UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

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

Plaintiffs,

v. Case No. 11-CV-236

JENNIFER KING VASSEL,

Defendant.

DEFENDANT JENNIFER KING VASSEL'S MOTION IN LIMINE TO PRECLUDE ANY REFERENCE THAT THE PRESCRIPTION OF OFF-LABEL USE OF FDA APPROVED PRESCRIPTION MEDICATION WAS MEDICAID FRAUD

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

To preclude any reference that the off-label use of federal Food and Drug Administration (FDA) approved prescription medication was Medicaid fraud.[1]

ARGUMENT

I. THE EVIDENCE PRESENTED AND MEDICAID REIMBURSEMENT LAW ESTABLISHES THAT OFF-LABEL USE IS PERMITTED.

Underlying the plaintiff's position that Medicaid should only reimburse for prescription medications that are supported by the compendia is the contention that physicians can never prescribe medications for off-label use for patients covered by Medicaid. This contention has been rejected by a multitude of courts, the field of medicine, and even the publications that comprise the

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[1]The plaintiff acknowledged this question as one of the two primary issues in this case. (Document 145, p. 7). As such, consultation did not occur with the plaintiff's attorneys. *See* (Document 100, p. 4).

compendia.

A. The Plaintiff Admitted that Off-Label Use Occurs.

The plaintiff made a number of significant admissions that acknowledge off-label use is "almost customary" and a recognized part of medical practice in Wisconsin and throughout the country. *Deposition of the Plaintiff* (Document 148-3, pp. 51-52).The plaintiff also admitted that off-label use of prescription medication is actually more common and more widely utilized by physicians than the approved FDA purpose. ***Id.***, p. 52. The plaintiff even admitted that it was up to a psychiatrist to determine the medical indications in a particular case: "It's a clinical judgment within the scope of what's allowable, I guess." ***Id.***, p. 25. The plaintiff further recognized doctors are allowed under the Food, Drug & Cosmetic Act [FDCA] to prescribe for uses that are not specifically addressed by the product labeling and marketing provisions of the FDCA. (Document 145-4, p. 60).

A prescription is approved for reimbursement pursuant to a formulary or prior authorization. *Report of Mr. Olson* (Dr. King's pharmacy expert) (Document 145-1, p. 2); *Affidavit of Dr. King* (Document 132, ¶ 2). The plaintiff agrees with this: "I do know that certain practitioners are given formularies that they are allowed to use or not use certain medications. And so pharmacies, in their systems, they have things that will ping and say, hey, this doctor wrote a prescription for this medication, it's a Medicaid patient, and it will flag saying we can't bill it, don't; the pharmacist will call back to the doctor at the clinic or the [. . .] and say, hey, you wrote this prescription for this, it's not authorized through the program, what else do you want to do. They'll send a new order over and do that. That happens routinely. That happens a lot." (Document 148-3, p. 69). "I mean there are clinics, hospitals and pharmacies that have these formularies that say these are the meds that you're allowed to use [. . . .]" ***Id.***, p. 70.

B. Congress, the FDA, and the Drug Compendia Disclaimers Explicitly State that They Do Not Regulate the Practice Of Medicine, as the Plaintiff Desires to Do With the Prosecution of this Case.

In enacting U.S.C. § 1396r-8(d)(1)(B), Congress stated that this law should not be used to interfere with the judgment of physicians.

> [T]he Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements - *i.e.*, assuring access by Medica[id] beneficiaries to prescription drugs where medically necessary [. . . .] *The bill would not [. . .] alter in any way the current relationships between Medicaid beneficiaries and their physicians or their pharmacists.*

Affidavit of Bradley S. Foley, Exhibit A, H. Rep. No. 881, 101st Congress, 2d Session at 98, reprinted in U.S. Congress and Administrative News, p. 2110 (emphasis added).

The Centers for Medicare and Medicaid Services (CMS) issued a Compendia Clarification to State Medicaid Directors dated May 4, 2006. *U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Medicaid Drug Rebate Program, Release #141, "News for State Medicaid Directors, Compendia Clarification,*" *May 4, 2006*. In that release CMS stated that the "statute [42 U.S.C. § 1396r-8(g)(1)(B)(i)(II)] requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II). Prior approval policies may be put in place, but prior authorization cannot be used to deny the off-label indications supported by citations included or approved for inclusion in the above-referenced compendia." ***Id.*** This is what Dr. King is asserting: that the peer-reviewed medical literature (section (ii)) applies, a section of the statute that the plaintiff ignores.

"FDCA's [Food, Drug, and Cosmetic Act] legislative history expresses a specific intent to prohibit FDA from regulating physicians' practice of medicine." ***Chaney v. Heckler***, 718 F.2d 1174, 1179 (D.C. Cir. 1983)*, reversed on other grounds by* 470 U.S. 821 (1985). This is further evidenced by the introduction to the Physicians' Desk Reference (PDR) and the introductions to the three publications that comprise the formulary. *See* 42 U.S.C. § 1396r-8(g)(1)(B(i)(I-III). The PDR foreword to the 2007 edition states that 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." *PDR Foreword* (Document 135-3).

The publisher of one of the three publications that comprise the compendia, the AHFS formulary, is the American Society of Hospital or Health-System Pharmacists (ASHP). ASHP issued a statement in 1992 that "ASHP supports third-party reimbursement for FDA-approved drug products appropriately prescribed for unlabeled uses." *"ASHP Statement on the Use of Medications for Unlabeled Uses"* (Document 135-5, p. 1). "In many clinical situations, *unlabeled use represents the most appropriate therapy for patients*." ***Id.*** (emphasis added).

More importantly, one of the three publications that comprise the compendia states at the beginning of the publication about the information provided in it:

> The nature of drug information is that it is constantly evolving because of ongoing research and clinical experience and is often subject to interpretation and the uniqueness of each clinical situation and patient. [. . .] Because of the dynamic nature of drug information, readers are advised that decisions regarding drug therapy must be based on the independent judgment of the clinician, changing information about a drug (e.g. as reflected in the literature), and changing medical practices.

AHFS 2006 Drug Information, "Notices" (Document 148-8). Thus it is incorrect for the plaintiff to state the compendia only tracks FDA approved uses.

The other two publications that form the compendia warn that they are not to be solely used for the treatment of patients, but rather ultimately defer to the physician's judgment in treating the patient. The United States Pharmacopeia Drug Information (USP DI) states that it contains "selected information and takes into account practice concerns. [. . . .] Ultimately, the information required is defined by the practice standards of medicine, pharmacy, nursing, dentistry, and the other health professions as well as by the information needs of the patient. **USP-DI is not intended to be 'full disclosure' information.**" *Affidavit of Bradley S. Foley, Exhibit B, USP DI 2005 "Description and Limitations of Information Included"*[2] (emphasis added). Another problem with referring to the USP is that each volume contains multiple versions. ***Id.***

> USP DI comprises three distinct volumes. The first volume, *Drug Information for the Health Care Professional*, includes the drug information monographs arranged in alphabetical order. The Volume I general index includes established names, cross-references by brand names (both U.S. and Canadian), and older non-proprietary names. In addition, an indications index, off-label use indices and appendices presenting categories of use and other useful information are included.
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> The second volume, *Advice for the Patient*, includes the lay language versions of the patient consultation guidelines found in Volume 1. These lay language versions of the patient consultation guidelines found in Volume I. These lay language versions are intended to be used at the discretion of the health care provider as an aid to patient consultation if written information would be of benefit or if it is requested by the prescriber. [. . .]
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> The third volume, *Approved Drug Products and Legal Requirements* is owned and published by USP and Thomson Micromedex is a distributer of that volume. It reproduces information from the Food and Drug Information on therapeutic equivalence and other

[2]The plaintiff has previously noted during the litigation of this case that the USP-DI cannot be located. *Affidavit of Bradley S. Foley, Exhibit C, November 8, 2013 email exchange between an assistant United States Attorney and the plaintiff's attorney.* The plaintiff desires that the USP be relied on by physicians, but he cannot locate a copy of the USP DI. ***Id.***

requirements relating to drug product selection.

Exhibit B, USP DI 2005, "Organization of USP DI."

The USP DI consists of three volumes, of which the plaintiff never indicates which volume to refer. Moreover, the first volume unequivocally states that it does not restrict the practice of medicine, and is to be used within the clinical judgment of the physician or other health care professional.

A second volume of the USP DI could not be located for the years listed in the complaint, but one was obtained for the year 1997. It is assumed that the reference warning contained in the preface is similar to that which would be present in the volumes from 2005-2008, as USP DI volume one maintains.

> **Notice:** The information about the drugs contained herein is general in nature and is intended to be used in consultation with your health care providers. **It is not intended to replace specific instructions or directions or warnings given to you by your physician or other prescriber or accompanying a particular product. The information is selective and it is not claimed that it includes all known precautions, contraindications, effects, or interactions possibly related to the use of the drug.** [. . .] **The information is not sufficient to make an evaluation as to the risks and benefits of taking a particular drug in a particular case and is not medical advice for individual problems and should not alone be relied upon for these purposes.** [. . .]
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> *If any of the information in this book causes you special concern, do not decide against taking any medicine prescribed for you without first checking with your doctor.*

Affidavit of Bradley S. Foley, Exhibit D, USP DI 1997, Volume II, Advice for the Patient, Notice Section (bold emphasis added; italics in original). The USP second volume defers to the clinical judgment of the practitioner.

The Drugdex Information System, accessed through Micromedex, similarly states that it

defers to the clinical judgment of the physician. *Affidavit of Bradley S. Foley, Exhibit E, Micromedex Disclaimer,* p. 2 (as can be seen on the first page of the exhibit)(this is a current disclaimer).

> All treatments or procedures are intended to serve as information resources for a physician or competent health professional performing the consultation or evaluation of a patient and must be interpreted in light of the available indications, contraindications, and other sources of information regarding the patient, only available to such a professional. Although such treatment or procedures are believed to be accurate, NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION ANY WARRANT OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE WHATSOEVER IS MADE REGARDING EITHER DATABASES OF THE SOFTWARE.

Affidavit of Bradley S. Foley, Exhibit E, Drugdex Warranty and Disclaimer (emphasis in original).

Furthermore, the plaintiff admitted that the drugs identified in the complaint[3] are listed on the Managed Health Services (MHS) Preferred Drug List, revised in April 2006. (Document 148-3, Number Three). Being on the MHS Preferred Drug List means MHS has approved the reimbursement regardless of age or diagnosis. Although the plaintiff admitted the above, he disputed that they were "in compliance with" the MHS preferred drug list, yet only cited to a provision discussing non-experimental indications and that medication coverage is limited to that. ***Id.***

The FDA agrees with Dr. King's position. The FDA, in its April 1982 Drug Bulletin, stated that it does not limit a physician's prescription of a medication. "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. [. . .] [A]ccepted medical practice often includes drug use that is not reflected in approved drug labeling." *FDA Drug Bulletin, April 1982* (Document 135-2,

[3]The plaintiff has raised the prescription of Geodon for the first time less than 20 days ago. Geodon, however, has also been on the MHS Preferred Drug List.

p. 5)(emphasis added).[4]

B. Many Courts Throughout the Country Support the Off-Label Use of Prescription Medication.

It is not unlawful for a physician to prescribe a drug for an off-label use. The United States Supreme Court has approved the off-label use of prescription medication. "[O]ff-label use is generally accepted" and under the law, "[p]hysicians may prescribe drugs and devices for off-label uses." ***Buckman Co. v. Plaintiffs Legal Committee***, 531 U.S. 341, 351 & n.5 (2001). "The decision to prescribe such 'off-label usage,' as it is called, is regarded as a professional judgment for the healthcare provider to make." ***Nightingale Home Healthcare, Inc. v. Anodyne Therapy, Inc.***, 589 F.3d 881, 884 (7th Cir. 2009). "[C]ourts and the FDA have recognized the propriety and potential public value of unapproved or off-label drug use." ***United States v. Caronia***, 703 F.3d 149, 153 (2d Cir. 2012).

"[I]t is standard medical practice in the United States for physicians to prescribe FDA-approved drugs in dosages and for medical indications that were not specifically approved - or even**,** contemplated - by the FDA." ***Planned Parenthood of Southwestern Ohio Region v. DeWine***, 696 F.3d 490, 496 (6th Cir. 2012)(citation and quotation marks omitted.) And this is what Dr. King did in her practice, as she testified at her deposition that she uses her best medical judgment in treating a patient, regardless of the compendia. When Dr. King prescribes medication for a patient, she uses her clinical judgment; her knowledge; what is "going on" with the patient; what has worked for the

[4]Wisconsin recognizes this as well. Wis. Admin. Code DHS 108.02 provides that the state Department of Health Services has the authority to establish reimbursement methods, payments, and levels for Wisconsin's Medicaid program services based on various requirements under federal (the minimum levels) and state law, and provides for the use of appointed advisory committees or professionals to provide expertise for the development of service and reimbursement policies.

patient in the past; what is the standard of care in the field of child psychiatry; and discusses all this with the patient and parent to make her decision on prescribing medication. (Document 145-4, p. 33, and pp. 47-48). She sees her job and role as "to provide services to children and adolescents to the best of my ability based on knowledge, standards of care, accepted medical practice. ***Id.***, p. 49. Accepted medical practice, however, does not mean just what was placed on a label by the pharmaceutical manufacturers. ***Id.***, pp. 49-50.

The plaintiff's proposed restriction of the practice of medicine would hurt children, usually the last group to participate in clinical studies, and the poor. "Congress would have created havoc in the practice of medicine had it required physicians to follow the expensive and time-consuming procedure of obtaining FDA approval before putting drugs to new uses." ***Chaney***, 718 F.2d at 1180. "[O]ff-label usage is not illegal or even disfavored under federal law. Rather it is an accepted and indeed valuable part of the practice of medicine." ***Riley v. Cordis Corp.***, 625 F.Supp.2d 769, 778 (D. Minn. 2009). "It is generally agreed that off-label prescribing can benefit both individual patients and patient populations as clinical experience leads to the formation of hypotheses to be tested in structured clinical trials." ***In re Zyprexa Products Liability Litigation***, 253 F.R.D. 69, 112 (E.D.N.Y. 2008), *rev'd on other grounds*, 620 F.3d 121 (2d Cir. 2010).

CONCLUSION

Medicaid clearly envisions reimbursement of off-label prescriptions contrary to the plaintiff's assertions. The legislative history establishes that Congress never intended to restrict a party from practicing medicine as long as it is within the standard of care (which is not at issue in this case). Last, the Seventh Circuit, the U.S. Supreme Court, and various district courts around the country have all come to the same conclusion: that the off-label use of prescription medication is not only

valid, but encouraged to further the development of medical science for patients. The plaintiff's view would hinder the treatment for mental health conditions for a patient population that arguably may need it the most: children in families that lack financial resources. Based on the foregoing arguments, defendant Jennifer King Vassel respectfully requests that the Court grant her motion.

Dated at Milwaukee, Wisconsin this 25th day of November, 2013.

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

s/ Bradley S. Foley
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