UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN
MILWAUKEE DIVISION

UNITED STATES OF AMERICA
AND THE STATE OF WISCONSIN,
EX REL. DR. TOBY TYLER WATSON,

Relator-Plaintiff,

Case No. 11-CV-236

v.

Honorable J.P. Stadtmueller

JENNIFER KING VASSEL,

Defendant.

MEMORANDUM OF AMICUS CURIAE WISCONSIN MEDICAL SOCIETY

INTRODUCTION

Wisconsin Medical Society respectfully submits this memorandum as amicus curiae. As more fully set forth in its motion, amicus is the largest physician advocacy organization in the State of Wisconsin, representing over 12,500 members. Amicus thus has an interest in this case, which has the potential to affect the use and prescription of off-label drugs and consequently interfere with the discretion of physicians in treating their patients.

Over a period of almost four years, Defendant Dr. King Vassel ("Dr. King") treated her minor patient in a manner consistent with her obligation to provide competent medical care. Dr. King's treatment decisions were based on her training, experience, and specific knowledge of her patient gained through the patient-

physician relationship. This course of treatment involved the prescription of a number of off-label psychotropic drugs.

The common practice of physicians in prescribing such off-label drugs tends to disprove Relator's necessary claim that Dr. King acted with the intent or reckless disregard required in a False Claims Act case. *See* 31 U.S.C. §3729(b)(1); Wis. Stat. §20.931(d). As explained below, Dr. King's knowledge and actions were in keeping with the medical community's practice of prescribing off-label drugs for patient treatment.

DISCUSSION

Dr. King prescribed drugs here that were warranted by the context: specifically, the symptoms shown by her patient and the results sought. "The [prescription] choice [a physician] makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative." *Reyes v. Wyeth Labs*, 498 F.2d 1264, 1276 (5th Cir. 1974).

Dr. King was treating a minor patient. Because few-FDA labelled drugs are available to physicians in their treatment of children, many physicians also are required to look to off-label medicines for patient care. *See* James M. Beck & Elizabeth D. Azari, "FDA, Off-Label Use and Informed Consent: Debunking Myths and Misconceptions," 53 Food & Drug L.J. 71, 80 (1998); *see also* Samer S. Shah, Matthew Hall, et al., "Off Label Drug Use in Hospitalized Children," 161(3) JAMA Pediatrics 282, 290 (2007) (documenting high frequency of off-label drug prescription for children in hospital for reasons including lack of testing).

In prescribing off-label drugs, a physician prescribes a drug "for uses or in treatment regimens or patient populations that are not included in approved labeling." *Weaver v. Reagen*, 886 F.2d 194, 198 (8th Cir. 1989) (quoting "Use of Approved Drugs for Unlabeled Indications," 12 FDA Drug Bulletin 4 (April 1982)). As the Eighth Circuit explained in *Weaver*, "the fact that the FDA has not approved labeling of a drug for a particular use does not necessarily bear on those uses of the drug that are established within the medical and scientific community as medically appropriate." *Id.*

Dr. King was treating her patient with the knowledge of physicians' widespread practice of prescribing off-label drugs for patient care. The *Physicians' Desk Reference* states that "once a product has been approved for marketing, a physician may choose to prescribe it for uses or in treatment regimens or patient populations that are not included in approved labeling. The FDA also observes that accepted medical practice includes drug use that is not reflected in approved drug labeling." *Physicians' Desk Reference*, Foreword (52d ed. 1998). As the Third Circuit explained in *In re: Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235 (3d Cir. 2012), "[p]rescription drugs frequently have therapeutic uses other than their FDA-approved indications." *Id.* at 239. *See also United States v. Caronia*, 703 F.3d 149, 166 (2d Cir. 2012) ("[o]ff-label drug usage is not unlawful and the FDA's drug approval process generally contemplates that approved drugs will be used in off-label ways"). The United States Supreme Court in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), referring to

medical devices and drugs, put it succinctly: "off-label use is generally accepted." *Id.* at 351 & n.5.

Such off-label drug prescription is especially common when looking at the use of psychotropic drugs. *See* Randall S. Stafford, "Regulating Off-Label Drug Use – Rethinking the Role of the FDA," 358 N. Eng. J. Med. 1427, 1427-1429 (2008); David S. Baldwin and Nick Kushy, "Off-label Prescribing in Psychiatric Practice," 13 Advances in Psychiatric Treatment 414, 414-422 (2007); *see also* "Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes," 27(2) Diabetes Care 596, 596-597 (2004).

This understanding by physicians such as Dr. King that *physicians* reach decisions about treating with off-label drug prescriptions is grounded in the precept that medical judgments are best made by physicians. This is why the FDA is to "regulate . . . without directly interfering with the practice of medicine." *Buckman Co.*, 531 U.S. at 350. And it was the Fourth Circuit's recognition in *Sigma-Tau Pharmaceuticals, Inc. v. Schwetz*, 288 F.3d 141, 147 (4th Cir. 2002), of "the longstanding practice of Congress, the FDA, and the courts not to interfere with physicians' judgments and their prescription of drugs for off-label uses," that caused the court to reject an inquiry into the FDA's approval of generic drugs. The Fourth Circuit did not want its decision to facilitate any interference with off-label use "[i]n light of the ensuing effects on the delivery of health care and drug prices in the country." *Id.*

One of the real "effects on the delivery of health care" of the decision urged by Relator here would be its interference with Dr. King's ability to effectively exercise her medical judgment to treat her patient consistently with medical theory and practice. In situations where the diagnosis and medical evidence support the physician's use of an off-label drug to provide treatment, a physician needs to be able to prescribe an off-label drug. Physicians should not be forced to ignore effective treatments that benefit patients solely because a patient's specific condition is not listed on the FDA-approved label.

Significant illnesses may not be treated effectively or, perhaps, at all. Among other things, the prescription of "[o]ff-label" drugs gives physicians "earlier access to potentially valuable medications" and "permits innovation in clinical practice." Randall S. Stafford, "Regulating Off-Label Drug Use – Rethinking the Role of the FDA," 358 N. Eng. J. Med. 1427, 1427-1429 (2008). In some cases, a physician's prescription of off-label drugs may provide the best care. These cases enjoy the benefit of approaches to medical treatment reported in and supported by medical literature. James M. Beck & Elizabeth D. Azari, "FDA, Off-Label Use and Informed Consent: Debunking Myths and Misconceptions," 53 Food & Drug L. J. at 77. In these circumstances, "[t]he pace of medical discovery invariably runs far ahead of FDA's regulatory machinery, and off-label use is frequently 'state-of-art treatment.'" *Id.* at 79.

Likewise, the result that Dr. King's exercise of medical judgment may be adversely affected by whether her patient seeks Medicaid reimbursement for any

prescriptions should be avoided. As the Eighth Circuit explained in *Weaver*, the "Medicaid statute and regulatory scheme create a presumption in favor of the medical judgment of the attending physician in determining the medical necessity of treatment." 886 F.2d at 200. In many ways, the physician is not the best situated to evaluate medical reimbursement coverage for drugs; that role is more suited to pharmacists, who cause the claims for reimbursement to be submitted and state Medicaid administrators who evaluate the state's own procedures for Medicaid reimbursement. For instance, in the State of Wisconsin, Wis. Adm. Code DHS 108.02(2) empowers the Wisconsin Department of Health Services to establish "reimbursement methods and payment levels" for Wisconsin's Medicaid program services based on various requirements under federal (the minimum levels) and state law. It further provides for the use of appointed advisory committees of professionals who bring "expertise for development of service or reimbursement policies," *id.* at DHS 108.02(3), to do so.

At bottom, the identification of drugs as off-label or as different from "FDA approved indications [was] not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient." *Weaver*, 886 F.2d at 198. Yet that interference seems to be precisely what Relator seeks to accomplish in this suit. Dr. King did not act, as Relator claims, with the knowledge or reckless disregard required under the False Claims Act. Dr. King exercised her medical judgment and prescribed off-label drugs

to treat her patient, consistent with the common practice of physicians to use off-label prescriptions—nothing more.

CONCLUSION

Amicus Medical Society of Wisconsin respectfully submits these observations in support of Defendant, Dr. King.

Respectfully submitted,

_s/ Anne Berleman Kearney___
Anne Berleman Kearney
APPELLATE CONSULTING GROUP
Post Office Box 2145
Milwaukee, Wisconsin 53201-2145
(414) 332-0966
Attorney for Wisconsin Medical Society