UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v. Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

DEFENDANT JENNIFER KING VASSEL'S MOTION IN LIMINE TO EXCLUDE EVIDENCE OF GEODON PRESCRIPTIONS

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

To exclude evidence of prescription medication Geodon (this is the brand name, it also known as ziprasidone) in this case.

ARGUMENT

THE PLAINTIFF HAS NEVER PLACED DR. KING ON NOTICE OF ANY CLAIM FOR ALLEGED FRAUDULENT GEODON PRESCRIPTIONS.

Yesterday the plaintiff first provided formal notice, buried in a footnote on page seven of a brief in opposition to a motion, that he was pursing a claim based on Geodon prescriptions written by Dr. King, but never stated the period of time in which the claim was being made.[1] *Plaintiff's brief in Opposition to Dr. King's motion in limine* (Document 158, p. 7 n. 2)(of significance, the plaintiff

[1] The plaintiff informally placed Dr. King on notice of his claim for Geodon prescriptions when he presented his draft pretrial report on November 22, 2013. In that report, he noted that he is making a claim for the period of time from March 3, 2005 to November 1, 2013.

also stated that he will dropping all medication claims based on treatment of N.B., but for the prescription of Risperdal). The plaintiff is producing an entirely new claim at the eleventh hour in a lawsuit pending for over two and a half years. *Complaint filed March 3, 2011* (Document 1).

The complaint does not reference Geodon. ***Id.*** The plaintiff has never amended the complaint to reference Geodon. The plaintiff has never amended his initial disclosures to assert that a claim is based on Geodon. *Affidavit of Bradley S. Foley, Exhibit A, Plaintiff's First Supplemental Disclosures; Second and Third Supplemental Disclosures* (Documents 166-2 and 166-3).

Dr. King was asked about Geodon at her deposition, but never in the context of N.B. or any other particular patient. *Deposition of Dr. King* (145-4, pp. 88-93). In fact at her deposition Dr. King testified that she does not typically prescribe Geodon. (Document 145-4, pp. 90 and 93). Dr. King considers continuing to prescribe medications which could include Geodon if they are already prescribed by a previous physician and the medication was beneficial. ***Id.***, p. 91 ("So they might have been on medication before that worked well for them.") Dr. King, off the top of her head, did not recall prescribing Geodon in the past year for any minors; she only recalled prescribing it for one adult patient. ***Id.***, pp. 88 and 89. In order to determine whether she would prescribe Geodon to a patient, she

> 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.

Deposition of Dr. King, p. 93.

The plaintiff's new focus on Geodon may arise out of discovery provided by the State of Wisconsin on November 6, 2013. In the discovery provided by the State, Geodon was listed as a

medication prescribed by Dr. King. The State produced 251 pages of prescription medications (it was 251 pages after being reduced to fit on single pages). Dr. King could not have been placed on notice at that time, as there were multiple other prescriptions listed as well at that time, *and the plaintiff never followed up to assert a new claim involving Geodon.*

In order to assess the Geodon prescriptions, Dr. King would need to be provided access to records, including her own treatment records, of the patients the plaintiff is now claiming to be part of the case. The plaintiff's new assertion of Geodon, less than two weeks before trial, prohibits this from occurring. This review would include, as noted above, assuming that Geodon was in fact prescribed as listed in the State records and was not incorrectly placed in the list because of an error, the age of the patient, the history and presenting symptoms in order for her to be provided an opportunity comment of the allegations. The total number of Geodon claims, based on the records provided by the State and alleged by the plaintiff, is approximately 139. *Joint Pretrial Report.* Only on rare occasions is the diagnosis even provided in the State records.

Federal courts have long ago abandoned trial by ambush. Modern trials are to be fair contests with the basic facts and issues disclosed to the fullest extent practicable, not games of poker and blind man's bluff. ***Hickman v. Taylor***, 329 U.S. 495, 507 (1947). The Federal Rules of Civil Procedure governing discovery and depositions were designed to ensure proper litigation in which each party comes to trial armed with mutual knowledge of all the relevant facts. ***Id.*** 329 U.S. at 507.

The Seventh Circuit has identified four factors that should guide a district court's discretion as to whether to exclude evidence for failure to disclose: (1) the prejudice or surprise to the party against whom the evidence is offered; (2) the ability of the party to cure the prejudice; (3) the likelihood of disruption to the trial; and (4) the bad faith or willfulness involved in not disclosing

the evidence at an earlier date. ***David v. Caterpillar, Inc.,*** 324 F.3d 851, 857 (7th Cir.2003). All of these factors are relevant here. Dr. King is unfairly prejudiced by the introduction of this evidence; she has not been provided an opportunity to assess and prepare a defense due to the lack of notice; this would provide new additional information at trial that was never noticed by the plaintiff; and notice of Geodon was not provided until yesterday. In sum, the plaintiff has failed to provide any notice that Geodon was the basis of a False Claims Act claim *until November 25, 2013.*

The presentation of an entirely new claim at the last minute must also be viewed in the context of Dr. King's defense. In order to obtain the appropriate records from the State regarding whether the medications listed in the complaint were covered by the State, it took nearly 30 days to receive those documents. *Affidavit of Bradley S. Foley, Exhibit B, Letter from the State Acknowledging Records Request; Affidavit of Bradley S. Foley, Exhibit C, Letter from the State Providing the Requested Information.* Given that notice was not provided of Geodon prescriptions, that information was not sought.

Moreover, according to one of the publications that comprise the compendia, the American Hospital Formulary Service (AHFS), the use of Geodon is not prohibited for pediatric use. *Affidavit of Bradley S. Foley, Exhibit D, AHFS 2005 Drug Information*, p. 2320. As stated in the "Notices" section at the beginning of the AHFS, "[b]ecause of the dynamic nature of drug information, readers are advised that decisions regarding drug therapy must be based on the independent judgment of the clinician, changing information about a drug (e.g. as reflected in the literature), and changing medical practices." (Document 148-8).

Similarly, the United States Pharmacopeia Drug Information (USP DI), also a publication that is part of the compendia, states under oral dosage forms/ ziprasidone capsules/ usual pediatric

dose, the "safety and efficacy have not been established." *Affidavit of Bradley S. Foley, Exhibit E, USP DI 2005 edition,* p. 3011. The Physicians' Desk Reference (PDR), 2005 edition, also states that the "safety and effectiveness of ziprasidone in pediatric patients have [sic] not been established." *Affidavit of Bradley S. Foley, Exhibit F, Physicians' Desk Reference*, *2005 Edition,* p. 4. Both the USP DI and PDR contain the similar deference to clinical judgment that is present in the AHFS. *See USP DI, "Descriptions and Limitations of Information,*" (Document 160-2) and *Foreword to the PDR* (Document 135-3). Two publications that are part of the compendia do not preclude the use of Geodon in pediatric patients, and always defer to the clinical judgment of the physician.

Most importantly, Geodon has been on the approved list for reimbursement by Managed Health Services, the Medicaid HMO, as a "preferred medication." *MHS Preferred Drug Lists,*, 2003/2004 edition (Document 153-3, p. 13); April 2006 edition (Document 153-4, p. 14); January 2007 edition (Document 153-5, p. 16).

One last point. The plaintiff received this information about Geodon prescriptions based on discovery provided by the State, *meaning that the State has approved these claims*. As amply documented throughout Dr. King's briefing since remand from the Seventh Circuit, if the State has paid the claim, then that means that the State Medicaid program has approved the reimbursement. The plaintiff cannot present a claim that Dr. King caused to be presented a false claim to Medicaid, when the State has paid the claim.

CONCLUSION

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

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

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

s/ Bradley S. Foley
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