Clearly, the FDA even says the term "unapproved use" is to some extent misleading and goes on to explain why. So that request is very hard to respond to other than to produce these documents that show the FDA has repeatedly said, as have some of the documents that comprise the compendium that specifically say drug labeling has nothing to do with whether something is an approved use or not.

BY MS. GIETMAN:
Q Dr. King, since getting served with this lawsuit, have you taken any steps to review the FDCA regarding the drugs that you have been prescribing to minor Medicaid patients?
A I'm not sure what you're asking.
Q Since getting served with this lawsuit have you reviewed the FDCA for the drugs that you are prescribing to minor Medicaid patients?
MR. LARSON: Object to the foundation for that question. Go ahead and answer, if you can.
THE WITNESS: I still don't understand. What do you mean have I reviewed the FDCA? Have I reviewed the actual Act?
BY MS. GIETMAN:
Q Have you looked up Risperdal under the FDCA?
MR. LARSON: Well, that's not -- wait a minute. Object to the form of that question. If you can understand that question and respond, go ahead.
THE WITNESS: I'm not sure specifically. I mean yes.
BY MS. GIETMAN:
Q You have. When did you do that?
A I don't know. I can't give you an exact date.
Q Well, was it --

A I don't understand. Have I looked and reviewed it where? I don't know what you're asking me.
Q Have you looked to see if Risperdal was approved for the use in children under five?
A I didn't need to look.
MR. LARSON: Again, object to the form of the question because it misstates the law.
THE WITNESS: That labeling is not used. So are you asking me -- they don't approve medications whether or not I can use it. They approve labeling for whether or not manufacturers can market the medications for certain uses.
BY MS. GIETMAN:
Q Have you reviewed the FDCA?
MR. LARSON: So are you talking about the legal Act? Not the product. You're -- there's two different things here. That's what I'm getting confused by. There's product labeling. Are we talking about product labeling or are we talking about something else?
MS. GIETMAN: Let me ask it a different way.
MR. LARSON: Okay.
BY MS. GIETMAN:
Q What uses are approved under the FDCA for Risperdal?

What are the uses approved under the FDCA for Risperdal?

MR. LARSON: Object to form and foundation for that question. It misstates things. Go ahead.

THE WITNESS: They don't approve uses. Are you asking me what labeling is approved?

BY MS. GIETMAN:

Q What labeling is approved under the FDCA for Risperdal?

A In what population?

Q Minors. Pediatric use.

A It has an FDA approval for, I believe it's five and over, for irritability and autistic spectrum disorder.

Q Since receiving this -- when is the last time you looked at the approved uses under the FDCA for the pediatric psychotropic drugs you prescribe?

A They don't approve usage.

MR. LARSON: Just wait. Let me object to the form, foundation. First of all, it's multiple in form and it's a mischaracterization of both the FD&C Act and -- so I think it's a very difficult question to answer. But go ahead and respond if you can in some way respond to the question.

THE WITNESS: I don't even understand the

pieces of the question. Have I looked it up where? There's not some, you know, book that I know of where it says, you know, this is what the FDA say that you as an individual practitioner with your experience and knowledge base and, you know, medical knowledge can only prescribe these medications for this use. I don't know of a book like that.

BY MS. GIETMAN:

Q Have you -- well, let's move on for a moment. We'll come back to that.

But looking at the documents that you were asked to bring, you were asked to bring all documents, references or other information, if any, you relied upon in determining whether uses for drugs are approved under the Food, Drug & Cosmetic Act from March 2nd, 2005 to date. You're saying you have no records like that because that is incorrect. Is that true?

A I'm saying the FDCA approved labeling. They do not -- they specifically say themselves that they do not determine what a physician should or should not do and they acknowledge that, you know, nonlabeled uses may be more appropriate in some instances.

Q So you have brought nothing responsive to this, other than to say we are misusing the term "approved" under

the FDCA?

MR. LARSON: Object to the form of that question. But --

THE WITNESS: Yes.

BY MS. GIETMAN:

Q Okay. You were also asked to bring all documents, references or other information, if any, you relied upon in deciding to write prescriptions for uses not approved under the FDCA from March 2nd, 2005 to date. Did you bring any documents responsive to that?

MR. LARSON: Object to the form and the foundation for that request.

THE WITNESS: And can you read that over, please?

BY MS. GIETMAN:

Q All documents, references or other information, if any, you relied upon in deciding to write prescriptions for uses not approved under the FDCA for March 2nd, 2005 to date.

A All the drugs that I prescribed are approved to be used, so no.

Q So what are you relying on that they're approved to be used?

A They're on the market. If they weren't approved to be used, they wouldn't be available in the

pharmacies.
Q So the --
A I don't use any investigational drugs or anything. I use things that were approved by the FDA to be marketed.
Q So you use labeling for what we're using as "use approved"?
A No.
Q You're using labeling to determine whether or not a drug is appropriate?
A No. I think that's what you guys are doing. I'm saying the FDA labels medications for the manufacturers to tell them how they can market the medication. They do not label medications to tell physicians how they can prescribe or use medications.
Q And I asked you to bring documents that -- all documents, references or other information, if any, you relied upon in deciding to write prescription for uses not approved under the FDCA from March 2nd, 2005 to date. And you told me if it's on the market you can prescribe it?
A That's correct, as a physician, based on my clinical judgment and the situation with the patient.
MR. LARSON: And just so that you're clear, the documents we've produced today, there's multiple

documents we've produced today that the FDA makes the statement that once a product has been approved for marketing, a physician may choose to prescribe it for uses or in treatment regiments or patient populations that are not included in approved labeling. It goes on to explain that it doesn't intend to impact or control what physicians consider appropriate uses.

BY MS. GIETMAN:

Q When you prescribe to a Medicaid patient, do you use any other criteria other than that?

A I use my clinical judgment. I use what's going on with the patient. I use what may or may not have worked for the patient in the past. I use what's standard of care in the field of child psychiatry.

Q Have you been deposed before?

A In a divorce.

Q Other than in your divorce -- that was your divorce you were deposed in --

A Yes.

Q -- or someone else's? Other than in your divorce, have you ever been involved in litigation?

A No.

Q Prior to meeting here today, other than with counsel, did you discuss with anyone the fact that you were being deposed?

A Yes.
Q With whom did you discuss it?
A With my teenage son. I told him where I was going today.
Q Anyone else?
A My sister.
Q Anyone else?
A No.
Q Have you discussed this litigation at all with anyone, other than counsel, other than your teenage son and sister about this deposition?
MR. LARSON: It was just asked and answered, but go ahead.
THE WITNESS: I mean I probably mentioned it, yes.
BY MS. GIETMAN:
Q To whom did you mention it?
A I don't know. Probably other family members.
Q Did you discuss any of this with anyone at work?
A I believe I told my -- I told -- actually, I told them why I was off today.
Q Other than regarding this deposition, I mean about the litigation in general, have you discussed that with anyone other than your teenage son, your sister and family members?

A What do you mean by discussed?
Q Told them that you were being sued, told anybody what the basis of the lawsuit was, talked to anyone other than your counsel, your son, your sister or family members?
A Sure. I've told coworkers that -- that this is in litigation, yes.
Q What coworkers?
A I don't recall which ones specifically.
Q Which place that you're working at?
A Probably both.
Q Did you tell them all?
A No, because I mean I would -- I didn't tell them all because I'm not friends with all.
Q Who are you friends with?
A I don't know if I'm friends outside of work with anybody. I wouldn't tell -- I mean I probably told Yvonne Bell-Gooden, who's a psychologist at Milwaukee Health Services.
Q Yvonne Bell-Good?
A Bell-Gooden.
Q Anyone else?
A And Deon Ramsey, who's a nurse there. And probably at 16th Street Clinic, I told Jaime Ruvalcaba. It's J-A-I-M-E, Ruvalcaba, which I think is

R-U-V-A-L-C-A-B-A.
Q Anyone at 16th Street?
A Jaime Ruvalcaba is at 16th Street.
Q I'm sorry. Anyone else?
A Not that I recall.
Q Other than those coworkers, have you discussed this litigation with anyone else? Family members and those coworkers, anyone else?
A No.
Q Did you discuss this litigation with Jacob Olson?
A No.
Q Do you know Jacob Olson personally?
A I know him professionally.
Q How long have you known him?
A I mean years ago, and I don't remember the exact date, we sat on a board together. But I haven't had any contact with him since then and I never had contact with him outside of the board meetings.
Q What board was that?
A It was Managed Health Services Pharmacy and Therapeutics Committee.
Q And what year was that?
A I don't recall the exact dates. Probably around 2004, 2005, but I don't know the exact dates.
Q Have you sent any e-mails to anybody regarding this

litigation other than your counsel?
A No.
Q Do you know Ronald J. Diamond?
A No.
Q Have you ever spoken with him?
A No.
Q Have you spoken with Mr. Olson about this litigation?
A No, I have not spoken to him outside of when we were on the committee together, which was years ago.
Q So you were a contract employee with Encompass?
A I wasn't an employee. I'm an independent contractor.
Q I'm sorry, independent contractor with Encompass. Why did you leave there?
A I just wanted to.
Q Why?
A I mean there was no real why. I just decided to leave. I don't -- I mean -- Managed -- I mean Milwaukee Health Services is a community health center and I wanted to be more involved in the community health center. So that's the population of patients that I like to serve.
Q How many days a week are you at Milwaukee Health Services?
A Right now, three.
Q What three days are those?

A Mondays, Tuesdays and Fridays, generally.
Q And do you tell them what days to schedule you for or do they schedule those days and then those are the days you work?
A It's a set schedule. So it's Monday, Tuesday and Friday, unless I take off.
Q And that's at Milwaukee Health Services?
A Correct.
Q And when do you work at 16th Street Community Health?
A Wednesdays and Thursdays.
Q Do you see the same patients at each?
A What do you mean?

MR. LARSON: Same individual people?

MS. GIETMAN: Yeah.

THE WITNESS: No. Those are two separate clinics with two separate patient bases.

BY MS. GIETMAN:
Q When you left Encompass did you take your patient base with you?
A No. If patients wanted to transfer over, because Encompass, after I left, didn't have a child psychiatrist. So some of those patients might have decided to come to Milwaukee Health Services. But I didn't take any, you know, records or -- I mean it was up to the individual.

Q When you started at Milwaukee Health Services was there already a pool of patients that needed your assistance or did you build up that pool?

MR. LARSON: Object to the form of that question.

BY MS. GIETMAN:

Q I can rephrase if that was confusing.

Were there already patients at Milwaukee Health Services that you're now seeing, or did you bring patients or get patients?

A I don't get the patients. So -- I mean it's a community health center, so there's pediatricians, family practice, so there's an internal referral base as well as external referral base. So I don't advertise or solicit for patients.

Q Is it the same at 16th Street Community Health?

A Yes.

Q So if you want to take a vacation, who at -- do you need permission from someone at Milwaukee Health Services to do that?

A No.

Q How about at 16th Street Community Health?

A No.

Q You just say, don't schedule me this week?

A I say I'm going to be off such and such -- right.

And if I don't work, I don't get paid. So...
Q Do you know Martha Rolli?
A I don't think so.
Q R-O-L-L-I. Prior to getting served the complaint in this action, did you take any steps to determine whether a medication you were prescribing to a Medicaid patient would be covered by Medicaid?
MR. LARSON: Object to the breadth of that question. If you can answer it, go ahead.
THE WITNESS: I mean, again, I used -- and I use the formulary to know whether or not it would be covered.
BY MS. GIETMAN:
Q Did you, after getting served the complaint, did you take any steps other than looking at formularies when you were prescribing Medicaid patients medications to see if it would be reimbursed?
MR. LARSON: Object to the foundation for that question. Go ahead.
THE WITNESS: No. And I don't treat my Medicaid patients any differently than I do any other patient. So I do what I think is in the best interest of my patients. I discuss it with the patient and the parents, and together we agree. And generally I prescribe medications that's on the

formulary so that it would be reimbursed.
BY MS. GIETMAN:
Q After getting served the complaint, did you look at anything other than a formulary to determine whether or not medications you wished to prescribe would be reimbursed?
A No. Well, that's not true. There's prior authorization forms so, you know, I may -- I'll fill out a prior authorization form if it's not on the formulary.
Q Did you fill out any prior authorization forms for NB?
A I believe possibly for Strattera, I believe.
Q Have you reviewed your records regarding NB?
A I don't have records for NB. I just have the copies that were provided to me by Encompass, and I have reviewed those.
Q Encompass provided you records directly?
A No, they gave me a copy. They didn't give me a copy; I got it through counsel.
Q Did you bring those records with you today?
A No, because they're the same records that counsel, I believe, provided to you guys, or Encompass did.
Q And when's the last time you reviewed those records?
A Probably I glanced at them two days ago.

Q And in those records did you see any prior authorization forms -- requests for NB?
A For the records I looked at two days ago, no, because I think it was just an e-mail from my attorney, and I didn't have the full records to look at that day, so no.
Q So there are records other than what your attorney showed you?
A No. That's nuts. I sent him an e-mail -- there has been multiple e-mails. So the one that I was reviewing --

MR. LARSON: She's not entitled to know anything about our communications, e-mail or otherwise. She can only ask you, and to the extent she's now getting in there, you can't answer those questions. She just wants to know what documents you saw. And I'll represent at one time she was provided with whatever Encompass provided as part of this litigation. That's it. That's the only thing we've provided her.

BY MS. GIETMAN:
Q In the records that you did review, NB's records, did you notice -- were you aware that there were records missing?
A From the entire thing you're asking me?

Q Yes.
A Yes.
Q Do you know why those records were missing?
A Only thing that I know of --
MR. LARSON: Object to foundation. Calls for speculation. Go ahead.
THE WITNESS: Only thing that I know is missing is my initial assessment from the original date I saw him at CAPS. And, no, I do not know why.
BY MS. GIETMAN:
Q Would that be something in your possession or Encompass's?
A Encompass.
Q And if you had prior authorizations they would have been kept in his file?
A The prior authorizations are in his file. You asked me what I reviewed two days ago. I only reviewed the notes that I wrote two days ago.
Q Other than the notes that you wrote, what else does NB's file contain?
A I would have to see the file again to recall that.
Q But you're aware that it potentially contains prior authorization forms?
A I recall seeing at least one prior authorization form in his chart, yes.

Q What else would a file generally contain that wasn't in the records that you reviewed for NB?

MR. LARSON: Object to the form of that question. I think that's different than what she testified, but go ahead.

THE WITNESS: Yeah. I'm not sure what you're asking. All I reviewed two days ago -- you specifically asked me the last time I reviewed it, which was two days ago, I just quickly glanced through the notes that I wrote when I saw him in the office. I didn't look at, you know, anything else.

BY MS. GIETMAN:

Q What else would there have been in his file when you were providing services to him other than your notes?

A There would have been a sheet with demographics, his name, his age, his birthdate, parents' name. There would have been -- there were at least one prior authorization form in there. That's --

Q That demographic sheet would have shown what insurance he had?

A It most likely would show which HMO he had.

Q When you prescribe medications to Medicaid patients are you -- do you consider at all whether or not the medication you're prescribing is proper under federal law for reimbursement for a Medicaid patient?

MR. LARSON: Let me object on multiple fronts. One, it's multiple; two, calls for a legal conclusion from this witness, and it also, I think, mischaracterizes the process. If you have an answer to that question, go ahead.

THE WITNESS: I don't even understand the question. So...

MS. GIETMAN: Can you read back the question, please?

(Question read.)

MR. LARSON: And also, I think it's been asked and answered in previous questions, but go ahead.

THE WITNESS: Okay. So I would -- my assumption was that if it's on Medicaid's formulary that they would make sure that it was legal and proper before they put it on their formulary. And if their formulary does not have any specific limitations into age or diagnosis that I can prescribe it for, then yes, that -- just the nature of that, then yes, I take into consideration.

BY MS. GIETMAN:

Q After getting served the complaint where you saw there was a concern being raised about whether it was proper for federal Medicaid to cover this drug, did

you change your analysis for what prescriptions you would write to a Medicaid patient?

A I continued to use the formulary.

Q After getting -- did you read the Court's decision in this case where your counsel's motion for summary judgment was granted last summer? Did you read that decision?

MR. LARSON: I'm going to object to the extent it calls for attorney-client communication. And I can't imagine, unless there's a specific question, I'm not sure where this could lead to the discovery of admissible evidence.

BY MS. GIETMAN:

Q Did you read the decision that the judge issued where he granted your lawyer's motion for summary judgment?

A Actually, did I read through the whole decision? No.

Q Did you read the judge saying "a false or fraudulent claim occurs when Medicaid pays for drugs that are not used for an indication that it is either approved by the Food, Drug & Cosmetic Act or supported by a drug compendium." Did you read that?

A I don't recall if I read that or not. But the medications that I do prescribe are supported by the compendium, because the compendium specifically says, at least what I know of the compendium, in their

Prefaces and Forwards, that even they understand that a physician's judgment and clinical decision-making should be taken into consideration and that it's not improper or fraudulent to prescribe medications that are off-label in terms of the labeling that's been in place for manufacturers.

Q What compendia are you relying on?

A I mean in all honesty, I don't use the compendium. I haven't seen the actual compendium. The Forwards to the compendium, the Forwards to the AHFS, or whatever that one is, says in their Forward. Yeah, the AHFS.

Q So have you researched these different drugs using any of the compendia since the judge --

A I've never physically actually seen a compendium. I don't even know where they're located. I don't know any colleagues who have a compendium or have knowledge of these. It's not what we generally use in practice.

Q After the judge's decision in October of last year, did you change at all how you wrote prescriptions for Medicaid patients?

A Once again, I don't write prescriptions for Medicaid patients any differently than I do any other patient. I use my clinical judgment, my knowledge, what's going on with the patient, what I think is in the

best interest of the patient, what I discuss with the patient and the parents to make my decision on prescribing medication. And after that decision I continued to do that.

Q So after this October decision you did not change anything in how you prescribed medication to Medicaid patients?

A And how I reach my decisions to prescribe medications? No, I did not change that.

Q After the -- did you read the Appeals Court decision in this case in August of this year?

A I didn't read through the whole thing, no.

Q Did you take note that the Appeals Court said, "Medicaid can only provide reimbursement for covered outpatient drugs. Covered drugs do not include any drugs used for medical indication which is not a medically accepted indication. Helpfully, medically accepted indication is a statutorily defined term that refers to prescription purpose approved by the Food, Drug & Cosmetic Act or supported by any of several identified compendia."

MR. LARSON: Well, let me object to the extent that -- first of all, you're asking her for a legal conclusion or are you just asking her whether she read that?

MS. GIETMAN: No. I asked whether she read it.

THE WITNESS: Even if I had read it, I wouldn't understand it because I'm not a lawyer. So I don't base my prescribing habits on statutes because I don't read statutes. I've never -- in medical school we did not go through statutes and implying to be approved for any of the HMOs to be one of their providers. They never, that I recall, sent me a statute saying sign this that you agree you won't prescribe outside these parameters or anything.

BY MS. GIETMAN:

Q So you didn't read it, or if you had, you wouldn't have understood it. Did you take any steps to try to understand it?

A I've been trying to understand this since this litigation started.

Q Did you try to understand what the Appeals Court was ruling?

A Okay. My understanding is that this has not been finalized yet, so I'm not going to change my prescribing habits if I know that what I'm doing is my best for the patients with my best -- you know, my job and my role is to provide services to children and adolescents to the best of my ability based on

knowledge, standards of care, accepted medical practice. And accepted medical practice doesn't mean just what was labeled for the manufacturers.

Q Dr. King, the question was, after getting this Appeals Court decision did you take any steps to try to understand what the Court was saying?

A Yes.

Q What steps did you take other than -- if it's discussion with counsel, I don't want to know it. Did you take steps other than discussing it with your counsel?

MR. LARSON: And I'm going to reinforce that.

THE WITNESS: No.

BY MS. GIETMAN:

Q Did you discuss with any other doctor or anyone other than your family, did you discuss the Appeals Court decision?

A No.

MS. GIETMAN: Can we take a break for a moment?

(Brief recess taken from 10:13 a.m. to 10:19 a.m.)

(Deposition Exhibit No. 1 marked for identification.)

BY MS. GIETMAN:
Q This document you produced, "CAPS records in compliance with the Court's qualified HIPAA Protective Order," did you create this document?
A No.
Q Who did?
A Counsel did.
Q Did you have records in your possession?
A Yes, and we sat down and went through them together.
MR. LARSON: To the extent -- now you're getting into attorney-client, so I don't think you're -- you can ask questions in different manners other than --
MS. GIETMAN: My question was, did you have records in your possession?
MR. LARSON: Yeah. And the answer to that was yes, and then you went on, I think, and asked a different question.
THE WITNESS: Right, and this is the summary from the records that were in my possession.
BY MS. GIETMAN:
Q So in a line that has -- for example, No. 1 says KG, and the line -- or the row below that has no labels. Is that a continuation of KG's medication or prescription history?

A That's just a different date of service --
Q For the same --
A -- for the same patient.
MR. LARSON: I think the patients are numbered, I believe, if I'm reading that correctly.
THE WITNESS: Right.
BY MS. GIETMAN:
Q The articles that you provided, ASHP Statement on the Use of Medications for Unlabeled Uses, FDA Drug Bulletin, the 2005 Physicians Desk Reference, AHFS 2004 drug information -- when did you first see this ASHP Statement on the Use of Medications for Unlabeled Uses?
MR. LARSON: To the extent it calls for attorney-client communication, don't divulge any communication. But the question is when.
BY MS. GIETMAN:
Q When did you first see this?
A I can't recall the first date. I mean I don't know the date of when.
Q Was it in the past year?
A Yes.
Q Was it in the past month?
A For that one?
Q ASHP Statement on the Use of Medications for

Unlabeled Uses.

A Within the last month probably, yes.

Q Was it within the past week?

A I don't recall the specific day. I don't know.

Q Did you discover this article?

MR. LARSON: Let me object to the extent it calls for attorney-client communication. I'm not quite sure what the point is and how that could potentially lead to the discovery of admissible evidence. So to the extent it calls for attorney-client communication, I'm going to tell her not to answer.

BY MS. GIETMAN:

Q The document titled FDA Drug Bulletin, when did you first see this document?

A I mean it's the same for all these documents.

Q What is the same?

A That it was attorney-client privilege and I don't know the exact dates.

Q All within the past month?

A I don't know, but probably.

Q None of these documents are things you relied on when writing NB's prescriptions --

A I mean I have the PDR in my office, and this is in the Forward of the PDR. It's in the Forward of every

PDR.
Q But you didn't bring the PDR with you?
A No, I did not.
MR. LARSON: Those are huge books. I mean it would be very -- I mean --
BY MS. GIETMAN:
Q I'm asking Dr. King.
A No, I did not.
Q I'm sorry. Did you say all of these you first saw within the past month?
A No, I did not say that. I said I don't recall when I saw them. And the PDR one I would have seen, you know, throughout the years I've been in practice because it's in the Forward of every PDR.
Q Did you physically copy this PDR?
MR. LARSON: How is that a relevant question?
THE WITNESS: That particular copy you have, no.
BY MS. GIETMAN:
Q Is this a document that you relied on in prescribing NB's prescriptions?
A Okay. I have lots of documents over the years that I've probably looked at that have become part of my common knowledge, so I cannot discern was this

specifically one or was there a different one. It's an accumulation of knowledge throughout the years.

Q And you haven't saved those articles or references anywhere?

A No.

Q Okay. And in responding to our request, you produced these records. Why?

A Because I think they speak to the fact that the FDA, the AHFS, the PDR, which is a much more common book that most practitioners would have in their office as opposed to the compendium, all state that it's legal, not fraudulent, and accepted medical practice to prescribe medications that may not have labeled uses in certain populations and for certain diagnoses.

Q Where in any of these documents does it say for a Medicaid patient it's not fraudulent to pay for certain prescriptions?

MR. LARSON: Object to the form and the foundation for the question.

THE WITNESS: It neither says that it is or it isn't.

MR. LARSON: I would point out to you if you look at the --

MS. GIETMAN: You're not testifying.

MR. LARSON: Okay. But for the record, I'd

like to make clear. If you look at the ASHP Statement on the Use of Medications for Unlabeled Uses, it -- right in the very beginning, the document that's provided to you. But just to clarify for the record that that document has been produced.

MR. GOTTSTEIN: Yeah, and it basically implies that third-party reimbursement is often not allowed.

MR. LARSON: It says it's encouraged.

THE WITNESS: It says, "ASHP supports third-party reimbursement for FDA-approved drug products properly prescribed for unlabeled uses."

MR. GOTTSTEIN: Right.

THE WITNESS: It says it does support that.

MR. GOTTSTEIN: Yeah, right, because third-party payors often don't pay for them.

MR. LARSON: May or may not.

MR. GOTTSTEIN: Right.

THE WITNESS: Well, they've paid for all the ones I've written for.

MR. GOTTSTEIN: You know, we know that.

THE WITNESS: Because they were on their formulary.

MR. GOTTSTEIN: We know that.

BY MS. GIETMAN:

Q You've, in the past year -- well, strike that.

Since 2005 you've prescribed Risperdal to minor Medicaid recipients. For what uses have you prescribed it?

MR. LARSON: Object to the breadth of the question, foundation for the question. Go ahead.

THE WITNESS: I mean it would depend on the specific case, but I've prescribed it for kids who fall in the autistic spectrum, who have problems with irritability or anger or aggression. I've prescribed it for minor children who have a mood disorder. I mean I would say those are the main things, but I don't know that those are the only things. It depends on the symptoms and sort of what other things have been going on with them and what they've tried, what worked in the past.

BY MS. GIETMAN:

Q So what uses -- do you know what use is approved under the FDCA for Risperdal to minors?

MR. LARSON: Object to the form and foundation for that question.

THE WITNESS: My understanding is they approve labeling. They don't approve necessarily uses.

BY MS. GIETMAN:
Q What's the labeling approval for Risperdal for minors?
A It has approval for irritability in autistic spectrum disorder kids. I believe it has approval for bipolar disorder, which is a mood disorder in adolescents.
Q Are you familiar with the ages that Risperdal is approved for use?
MR. LARSON: Again, I object to the form and the foundation of that question. It's multiple. There's a variety of form problems with the question. If you can answer the question, go ahead.
THE WITNESS: I mean I believe for the autistic spectrum disorder it's -- five is the minimum age, I believe. For bipolar disorder, I don't recall the exact age off the top of my head.
BY MS. GIETMAN:
Q So if you had someone in your office who didn't have autistic disorder with irritability, would you look up what was appropriate under their labeling use?
A I don't prescribe medications --
MR. LARSON: Let me object. That's a mischaracterization of what the document is, but -- and so there's a lack of foundation. Go ahead and answer the question.

THE WITNESS: Right. As a child psychiatrist it's not necessarily okay if it's labeled, as in this is what the manufacturer can market this for. It's based on -- Risperdal has been out since I was in training, so I learned to use Risperdal as well as most of these other medications as far back as residency and fellowship training. And so the training that I received, the experience that I had through that, is what I base it on.

BY MS. GIETMAN:

Q So if you have a child who doesn't have autistic disorder with irritability, you don't look at what the approved uses is?

MR. LARSON: Well, again, let me just object. You keep using the term "approved uses" and the FDA says that's not how this works. I don't know how you can speak directly contrary to what the FDA has published for decades.

MR. GOTTSTEIN: Well, it's not contrary to what the FDA says, but that's -- we understand that's your position.

MR. LARSON: It's right in those documents.

MR. GOTTSTEIN: We understand that's your position.

MR. LARSON: It's what it says.

MR. GOTTSTEIN: It's not what it says.

MR. LARSON: I have a problem with continually asking questions in that way. If you want to talk about labeling, make sure the question is clear about labeling. But when you talk about medically indicated, the FDA clearly says, we don't limit patient populations. It says it right at the front, the FDA does not limit patient populations. So don't imply that it does because that's a misstatement of the law.

MR. GOTTSTEIN: That -- well, let's clarify it a little bit. They -- it's accurate to say that the doctors are allowed under the Food, Drug & Cosmetic Act to prescribe for uses that are not approved under the -- approved by the FDCA. But that is different than saying that the FDA does not approve drugs for specific uses.

MR. LARSON: But to say that that somehow impacts a physician is misleading because the FDA clearly says the only thing that it impacts is marketing.

MR. GOTTSTEIN: Well, we're talking about two different statutes. So one is the FDA and one is the Medicaid reimbursement statute. And so --

MR. LARSON: And the Medicaid reimbursement

statute talks about the compendia only being a part of the decision-making and that peer-reviewed medical literature, which is clearly part of that statute, is another function.

MR. GOTTSTEIN: We've got a legal dispute over that.

MR. LARSON: It's not a legal dispute. It's in the statutes.

MR. GOTTSTEIN: That's not what the Seventh Circuit said.

MR. LARSON: I'm sorry. If that's -- I have -- to a degree, if they omitted a portion -- a relevant portion of the statute, then it's dicta, because all the issue that was in front of them had to do with whether or not summary judgment was appropriately granted on the issue of expert testimony. The statute speaks for itself. It's rather plain and clear. And I'm not aware of anybody saying they can somehow -- that a portion of the statute that's in existence and enforceable somehow becomes irrelevant.

MS. GIETMAN: We have -- we have the Court's decision that says -- refers to a prescription purpose approved by the Food, Drug & Cosmetic Act. All I'm asking is according to that

Court's ruling whether or not she believes this is a purpose approved by the FDCA.

MR. LARSON: Well, I think that's a -- it mischaracterizes the import and effect of that decision, and especially as the District Court has clearly indicated in some of its more recent discovery decisions, there are other issues.

MS. GIETMAN: But I'm not asking about those other issues right now. I'm asking about what her understanding is about approval under the FDCA and that is the language the Court used.

MR. LARSON: Okay. But I -- okay. I think it's taking it out of context and it's misleading, especially in the context of the other information that's clearly available.

So I have a problem with the question, the way you're phrasing it, because it's inconsistent with the documents that have been produced, clearly the statements by the FDA itself. I don't know how we can -- it would be like saying we have to assume the sun rises in the west. I don't know how we can do that.

MR. GOTTSTEIN: Well, I think -- one of the things --

MR. LARSON: If you want to ask her

hypothetically to assume the sun rises in the west, I guess you can do that. I don't know how you're going to get a meaningful answer to it.

MR. GOTTSTEIN: Here's the way I see it; is that Dr. King is really using the word labeled -- you know, "labeled uses" for the same thing that we are using to say uses approved under the FDCA. I mean that's basically what's happening here.

MR. LARSON: But I don't know that that's --

THE WITNESS: I don't agree with that.

MR. LARSON: I don't know that that's completely accurate.

MR. GOTTSTEIN: Well, I think that --

MR. LARSON: All I'm looking at -- I see where the FDA says -- the FDA has also recognized that the FD&C does not, however, limit the manner in which a physician may use an approved drug. So the question really is, is the drug approved or not approved. It's not the use that's approved. I don't -- that's where I think we're having a major problem here.

MR. GOTTSTEIN: That's not accurate.

MR. LARSON: No, it's not what it says.

MR. GOTTSTEIN: It is, too.

MR. LARSON: It does not. I'm reading that. The FDA -- this is a quote. "The FDA has also recognized that the FD&C Act does not, however, limit the manner in which a physician may use an approved drug."

MR. GOTTSTEIN: I understand that.

MS. GIETMAN: And we're saying is this approved under the FDCA.

MR. LARSON: That's what -- the FDA doesn't --

MS. GIETMAN: It says approved under the FDCA.

MR. GOTTSTEIN: There's two types of a --

MR. LARSON: No. Whether a drug is approved to be available in the market.

MR. GOTTSTEIN: Right.

MR. LARSON: You are mischaracterizing, and that's one of the fundamental problems here. You are mischaracterizing. The FD&C Act does not determine usage; it determines whether a drug is available on the market. And once it's available on the market, the FDA says we know the FD&C Act doesn't control use.

MR. GOTTSTEIN: That's correct.

MR. LARSON: So for you to say it does

control use is completely contrary to what the FDA says.

MS. GIETMAN: I haven't said that.

MR. LARSON: Yeah, you have.

MR. GOTTSTEIN: No, no, no.

MR. LARSON: It's the form of the question.

MR. GOTTSTEIN: No, no, no.

MR. LARSON: Well, then you need to clarify --

MR. GOTTSTEIN: Now hang on a second.

MR. LARSON: Then you need to clarify more.

MR. GOTTSTEIN: And I'm trying to kind of walk through it. There are -- approved as used in two contexts here. A drug is approved and it's also -- there are also uses approved. And under the -- there is.

MR. LARSON: There isn't. There is limitations on what a manufacturer can market for uses. That's different.

MR. GOTTSTEIN: And the Medicaid statute says that covered drugs only include uses -- using your nomenclature, is uses that the drug companies can market for, labeled uses, or if they're off-label uses, if they have support in the compendia.

MR. LARSON: And, and there is another

provision, and that is, peer-reviewed medical literature.

MR. GOTTSTEIN: Not in that part.

MR. LARSON: Yeah, it is. It's right there. It's the next section.

MR. GOTTSTEIN: No, no.

MR. LARSON: It's not the next section. It's the next subpart, and that's one of the factors. The compendia are only an optional --

MS. GIETMAN: At this point I'm --

MR. LARSON: -- under the statute.

MS. GIETMAN: I'm not asking her about the compendium. I'm not asking her about what she believes are other options. I'm asking her about the FDCA.

MR. GOTTSTEIN: You're concerned about that --

MR. LARSON: But you are miss -- what my problem with the questions consistently have been -- it's not even how it really should be. But the FD&C Act, they talk about a process of approving for marketing. It doesn't talk about uses by physicians. So your question should then be specific to whether it's approved for marketing. If you want to use that phraseology, I don't have a problem with it. But any

time you use any other phraseology that implies that the FDA somehow controls the manner in which physicians can prescribe, then, then that's -- then that's an improper question, because it's --

MS. GIETMAN: It is not an improper question according to the Court. The Court has said -- the Court has said repeatedly, we have this circuit court and we've got the Appeals Court having said that it is approved -- if it's not approved use under the FDCA.

"Medically accepted indication is a statutorily defined term that refers to a prescription purpose approved by the FD&C Act or supported by any of the several identified compendia." I'm asking her about the beginning of that, "purpose approved by the Food, Drug & Cosmetic Act." We've got that in the Appeals Court and we've got the circuit court ruling.

MR. LARSON: Then we got to clarify. Then you're talking about the labeling. If you want to ask her about whether it's approved under --

MS. GIETMAN: I'm not going to use your language. I'm going to use the Court's language. The Court said a purpose approved by the FDCA. You're using the labeling --

MR. LARSON: Then you're going to get the same objections continuously because it's unclear how you're using it. Because that's not -- that language is too imprecise to use in this context. Plus, the judge in his most recent ruling disagreed with you, so I dispute that as well. He clearly said there's an ambiguity in the use of the word "use."

MS. GIETMAN: I'm going by what the federal statute says, what the Appeals Court said, and what the judge said.

MR. LARSON: No, you're not. You're ignoring the federal statute, because you've ignored the whole section about peer-reviewed medical literature; in fact, to the extent that I think you guys misled the courts. That's another topic, too, because you only cited a portion of the statutes, continuously.

MS. GIETMAN: I haven't asked her -- I haven't asked her about the compendia yet either. I'm trying to do step one; is it in the FDCA. If not, then where's your compendia support. I can't even get there.

MR. LARSON: Okay, because that's not how it works.

MR. GOTTSTEIN: Let me just say one other

thing. This question actually was addressed by the Seventh Circuit.

MR. LARSON: It wasn't.

MR. GOTTSTEIN: Can I read something? It says, quote, "Off label prescription is one written for a purpose that has not been approved by the Food & Drug Administration." Then it says, "Once a drug has been approved for one use, however, the FDA cannot prevent physicians from prescribing a drug for other uses."

Then it goes on to say, "The legality of the prescription, however, does not answer questions such as whether an individual off-label prescription is -- whether the government is obligated to pay for Medicaid patients off-label prescriptions."

MR. LARSON: You're right, but it doesn't read in as much as what you're reading into it. It just says it doesn't answer that question because there's other factors; peer-reviewed literature, all the other stuff that everybody else --

MR. GOTTSTEIN: Then they go on to answer the question later on, they answer the question there. That's the foundation for the question.

MR. LARSON: Okay. But -- okay. But it's

still ambiguous. You got a question you want to ask, I'll object as appropriate.

MS. GIETMAN: What was the last question?

(Question read as follows: "So if you have a child who doesn't have autistic disorder with irritability, you don't look at what the approved uses is?")

MS. GIETMAN: And did she answer it?

COURT REPORTER: No. There was no answer. You just argued.

BY MS. GIETMAN:

Q Okay. When you use the phrase -- when you are looking at what the FDA can market a certain drug for, you're using the term "labeled use;" is that correct?

MR. LARSON: Let me object to the foundation for that very question in the first place, but go ahead. It assumes facts not in evidence. Go ahead.

THE WITNESS: Say that over.

BY MS. GIETMAN:

Q If you're looking at what the FDA is marketing a drug for, are you calling that the labeled use?

MR. LARSON: Just wait. Object to the form. Go ahead.

THE WITNESS: Yeah, the FDA doesn't market.
MR. LARSON: She gave you an answer.
MS. GIETMAN: Thank you.
MR. LARSON: Okay. Well, no. We're sitting here and I thought maybe there was some question. But okay.
BY MS. GIETMAN:
Q You have a current patient whose initials are ZN who's five years old?
A And how do I know this?
Q Do you have a current patient whose initials are ZN?
A I would not -- I have no idea. I don't know the initials of my patients.
Q Do you know the names of your patients?
A Off the top of my head some of them. Not all of them. I have hundreds of patients.
Q Do you know a -- do you have a five-year-old patient whose initials are ZN?
A I have no idea unless I see a chart.
Q How many patients do you have currently?
A I do -- I couldn't tell you. It would be hundreds.
Q And is it common practice for you to prescribe Risperdal to a five-year-old?
A Depends on what's going on with the five-year-old.
Q Is it common practice for you to prescribe Risperdal

to a four-year-old?
A Depends on what's going on with the four-year-old.
Q Is it common practice for you to prescribe Risperdal to a three-year-old?
A Depends what's going on and how severe their symptoms are.
Q Have you ever prescribed Risperdal to a two-year-old?
A Not that I recall.
Q Is there some age that is not appropriate to prescribe Risperdal to a child?
A Depends on -- I don't see kids under three typically. So -- and I have maybe a few patients who are three. But it depends on how distraught, how much distress that this child is going under.
Q So is distress one of the symptoms you prescribe Risperdal for?
A Distress is usually what brings patients into my office. So, no, it's not a symptom. But most people who come into my office come because there's some level of distress or -- I mean, you know, child psychiatrists, you typically see the worst of the worst cases.
Q So is there any age where you would say I absolutely would not prescribe Risperdal to that child based on age?

A I don't see kids under three.
Q If you were to.
A I don't, though. I don't treat kids under three.
Q Is there any age of a child where you would say it is not appropriate for a child that age to be taking Risperdal?
A It depends on the clinical situation with that child.
Q So age is unimportant?
A I didn't say that.
Q That is my inquiry to you.
A I said it's not based just on age.

MR. LARSON: The question is argumentative now.

MS. GIETMAN: I'm just looking for an answer. Is there any age where --

THE WITNESS: It's not based just on age, so I can't answer that.

BY MS. GIETMAN:
Q Is there any age where Seroquel would not be appropriate to prescribe because of the age of the child?
A I don't take age as an isolated --

MR. LARSON: Object.

THE WITNESS: It depends on the clinical situation with the child.

BY MS. GIETMAN:
Q I agree. But is there any age where you would say I absolutely would not -- it is not appropriate for Seroquel to be prescribed?
A It depends on the clinical situation with the patient.
Q So there is no age cutoff?
A My answer is it depends on the clinical situation with the patient. Age is one consideration, but not the only consideration.
Q Under what situation would it be appropriate for a two-year-old to be prescribed --
A I don't treat two-year-olds.
Q That wasn't my question.
A I don't know, because I don't treat two-year-olds. So you're asking me to answer a question outside the scope of my practice.
Q Under what situation would it be appropriate to prescribe Risperdal to a three-year-old?
MR. LARSON: Let me ask -- well, let me object to the form and foundation --
MS. GIETMAN: You can, and then she can answer.
MR. LARSON: No. You can stop cutting my objection off. And I will tell you right now, first

of all, this is not a malpractice case.

MS. GIETMAN: You objected to the form and your objection is noted. And now she can answer.

MR. LARSON: And I'm also making a further objection. This is not a malpractice case. You've stipulated this is not a malpractice case. So the whole question of reasonable care, I'm lost right now as to how this is a relevant inquiry by you, how it could even lead to the admission of relevant evidence since you've stipulated it's not a standard of care case. You haven't named an expert to say that this is somehow below the standard of care what a reasonable child psychiatrist would do. So are we now expanding this case?

MS. GIETMAN: No, we're not.

MR. LARSON: Okay. Then I'm not sure how we can even go to there.

BY MS. GIETMAN:

Q Under what situation would it be appropriate for a three-year-old to be prescribed Risperdal?

A So you want me to give you a hypothetical situation or do you have a patient in mind?

MR. LARSON: Same objections.

BY MS. GIETMAN:

Q What diagnosis would be appropriate to prescribe

Risperdal to a three-year-old?
A So in treating children and adolescents, a lot of standard of care practice is it's not based on diagnosis; it's based on symptoms and level of distress and what's going on with the child.
Q So if this three-year-old child is a Medicaid patient, what would you consider before -- when determining whether or not to prescribe Risperdal to that child?
A I would consider the symptoms that they present with. I would consider their medical history. I would consider whether or not they had tried and failed any other medications. I would consider the severity of their symptoms and weigh the risks versus benefits just like I do with all my patients.
Q When you weigh the risks versus benefits are you consulting with specific data?
A I mean through the knowledge base that I've gained over time, yes.
Q And what data is it that you would be reviewing, what knowledge base would you be reviewing when you determine whether or not to give Risperdal to a three-year-old?
A Standard of care, articles that I've read, things that I've learned in training, what I know to be

standard practice, sometimes maybe consultation with the peer.
Q What peer -- do you consult with a peer?
A I mean I have throughout my career.
Q When's the most recent peer consultation you've had?
A I wouldn't be able to give you a date.
Q Well, what year?
A I don't recall.
Q Was it this year?
A I don't recall.
Q What was the peer -- who was the peer you consulted with?
A In what case?
Q Most recently.
A I don't recall.
Q In the past five years what peers have you consulted with?
A When I say consult, it would be if there's another person in the office working with me or whatever. So currently I'm the only child psychiatrist at Milwaukee Health Services, and I haven't -- so there's no one there that I would consult with.
Q In the past five years what peers have you consulted with?
A I can't recall.

Q So in the past five years what articles have you reviewed?

MR. LARSON: This has been asked and answered. We went through this at the beginning of the deposition, unless I'm missing something here.

THE WITNESS: Yeah, and I don't have a list. I don't catalog a list and commit the date to memory. I don't keep -- I would have stacks of stuff up the walls. I don't do that. I read it, I gather the knowledge, I put it in my working knowledge base and then I use it to help me make decisions.

BY MS. GIETMAN:

Q Did you see last year the -- or last week, I'm sorry, the settlement regarding Risperdal between the pharmaceutical company and the State of New York for false claims?

A No. But that was involving a pharmaceutical company. I'm a clinician. Labeling applies to pharmaceutical companies, not clinicians.

Q Have you looked at recent articles regarding Risperdal?

A What do you mean by recent?

Q Articles within the past two months regarding Risperdal?

A Not that I recall.

Q Have you ever met with a pharmaceutical rep?
A Have I ever met with a pharmaceutical rep when? Ever?
Q Yes.
A Yes.
Q When did you most recently meet with a pharmaceutical rep?
A Probably -- what do you mean "met with"?
MR. LARSON: Just in the broad sense, met.
THE WITNESS: I don't know what you mean "met with." They show up at the office sometimes.
BY MS. GIETMAN:
Q And have you talked with them about psychotropic medications for children?
A I mean the most recent rep, and probably one of the only reps that call on me, is a rep for Vyvanse.
Q Have you met with a rep since 2005 regarding Risperdal?
A I could not tell you. I generally try not to meet with drug reps.
Q So to your knowledge you haven't?
A I don't know when -- I don't know when Risperdal went generic. Once it goes generic, there are no drug reps, so I can't tell you specific dates.
Q Do you remember --

A But I can't say I've never -- I don't recall specifically meeting with them, but I can't say that I have not.
Q So is that literature that you've been provided from a drug rep regarding any drug they provide literature about, does that go into your repertoire of knowledge that you're basing your prescription practices on?
A Generally not.
Q Have you met with drug rep regarding Seroquel?
A Ever?
Q In the past five years.
A I'm a child and adolescent psychiatrist, so most drug reps can't market their drugs to me.
Q Have you met with a rep regarding Seroquel in the past five years?
A There's a drug rep that come in the office. I don't think I specifically sat down and had tons of conversation. There's a drug rep for Seroquel XR who recently in passing said, oh, did you hear that we got labeling for Seroquel XR in adolescents for bipolar disorder? Did I take him in my office and sit down and have a conversation? No.
Q Did you take any literature from him?
A No.
Q When was this?

A I don't know. It was in the last month.
Q And before that month do you remember when the last time you spoke with someone about Seroquel, a rep, about Seroquel?
A No, I do not.
Q How about Zoloft; have you met with a rep about Zoloft?
A Zoloft has been generic for years so there's no drug rep, I don't believe.
Q So in the past five years you haven't?
A I don't think so.
Q So as we sit here right now, you do not recall a patient who's five years old whose initials are ZN who you've seen within the past three weeks?
A Off the top of my head, no. I would have to see the chart.
Q Do you recall a patient NT who's also five years old who you've seen within the past month?
A I don't recall any of my patients by initials.
Q Well, if you think of their names and can reduce their names to initials --
A I don't recall my patients by initials.
MR. LARSON: Do you have some document you want to show her or are you --
MS. GIETMAN: It's a -- let's go off the

record a second. Okay?

(Discussion off the record.)

(Deposition Exhibit No. 2 marked for identification.)

BY MS. GIETMAN:

Q Okay. I'm handing you what we have marked as Exhibit 2, which is taken from the data provided by the state regarding your Medicaid patients. Looking at the first patient there, they have under the name, the initial ZN, date of birth January 8th, 2012 -- I'm sorry, January 12th, 2008, the date that this prescription was filled, which was October 29th, 2013, five-year-old on Risperidone. Do you recall a patient who would fit those details?

A Like I said, I would have to see the chart. I can't recall a patient off the top of my head. I can tell you, though, for -- well, you didn't ask that.

Q So you don't recall ZN independently just by looking at this?

A No.

Q Do you recall NT by the date of birth, the age, the prescription, and the date the prescription was filled, which I assume you would have seen the child right around there?

A No. I can't separate out the patients by initials.

Q In the past month how many five-year-olds have you prescribed Risperidone to?
A I would have no way of knowing that unless I saw the charts. I can't memorize, you know, every prescription I wrote for which kid on which day. I can tell you for Risperidone, for all these patients on this first page, if they have Medicaid, Medicaid has a prior authorization form which has to be completed for kids under the age of seven who are prescribed antipsychotic medication, and that I provided -- I would have had to provide that information to Medicaid in order for them to be reimbursed for this prescription.

MR. GOTTSTEIN: Under seven?

THE WITNESS: Seven and under. And on there you check off which symptom you're prescribing it for, not which diagnosis; irritability, anger, aggression, poor impulse control. That's on Medicaid's prior authorization form.

BY MS. GIETMAN:
Q And if you look through these pages, looking at the initials, you recognize none of these patients?
A That's not how I remember patients. So...

MR. LARSON: And to the extent -- I mean I'm not sure what you're asking her to do with that,

because I think the Court made it clear they didn't want patient names to be disclosed.

MS. GIETMAN: I'm not asking for the names.

MR. LARSON: Just so we're clear.

MS. GIETMAN: I'm trying to see if she can identify in her head who this patient is so I can ask questions.

MR. LARSON: You asked that several times.

MS. GIETMAN: I asked about ZN. I was asking if there were any on here that she could.

MR. LARSON: I apologize.

THE WITNESS: That's not how I remember patients, so I'm not going to be able to recall them up by initials and a date.

BY MS. GIETMAN:

Q How do you recall them?

A By their face a lot of times, and mostly by reviewing my notes, and then I put my notes with their face and the parents' face and the history.

Q Are you the only child psychiatrist at both places you're working?

A No. I'm the only child psychiatrist at Milwaukee Health Services, but not at 16th Street.

Q Do you share your clientele with the other psychiatrists, or are you each assigned certain

patients?
A Yeah, we each have our own patients.
Q You've prescribed Zoloft to minor Medicaid patients. What have you prescribed Zoloft for?
MR. LARSON: Object to the form. Foundation. I've got the same objections about standard of care issues, but to the extent this is discovery, go ahead.
MS. GIETMAN: Could you mark this, please?
THE WITNESS: For anxiety disorders, for depression, for obsessive compulsive disorder, for poor impulse control sometimes. Those would probably be the most common. Post traumatic stress disorder.
MR. GOTTSTEIN: This is marked as Exhibit 2?
MS. GIETMAN: Three, I believe.
MR. GOTTSTEIN: Oh, three.
(Deposition Exhibit No. 3 marked for identification.)
BY MS. GIETMAN:
Q I've handed you a document marked as Exhibit 3. That's a summary of the Zoloft prescriptions produced by the state regarding your Medicaid patients that you've written that script to.
MR. LARSON: Just so I understand. Is this

the -- is this the format that this was produced by the state or has this been -- is this a compilation?

MS. GIETMAN: We've pulled it out by --

MR. GOTTSTEIN: It's an extraction.

MR. LARSON: So this isn't a document from the state? This is -- this is a document that was created by the party?

MS. GIETMAN: Correct, using the data from the state.

MR. LARSON: Okay.

BY MS. GIETMAN:

Q Looking at this, are you able to recognize any of these patients? I know we don't have their faces or their file here, but can you --

A No.

Q Do you know what the labeled use is for Zoloft?

MR. LARSON: Object to the form.

BY MS. GIETMAN:

Q I believe you said off-label use. No?

A I didn't say off-label use.

Q Do you know what the labeled use of Zoloft is?

MR. LARSON: Same thing. Object to form and foundation. Go ahead. Answer if you can.

THE WITNESS: I mean generalized anxiety disorder, social phobia, depression.

BY MS. GIETMAN:
Q And isn't obsessive compulsive disorder the only labeled use for Zoloft under the FDCA for children under 18? Sorry.
A It might be for Zoloft, but for other similar medications with the same action, then they have other labeled uses.
Q Sertraline HCL is Zoloft, isn't it?
A Yes.

MS. GIETMAN: Could I have this marked, please.

(Deposition Exhibit No. 4 marked for identification.)

BY MS. GIETMAN:
Q Dr. King, I'm giving you Exhibit No. 4. That is a summary for recent prescriptions you wrote to minor Medicaid patients for Seroquel. Looking at that, are you able to identify any of those patients?
A No.
Q Do you know what the labeled use for minor patients is for Seroquel?

MR. LARSON: Same form and foundation objection, but go ahead.

THE WITNESS: Seroquel XR has labeled use to be used for bipolar disorder in adolescents.

BY MS. GIETMAN:
Q And do you know if these patients are all suffering from bipolar disorder?
A I would have to see the chart.
(Discussion off the record.)
BY MS. GIETMAN:
Q You've prescribed Geodon to minor Medicaid recipients?
A Is that a question?
Q Yes.
A I don't recall. I'd have to see the chart.
Q Have you ever prescribed Geodon to minors?
A I can't say off the top of my head. I would have to see records.
Q Have you met with any drug reps regarding Geodon?
A Not that I recall.
Q But in the past year you don't recall prescribing Geodon to any minors?
A Off the top of my head, no.
Q Do you have adult patients or are all your patients minors?
A Some of my patients are over the age of 18. The majority are minors.
Q Well, in the past year do you recall prescribing Geodon to anyone?

A Yes.
Q And what's the labeled use for Geodon in minors?
MR. LARSON: Same objection. Form and foundation.
THE WITNESS: I didn't say I recall prescribing it to a minor. I said I recall prescribing it. It was an adult patient. I just saw him last week. That's why I recall.
BY MS. GIETMAN:
Q Do you recall what the labeled use for Geodon is in pediatric patients?
MR. LARSON: Again, same form and foundation, but go ahead.
THE WITNESS: Labeled use? I don't think there is a labeled use, but other people prescribe Geodon. If I have a minor who's on Geodon most likely I did not start them on that medication. They might have come to me already on the medication.
BY MS. GIETMAN:
Q So do you do your own analysis if that's appropriate for the --
A Yes.
Q And when you do that analysis, what do you consider?
A I consider, one, if they're having side effects; two, if it's been effective and helped them with whatever

issues it was prescribed for; three, if it's something that, you know, if they were pleased with it and said it helped and they got stable and they did better, I'm more likely to continue it than discontinue it. If it's not working and they're having side effects, then I would probably be more likely to try something different.

Q Have you done research on Geodon?

A Research meaning what?

Q Have you looked up articles on Geodon, spoken with any peers about Geodon?

A Ever? What are you asking?

Q Yeah.

A I'm sure I have.

Q When did you do that?

A I don't recall the specific time. Like I said, Geodon isn't a medication that I prescribe frequently.

Q So if it's not a patient who comes to you already on Geodon, what use would you have for prescribing it?

A I typically don't.

Q But in cases where you have --

A It's not where it's inappropriate; I just don't. I think lots of physicians just sort of use a repertoire of medications they found work well and

are safe and are tolerated well. So it would not be inappropriate to use Geodon, but it's just not something that I prescribe frequently.

Q So with most of your prescribing decisions you rely on what your experience has shown you their interaction or their effectiveness is?

A Not just my experience. You know, on literature. But a lot of patients come to me with a history. They don't -- you know, this is child psychiatry. So, like I said, we see the worst of the worst. So we're not -- occasionally is it a simple, straightforward case? Yes. But lots of times they've seen five other doctors. They've been in a hospital. They have a history. So they might have been on medication before that worked well for them. They come to me on a list of medications. So it's not always just a naive patient that's showing up.

Q But Geodon, for example, you don't recall in the past five years what research you have done? You think you might have; is that right?

A Geodon specifically?

Q Yes.

A Do I recall a specific article that I've read? No.

Q So when you're prescribing, is there an age that it is too young, you believe it's too young for a child

to take Geodon?
A It depends on the clinical situation and the history of the patient.
Q But is there ever an age where it's too young?
A Depends on the situation and the clinical history of the patient.
Q So all things being equal, if you had a three-year-old come to you with the same symptoms you saw in a 15-year-old patient who was on Geodon, would you consider putting that three-year-old on Geodon?
MR. LARSON: Object to the form and foundation for that question. If you can answer that hypothetically, go ahead.
THE WITNESS: Yeah, that's a hypothetical because the three-year-old would come with a history and a 15-year-old would come with a different history, so they're not the same patient. So I make my decisions based on their individual and their clinical situation and their history.
BY MS. GIETMAN:
Q And all things being equal, that three-year-old, would you prescribe Geodon?
A All things wouldn't be equal. One would be three; one would be 15. They're not equal.
Q So is three too young to prescribe Geodon?

A It depends on the clinical situation and what's going on.
Q Hypothetically, when would you use Geodon on a three-year-old?
A I don't typically prescribe Geodon, so I couldn't answer that.
Q There's no hypothetical you can think of?
A I mean I would have to have a whole history. I would have to have a family history, I'd have to have a developmental history, I would have to have has this kid been on medication before, what were they using it for, was it helpful, was it tolerated, did they not, can they swallow a capsule. Most three-year-olds can't. So there's lots of things that's taken into consideration. It's not just, okay, this is a three-year-old. I would absolutely never ever, ever do that.
Q Is anyone financially assisting you with your defense in this case?
MR. LARSON: Let me object to the extent I don't know how that could possibly lead to the admission of -- or the discovery of admissible evidence, how her defense would be paid for or not paid for, and I'm going to instruct her not to answer. I don't imagine how you can -- you explain

to me how that's a potentially relevant question.

MS. GIETMAN: I believe it's required initial disclosure.

MR. LARSON: As to what? Who's paying for attorneys' fees?

MS. GIETMAN: Whether there's financial assistance --

MR. GOTTSTEIN: Indemnification agreement.

MR. LARSON: Oh. I can tell you there's no indemnification agreement of any kind, shape or form. I mean that we've gone through. We've provided the insurance policy at issue for your analysis. But the financial arrangements between her and counsel, that's none of your business. I don't know how that could possibly be your business. So the way the question is phrased, I'm not going to let her answer, but if you've got a different question, I'll reconsider it. But...

BY MS. GIETMAN:

Q Have you been -- is there any agreement for anyone to pay a judgment that might arise out of this lawsuit?

A No.

Q Has anyone approached you expressing an interest in this case?

A No.

MR. LARSON: Okay. And I don't know where we're going with this. Again, I don't know how this is possibly relevant to anything, but she's already answered the question.

BY MS. GIETMAN:

Q Have you ever been audited by Medicaid or Medical Assistance, any office associated with Medicaid?

A Not that I know of.

MS. GIETMAN: Let's take a short break, if we could, just about ten minutes?

MR. LARSON: Okay.

MS. GIETMAN: Unless you need -- it's probably going to be about two hours yet. And I don't know if you're hungry; now might be a good time for lunch, or if you want to plug through. It's 11:30.

MR. LARSON: It's 11:20. Let's keep going. But I just need to use a restroom.

(Brief recess taken from 11:23 a.m. to 11:42 a.m.)

BY MS. GIETMAN:

Q Dr. King, you provided this "CAPS Records in Compliance with the Court's Qualified HIPAA Protective Order" document. And these are from records that you keep at your house or had kept at

your house?
A Correct.
Q And those records -- do you also have billing records?
A No.
Q So when your office manager for CAPS did your billing, where are those records kept?
A I don't keep billing records. I mean she did it electronically, I believe. But I -- it would have been on the computer, but I don't keep billing records.
Q Do you still have that computer?
A No.
Q So when you look at No. 1, KG, a female, you have the date of birth, 1/25/91, the diagnosis, 3/22/05, that was the day you diagnosed her? Is that what that column means?
A That column is the date of service. I think this is just skewed when they printed it.
Q Oh, I see. Date of service, 3/22/05. Diagnosis is mood disorder, NOS and ADHD?
A Right.
Q Service provided was medication management?
A Well, that's more sort of what -- in billing, it would be a medication management code, most likely.

Q Okay. And then medications, those were the prescriptions you wrote at that office visit?
A I believe so.
Q Abilify, Seroquel --
A That's supposed to say Clonidine. It looks like the C is missing. It's supposed to be Clonidine.
Q And Adderall XR and the payor UBH. What's UBH?
A United Behavioral Health. That's the HMO.
Q So if you -- you didn't keep any of these billing records either?
A No. Those are the ones we were talking about, isn't it?
Q I'm sorry. I meant to ask about NB's, but that's fine. You kept none of the --
A Yeah. I don't have any billing records.
Q -- CAPS billing records?
A No.
Q And how did you know who the payor was when you --
A It's on the demographic sheet. It's whatever the patient's parent tells us when they make the appointment.
Q I see. Okay. So looking at this, do you recall who KG is? I don't want to know the name, but do you recall that patient?
A Oh, no. These patients are from so long ago, I

don't --
Q Are any of these patients patients that you recall?
A No, not just with their initials. I mean this is like eight years ago.
MS. GIETMAN: Could I have that marked, please.
(Deposition Exhibit No. 5 marked for identification.)
MS. GIETMAN: Can we be off a second?
(Discussion off the record.)
BY MS. GIETMAN:
Q Okay. I have handed you what's marked as Exhibit No. 5, which are NB's medical records that were provided by Encompass. But if you look through, these are your records, correct?
MR. LARSON: Well, object.
THE WITNESS: These are my notes.
BY MS. GIETMAN:
Q I'm sorry. Your notes for NB?
A I mean it's what Encompass -- I can't verify whether it's all or not, because I don't have access to the chart, but I wrote the notes in here.
Q Now, you said you reviewed some medical records prior to your deposition here. Did you review any other documents, other than these you've produced to us and

these medical records, did you review any other documents prior to your testimony?

MR. LARSON: Other than attorney-client communication? To the extent she's asking for attorney-client communication, you can't divulge those. But if she's asking for something other than that, go ahead.

THE WITNESS: No.

BY MS. GIETMAN:

Q So do you remember NB?

A I mean I remember -- I don't remember details of him other than what I read in here, but -- I mean I have some recollection of him, yes.

Q And we're just going to walk through some of these because I struggled a little bit to read your handwriting. Okay? There is a note from November -- oh, sorry. Just a moment. So there is a --

MR. LARSON: Just so the record's clear. There are some things in here that are not -- it looks like it's been annotated by somebody other than Dr. King. I don't know if it's your office, but there's some things that are highlighted and arrowed.

MS. GIETMAN: I didn't, but as we get to that document, you can point that out.

BY MS. GIETMAN:
Q So there's one of your notes here from March 23rd, and I apologize, these aren't in order.
MR. LARSON: They're not. Okay.
MS. GIETMAN: March 23rd, 2005. And it would be on a CAPS head.
THE WITNESS: March 23rd?
BY MS. GIETMAN:
Q Yes, 2005. And can you read what it says under Interim History Since Last Appointment.
A "Overall patient has been doing okay. Patient sometimes naps and sometimes doesn't. Mother still awaiting in-home therapy to start. Patient has become more verbal. Mother says patient at times won't be quiet at school. Appetite seems to be okay and may have improved."
Q And under Mental Status examination, Appearance, what does it say?
A "Patient alert, cooperative, played appropriately."
Q Under Speech?
A "Initially very talkative but then quieted down."
Q Under Mood/Affect?
A "Euthymic mood and affect."
Q And under Thought Process?
A "Goal directed."

Q Under Thought Content?
A It says "No AVH," which is no auditory or visual hallucinations.
Q Any Suicidal or Homicidal Ideation?
A And that's a no.
Q The Plan?
A Says continue Clonidine .1 milligram, one every morning, two at bedtime. Risperdal .5, one three times a day. Ritalin, 15 milligrams. I believe that says TID, which is three times a day. And then follow up in two months.
Q Do you recall when you write prescriptions for medications and they're not going to be seen for two months, do you give them refills?
A Typically.
Q Well, in this case would you have given them a refill?
A I mean I don't know, but typically I give them enough until the next appointment. You can't have refills on Ritalin, though. It's a controlled substance, so you have to have a written prescription.
Q There is another note dated 7/21/05. I'm sorry. For what use were you prescribing Risperdal and Clonidine in March of 2005?
A Clonidine is to target ADHD symptoms. Risperdal, the

irritability and aggression.
Q Do you know what NB's diagnoses were?
A It was ADHD. It was PDD-NOS at the time, which is not otherwise specified. And then there's lots of working diagnoses that I use to help in decision-making in terms of medication choices.
Q Were any of the notations on 3/23/05 not yours? Your counsel raised some questions about different notations.
A That one, I lost the page.
MR. LARSON: It was 22 of 31, at least on my copy.
MR. GOTTSTEIN: Yeah, that -- we didn't get those copies.
THE WITNESS: Whoever wrote his name at the bottom of the page.
MR. GOTTSTEIN: If you could make copies of that set there would be page numbers. Her set doesn't have page numbers.
MR. LARSON: I know, but that's the one that's marked. But it's up to you.
THE WITNESS: Whoever wrote his name over here, that's not my writing.
BY MS. GIETMAN:
Q Oh. On the second page?

A Um-hmm.
Q Okay. You said working diagnoses. Where are those listed on here?
A I don't necessarily write them down. They're sort of in my head in caring for the patient.
Q They're -- I'm sorry. They're in your head? Is that what you said?
A Yeah. These are, you know, kids, and I don't necessarily write down all the diagnoses; if paperwork goes somewhere else, if they get stuck with the label, whatever. So a lot of times I have sort of working diagnoses in my head which I use also to base treatment on, and it may not be reflected in the notes.
Q We have another date of service, 7/21/05. Yes, 7/21/05.

MR. LARSON: I'm sorry. What's the date?

MS. GIETMAN: 7/21/05. My copy seems to be missing that.

(Discussion off the record.)

MR. LARSON: On the second page of this one -- there's multiple things that would appear to be -- first of all, the name on the bottom, I don't know who's annotating that. There's stuff I can only presume was highlighted on some document with arrows

that talk about age approval. I'm assuming, and maybe I'm wrong, but I thought -- wasn't that Dr. Watson that did that at some point in time?

MS. GIETMAN: Okay. So the two highlighted and the two arrows, Dr. Watson thinks his staff put that on there.

Q So is there anything else on these documents that aren't your annotations?

MR. LARSON: Just these two pages for the 5/29 --

MS. GIETMAN: Yeah, just looking at 5/29/05.

THE WITNESS: No.

BY MS. GIETMAN:

Q Okay. So what does it say under Interim History Since Last Appointment?

A "Mother says patient was denied for SSI and now patient can't have in-home therapy because of it. Patient has recently been aggressive at school in the morning and also in the afternoon at preschool. Mother didn't start Concerta because in past she thinks patient developed a tic on it."

Q And under Appearance?

A "Patient played appropriately with toys."

Q Speech?

A "Normal rate and tone."
Q Mood/Affect?
A "Euthymic mood, blunted affect."
Q Thought Process?
A "Logical, overfocused on fixing basket."
Q Thought Content?
A "No AVH."
Q Any Suicidal or Homicidal Ideation?
A No.
Q What do the annotations next to the zero with the line through it --
A "No SI/HI." No suicidal or homicidal ideation.
Q And the second page?
A "Mother to try Concerta." Looks like -- I don't know. Dose is missing. Maybe 36 milligrams. "PL Q AM, and if patient tolerates this, discontinue the Ritalin. If not, resume the Ritalin. If change to Concerta doesn't decrease aggression, then discontinue the Risperdal and try Abilify 2.5 milligrams at bedtime. Continue Clonidine .1 milligram TID. Mother to call and notify M.D. of med regime that works. Follow up two months."
Q So on this date of service did you prescribe Clonidine?
A I mean he was already on Clonidine. So I don't -- I

mean this doesn't say if I wrote the prescription that day or not. He might have already had refills. I don't know.

Q And what were you prescribing Clonidine for on this day?

A ADHD.

Q Are you required to keep your client's records for a certain length of time?

A Yes.

Q But you didn't keep any of their billing records?

A I'm not required to keep billing records. I didn't do the billing. The billing was never in the chart.

Q So if we turn to 7/21/05 --

A (Witness complies.)

Q -- the Interim History Since Last Appointment says --

A "Patient recently has been aggressive and real bouncy at daycare. Has been restless at home as well. Patient has been taking Ritalin, Risperdal and Clonidine. The Clonidine is taken in the afternoon and two at night. Patient became more oppositional on the Concerta and he was very irritable. Appetite recently has been fair with the increased appetite after 7:00 p.m. Patient takes the Risperdal, one every morning, two every afternoon, and one at bedtime."

Q And the second page, Mental Health (sic) Exam.
A "Sat and played with puzzles. Ignored writer's questions initially. Irritable when told he" -- not sure what that says. Oh. "Needed to answer or have puzzle taken away. Flat affect."
Q Plan/Prescription?
A "Increase Ritalin, 20 milligrams PO TID. If no improvement in one week, then increase Risperdal 1 milligram PO TID. Continue Clonidine .1 milligram PO Q afternoon and 2 Q HS. Follow up two months."
Q These notations on the bottom, are these yours?
A The 9/11/05, that's my handwriting, yes.
Q And what does that say?
A "Spoke with mother. Daycare feels behavior worsened with increased meds. Will decrease Ritalin back."
Q At this time his diagnoses were still PDD-NOS and ADHD?
A I believe so, yes.
Q Okay. If you can turn to the discharge summary, which should be the first page. 4/29/08.
MR. LARSON: And again, for the record, I'm assuming certain marks on there were made by Dr. Watson, not Dr. King, or Dr. Watson's office, because they appear to have been highlighted and reflect other information.

BY MS. GIETMAN:
Q You did not make those notations with the highlighting and the arrows?
A No, and I did not fill this form out either but I signed it. There's somebody in the office who filled out this form.
Q And before you signed it, did you review the records to determine that it was correct?
A I mean I don't know if I reviewed all of the records. This is when I was leaving the clinic and there were lots of discharges. I would have read this form, but I don't know -- I can't recall that I reviewed the records.
Q Well, it says "Initial session, 9/8/05." Was that the initial session through Encompass, or what is that date referring to?
A I mean I would have to look and see when the initial -- I don't know that now off the top of my head. Yes, I believe that was the first date I saw him at Encompass.
Q At Encompass?
A Yes.
Q So did you have a discharge summary like this when you went from CAPS to Encompass?
A No.

Q Under Discharge Diagnosis Axis 1 on this discharge summary, it says "ADHD combined." What does that mean?
A It's ADHD with problems with -- that's just a diagnosis that goes with that code. So...
Q And Asperger's.
A Which is an autistic spectrum disorder.
Q And that changed -- do you know when your diagnosis changed from PDD-NOS to Asperger's?
A It's all on a continuum, so it's not necessarily a change.
Q Well, do you know when you identified Asperger's?
A No.
Q If you look at the Encompass provider note, I believe it has a number of dates on it; 9/8/05, 9/15/05, 9/20/05. Can you read to me what it says next to 9/8/05? Read that paragraph.
A "Patient previously seen at CAPS and has been diagnosed with PDD-NOS. Patient was treated on Ritalin in past and seemed to have an increase in unprovoked aggression at home and daycare. Patient was briefly treated on Abilify but mother stopped it because she felt it wasn't working after a few days. Patient was more irritable when tried on Concerta. Patient has been taking the 1 milligram of Risperdal

three times a day. Patient is throwing things at his sister. Clonidine is being given, two at bedtime. Mental Status Exam, patient very bouncy but happier and more talkative and interactive.

Assessment, probable underlying ADHD although increased motor activity may be secondary to PDD symptoms. Plan, will try Adderall 2.5 milligrams PO Q a.m. and may increase to BID. Continue Risperdal, 1 milligram TID, Clonidine .2 milligrams at bedtime. Follow up one month."

Q And then there's a notation for 9/15/05.

A "Spoke with mom by phone. Patient has been taking 5 milligrams of Adderall and he does a little better in the morning but doesn't focus well or sit still, especially in the afternoon. Will increase to 7.5 Q a.m. and monitor. Mother to call back next week."

Q And on 9/20/05.

A "Patient is still doing okay in the mornings at school though still has some trouble focusing and completing work." Don't know what that word is. "He is very aggressive in the afternoon." I think that says "but he is very aggressive in the afternoon. Will increase Adderall to 7.5 milligrams every morning and noon."

Q Even you can't read your writing. There is another

one dated 10/4/05. Can you read me that note for that date?

A "Patient is taking the Adderall 7.5 milligrams BID. Weight 47.4 pounds. Patient remains bouncy throughout the day. Patient with some pushing and shoving of other kids at school.

"Mental Status Exam, patient very hyperactive. Jumping on the couch. Pushing the pillows on the floor. Affect, bright. Patient more talkative.

"Assessment, continued hyperactivity and impulsivity. Unclear if it is related to ADHD or is side effect from medicine. Plan, increase Adderall 10 milligrams Q a.m. and noon. Continue Risperdal, 1 milligram PO TID but may need to decrease dose to .5 Q a.m. and noon and 1 milligram at bedtime if it seems akathisia is a problem." Akathisia, which is A-K-A-T-H-E-S-I-A, and then "follow up one month."

Q And what does it say under 10/20/05?

A And I did not write that. That's not my handwriting. That's office staff.

Q Have you read that note?

A When I read through the chart, probably.

Q Okay. You gave mom some direction on that day?

A Yes. That's a reference to the Adderall.
Q So if -- when you change a diagnosis, for example with NB, his diagnosis changed from PDD-NOS to Asperger's, where do you make note in your records of that change?
A Okay. I don't know if I officially changed it or if that's what she put on the discharge summary based on a code somewhere. But it's not really a change in diagnosis, like I said. PDD-NOS is -- and now there's only one diagnosis, autistic spectrum disorder, so they're all just on a continuum.
Q But at the time there were two different disorders?
A They're not two different disorders. They're very similar, but right.
Q Two different labels -- labeled diagnosis? I mean one's PDD-NOS and one's Asperger's, right? What's the criteria that's different?
A The main criteria -- if you do PDD-NOS, those kids, one, you might do it while you're still getting to know the kid, the patient, before you have a full understanding. So some kids may start off with PDD-NOS because it's saying, well, yeah, he has a lot of symptoms that fall in the autistic spectrum; I'm not sure if he meets full criteria or not.
And so over time it may become clear

and then he sort of has enough criteria to have the autism diagnosis, which is how it used to be.

Asperger's is just high-functioning autistic disorder. And the big distinction is, by definition, their speech and language develop normally.

Q But there's different codes that have to be submitted on the billing forms for what their diagnoses are and there are different codes for PDD?

A The billing codes for the office visit, or for which billing are you referring to?

Q Well, billing codes associated with NB's records at the time show a change in code from PDD-NOS to Asperger's.

A Um-hmm.

MR. LARSON: Object to the foundation for the question, or the statement, actually.

MS. GIETMAN: But there's not a notation in his record for that, unless there's somewhere else -- that's why my inquiry.

Q Where do you put what your diagnosis is for this child? Is that something you would normally record in your office visit notes?

MR. LARSON: Let me just object to the foundation for that question and the form of the

question. It's multiple and has all kinds of facets to it, so it's vague and ambiguous. Go ahead.

THE WITNESS: So when I write my notes -- when I write notes, I write notes for me so that when I do see a patient I can recall sort of what my thought processes are and sort of where my train of thoughts are. So I don't write notes specifically for anyone else. It's so I saw this patient, what did I do, what was my train of thought. So I may or may not put the diagnosis on there.

For billing, when I see the patient in my office, on the billing form there's checkoff codes. So if I changed it, I may check it off on the actual billing form, not for prescriptions, because I don't bill for prescriptions, but for the office visit, then I would change it on there.

BY MS. GIETMAN:

Q So you fill out the form and then somebody else submits it for you?

A Not now, no. Only when I had CAPS. Well, no, that's not true. When I do billing I bill -- I put what the office visit entailed, so I pick that code, and I put the diagnosis on the office visit billing sheet.

Q I see. So then, just so I understand the process, you fill out the form, you check the code box, and

then you give that to currently the two different places you work, you give that to whomever at that office handles the billing?

A Currently it's electronic, so it's electronically sent to billing.

Q So how do you electronically choose the codes?

A There's a check-off box. The forms -- it's just electronic medical records.

Q So you do something on a computer and then the office manager pulls that up and submits it?

A Well, the billing department.

Q The billing department.

A Right. It's just an electronic billing instead of a piece of paper.

Q Okay. But it's not somebody else deciding what -- the code is for the diagnosis. That's you?

A That's me.

Q And that was the same with Encompass?

A Well, that was -- right, paper, but I put the code on the billing, yes.

Q Okay. Oh. The notes that you have for your current patients, are those electronic as well or are those paper like these are?

A Well, both. At Milwaukee Health Services I believe we went electronic maybe in July. So prior to that

there were paper charts.
Q And then at the other place?
A And then at 16th Street it's been longer than that, but I don't know the exact date. Now when I enter at either place it's electronic.
Q Okay. There is an Encompass Effective Mental Health Services sheet with two dates on it, 11/3/05 and 12/13/05. Can you read me --
A This is a bad copy, so I'll read what I can. It's a dark copy so -- 11/3/05. "Mom says on the 10 milligram of Adderall patient seemed more aggressive. Mom is trying vitamins and other OTC preparations. Patient is taking .5 TID. Patient recently has had more episodes of encopresis. Patient has been off Adderall since last week.

"Mental Status Exam, patient hyperactive, trouble sitting still but not as bouncy as before. Euthymic mood and affect. Repeatedly touching things throughout the office. Assessment, poor response to stimulant medication. Possible akathisia from Risperdal. Plan, continue Risperdal .5 TID, Clonidine .2 Q HS. Follow up six weeks."
Q And under 12/13/05?
A "Weight, 47.8 pounds. Mother had been weaning patient off his Risperdal but patient had increased

aggression and problems at school. Patient is also taking some supplements. Mother took patient to see Dr. Semen (ph) who started Nystatin and put patient on a special diet. Patient has been less bouncy. Patient is now taking Risperdal .25 BID. Patient continues on Clonidine .2 milligrams. Patient continues to have trouble concentrating at school.

"Patient is receiving in-home weekly" -- I don't know what that says -- "from Dr. Todd. Mental Status Exam, patient wandered around the office a lot. Less fidgety. Euthymic mood and affect. Current ongoing ADHD-like symptoms.

"Plan, Strattera 18 milligrams, S-T-R-A-T-T-E-R-A, 18 milligrams PO Q day times one week and increase to 25 milligrams PO Q day. Continue Risperdal .25 milligrams BID, Clonidine .2 milligrams PO Q HS. Follow up six weeks."

Q And then there's a note from 2/7/06. Also a very bad copy.

MR. LARSON: And other dates and entries on the same sheet.

MS. GIETMAN: Yes.

THE WITNESS: I'm sorry. What's the date?

MS. GIETMAN: 2/7/06.

MR. LARSON: It's very dark.

THE WITNESS: I went the wrong way. Okay.
BY MS. GIETMAN:
Q And what does it say under 2/7/06?
A I'll read what I can. "Patient has been on Strattera for about two months. Patient has a meeting tomorrow at school. Patient overall has been less hyperactive. Patient has been sleeping pretty well the last couple of weeks. Patient is also taking Nystatin and the malt barley" -- I don't know what that says.

"Mental Status Exam, patient alert, less hyperactive overall. Euthymic mood, blunted affect. Appropriately behaved.

"Assessment, some off-and-on disruptive behavior but overall doing okay. Plan, continue Straterra 25 milligrams every morning, Risperdal .25 BID and Clonidine .2 PO Q HS. Follow up six to eight weeks."
Q And then on 2/1/06, is that your handwriting?
A No. That 2/21/06? That's not my handwriting.
Q Okay. And then 2/22/06, that's not your handwriting either, right?
A Correct.
Q 4/6/06, is that your handwriting?
A Yes.

MR. LARSON: You skipped over 2/23/06. That's not her handwriting either.

BY MS. GIETMAN:

Q Oh, I'm sorry. Those are your office -- someone at your office?

A That's someone at Encompass' office.

Q Encompass' office. Okay. But 4/6/06 is yours?

A Right.

Q And what does it say there?

A "Mom said behavior has been fair. Patient is taking some enzymes from a holistic doctor. Mother says this was prescribed after urinalysis showed that patient isn't processing sugar appropriately. Weight 48.6 pounds. Patient had an IEP meeting at school and he will be receiving extra help if needed. No recent aggressive outbursts at school.

"Mom says patient is whiny at times at home. Mental Status, patient alert, a little hyperactive but easily redirected. Euthymic mood and affect. Assessment, overall doing okay with some intermittent behavior problems. Plan, continue Risperdal .25 PO Q a.m. and HS. Clonidine .2 milligrams Q HS."

Q And then there's a note dated 6/6/06.

MR. LARSON: You want her to read

something?

MS. GIETMAN: Just one second.

MR. LARSON: Okay.

BY MS. GIETMAN:

Q Yeah. What does it say under Interim Data?

A "Patient with increased aggression over the last few weeks, but mother admits that she stopped the Strattera about six weeks ago because she didn't think it was helping."

Q And then "compliant with medication;" you checked yes?

A Correct.

Q "Any complaints of side effects?" You checked no?

A Correct.

Q "Any recent suicidal, homicidal ideation," you checked no?

A Correct.

Q And what does it say next to "significant mental status exam findings"?

A "Patient extremely hyperactive, standing on the couch, trying to hide in the cabinet."

Q And the Assessment?

A "Patient seemed more hyperactive, aggressive and impulsive without Strattera. Mother continues to change medications on her own."

Q And the Plan?
A "Will recommend restarting Strattera but mother reluctant to do this. Will try Prozac 10 milligrams PO Q a.m. to target aggression and impulsivity. Continue Risperdal .25 milligrams Q a.m. and HS, Clonidine .2 milligrams PO" -- I don't know what that says.
Q And follow up one month?
A Correct.
Q There's one dated 7/10/06. Can you read what it says by Interim Data?
A Got to find it first.
Q Oh, sorry. I'm sorry. If we go back to 6/6/06. You diagnosed -- or I mean you prescribed Prozac. Why did you prescribe Prozac? What use was that for?
A It says right here, to target aggression and impulsivity.
Q And how about the Risperdal?
A He's been on the Risperdal. Why did I prescribe it on that day? Because that was the medication he was on and was continuing per the irritability and the aggression with the autistic spectrum disorder diagnosis.
Q Okay. So on 7/10/06, can you read what it says under Interim Data?

A "Mom says patient is having an EEG this Friday. Patient on Prozac. Isn't really any better or worse. Patient hasn't been extremely hyperactive. Patient has had periods of irritability and aggression. Patient at home will wander off. Mom says his morning seems better and then in the afternoon he gets worse."

Q And significant mental status exam findings?

A "Patient oppositional/defiant and at one point tipped over a chair, tried to leave the office."

Q And under the Assessment?

A "More irritable/labile and uncooperative since coming off Strattera."

Q And the Plan?

A "Increase Risperdal .25 milligrams PO Q a.m., .5 milligrams PO Q day at 1:00 p.m. Continue Prozac 10 milligrams PO Q a.m. Clonidine .2 milligrams Q HS."

Q There's an updated 11/5 -- I'm sorry -- 11/15/06. Could you read what it says under Interim Data.

A I can try. Again, it's another bad copy. "Patient has been taking" -- I don't know what that says -- "a quarter tab," I think, "of Clonidine in the morning at 5:00 p.m. because one-half made him tired. Patient over last week has been more

disruptive/aggressive at school. Patient does better with one-on-one attention at school."

Q And under significant mental status exam findings?

A "Patient alert, hyperactive, aggressive towards his mother with the toy," I think that says.

Q Assessment?

A Says "ongoing impulsivity/aggression."

Q And Plan?

A "Add Zoloft 12.5 PO Q day times one week. Then increase to 25 PO Q day. Continue Risperdal .25 PO Q a.m. and 4:00 p.m. and .5 Q day at noon. Strattera 25 PO Q day. Clonidine .05 PO Q a.m. and noon, and .2 milligrams at bedtime."

Q And what was Zoloft prescribed for?

A I don't have that in my notes, so I would be speculating.

Q I'm sorry?

A I don't have it listed in here specifically, and this was from '06. So I can speculate and tell you what I think it was probably prescribed for.

MS. GIETMAN: We may be just about ready to wrap it up. Could we just have a few minutes?

MR. LARSON: Sure.

(Brief recess taken from 12:35 p.m. to 12:40 p.m.)

BY MS. GIETMAN:
Q There's just one more I need you to read. It's 2/5/07. Here it is. So under 2/5/07, the star above the date, is that your --
A No.
Q And the star down on the bottom next to the word "Zoloft"; is that yours?
A No. And then there is another star next to Clonidine. That's not mine either.
Q Oh, okay. Thank you. Can you read what it says under Interim Data.
A "Patient overall has been doing okay behaviorally but he wakes up around 6:00 and is very unruly. Patient has been doing fairly well at school. Patient doesn't listen well at home with mom. No noted side effects from meds. Patient has been eating okay."
Q And under significant mental status exam findings?
A "Patient sleeping on the couch. Didn't want to get up and have his weight checked. Not hyperactive."
Q Assessment?
A "Doing better overall."
Q And the Plan?
A "Continue Strattera 25 milligrams PO Q a.m. Clonidine .05 milligrams PO Q a.m. and noon and 5:00 p.m. Clonidine .2 milligrams PO Q HS.

Risperdal .25 milligrams PO Q a.m. and two at noon, and one Q day at 4:00 p.m.," I believe, and "Zoloft 25 milligrams PO Q a.m."

Q And then follow up in two months?

A Correct.

Q Looking at these records that Encompass has produced to us, can you tell from these records when your diagnosis of NB changed, the official label changed from Asperger's to ADHD -- or I mean Asperger's to --

A From PDD to Asperger's?

Q NOS to Asperger's.

A No, but like I said, it's all a continuum. So coding-wise there's a different code. But symptom-wise and diagnostically there's not that big of a difference, which is why now DSM V has lumped it all together as autistic spectrum disorder.

Q Right. But back in '05, '06, '07 when you were seeing NB, there were differences and different codes, and at one point the code changed. But by looking at these records, can you see when you did that --

A No.

Q -- when you changed from PDD-NOS to Asperger's?

A No. Because in my mind -- I mean I might have been thinking Asperger's all along but I was making sure I

knew him better and that it was long term and getting a better idea. So from these records, no, I cannot.

Q So these other records that you produced from CAPS' records, you did provide a diagnosis for the children on these. How did you maintain these records differently than you maintained NB's records that you could identify what the diagnosis was?

A I can identify what the diagnosis was for NB as well. There was no difference.

Q What on these documents tells you NB -- NB's diagnosis was PDD-NOS?

A I'm pretty sure it's in some of the pages. It wasn't the ones you asked me to read to you today but --

Q Well, why don't you look through and tell me where you see PDD-NOS.

A The first appointment at Encompass says that. And I actually did read that to you, I believe. It was September 9, 8:05. "Patient previously seen at CAPS and has been diagnosed with PDD-NOS."

Q Okay. And then where does it show a diagnosis of Asperger's in these records?

A On the discharge summary.

Q So between the discharge summary and -- which isn't your note. It was a note from someone else, correct?

A It's not a note.

MR. LARSON: Object to the form of the question. Go ahead.

THE WITNESS: It's not a note.

BY MS. GIETMAN:

Q The discharge summary, the information was put in by someone else, correct?

A Correct.

Q So where in your notes does it show the Asperger's diagnosis?

A So the same person that did this sheet is the same person that at this office handled billing, so she may have gotten it off the billing code.

Q But I'm asking off your notes, where does it show the Asperger's diagnosis?

A I don't know that it does say that in there.

Q So is there -- was there a different way of handling the files for these children -- you said you don't have any billing records for these children, correct?

A I do not. The diagnoses that are listed here would have came out of at least a note. So just like in here, it's not that it never says. It says in several of the notes that I read to you that he also has ADHD. And, like I said before, my notes are for me, so to help me from appointment to appointment to keep track of what I do for these children. I don't

write my notes for the insurance company or anybody else. If they want copies, they can have copies of the consents. But the notes are for me. So I don't each time necessarily on my note write down the diagnosis. When I bill for the services, then I would put the code on the billing sheet.

Q Did you have any records that you were storing at your house that were for a child on Medical Assistance where you didn't have the diagnosis in that file at your house?

A Not that I recall, no.

MS. GIETMAN: I don't think we have anything further.

MR. LARSON: Okay. Thank you.

MS. GIETMAN: Let's make sure we have all the exhibits, though.

(Deposition concluded at 12:49 p.m.)

(Original exhibits attached to Original transcript. Copies of exhibits are attached.)

STATE OF WISCONSIN)
) SS:
MILWAUKEE COUNTY)

I, Rosanne E. Pezze, RPR/CSR/CRR and Notary Public in and for the State of Wisconsin, do hereby certify that the deposition of JENNIFER KING, M.D. was recorded by me and reduced to writing under my personal direction.

I further certify that said deposition was taken at 735 North Water Street, Milwaukee, Wisconsin, on the 11th day of November, 2013, commencing at 9:15 a.m.

I further certify that I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel, or financially interested directly or indirectly in this action.

In witness whereof, I have hereunto set my hand and affixed my seal of office on this 12th day of November, 2013.

_____
ROSANNE E. PEZZE, RPR/CSR/CRR
Notary Public
My commission expires January 26, 2014

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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, *et al.*,

Defendant.

NOTICE OF SUBPOENA TO TESTIFY AT A DEPOSITION AND PRODUCE RECORDS

PLEASE TAKE NOTICE that Dr. Jennifer King is hereby commanded to appear and testify in the above titled matter on **November 11, 2012**, commencing at **9:00 AM, at Gutglass, Erickson, Bonville & Larson, S.C., 735 North Water Street, Suite 1400 in Milwaukee, WI**, before an official court reporter. Her testimony shall be recorded by stenographic means.

THE DEPONENT IS FURTHER COMMANDED to bring the following:

1. All notes, reports, and/or records related to N.B.'s care from March 2, 2005 through the present, including but not limited to medical records, billing records, and pre-authorizations.

2. All documents, references, or other information, or any combination, she relied upon since March 2, 2005 through present before writing a prescription for a Medicaid recipient to determine whether such prescription was covered for purposes of reimbursement, i.e., properly paid by Medicaid.

3. All documents, references, or other information, or any combination, she relied upon in prescribing medications to N.B..

4. Any and all written communications with any person, entity, or governmental agency, other than counsel, regarding this litigation.

5. Any and all documents, references, or other information, or written communications with any person, entity, or governmental agency, other than counsel, from the time she was licensed to practice medicine in Wisconsin to date, regarding Medicaid drug coverage.

6. All notes, reports, and/or records related to your current minor Medicaid patients, including but not limited to medical records, billing records, and pre-authorizations, produced in compliance with the Court's Qualified Protective Order.

7. All documents, references, or other information, if any, she relied upon in determining whether uses for drugs are approved under the Food, Drug and Cosmetic Act (FDCA), from March 2, 2005 to date.

8. All documents, references, or other information, if any, she relied upon in deciding to write prescriptions for uses not approved under the FDCA, from March 2, 2005 to date.

This examination by oral deposition will be subject to continuance or adjournment from time to time and place to place until completed. You are invited to attend and cross examine.

Date: Nov. 6, 2013

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ASHP Statement on the Use of Medications for Unlabeled Uses

The freedom and responsibility to make drug therapy decisions that are consistent with patient-care needs is a fundamental precept supported by ASHP. This activity is a professional duty of pharmacists not limited by language in Food and Drug Administration (FDA)-approved product labeling.

The prescribing, dispensing, and administration of FDA-approved drugs for uses, treatment regimens, or patient populations that are not reflected in FDA-approved product labeling often represent a therapeutic approach that has been extensively studied and reported in medical literature. Such uses are *not* indicative of inappropriate usage. Health-care professionals should appreciate the critical need for freedom in making drug therapy decisions and understand the implications of unlabeled uses. ASHP supports third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses.

Definition of Unlabeled Use

The FDA approves drug products for marketing in the United States. Such a product approved for marketing is often termed an "FDA-approved drug." FDA also approves each drug product's labeling (container label, package insert, and certain advertising); the term "FDA-approved labeling" applies here. Drug uses that are not included in the indications or dosage regimens listed in the FDA-approved labeling are defined as "unlabeled uses." For purposes of this document, unlabeled use includes the use of a drug product in (1) doses, (2) patient populations, (3) indications, or (4) routes of administration that are not reflected in FDA-approved product labeling.

It is important to recognize that FDA cannot approve or disapprove physician prescribing practices of legally marketed drugs. FDA does regulate what manufacturers may recommend about uses in their products' labeling and what manufacturers can include in advertising and promotion.

The sometimes-used term "unapproved use" is a misnomer, implying that FDA regulates prescribing and dispensing activities. This term should be avoided.[1] Other terminology that is sometimes used to describe unlabeled use includes "off-label use," "out-of-label use," and "usage outside of labeling."

According to FDA, unlabeled use encompasses a range of situations that extend from inadequate to carefully conceived investigations, from hazardous to salutary uses, and from infrequent to widespread medical practice. Accepted medical practice often involves drug use that is not reflected in FDA-approved drug-product labeling.[2]

Health-Care Issues Related to Unlabeled Use

Access to Drug Therapies. The prescribing and dispensing of drugs for unlabeled uses are increasing.[3,4] In many clinical situations, unlabeled use represents the most appropriate therapy for patients. Failure to recognize this or, more importantly, regarding such use as "unapproved" or "experimental" may restrict access to necessary drug therapies.

Lack of Practice Standards. Well-defined medical practice standards that differentiate between experimental therapies and established practice will probably always be somewhat lacking, owing to the advancement of medical science and the dynamic nature of medical practice. Standards of practice for certain drug therapies, particularly biotechnologically produced drugs, cancer chemotherapy, and AIDS treatments, are continually evolving. The dynamic nature of these drug therapies makes it difficult for professional societies to review scientific data expediently and to develop standards that remain absolutely current.

Failure of Package Insert and FDA-Approved Labeling to Reflect Current Practice. For FDA-approved product labeling to be modified, scientific data must be submitted by a product's manufacturer to FDA to support any additional indication(s) and dosage regimen(s). Once they are submitted, FDA must review the data and make a decision to permit alteration of the package insert.

Knowing that unlabeled uses are permitted, and knowing that the accumulation and submission of scientific data to FDA to modify labeling is a time-consuming and often expensive process, some pharmaceutical manufacturers elect not to pursue labeling changes. Therefore, a product's labeling sometimes fails to represent the most current therapeutic information for a drug, and situations naturally occur when it is appropriate to prescribe drugs for unlabeled uses.

Pharmacist's Role

ASHP believes that pharmacists in organized health-care settings bear a significant responsibility for ensuring optimal outcomes from all drug therapy. With respect to unlabeled uses, the role of the pharmacist should be to

1. Fulfill the roles of patient advocate and drug information specialist.
2. Develop policies and procedures for evaluating drug orders (prescriptions) and dispensing drugs for unlabeled uses in their own work settings. Such policies and procedures might address the documentation of scientific support, adherence to accepted medical practice standards, or a description of medical necessity.
3. Develop proactive approaches to promote informed decisionmaking by third-party payers for health-care services.

Role of Drug Information Compendia

The Medicare Catastrophic Coverage Act of 1988 (now repealed) included the statements that "in carrying out the legislation, the Secretary [of Health and Human Services] shall establish standards for drug coverage. In establishing such standards, which are based on accepted medical practice, the Secretary shall incorporate standards from such current authoritative compendia as the Secretary may select."[5] Specific compendia recommended were the *AHFS Drug Information,*

AMA Drug Evaluations, and *USP Dispensing Information, Volume I*. Despite the repeal of the Act, some third-party payers have adopted guidelines that endorse these three compendia as authoritative information sources with respect to unlabeled uses for drug products.

Positions on Unlabeled Use

FDA Position. A statement entitled "Use of Approved Drugs for Unlabeled Indications" was published in the *FDA Drug Bulletin* in April 1982 to address the issues of appropriateness and legality of prescribing approved drugs for uses not included in FDA's approved labeling. This statement included the following:

> *The Food, Drug and Cosmetic Act does not limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.*[1]

Other Organizations. Other organizations that have published positions on the issue of unlabeled uses of drug products are the Health Care Financing Administration (HCFA),[6] the Blue Cross and Blue Shield Association of America (BC/BS),[7] and the Health Insurance Association of America (HIAA).[8]

The American Medical Association, American Society of Clinical Oncology, Association of American Cancer Institutes, Association of Community Cancer Centers, Candlelighters Childhood Cancer Foundation, Memorial Sloan Kettering Cancer Center, National Cancer Institute, and the National Institute of Allergy and Infectious Diseases jointly developed a consensus statement and recommendations regarding use and reimbursement of unlabeled uses of drug products.[9]

These statements are consistent with the ASHP position.

Reimbursement Issues

As a cost-containment measure, most third-party payers exclude coverage for experimental therapies. Drug therapy coverage decisions are complicated, because often it is difficult to differentiate among an accepted standard of practice, an evolving standard of practice, and investigational therapies. Data demonstrating medical necessity and improved patient outcome are often difficult to retrieve. Consequently, insurance carriers and managed care providers have sometimes elected to cover only those indications included in FDA-approved drug-product labeling and have frequently denied coverage for unlabeled uses of drug products.

ASHP believes that such coverage denials restrict patients from receiving medically necessary therapies that represent the best available treatment options. A growing number of insurance carriers are following the BC/BS and HIAA guidelines that encourage the use of the three authoritative drug compendia, peer-reviewed literature, and consultation with experts in research and clinical practice to make specific coverage decisions. ASHP supports informed decisionmaking that promotes third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses.

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HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration, HFI-22
Rockville, Maryland 20857

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Volume 12 Number 1

FDA Drug Bulletin

New Angina Drugs

Two calcium channel blockers, nifedipine and verapamil, have been approved for treatment of vasospastic and classical effort-associated angina. These drugs are also referred to as "calcium entry blockers" or "calcium antagonists."

Drugs of this pharmacologic class have some common properties but also have important differences in clinical use.

Both agents inhibit transmembrane reflux of extracellular calcium into cardiac and vascular smooth muscle, and produce, in isolated tissues, negative inotropic effects, depressed sino-atrial (S-A) and atrio-ventricular (AV) node function, and vasodilation. At clinical doses in humans, however, the vascular effects are usually predominant, causing reduced peripheral vascular resistance and lower blood pressure and preventing or reversing coronary spasm. The effects on cardiac tissues are usually less prominent, probably because of afterload reduction and reflex sympathetic responses to vasodilation. In patients with normal cardiac function not on other negatively inotropic drugs, the negative inotropic effects of the drugs are not usually manifested.

In some cases, however, heart failure can be induced or worsened, and particular care must be paid to concomitant use of calcium channel blockers with beta blockers and to use in patients with aortic stenosis, where vasodilation would not be expected to produce significant afterload reduction.

Effects on AV and SA node function are also not prominent *in vivo* with nifedipine, although they can occur with verapamil.

Effectiveness

Verapamil, but not nifedipine, is an effective agent intravenously in interrupting supraventricular tachycardia and slowing the heart rate in atrial fibrillation.

Both drugs are effective in angina due to vasospasm and in chronic stable angina. Current labeling for nifedipine recommends it for use in stable angina only in patients "who remain symptomatic despite adequate doses of beta blockers and/or organic nitrates or who cannot tolerate those agents." This reservation is based on the limited long-term evidence of safety and effective-

FDA Drug Bulletin

Information of Importance To Physicians and Other Health Professionals

ness in people with stable angina.

Although the effectiveness of these agents in angina is documented, many aspects of their effectiveness remain to be defined. Uncontrolled reports[1] and studies in which these agents have been added to, or substituted for, organic nitrates that had proved insufficiently effective[2,3] in vasospastic angina seem to indicate a special ability of the calcium antagonists to prevent vasospastic angina. In two well-controlled studies comparing nifedipine with isosorbide dinitrate, however,[4,5] there was little difference between the two treatments. There are no similar direct comparisons of verapamil and organic nitrates.

Safety

The side-effect profile of these agents overlaps but is by no means identical. In general, nifedipine appears to have a somewhat greater tendency to decrease peripheral resistance and lower blood pressure than verapamil, and does not tend to inhibit SA or AV nodal conduction. There is often a small increase in heart rate, and typical symptoms and signs of vasodilation (dizziness, flushing, numbness and tingling of extremities, peripheral edema, or palpitations) are common but usually tolerable.

More serious reactions can also occur. Excessive hypotension occurs occasionally with the use of nifedipine, usually during the initial titration or at the time of upward dosage adjustment. It may be more likely in patients taking beta blockers concomitantly.

A few patients have developed increased frequency, duration, or severity of angina upon starting nifedipine or at the time of dosage increases.[6]

Nifedipine dosage should be titrated over a 7 to 14 day period, if possible, to enable the physician to assess response at each dose level and monitor blood pressure before proceeding to higher doses.

There are isolated reports of patients recently withdrawn from beta blockers who have developed marked worsening of angina and even infarction.[7]

If possible, it is advisable to taper beta blockers before stopping them and beginning nifedipine. It does not appear that nifedipine can treat the increased angina sometimes associated with beta blocker withdrawal.

Concomitant use of nifedipine and beta blockers is usually well tolerated. However, there is little controlled experience with the combination, which is known to increase the likelihood of congestive heart failure and severe hypotension.

In rare instances, patients have developed heart failure after beginning nifedipine, usually when the drug was added to a beta blocker.[8] Patients with tight aortic stenosis may also be at greater risk of developing heart failure with nifedipine.[9]

Nifedipine may be given concomitantly with nitrates, but there have been no controlled studies to assess the antianginal effectiveness of this combination.

Nifedipine has been reported to increase serum digoxin concentrations by about 50 percent and must be used with great caution with concomitant digoxin.[10]

Blood pressure falls with oral verapamil, but marked decreases appear unusual. There is usually a slight decrease in heart rate. Symptoms of vasodilation are not common. On the other hand, verapamil can inhibit SA node function and AV conduction, and cause sinus bradycardia, nodal escape rhythm, and/or AV block. It is, therefore, contraindicated in patients with pre-existing AV conduction abnormalities or sick sinus syndrome.

Verapamil has generally been avoided in patients with pre-existing

heart failure and is contraindicated in patients with severe left ventricular dysfunction because it can worsen heart failure.

There are few studies of verapamil given in combination with beta blockers, but it is clear that the combination can impair cardiac function in some patients,[11] even when cardiac function was initially good.[12]

Verapamil can cause constipation, which is usually mild.

In studies carried out in the United States, there were two reported instances of rechallenge-confirmed liver injury among the first 1,000 patients treated.[13] The patients had a picture of predominantly hepatocellular injury (transaminases in the 1,000 unit range), although there were no liver biopsies to confirm this; there was prompt resolution on discontinuation of the drug. In nearly 4,000 patients treated since that time, only isolated instances of enzyme abnormalities have been reported. The world literature does not include any reports of liver injury similar to the one previously cited.[13]

Patients on verapamil should have periodic liver function tests. The drug should be stopped if abnormalities are seen. Physicians can help define the frequency and severity of this adverse reaction by reporting observed cases promptly to FDA.

In patients with impaired liver or kidney function, verapamil should be administered only with great caution. (Verapamil is highly metabolized by the liver and 70 percent of an administered dose is excreted as metabolites in the urine.)

Verapamil increases serum digoxin levels in patients on chronic digoxin therapy and must be used with caution in such patients. Maintenance digoxin doses should be reduced and the patient should be carefully monitored to avoid over- or under-digitalization when verapamil is administered.

Disopyramide should not be given within 48 hours before or 24 hours after verapamil due to the combined negative inotropic effects of the two drugs.

Until further data are available, verapamil and quinidine should be used together cautiously, especially in patients with hypertrophic cardiomyopathy, because there have been a few reports of pulmonary edema in patients given the combination.[14]

As with nifedipine, verapamil may be given concomitantly with nitrates, although the effectiveness of the combination has not been evaluated.

More complete information for prescribing these drugs is available in the package inserts.

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Sucralfate Approved for Duodenal Ulcer

Sucralfate (Carafate), a basic aluminum salt of polysulfated sucrose, has been approved for short-term (up to 8 weeks) treatment of duodenal ulcer. The drug is chemically unlike any other drug used for treatment of duodenal ulcer.

Sucralfate exerts its effect through local rather than systemic action, and there is little systemic absorption. Although the mechanism of sucralfate's anti-ulcer activity has not been fully defined, studies suggest that, with extracellular protein, it forms an ulcer-adherent complex that covers the ulcer site and protects it against further attack by acid, pepsin, and bile salts. The medication has negligible acid-neutralizing capacity and its anti-ulcer effects cannot be attributed to neutralization of gastric acid.

In two U.S. multicenter, placebo-controlled studies with endoscopic evaluation at 2 and 4 weeks, sucralfate was more effective than placebo in promoting complete healing, and statistically significantly better at 4 weeks. In the first study, the ulcer healing rate at 4 weeks was 75.2 percent for sucralfate and 63.6 percent for placebo. In the second study the 4-week ulcer healing rate was 92 percent for sucralfate and 58 percent for placebo.

The better result in the second study may be attributable to the dosage schedule used. In the first trial, sucralfate was given 2 hours after meals and at bedtime rather than as now recommended, 1 hour before meals and at bedtime. The latter regimen was used in several foreign studies and in the second U.S. study.

There are no known contraindications to the use of sucralfate. Adverse reactions in clinical trials involving more than 2,400 patients were minor and only rarely led to the discontinuation of the drug. The most frequent complaint was constipation, which was reported by 2.2 percent of patients. Other adverse effects reported in no

more than 1 of every 350 patients were diarrhea, nausea, gastric discomfort, indigestion, dry mouth, rash, pruritus, back pain, dizziness, sleepiness, and vertigo.

No long-term studies have been carried out and there is no recognized reason for long-term use of sucralfate. Specifically, it is not known whether sucralfate can prevent ulcer recurrence. Long-term studies will be needed to assess the possibility of adverse effects associated with long-term use, e.g., effects on absorption of fat-soluble vitamins.

The recommended adult dosage is 1 g four times a day on an empty stomach. Antacids may be prescribed as needed for relief of pain but should not be taken within 30 minutes before or after administration of sucralfate.

While healing with sucralfate may occur during the first week or two, treatment should be continued for 4 to 8 weeks unless healing has been confirmed by X-ray or endoscopy.

Ritodrine Update

Since the approval of ritodrine (Yutopar) for use in premature labor (see November 1980 and July 1981 *Drug Bulletins*), FDA has been monitoring several areas of concern about the drug's known cardiovascular effects. In light of a number of adverse reaction reports, the labeling of ritodrine has been updated to warn about:

- the need to monitor the patient's state of hydration;
- the possibility of pulmonary edema with or without the concomitant use of corticosteroids, many cases of which seem to be related to overhydration;
- the possible unmasking of occult cardiac disease, the first sign of which may be chest pain.

Ritodrine, a beta$_2$-sympathomimetic drug, may be useful in preterm labor in pregnancies of at least 20 weeks gestation when contraindications have been ruled out.

However, in pregnancies of more than 32 weeks, physicians should carefully weigh the risks and benefits before administering the drug.

When gestational age is in doubt, intrauterine growth retardation should be considered in the differential diagnosis of preterm labor. Among low birth weight infants, about 9 percent may be growth retarded for gestational age. Prolongation of labor beyond term will not correct the growth retardation of these babies.

Initial administration of ritodrine is intravenous. To minimize the risk of hypotension, the patient should be maintained in the left lateral position during infusion and careful attention should be given to her state of hydration. The amount of i.v. fluids administered should be monitored to avoid either circulatory fluid overload (overhydration) or inadequate hydration. An excess sodium load should be avoided in hydrating the patient.[1]

The boxed warning for ritodrine has been amended to read:

> Maternal pulmonary edema has been reported in patients treated with Yutopar, sometimes after delivery. While occurring infrequently, it has occurred more often when patients were treated concomitantly with corticosteroids. Maternal death from this condition has been reported with or without corticosteroids given concomitantly with drugs of this class.
>
> Patients so treated must be closely monitored in the hospital. The patient's state of hydration should be carefully monitored. (See Dosage and Administration.) If pulmonary edema develops during administration, the drug should be discontinued. Edema should be managed by conventional means.
>
> Because cardiovascular responses are common and more pronounced during intravenous administration of Yutopar, cardiovascular effects, including maternal pulse rate and blood pressure and fetal heart rate, should be closely monitored. Observe for premonitory or actual maternal signs and symptoms of pulmonary edema. A persistent high tachycardia (over 140 beats per minute) and/or persistent tachypnea (respiratory rate over 20 per minute) may be signs of impending pulmonary edema with drugs of this class.
>
> Occult cardiac disease may be unmasked with the use of Yutopar. If the patient complains of chest pain or tightness of chest, the drug should be temporarily discontinued and an ECG should be done as soon as possible.
>
> The drug should not be administered to patients with mild to moderate preeclampsia, hypertension, or diabetes unless the attending physician considers that the benefits clearly outweigh the risks.

Reference:

1. Philipsen T, et al.: Pulmonary edema following ritodrine-saline infusion in premature labor. *Ob Gyn* 1981; 58(3): 304-7.

Use of Approved Drugs for Unlabeled Indications

The appropriateness or the legality of prescribing approved drugs for uses not included in their official labeling is sometimes a cause of concern and confusion among practitioners.

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, a drug approved for marketing may be labeled, promoted, and advertised by the manufacturer only for those uses for which the drug's safety and effectiveness have been established and which FDA has approved. These are commonly referred to as "approved uses." This means that adequate and well-controlled clinical trials have documented these uses, and the results of the trials have been reviewed and approved by FDA.

The FD&C Act does not, however, limit the manner in which a physician may use an approved drug. Once a product has been approved for marketing, a physician may prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. Such "unapproved" or, more precisely, "unlabeled" uses may be appropriate and rational in certain circumstances, and may, in fact, reflect approaches to drug therapy that have been extensively reported in medical literature.

The term "unapproved uses" is, to some extent, misleading. It includes a variety of situations ranging from unstudied to thoroughly investigated drug uses. Valid new uses for drugs already on the market are often first discovered through serendipitous observations and therapeutic innovations, subsequently confirmed by well-planned and executed clinical investigations. Before such advances can be added to the approved labeling, however, data substantiating the effectiveness of a new use or regimen must be submitted by the manufacturer to FDA for evaluation. This may take time and, without the initiative of the drug manufacturer whose product is involved, may never occur. For that reason, accepted medical practice often includes drug use that is not reflected in approved drug labeling.

With respect to its role in medical practice, the package insert is informational only. FDA tries to assure that prescription drug information in the package insert accurately and fully reflects the data on safety and effectiveness on which drug approval is based.

Hepatitis B Vaccine for Use in Selected Populations

An inactivated hepatitis B vaccine (Heptavax-B) has been licensed for use in the United States. It is intended for selected populations at high risk of acquiring hepatitis B, one of three known forms of viral hepatitis. (The others are hepatitis A and non-A non-B hepatitis.)

The vaccine is the first to be made from human blood. Noninfectious antigen is purified from the plasma of asymptomatic human carriers of hepatitis B. After a series of chemical treatments, followed by the addition of alum adjuvant, the vaccine is administered in three intramuscular injections over a 6-month period.

Vaccination is not intended for the general population, but is recommended for persons older than 3 months of age who are at increased risk of hepatitis B virus infection. These persons will include health care workers, institutionalized patients, laboratory workers, hemodialysis staff and patients, family contacts of carriers, some military personnel, and persons with numerous sexual partners.

There continues to be a dialogue among government agencies, industry, and the medical community about use of the vaccine in selected high-risk groups. The Advisory Committee on Immunization Practices (ACIP) of the U.S. Centers for Disease Control (CDC), with assistance from representatives of FDA, the National Institutes of Health, and the medical community, has met several times to discuss specifically which population groups should receive this vaccine. The ACIP will meet once more in May of this year to draft final guidelines for use of this vaccine.

Efficacy

In clinical trials, 85 to 96 percent of persons receiving three doses of either 20 mg or 40 mg of vaccine were immune to infection. The duration of protection is presently unknown. However, in clinical trials, vaccine-induced antibodies, shown to provide protection against infection, persisted for at least 24 months in those receiving all three doses and will probably last for at least 5 years. After this time, a booster may be necessary to maintain immunity.

Side effects have been mainly local, mild, and transitory.

Availability

Due to the complexity of the methods used for producing the vaccine, it will be summer or fall of 1982 before the product is generally available from Merck, Sharp & Dohme. This manufacturer can supply complete physician information.

Advice on Limiting Intake of Bonemeal

Due to the unknown but often substantial lead content of individual samples of bonemeal and dolomite, FDA advises practitioners that these substances should be used as little as possible in infants, young children, and pregnant or lactating women.

Bonemeal is used primarily as calcium and/or phosphorus supplements. Bonemeal supplements are usually composed of finely crushed, processed bone and are packaged in powder, capsule, tablet, or wafer form. The source of bone is usually cattle but sometimes also horses. Bone marrow may also be added to this product. All bonemeal products contain lead which originates primarily from the diet of the animals from which the bone is taken. Bone serves as a repository for lead in the body and, in general, the older the animal the more lead in its bones.

Dolomite is a mineral deposit, consisting of calcium-magnesium carbonate with traces of other elements, including lead. Dolomite is used as a calcium and magnesium supplement and, like bonemeal, may be purchased in powder, capsule, tablet, or wafer form.

While a large portion of the small amounts of dietary lead ingested by humans is excreted, some is deposited in the mineral fabric of bone and some goes into soft tissue. Infants and children tend to absorb lead more efficiently than adults. When it is consumed in excess, lead may produce toxic reactions including central nervous system damage, anemia, and abdominal pain. As in animals, the accumulation of lead in human bone increases with age. Additionally, studies with

adult volunteers have shown that over a long time, the accumulation of lead in the body is proportional to the level of intake.

FDA Surveys

FDA has undertaken limited surveys to identify the extent of lead contamination of bonemeal and to determine whether the problem is limited or industry-wide.

One survey by FDA's Division of Consumer Studies of approximately 3,000 persons, 16 years of age and older, determined that about 1 percent of the population surveyed consumed bonemeal as a calcium source. More than 90 percent of the individuals consuming bonemeal were women, 50 years of age or older. The available information suggests that the average intake of bonemeal does not usually exceed 10 g/day.

No reliable information is available on the use of bonemeal as a calcium source for young children or infants. However, it is possible that bonemeal has been used as a calcium supplement for infants who have an intolerance for milk.

Although levels are usually lower, FDA scientists have found some samples of bonemeal containing lead at concentrations as high as 17 to 20 parts per million (ppm). Comparably high levels of lead have also been detected in some samples of dolomite.

It is known that the consumption of bonemeal containing 5 to 10 ppm lead by infants and children may result in lead intakes that clearly exceed the FDA recommended tolerable or maximal daily intake from all sources. For the infant, lead intake should be as low as possible and less than 100 micrograms/day, and for children between 6 months and 2 years the intake of lead should be no more than 150 micrograms/day.

pecial Risk

Individuals at special risk of lead toxicity from the consumption of bonemeal or dolomite include infants, children, women of childbearing age, and possibly the elderly. Others who ingest bonemeal at the recommended doses (usually not more than 5 to 10 grams/person/day) would not ordinarily exceed the WHO/FAO (World Health Organization/Food and Agriculture Organization) guideline for a tolerable daily adult intake of 430 micrograms of lead. However, individuals who consume more than two to three times the recommended dose would be at greater risk if the lead content of the bonemeal is high.

Pregnant or lactating women taking bonemeal or dolomite to meet increased calcium needs may have sufficient increased lead intake and absorption to present a health hazard to the developing fetus, via placental transfer of lead, or to the nursing infant from its mother's milk.

Bendectin PPI Available

A patient package insert (PPI) for Bendectin, an antiemetic combination of doxylamine and vitamin B_6 used in pregnancy, has been issued by the manufacturer, Merrell Dow Pharmaceuticals.

Pads of the PPIs are being distributed to retail pharmacies and physicians who are high prescribers of the drug, and are available to other health professionals from the manufacturer, upon request.

A Spanish language version of the PPI will be available upon request from the manufacturer.

In its summary section, the PPI explains: "Bendectin is used to treat the nausea and vomiting that may occur during the first few weeks of pregnancy. You should take this drug only if nausea and vomiting interfere with your eating or daily activities and if other treatments prescribed by your doctor do not relieve your symptoms. These other treatments include eating soda crackers or dry toast, or drinking hot or cold liquids as soon as you wake up in the morning.

"There is no way to prove that any substance taken by pregnant women does not cause birth defects on rare occasions. For this reason, no drug, including Bendectin, should be taken during pregnancy unless it is clearly necessary."

As was discussed in the March 1981 issue of the *Drug Bulletin*, the revised physician labeling for Bendectin cautions physicians that the drug should be used only when more conservative treatment for nausea and vomiting in pregnancy has failed and when symptoms are sufficiently distressing to require drug intervention.

Class I Recalls

As a special service to health professionals, the *Drug Bulletin* is publishing information on recent Class I recalls. The following products have been withdrawn voluntarily in firm-initiate Class I recalls because they pose serious health hazards:

Infant Formula

Nursoy Concentrated Liquid, 13-ounce cans, coded A26M, B2M, and B9M, and Nursoy Ready-to-Feed 32-ounce cans coded A28M and B11M. Codes may be preceded by a number such as 1,2, or 3, which can be ignored. Example: 2A26M. Formula lacks vitamin B_6, which can result in serious health effects ranging from irritability to convulsions. Cans may be returned to the retailer for refund or replacement. Recall date: March 3, 1982.

SMA powder and liquid with code numbers A25M through A31M, and B1M through B15M. Code numbers may be preceded by a number such as 1,2, or 3, which can be ignored. Example: 2A25M. Formula is deficient in viramin B_6, which can result in serious health effects ranging from irritability to convulsions. Cans may be returned to the retailer for refund or replacement. Recall date: March 12, 1982.

Defibrillator

Safeguard 3, serial numbers 290, 374, 379, 380, 1001, 1002, 1006. The storage capacitor may fail, resulting in low discharge energy and consequent failure to defibrillate. The manufacturer, Safeguard Medical Systems, Inc., Beltsville, Md., will replace faulty condensors. Recall date: Dec. 14, 1981.

AHFS DRUG INFORMATION 2004

2004

American Society of Health-System Pharmacists®

PREFACE

An Evidence-based Foundation for Safe and Effective Drug Therapy

The mission of *AHFS Drug Information*® is to provide an evidence-based foundation for safe and effective drug therapy. Widely trusted for its established record in refuting unfounded efficacy claims, its rigorous science-based editorial process, and its independence from the influence of pharmaceutical manufacturers, *AHFS Drug Information*® has remained true to its mission for almost 50 years.

With the 2004 edition, the *American Hospital Formulary Service*® (*AHFS*™) marks the 46th year of continuous publication by the American Society of Health-System Pharmacists (ASHP). First published in 1959, the *Formulary Service*™ has evolved to address increasingly complex issues related to drug therapy and formulary management. Over the years, it has been the responsiveness of the *Formulary Service*™ to changing drug information needs that has allowed it to maintain a place of prominence among the world's drug information resources.

AHFS Drug Information 2004® is a collection of drug monographs kept current by periodic updates (e.g., *AHFSfirst*Releases™, MedWatch notices, http://www.ahfsdruginformation.com) and by a revised master volume issued each year. *AHFS Drug Information 2004*® is prepared for the purpose of disseminating comprehensive, evaluative drug information to the entire medical and paramedical community. The *AHFS*™ was first published in 1959 as an adaptation from the *Hospital Formulary of Selected Drugs* by Don E. Francke. *AHFS* had its roots in the hospital formulary system, which was intended to establish the sound therapeutic and economic basis for drug policy. Originally, the *Formulary Service*™ was conducted through the Committee of Pharmacy and Pharmaceuticals of the American Society of Hospital (now Health-System) Pharmacists to assist the pharmacy and therapeutics committee of each hospital in preparing its hospital formulary. Since then, *AHFS Drug Information*® has developed beyond its original purpose to become the most comprehensive, authoritative source of evaluative, evidence-based drug information available. Paramount to providing such information is the critical, evidence-based evaluation of pertinent clinical data concerning drugs, with a focus on assessing thoroughly the advantages and disadvantages of various therapies, including interpretation of various claims of drug efficacy.

■ Comparative, Unbiased, Evaluative Drug Information

AHFS Drug Information® is a tested and proven source of comparative, unbiased, and evidence-based drug information containing a monograph on virtually every molecular drug entity available in the US. Drug monographs are prepared by a professional editorial and analytical staff, who critically evaluate published evidence on the drug. The monographs incorporate the expert advice of leading medical scientists, physicians, pharmacists, pharmacologists, and other clinicians and professionally qualified individuals; there currently are approximately 500 expert reviewers. Reviewers provide a full disclosure of interest, including any affiliation with or financial involvement in the manufacturer of the drug(s) under consideration in a given review as well as for competitive products. *AHFS Drug Information*® monographs are reviewed by many consultants in the specific field of therapy under consideration, including experts from major research and clinical institutions as well as public bodies such as the National Institutes of Health (NIH) and US Centers for Disease Control and Prevention (CDC) and professional associations with therapeutic authority. It is this preparation by a professional staff and the exhaustive review process that make *AHFS Drug Information*® monographs unbiased and authoritative.

Using an independent, evidence-based, evaluative process, *AHFS Drug Information*® monographs incorporate information from pertinent references in the literature and expert therapeutic guidelines. The monographs also address the labeling approved by the FDA, in some cases challenging outdated and clinically irrelevant information. *AHFS Drug Information*® monographs continue to include information on uses, dosages, and routes and/or methods of administration that may not be included in the FDA-approved labeling for the drug ("off-label/unlabeled uses"). (See Uses in the Users Guide, p. xv.) A typical monograph on a new drug incorporates information from several hundred published references, and some general statements and individual monographs incorporate information from several thousand references. The current database includes 70,000 uniquely cited references linked to 500,000 statements. Tens-of-thousands of additional references from the *AHFS*® archives provide support for monographs on drugs introduced into the US market prior to 1984. It is this point-by-point analysis and evaluation of the literature that make *AHFS Drug Information*® monographs comprehensive, evaluative, and considerably beyond the FDA-approved labeling in their scope.

■ Widely Used in Print and Electronic Formats

AHFS Drug Information® is widely used as a source of complete drug information by physicians, pharmacists, dentists, nurses, and other health-care professionals and by schools of pharmacy, nursing, and medicine and is available in a variety of formats including electronic (e.g., AHFS*first*WEB™, *AHFS*® for PDAs, ASHPaccess™, STAT!Ref®, Drug Information Full-text® [DIF®]) and print. In hospitals, extended-care facilities, nursing homes, health maintenance organizations, and other organized health-care settings, *AHFS Drug Information*® as print and/or electronic databases is accessible in patient-care areas for ready use by physicians, nurses, pharmacists, and other health-care professionals. *AHFS Drug Information*® also is used in pharmacy practice (e.g., community pharmacies) and other professional practice settings and is available in most medical libraries.

Putting "Formulary" Back into AHFS

ASHP, in partnership with ePocrates, recently introduced an electronic hospital formulary hosting service—ePocrates Rx Online™ + AHFS DI®—an important resource for medical, pharmacy, and nursing staff. This formulary hosting service integrates inpatient formulary information with ePocrates Rx® and *AHFS Drug Information*® clinical drug monographs. Hospital pharmacists, physicians, and staff will be able to access their hospital formulary information on a handheld (PDA) or desktop computer. Formulary managers will be able to update their formulary and clinical information easily and frequently using a simple loading tool. The *AHFS Drug Information*® database will be available on desktops throughout the institution, via this new product.

This hospital formulary hosting service will improve patient care and safety, manage rising drug and administrative costs by increasing therapeutic substitution and formulary compliance, eliminate the need for quickly outdated printed institutional formularies, require almost no IT resources, increase satisfaction among clinicians, and support JCAHO compliance. Furthermore, staff adoption will be a breeze since 340,000 of them already use ePocrates' outpatient formulary service—the most widely used PDA drug information. Why force your staff to learn a different, unfamiliar electronic formulary service, when they already are familiar with *ePocrates*, relying on it as an indispensible part of their day-to-day practice?

■ Highly Recognized Authority

AHFS Drug Information® is supported solely through subscriptions. *AHFS Drug Information*® has been officially adopted by the US Public Health Service and the Department of Veterans Affairs; recommended by the National Association of Boards of Pharmacy as part of the standard reference library; recommended by the American College of Physicians-American Society of Internal Medicine as part of a library for internists; included in the Standards for Medicare; approved by the American Pharmaceutical Association, American Health Care Association, American Hospital Association, and Catholic Health Care Association of the United States; recognized by the US Congress, Centers for Medicare & Medicaid Services (CMS; formerly Health Care Financing Administration [HCFA]), Health Insurance Association of America (HIAA), National Blue Cross and Blue Shield Association, National Association of Insurance Commissioners, and various third-party health-care insurance providers for reimbursement decisions on off-label (unlabeled) uses; and included as a required or recommended standard reference for pharmacies in many states.

The authority of *AHFS Drug Information*® also includes Federal recognition through legislation and regulation as an "official" compendium for information on medically accepted uses of drugs. The Federal compendial recognition for *AHFS Drug Information*® originated in Public Law 100-630 (Medicare Catastrophic Coverage Act) following careful consideration by Congressional staff and establishment of standards for such designation. HCFA (now CMS) determined that *AHFS Drug Information*® met the compendial selection criteria established by Congress and adopted the compendium for carrying out certain aspects of the Act and in meeting the need of the US Secretary of Health and Human Services (HHS) to establish standards based on accepted medical practice for the prescribing, dispensing, and utilization of covered drugs. This established the Federal precedent for use of *AHFS Drug Information*® as a compendial standard in subsequent legislative and regulatory initiatives, including OBRA 90 and OBRA 93. Federal compendial recognition continues under part 456 of CMS regulations governing utilization control for Medicaid and under section 1927 of the Social Security Act.

Highlights of 2004 Revisions

The 2004 edition has been updated extensively, incorporating revised information on uses, therapeutic perspective, cautions, drug interactions, new products, and other new developments. Each year more than 60% of the monographs are revised. The average age of *AHFS Drug Information*® monographs is less than 1 year. In addition, the coverage in the 2004 edition has been expanded by 52 new drug monographs.

■ JCAHO's 2004 National Patient Safety Goals

Information published in *AHFS Drug Information*® was revised throughout the 2004 edition to address the prohibited abbreviations requirement under goal

#2 of the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO's) 2004 National Patient Safety Goals. Of the 5 dangerous abbreviations, acronyms, and symbols included on JCAHO's minimum list for *handwritten, patient-specific* communications, only "IU" (for international units) and "U" (for units) were previously used in *AHFS Drug Information®*. These abbreviations have been replaced throughout the *AHFS* database, including print (*AHFS Drug Information®*) and electronic versions of the information. While these abbreviations still appear in definitions for official standards (e.g., USP definitions of potency) in the monographs of the affected drugs, the spelled-out term "units" (rather than IU or U) is used for specific dosage recommendations and commercial product concentrations throughout the monographs. JCAHO's requirement that these abbreviations not be used in *handwritten communications* is in response to errors (mistaking U as zero, four, or cc) in interpreting written orders and other forms of clinical documentation in JCAHO-accredited facilities.

In addition to the minimum required list, JCAHO has published an additional list of abbreviations that should not be used, at least 3 of which also should be included on the "do not use list" of a JCAHO-accredited facility. Of the abbreviations included on this list, only "μg" (for microgram) was previously used in *AHFS Drug Information®*. This has been replaced throughout the *AHFS* database by "mcg." JCAHO's requirement that this abbreviation not be used is in response to errors (mistaking μ for mg, resulting in a one-thousand-fold overdose error) in interpreting handwritten orders and other forms of clinical documentation in JCAHO-accredited facilities.

Although medical publishers and printed or electronic information are not subject to these JCAHO standards, and the likelihood of misinterpreting the *typeset* versions of these abbreviations would be far less than with *handwritten* versions, a decision to change these abbreviations throughout the *AHFS Drug Information®* database was made in order to reinforce the standards for good handwritten clinical documentation, with the ultimate goal of reducing medication errors.

■ Greatly Expanded Subdivision of the AHFS Classification

The *AHFS®* Pharmacologic-Therapeutic Classification has been extensively subdivided and reorganized to provide more specific subgroupings of numerous drugs along therapeutic and pharmacologic lines. The principal major classes affected by this subdivision are sections 4:00 Antihistamines, 8:00 Anti-infective Agents, 20:00 Blood Formation and Coagulation, 24:00 Cardiovascular Drugs, 28:00 Central Nervous System Agents, 52:00 EENT Preparations, 56:00 Gastrointestinal Drugs, 68:00 Hormones and Synthetic Substitutes, and 84:00 Skin and Mucous Membrane Agents. A total of 96 new pharmacologic-therapeutic subclasses (e.g., COX-2 Inhibitors, Proton Pump Inhibitors, Atypical Antipsychotics) have been added, providing more specific subdivision of numerous classes of drugs and affording greater power and flexibility to users of the classification for organizing and tracking information about the affected drugs. For additional details on the new subclasses and affected drug monographs, see the 2004 AHFS Pharmacologic-Therapeutic Classification® System Revisions by visiting the homepage at www.ahfsdruginformation.com.

In addition, section 92:00 Unclassified Therapeutic Agents has been renamed Miscellaneous Therapeutic Agents and has been reorganized to present the monographs in pharmacologic-therapeutic groupings (e.g., Antidotes, Antigout Agents, Bone Resorption Inhibitors, Disease-modifying Antirheumatic Drugs, Immunosuppressive Agents, Platelet-aggregation Inhibitors). This is an interim reorganization of section 92:00 while 2 proposed reclassification schemes are circulated for comment and finalization. One proposed scheme involves moving most of the drugs out of section 92:00 and into other major classes while the other scheme involves principally further subdividing section 92:00 into more specific alpha-numeric subclasses. Pending finalization and implementation of one of these proposals, the afore-mentioned groupings have been created to aid in a more logical review of related drugs.

To aid in locating specific drugs in the new subclasses as well as related drugs in other subclasses, extensive cross-referencing appears. For example, under Platelet-aggregation Inhibitors, there is a cross-reference to Aspirin 28:08.04.24. Users of the classification can use either the primary class (e.g., Salicylates for Aspirin) or the secondary class (i.e., the class to which the drug in question is cross-referenced; e.g., Platelet-aggregation Inhibitors for Aspirin) or both, depending on their need. In electronic versions of *AHFS Drug Information®*, both primary and secondary classes are used. In addition, users who are unable to accommodate or do not wish to use a 4th tier of the classification can simply fall back to the less specific 3rd tier (e.g., use 8:12.06 Cephalosporins rather than 8:12.06.04 First Generation Cephalosporins for a drug like Cephalothin). The added specificity ("granularity") is there for those who wish to apply it to their use of the classification.

■ Extensively Revised Product Listings

The product listings in *AHFS Drug Information®* are reviewed each year and a substantial number of revisions are made, including information on newly marketed dosage forms and strengths and reformulated products as well as ongoing manufacturer changes. Over a thousand such revisions have been made in the 2004 edition.

■ Improved Format Focusing on the Most Clinically Relevant Information

The 2004 edition of *AHFS Drug Information®* monographs continues the major reorganization of content that makes it easier for health-care practitioners to locate the most clinically relevant and frequently needed information. Information on Uses and on Dosage and Administration appears at the beginning of each monograph, followed by cautionary information on adverse effects, precautions, contraindications, drug interactions, and acute and chronic toxicity. Less frequently used sections on Pharmacology, Pharmacokinetics, and Chemistry and Stability appear at the end of the monographs. In addition, subheadings within the monographs have been expanded to aid in locating specific information.

■ Current Authoritative Therapeutic Guidelines

AHFS Drug Information® monographs also are updated each year to include the current recommendations of numerous authorities. For example, many monographs in the 2004 edition have been revised to include:

- *Seventh Report of the Joint National Committee (JNC 7) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.* The December 2003 guidelines, which replace those last revised in November 1997, reflect the recent findings of the *ALLHAT* study, further strengthening the recommendation for the use of thiazide diuretics as initial therapy in most hypertensive patients based on cost, cardiovascular benefit, and patient tolerance considerations. Participating in this evidence-based process were 39 professional associations, including the American Society of Health-System Pharmacists (ASHP), and 7 Federal agencies, working under the auspices of the National Heart, Lung, and Blood Institute's (NHLBI's) National High Blood Pressure Education Program (NHBPEP).

  Key issues addressed by JNC 7 include greater emphasis on thiazide diuretics, the importance of systolic blood pressure for cardiovascular risk in those older than 50 years of age, introduction of a prehypertensive (SBP of 120–139 or DBP of 80–89 mm Hg) category that requires lifestyle modification, compelling indications for certain classes of antihypertensive agents in high-risk patients, the likelihood that most patients will require 2 or more antihypertensive agents, consideration for initiating therapy with 2 antihypertensives in those whose BP exceeds goal BP by 20/10 mm Hg, decreased emphasis on escalating dosages versus use of additional drugs, and changes in usual recommended dosages for many drugs. Relevant portions of the *European Society of Hypertension–European Society of Cardiology* guidelines also were addressed. Approximately 70 monographs were affected by these guidelines, with the Thiazides General Statement serving as the main overview.
- *American Urological Association* guideline on the management of benign prostatic hyperplasia (BPH) regarding the role of α-adrenergic blocking agents and 5-α-reductase inhibitors and recent evidence that combined therapy may be more effective than monotherapy in preventing long-term BPH symptom progression and more effective than α-blocker monotherapy in reducing the risk of long-term urinary retention and need for invasive therapy.
- *Institute of Medicine (IOM) of the National Academies* assessment of testosterone and aging, which concluded that there currently are insufficient data to establish that hormone replacement therapy in older men is associated with clear evidence of benefit for any of the outcomes examined in the absence of a clinical diagnosis of hypogonadism.
- *American Heart Association (AHA)* and *American Diabetes Association (ADA)* consensus statement on use of thiazolidinedione oral antidiabetic agents (pioglitazone, rosiglitazone) and the risk of fluid retention and congestive heart failure.
- *ADA* clinical practice recommendations on diabetic nephropathy, treatment of hypertension in diabetic adults, and standards of medical care for diabetes mellitus. These sets of guidelines affected numerous antidiabetic and cardiovascular monographs.
- *National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)* recommendations about diabetic neuropathies.
- *NIH* asthma guidelines, updating inhaled and systemic corticosteroid monographs to include revised information on the use of corticosteroids in children and attainment of adult height.
- Expanded discussion of the advanced cardiovascular life support (ACLS) guidelines regarding the value of vasopressin as an alternative to epinephrine for vasopressor therapy in out-of-hospital cardiopulmonary resuscitation, particularly asystolic cardiac arrest.
- *US Centers for Disease Control and Prevention (CDC)* recommendations for the use of smallpox vaccine for prophylaxis against monkeypox.
- Updated *CDC* recommendations for smallpox vaccination, including new information on adverse effect profile and duration of immunity.
- *CDC* recommendations on the use of cidofovir for the management of smallpox vaccine complications and the treatment of monkeypox infection.
- Additional findings from the *Women's Health Initiative (WHI)* study that hormone replacement therapy (HRT) [illegible] not have a beneficial effect on cognitive function.

- *US Public Health Service Advisory Committee on Immunization Practices (ACIP)* recommendation that routine influenza vaccination be extended to children 6–24 months of age for the upcoming 2004–2005 season, based on pediatric experience during the 2003–2004 influenza season. Review by the *American Academy of Pediatrics (AAP)* is under way.
- *CDC, AAP*, and other expert recommendations for the treatment of pediculosis capitis.
- *Various authoritative groups*, such as *CDC, the US Department of Health and Human Services (DHHS), National Institutes of Health (NIH), Health Resources and Services Administration (HRSA), National Pediatric and Family HIV Resource Center (NPHRC)*, and *Perinatal HIV Guidelines Working Group*, for HIV infection treatment and prevention in adults, pediatric patients, and pregnant women. Incorporates extensive changes in the regimens used for initial treatment of HIV-infected adults as well as changing strategies to employ and regimens to use in experienced patients with virologic failure. Also incorporates changes in recommended pediatric dosages.
- *CDC, American Thoracic Society (ATS)*, and *Infectious Diseases Society of America (IDSA)* recommendations on tuberculosis treatment, including precautionary information about the use of rifampin/pyrazinamide regimens in latent tuberculosis.
- *ACIP, CDC*, and *US Food and Drug Administration (FDA)* guidelines on pneumococcal vaccination in cochlear transplant recipients.
- *American Society of Clinical Oncology (ASCO)* recommendations for chemoprotectants.
- *Stroke Council of the American Stroke Association* guidelines on the early management of stroke, including use of insulin infusions in selected patients.
- *AAP* guidelines for monitoring and management of pediatric patients after sedation for diagnostic and therapeutic procedures.
- *AAP* guidelines on pediatric potassium iodide therapy for radiation disasters.
- *Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation* on the treatment of hemophilia and other bleeding disorders.
- *American Academy of Child and Adolescent Psychiatry (AACAP)* guidelines on the treatment of attention deficit hyperactivity disorder (ADHD) in adolescents and adults as well as those of the *American Psychiatric Association (APA)* and other experts on ADHD diagnostic and other criteria in these age groups.
- The latest *(January–December 2004) Unified Recommended Childhood and Adolescent Immunization Schedule*, which was issued jointly by the *CDC, AAP*, and *American Academy of Family Physicians (AAFP)*. A revised *Adult Immunization Schedule (2003–2004)* that incorporates the recommendations of *CDC, AAP, AAFP, ACP-ASIM*, and *ACOG* has been added for the 2004 edition.
- *National Committee for Clinical Laboratory Standards (NCCLS)* on interpretive standards for in vitro susceptibility testing of bacteria from clinical specimens.

New and Revised Labeled and Off-label Uses

Space does not allow a complete listing of other changes, but major revisions of evolving therapeutic information that involved numerous monographs, both as off-label (unlabeled) and labeled uses, were incorporated on pediatric use of antidepressants, including new precautionary information, geriatric use of atypical antipsychotics, mexiletine for diabetic neuropathy, vasopressin for out-of-hospital cardiopulmonary resuscitation, testosterone for male climacteric, aspirin for colon cancer prevention, low-intensity warfarin for long-term prevention of recurrent idiopathic deep-vein thrombosis, pseudoephedrine for otitic barotrauma associated with flying and underwater diving, lorazepam for sedation in critical-care settings, and revised thinking on the use of enoxaparin in pregnant women with mechanical prosthetic valves. In addition, hundreds of monographs were revised to include evolving therapeutic perspectives reflected in numerous authoritative guidelines (see Highlights of 2004 Revisions: Current Authoritative Therapeutic Guidelines), both as labeled and off-label uses.

Just a few of the newly approved uses in *AHFS Drug Information 2004®* include combined use of olanzapine and fluoxetine for depressive episodes associated with bipolar disorder, simvastatin for pediatric patients, extended-cycle (3-month dosing regimens) oral contraception with Seasonale®, once-weekly dosing of risedronate for postmenopausal osteoporosis, introduction of a new digoxin immune Fab preparation, new formulation and dosing information on cyclobenzaprine, new OTC omeprazole preparation, new maximum OTC strength for famotidine, OTC loratadine preparations, tazarotene for photoaging, eplerenone for congestive heart failure, infliximab for Crohn's disease, prussian blue for "dirty bomb" exposures, pyridostigmine for preexposure prophylaxis against soman nerve gas poisoning in the military, fluoxetine for depression in pediatric patients, and expanded discussion of thiopental for narcoanalysis and narcosynthesis.

Major Cautionary Information

Some major cautionary information added or revised for *AHFS Drug Information 2004®* includes dozens of FDA MedWatch notices, new findings about sulfonamide cross-sensitivity (e.g., with thiazides), updated adverse effects with smallpox vaccine, updated discussions on vaccine reformulations addressing concerns about thimerosal, updated information on West Nile virus testing of biologic preparations, warning about life-threatening asthma exacerbations with salmeterol, FDA final rule on risks of concomitant topical and systemic diphenhydramine use, additional findings (e.g., Rand Report) on the risks of ephedra (at the time the 2004 edition of *AHFS Drug Information* went to press, FDA announced that it plans to ban the sale of ephedra-containing products in the US sometime in early 2004), overdosage resulting from misinterpretation of mg for mL with highly concentrated morphine solutions, pergolide and cardiovalvulopathy as well as risk of suddenly falling asleep, topiramate and risk of metabolic acidosis as well as oligohydrosis and hyperthermia, potentially fatal hepatotoxicity with leflunomide, suicidality with antidepressant use in pediatric patients, risk of hyperglycemia and diabetes with atypical antipsychotics, quinidine and grapefruit juice interaction, potentially fatal bronchial anastomotic dehiscence in lung transplants, removal from the US and European markets of levomethadyl acetate hydrochloride (ORLAAM) because of serious cardiotoxicity, high rates of hospitalization and death with combined rifampin and pyrazinamide therapy for latent tuberculosis, lindane risks, and numerous sound-alike drug names that could result in medication errors.

This is just a small sampling of the numerous revisions that are included in *AHFS Drug Information 2004®*. Each monograph that has been revised in 2004 includes the statement: "Selected Revisions January 2004."

www.ahfsdruginformation.com

With the 2004 edition, *AHFS Drug Information®* print subscribers will continue to have free access to ASHP's ahfsdruginformation.com, a companion Web site designed to provide timely ongoing updates as part of their subscription service. This service replaces the previous print Supplements and AHFS*first*FAXes™. A username and password appear at the end of the Preface and will be required to access the subscriber-only portions of the new Web site. Without them, only general marketing information regarding the *AHFS®* product line can be accessed.

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The Editorial staff wishes to express appreciation to the many consultants and reviewers for their excellent guidance and cooperation and to our subscribers for their support and comments.

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FOREWORD TO THE FIFTY-NINTH EDITION

PDR enters its fifty-ninth year offering a wider array of pharmaceutical reference options than ever before. Long available unabridged—in print, on CD-ROM, and via the Internet—*PDR* also provides essential prescribing information in other forms as well, detailed later in this foreword.

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