

UNITED STATES DISTRICT COURT  
DISTRICT OF SOUTH DAKOTA  
WESTERN DIVISION

BONNIE ROMERO,	)	CIV. 08-5040-JLV
	)	
Plaintiff,	)	
	)	ORDER DENYING
vs.	)	DEFENDANT HANISCH'S
	)	SECOND MOTION FOR
DENISE HANISCH, M.D.; and	)	SUMMARY JUDGMENT
REGIONAL HEALTH	)	
PHYSICIANS, INC., d/b/a	)	
Edgemont Regional Medical	)	
Clinic and Custer Regional	)	
Medical Clinic,	)	
	)	
Defendants.	)	

**INTRODUCTION**

This matter is before the court pursuant to a motion for summary judgment<sup>1</sup> filed by Dr. Denise Hanisch pursuant to Fed. R. Civ. P. 56(b). (Docket 43). Dr. Hanisch, a physician practicing family medicine, alleges that plaintiff has failed to identify an expert witness qualified to testify as to the standard of care applicable in this case and as to whether Dr. Hanisch deviated from the standard of care. Id.; Docket 44 at p. 6. Plaintiff Bonnie Romero resists Dr. Hanisch's motion for summary judgment, arguing that her expert witness, a licensed pharmacist, is qualified to testify as to these issues. (Docket 51). The motion is ripe for adjudication.

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<sup>1</sup>Although this is Dr. Hanisch's second motion for summary judgment, the court will refer to it simply as a motion for summary judgment.

## **FACTS AND PROCEDURAL HISTORY**

The following recitation includes those facts pertinent to Dr. Hanisch's motion for summary judgment. These facts are undisputed by Ms. Romero and Dr. Hanisch and are contained in their respective statements of facts. (Dockets 45, 52, & 60).

In 1999, Ms. Romero and her husband moved near Edgemont, South Dakota. Ms. Romero began treatment with Dr. Hanisch and the Edgemont Regional Medical Clinic. Dr. Hanisch is a licensed physician practicing medicine in South Dakota. At the times alleged in the complaint and up to August of 2006, Dr. Hanisch practiced medicine in Custer and Edgemont, South Dakota.

In September of 2000, Dr. Hanisch prescribed medication to Ms. Romero for the treatment of high cholesterol, a condition known as hyperlipidemia. From September of 2000 until December of 2006, while under the care of Dr. Hanisch, Ms. Romero continued to take a series of medications to treat her hyperlipidemia.

In October of 2004, Dr. Hanisch prescribed a combination of Zetia and Crestor, each to be taken once a day in 10 mg. doses. Two months later, Dr. Hanisch ordered a lipid profile test. Test results from Custer Regional Hospital Laboratory dated December 16, 2004, indicated that Ms. Romero's ALT (alanine transaminase) and HDL (high density lipoprotein) levels were slightly elevated. On July 26, 2005, the Custer

Regional Hospital Laboratory tested Ms. Romero's liver function, but not her lipid profiles. Dr. Hanisch noted on Ms. Romero's chart that "all labs are excellent" and that her liver function and lipids should be retested in a year.

On April 11, 2006, Ms. Romero went to the Edgemont Regional Medical Clinic for an annual physical examination, which included a review of her medications. A blood sample was taken, and Dr. Hanisch informed Ms. Romero that all of her test results were normal.<sup>2</sup> Dr. Hanisch refilled all of Ms. Romero's medications for another year. Dr. Hanisch last treated Ms. Romero on April 11, 2006.

In December of 2006, Ms. Romero became ill while in Wisconsin and was diagnosed with acute hepatitis. Ms. Romero was referred to the Mayo Clinic. Due to failing liver function, Ms. Romero underwent an emergency liver transplant on January 28, 2007.

On April 2, 2008, Ms. Romero filed a complaint in this court against Dr. Hanisch, Regional Health Physicians, Inc., doing business as Custer Regional Medical Clinic and Edgemont Regional Medical Clinic, and Regional Health Network, Inc., doing business as Custer Regional Hospital. (Docket 1). Ms. Romero asserts a claim of negligence against defendants and seeks to recover for alleged economic and non-economic losses, the loss of the ability to enjoy life, and the costs of the lawsuit including prejudgment interest. Id. Each defendant filed a separate answer denying

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<sup>2</sup>Ms. Romero denies that tests were performed as reported by Dr. Hanisch.

liability, asserting affirmative defenses, moving for dismissal of the complaint, demanding a trial by jury, and seeking reimbursement for costs. (Dockets 11, 12, & 17).

On February 20, 2009, Ms. Romero disclosed her one and only expert witness in this case, Dr. Richard Kingston. Dr. Kingston is a licensed pharmacist and clinical toxicologist. Dr. Kingston will testify as to the standard of care applicable to Dr. Hanisch in her care and treatment of Ms. Romero, as to whether Dr. Hanisch breached this standard of care by failing to monitor Ms. Romero's liver functions, and as to whether the statin drugs prescribed by Dr. Hanisch caused Ms. Romero's liver failure.

Dr. Hanisch moved for summary judgment on the ground that Ms. Romero allegedly failed to present any competent expert witness testimony on the standard of care applicable to family practice physicians and on the issue of whether Dr. Hanisch deviated from the standard of care. (Dockets 43 & 44). Dr. Hanisch argues that Dr. Kingston, as a pharmacist, is incompetent *as a matter of law* to testify on these issues as he lacks the necessary training, education, and experience of a family practice physician. (Docket 44 at p. 6). In support of her argument, Dr. Hanisch relies on the following uncontested facts: Dr. Kingston is not a medical doctor; Dr. Kingston is not licensed to practice medicine by any board; Dr. Kingston does not hold medical staff privileges anywhere; Dr. Kingston has never

been licensed to make medical diagnoses or prescribe medications; and Dr. Kingston has never prescribed a statin drug like Crestor or Zetia.

Ms. Romero resists summary judgment. She argues that the Eighth Circuit does not espouse an absolute rule that, as a matter of law, pharmacists cannot testify as to the standard of care applicable to physicians and as to whether a physician deviated from that standard of care. (Docket 51 at p. 2-3). Ms. Romero alleges that Dr. Kingston is qualified to testify as to these issues. Further, Ms. Romero argues that summary judgment is inappropriate because the proper method to assess Dr. Kingston's knowledge, qualifications, and expertise as an expert witness is to conduct a Daubert<sup>3</sup> hearing.

#### **STANDARD OF REVIEW UNDER RULE 56**

Under Fed. R. Civ. P. 56(c), a movant is entitled to summary judgment if the movant can “show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(c)(2). Once the moving party has met its burden, the nonmoving party may not rest on the allegations or denials in the pleadings, but rather must produce affirmative evidence setting forth specific facts showing that a genuine issue of material fact exists. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986). Only disputes over facts that might affect the outcome of the case under the governing substantive law will properly

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<sup>3</sup>Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 597 (1993).

preclude summary judgment. Id. at 248. Accordingly, “the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact.” Id. (emphasis in original).

If a dispute about a material fact is genuine, that is, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party, then summary judgment is not appropriate. Id. However, the moving party is entitled to judgment as a matter of law if “the nonmoving party has failed to make a sufficient showing on an essential element of her case with respect to which she has the burden of proof.” Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). In such a case, “there can be ‘no genuine issue as to any material fact,’ since a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” Id. at 323.

In determining whether summary judgment should issue, the facts and inferences from those facts must be viewed in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587-588 (1986). The key inquiry is “whether the evidence presents a sufficient disagreement to require submission to a jury or whether it is so one-sided that one party must prevail as a matter of law.” Anderson, 477 U.S. at 252.

## DISCUSSION

Federal jurisdiction in this case is based on diversity. In diversity actions, courts apply federal procedural rules, but state substantive law. Sosna v. Binnington, 321 F.3d 742, 744-45 (8th Cir. 2003) (citing Erie Railroad Co. v. Tompkins, 304 U.S. 64, 78 (1938); Potts v. Benjamin, 882 F.2d 1320, 1324 (8th Cir. 1989)). Under South Dakota law, “[t]he negligence standard for doctors is no different than that for other professionals.” Magbuhat v. Kovarik, 382 N.W.2d 43, 46 (S.D. 1986) (additional citations omitted). “The issue on which the jury should be instructed in a medical malpractice action is whether the doctor deviated from the required standard of care.” Id.; see also Schrader v. Tjarks, 522 N.W.2d 205, 210 (S.D.1994) (“In a medical malpractice case, plaintiff has the burden to show whether the doctor deviated from the required standard of care.”) (internal quotation marks and citation omitted). Deviation from the standard of care “is not conditioned on bad faith or the physician’s state of mind at the time of the alleged negligence.” Magbuhat, 382 N.W.2d at 46.

Under South Dakota law, the use of expert witnesses in medical malpractice cases is well established:

The general rule in medical malpractice cases is that negligence must be established by the testimony of medical experts. . . . [A] verdict in a malpractice case based on inferences stemming from speculation and conjecture cannot stand. However, expert evidence is not exclusively required to establish negligence. For example, if a physician operates on a patient’s knee, testimony of lay witnesses could establish that the wrong knee was treated without indulging in speculation and conjecture or knowledge beyond a layperson's realm.

The rule does not exclude the opinions and conclusions of lay witnesses on subjects which are within the common knowledge and comprehension of persons possessed of ordinary education, experience and opportunity.

Id. (internal citations omitted).

In a diversity case, the Federal Rules of Evidence govern the admissibility of evidence, including expert testimony. Sosna, 321 F.3d at 744-45 (citing Potts, 882 F.2d at 1324). Federal Rule of Evidence 702 governs the admissibility of expert testimony and provides as follows:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702.

A district court has “great latitude” in determining whether expert testimony satisfies the admissibility requirements of Rule 702. Allen v. Brown Clinic, P.L.L.P., 531 F.3d 568, 573 (8th Cir. 2008) (citing Craftsmen Limousine, Inc. v. Ford Motor Co., 363 F.3d 761, 776 (8th Cir. 2004)). “Under Rule 702, the trial judge has the gatekeeping responsibility to ‘ensur[e] that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.’” Id. (citing Kumbo Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 141 (1999)); see also Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (“[T]he trial judge must ensure that any and

all scientific testimony or evidence admitted is not only relevant, but reliable.”). To determine if testimony is both reliable and relevant, a district court may evaluate one or all of the following factors: “1) whether the theory or technique can be or has been tested; 2) whether the theory or technique has been subjected to peer review and publication; 3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operation; and 4) whether the theory or technique is generally accepted in the scientific community.” Allen, 531 F.3d at 573-74 (citing Daubert, 509 U.S. at 593-94. “Regardless of what factors are evaluated, the main inquiry is whether the proffered expert’s testimony is sufficiently reliable.” Id. at 574 (citing Unrein v. Timesavers, Inc., 394 F.3d 1008, 1011 (8th Cir. 2005) (“There is no single requirement for admissibility as long as the proffer indicates that the expert evidence is reliable and relevant.”))).

It is with this understanding of the interplay of state and federal law that the court considers Dr. Hanisch’s motion for summary judgment. Dr. Hanisch premises her motion on the argument that Dr. Kingston, *as a matter of law*, is not qualified to testify as an expert in this case. In support of her position, Dr. Hanisch cites to numerous cases from state courts in other circuits. However, the court declines to follow the holdings in these state cases because it is the Federal Rules of Evidence, not state law, that governs the admissibility of expert testimony. This distinction is explained as follows:

. . . [An] issue concerning the scope of Rule 702 concerns its application in a civil action where, under the so-called Erie Doctrine, state substantive law controls. The starting point for analysis is that the Federal Rules of Evidence usually control admissibility issues in such cases because admissibility is generally considered procedural, rather than substantive, in nature. While the Evidence Rules expressly recognize a few exceptions to this general approach, no such exceptions are provided in the rules concerning expert witnesses. Accordingly, many courts have held that Rule 702 governs the admissibility of expert witness testimony even in cases where state substantive law controls under Erie. But state law should control a few issues related to the admissibility of expert testimony that are actually substantive in nature. For example, state law can control where the question is whether expert testimony is relevant. This is because what is “of consequence” under Rule 401 is a function of the applicable state substantive law. For the same reason, state law controls where it makes a precondition to recovery in a medical-malpractice action the proffer of expert testimony to prove an element of the substantive-law claim, such as standard of care or causation. Similarly, state law controls where it limits the relevant standard of medical care to the practice within a given geographic area. . . .

29 Charles Alan Wright & Victor James Gold, Federal Practice and Procedure § 6263 at pp. 202-04 (1997).

In order to resolve Dr. Hanisch’s motion, the court looks to federal law. Neither party suggests nor is the court aware of a bright-line rule within the Eighth Circuit precluding a licensed pharmacist from offering expert testimony on the standard of care applicable to physicians. Few cases within the Eighth Circuit address this precise issue. However, as noted by Ms. Romero, one such case is United States v. Smith, 573 F.3d 639 (8th Cir. 2009).

In Smith, the defendant sold millions of dollars of prescription drugs through Internet websites and spam emails. Id. at 643. Smith required

each customer to complete an online questionnaire that inquired as to the customer's name, address, date of birth, phone number, height, weight, medical conditions, medical allergies, the drugs they wish to receive, and the quantities. Id. Smith employed Philip Mach, M.D., a medical doctor licensed in New Jersey, to issue prescriptions to customers. Id. at 643-44. Dr. Mach issued prescriptions without consulting with customers face-to-face, reviewing medical records, or verifying the limited information provided on the questionnaire. Id. at 644. Each prescription issued stated that it was provided following a "doctor consultation." Id.

Many of these questionnaires lacked the information necessary to issue a valid prescription. Id. Because Smith was not licensed to distribute controlled substances directly, he contracted with small, traditional pharmacies to fill orders for controlled substances like hydrocodone. Id. at 644-45. Dr. Mach issued the prescriptions, and Smith filled the orders for controlled substances via the pharmacies. Id.

Following a federal investigation into Smith's operation, the government indicted Smith on multiple offenses ranging from conspiracy to distribute and dispense controlled substances with a valid prescription to conspiracy to commit money laundering. Id. at 643. A jury convicted Smith on all nine counts of the indictment. Id. at 646. Smith appealed, alleging, among other claims, that the district court erred in admitting expert testimony from a pharmacist, Dr. Carmen Catizone. Id. Smith argued that

Dr. Catizone exceeded the scope of his expertise when he testified as to the standard of care governing the proper method of prescribing controlled substances by medical doctors. Id. at 653.

The Eighth Circuit rejected Smith’s argument, finding that, although Dr. Catizone was not a medical doctor, he was qualified to testify as to the type of information a medical doctor should have to prescribe a drug and as to whether Dr. Mach deviated from the standard of care. Id. In reviewing Dr. Catizone’s impressive credentials, the Eighth Circuit noted that Dr. Catizone’s work with the National Association of Boards of Pharmacy required “working knowledge of what constitutes a valid prescription, and this cannot be divorced from having an awareness as to the quantity and quality of patient information a doctor must have in order to prescribe a particular drug.” Id. at 654 (citing United States v. Jones, 570 F.2d 765, 769 (8th Cir. 1978) (“Dr. Burton testified that before prescribing any drug, a physician must take a medical history and make some physical examination. Witness Burton possesses a Ph.D. in pharmacology. Although not an M.D., his twenty years of teaching at the Washington University Medical School qualifies him as an expert entitled to express an opinion as to medical procedures in prescribing drugs . . . .”); and United States v. Bek, 493 F.3d 790, 797 (7th Cir. 2007) (noting “expert testimony from a pharmacist who explained that [the doctor’s] practices were dangerous and very unusual” and that the doctor “should have conducted

several diagnostic tests and reviewed patients' medical histories before prescribing drugs such as Vicodin”).

The Eighth Circuit cautioned that “there may be instances in which a pharmacist is not qualified to provide expert testimony on the standard of care necessary to prescribe a particular drug.” Id. at 654. However, given Dr. Catizone’s credentials, the court found that he possessed the expertise to testify as an expert witness in the case. Id.

The court acknowledges Dr. Hanisch’s objection that Smith should be “examined critically” because it is a criminal case, not a civil medical malpractice case. However, the Federal Rules of Evidence, including Rule 702, apply in equal measure to criminal and civil cases. Further, Smith simply highlights the fact that the Eighth Circuit does not have an absolute rule prohibiting pharmacists from testifying as expert witnesses in cases involving the alleged malpractice of physicians. It is the qualifications of the expert witness that are important, not his job title or designation, and an examination of case law from other circuits supports this conclusion. See Crisostomo v. Stanley, 857 F.2d 1146, 1153 n. 18 (7th Cir. 1988) (finding “no reason why a witness who is not a medical doctor should be automatically disqualified as a medical expert, if he is otherwise well schooled in the field”) (citing Backes v. Valspar Corp., 783 F.2d 77, 79 (7th Cir. 1986) (nonphysicians can opine on the causes of illness); Dawsey v. Olin Corp., 782 F.2d 1254, 1262 (5th Cir.1986) (nonphysician may testify

about the effects of phosgene)); see also Jenkins v. United States, 307 F.2d 637, 646 (D.C. Cir. 1962) (“The critical factor in respect to admissibility is the actual experience of the witness and the probable probative value of his opinion. The trial judge should make a finding in respect to the individual qualifications of each challenged expert.”).

The court rejects Dr. Hanisch’s argument that Dr. Kingston, *as a matter of law*, is precluded from testifying as an expert witness in this case simply because he is not a medical doctor. The key question is not whether a *pharmacist* can testify as to the issues in this case, but whether *Dr. Kingston* has the requisite knowledge, skill, experience, training, or education to qualify as an expert. Such a question is best resolved by a Daubert hearing, not by summary judgment.

### **CONCLUSION**

In accordance with the above discussion, it is hereby  
ORDERED that Dr. Hanisch’s motion for summary judgment  
(Docket 43) is denied.

Dated May 3, 2010.

BY THE COURT:

/s/ Jeffrey L. Viken

JEFFREY L. VIKEN  
UNITED STATES DISTRICT JUDGE