IN THE COURT OF APPEALS OF TENNESSEE
AT JACKSON
MAY 20, 2004 Session

STEPHANIE DUBOIS v. RADWAN HAYKAL, M.D., ET AL.

Direct Appeal from the Circuit Court for Shelby County
No. 92035-1 T.D. John R. McCarroll, Jr., Judge

No. W2003-01549-COA-R3-CV - Filed November 2, 2004

This appeal arises out of a grant of summary judgment in favor of Appellees in a medical malpractice action. The trial court held a preliminary hearing, without a jury, to determine if Appellant could establish the essential elements of such an action, particularly the element of causation. After Appellant presented her experts' testimony regarding causation for Appellant's medical malpractice action, the trial court granted Appellees' motions for summary judgment. Appellant filed an appeal to this Court, and, for the following reasons, we reverse and remand for further proceedings consistent with this opinion.

Tenn. R. App. P. 3; Appeal as of Right; Judgment of the Circuit Court Reversed and Remanded

ALAN E. HIGHERS, J., delivered the opinion of the court, in which DAVID R. FARMER, J., and HOLLY M. KIRBY, J., joined.

Mimi Phillips, R. H. "Chip" Chockley, Memphis, TN, for Appellant

Michael E. Keeney, John Dotson, Memphis, TN, for Appellee Radwan Haykal, M.D.

Karen S. Koplon, Virginia M. Patterson, Memphis, TN, for Appellee Margaret H. Sauter

R. Douglas Hanson, Memphis, TN, for Appellee Walgreen Co.

OPINION

Facts and Procedural History

In March 1996, Stephanie Dubois ("Dubois" or "Appellant") entered into a physician/patient relationship with Dr. Radwan Haykal ("Haykal"), following her admission for partial hospitalization to Charter Lakeside Hospital. Haykal treated Dubois for post-traumatic stress disorder and bipolar disorder, stemming from Dubois' divorce in the previous year and the developmental problems experienced by her son, Max, who was born with significant birth defects. Dubois began taking Wellbutrin in March 1996 for treatment of her stress. She concluded her treatment with Charter Lakeside Hospital on April 12, 1996, but she continued to see Haykal for further counseling. During the counseling, Dubois informed Haykal she was currently in another monogamous relationship and was taking Norinyl 135, an oral contraceptive. In June 1996, in order to treat Dubois' bipolar disorder, Haykal prescribed for Dubois a drug called Tegretol, traditionally an anticonvulsant with an off-label use to treat bipolar disorder. Dubois subsequently filled her first prescription of Tegretol on June 6, 1996, at a Super D pharmacy. Additionally, Dubois submitted a prescription to be filled for one, 21-pill, 7-day Tegretol prescription at a Walgreen's pharmacy ("Walgreen's") on July 10, 1996, and picked up the Tegretol medication on July 12, 1996. There is no record of Walgreen's filling any other Tegretol prescription for Dubois, and she stated that she utilized a mail order pharmacy to fill any further Tegretol and Wellbutrin prescriptions. Dubois additionally filled her prescriptions for oral contraceptives with Walgreen's on May 20 and August 27, 1996, and there is no record of Walgreen's filling any other oral contraceptive prescription for Dubois during the time frame at issue in this case.

On July 11, 1996, Dubois began a gynecologist/patient relationship with Dr. Robert Sauter ("Sauter" or, collectively with Walgreen's and Haykal, the "Appellees"). Previously, Dubois' gynecologist was Dr. Sharfman, an internist, who had been prescribing Dubois her oral contraceptive, Norinyl 135. However, because of problems related to Dubois' menstrual cycle, Sauter changed Dubois' oral contraceptive prescription to Ortho-Tricyclen. Dubois discovered on December 18, 1996, after missing her period, that she was pregnant, despite her consistent use of oral contraceptives. This was confirmed when she was tested by another gynecologist, Dr. John Austin ("Austin"). Austin reviewed Dubois' medications and informed her that Tegretol could cause birth defects if used during the pregnancy. On December 28, 1996, Dubois had an abortion, primarily to avoid having another child with birth defects. Employees at the abortion clinic further informed Dubois that Tegretol has been known to negatively impact the effectiveness of oral contraceptives.

On December 18, 1997, Dubois filed the instant action in the Shelby County Circuit Court against Haykal, Sauter,[1] and Walgreen's, alleging medical malpractice on the basis that such

[1] On April 12, 2000, after the death of Sauter, a consent order was entered substituting Margaret Sauter, executrix of Sauter's estate, as a party to the lawsuit.

defendants failed to warn Dubois of the interaction between Tegretol and her oral contraceptive.[2] Subsequently, after taking discovery, Haykal, Sauter's estate, and Walgreen's each filed a motion for summary judgment. On May 27, 2003, after reviewing the record and taking testimony from two of Dubois' expert witnesses, the trial court entered an order granting each defendant's motion for summary judgment on the basis that Dubois failed to establish the element of causation as to any defendant. From the record, it appears the trial court determined that Dubois' expert witnesses' testimony on the element of causation was unreliable and, therefore, inadmissible, making a grant of summary judgment in favor of Appellees appropriate. Dubois filed an appeal with this Court and presents the following issue for our review: whether the trial court erred when it determined that Dubois' expert witnesses' testimony on the element of causation was unreliable and granted Appellees motions for summary judgment. For the following reasons, we reverse and remand for further proceedings consistent with this opinion.

Standard of Review

Although this case comes to this Court with the final order granting summary judgment, we must analyze this action under an abuse of discretion standard of review. In this instance, the trial court held a *Daubert/McDaniel* hearing to determine the basis for Appellant's expert witnesses' opinions and the reliability of the research and data upon which they based their opinions. After such hearing, the trial court determined that Appellant's expert witnesses' opinions were inadmissible, and, therefore, granting Appellees summary judgment would be appropriate for a lack of proof of causation. Therefore, we address a question regarding the admissibility, qualifications, relevancy and competency of expert testimony, which is left to the discretion of the trial court. *McDaniel v. CSX Trans., Inc.*, 955 S.W.2d 257, 263 (Tenn. 1997) (citing *State v. Ballard*, 855 S.W.2d 557, 562 (Tenn. 1993)). As such, "[t]he trial court's ruling in this regard may only be overturned if the discretion is arbitrarily exercised or abused." *Id.* (citing *Ballard*, 855 S.W.2d at 562).

Law and Analysis

Appellant argues that the testimony and depositions of Dr. Donald Block ("Block"), an OB/GYN, and Dr. Richard Brown ("Brown"), a clinical pharmacist, sufficiently establish the element of causation and that such expert opinions were based on trustworthy facts and data. Tennessee Rules of Evidence 702 and 703 govern the admissibility of scientific proof for Tennessee courts. Tennessee Rule of Evidence 702 provides:

---

[2] On August 2, 2000, Dubois amended her complaint to add Super D Drugs Acquisition, Co. ("Super D"), Stephen L. Lafrance Holdings, Inc., Stephen L. Lafrance Pharmacy, Inc., SAJ Distributors, Inc., SAJ Enterprises, Inc., M & H Drugs Franchising, Inc., and USA Drugs, Inc. as defendants. Subsequently, the trial court held a hearing on M & H Drug's motion to dismiss or for summary judgment and granted such motion pursuant to the applicable statute of repose and Tenn. R. Civ. P. 54.02. Though the trial court order dismissing Dubois' complaint stated such action was dismissed as against M & H Drug, we presume that such order dismissed the action against all added defendants, because they no longer appear as parties in the record and are not parties to this appeal.

> If scientific, technical, or other specialized knowledge will substantially 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 in the form of an opinion or otherwise.

Tenn. R. Evid. 702 (2004). Tennessee Rule of Evidence 703 states:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence. The court shall disallow testimony in the form of an opinion or inference if the underlying facts or data indicate lack of trustworthiness.

Tenn. R. Evid. 703 (2004).

When performing its "gatekeeping" function of determining whether an expert's opinion is based upon trustworthy underlying facts or data,

> A Tennessee court may consider in determining reliability: (1) whether scientific evidence has been tested and the methodology with which it has been tested; (2) whether the evidence has been subjected to peer review or publication; (3) whether a potential rate of error is known; (4) whether, as formerly required by *Frye* [*v. United States*, 293 F. 1013 (D.C. Cir. 1923)], the evidence is generally accepted in the scientific community; and (5) whether the expert's research in the field has been conducted independent of litigation.

McDaniel, 955 S.W.2d at 265. We note that Tennessee courts are not required to consider these factors and such factors are not exclusive. *Id*.; *Brown v. Crown Equip. Corp.*, No. W2002-02228-COA-R3-CV, 2004 Tenn. App. LEXIS 114, at *10 (Tenn. Ct. App. Feb. 25, 2004). If the scientific evidence is invalid, it will neither substantially assist the trier of fact nor will its underlying facts and data appear to be trustworthy. *McDaniel*, 955 S.W.2d at 265. However, we are mindful that there is no requirement that scientific evidence be generally accepted. *Id*. A trial court does not need to weigh or choose between two legitimate but conflicting scientific opinions, rather it must assure itself that "the opinions are based on relevant scientific methods, processes, and data, and not upon an expert's mere speculation." *Id*. (citing *Joiner v. Gen. Elec. Co.*, 78 F.3d 524, 530 (11th Cir. 1996)).

In order to maintain an action in tort for medical malpractice, a claimant has the burden of proving: (1) the standard of acceptable professional practice in the profession that the defendant practices in the defendant's community or a similar community at the time of the alleged wrongful action; (2) the defendant acted with less than, or failed to act with, ordinary and reasonable care in accordance with such standard; and (3) the claimant's injuries suffered are the proximate result of

the defendant's negligent act or omission. Tenn. Code Ann. § 29-26-115(a) (2000). The Tennessee Code codifies the five common law elements of negligence: duty, breach of duty, causation, proximate cause, and damages. *Kilpatrick v. Bryant*, 868 S.W.2d 594, 598 (Tenn. 1993) (citing *Cardwell v. Bechtol*, 724 S.W.2d 739, 753 (Tenn. 1987); *Dolan v. Cunningham*, 648 S.W.2d 652, 654 (Tenn. Ct. App. 1982)). Without any one of these elements, Appellant's claim for medical malpractice cannot succeed. *Id*. (citing *Bradshaw v. Daniel*, 854 S.W.2d 865, 869 (Tenn. 1993)). Finally, with regard to causation, the Tennessee Supreme Court has stated the following:

> [P]roof of causation equating to a "possibility," a "might have," "may have," "could have," is not sufficient, as a matter of law, to establish the required nexus between the plaintiff's injury and the defendant's tortious conduct by a preponderance of the evidence in a medical malpractice case. Causation in fact is a matter of probability, not possibility, and in a medical malpractice case, such must be shown to a reasonable degree of medical certainty.

Id. at 602 (citing *White v. Methodist Hosp. S.*, 844 S.W.2d 642, 648-49 (Tenn. Ct. App. 1992)).

In this case, the trial court granted summary judgment in favor of the Appellees because Appellant failed to establish, after admittedly presenting all her evidence of causation, that the Tegretol prescription reduced the efficacy of Appellant's oral contraceptives. After our review of the record and for the reasons below, we disagree with the grant of summary judgment.

Appellant presented two expert witnesses to demonstrate the causal nexus between her injury and Appellees' failure to warn her of Tegretol's effects. First, Dr. Brown, a clinical pharmacist, stated that, although he had no experience filling prescriptions of Tegretol and had never personally performed studies on the drug, he explained that his research revealed Tegretol's ability for inducing the liver to produce the enzyme responsible for metabolizing oral contraceptives. He also stated that he was familiar with the oral contraceptives Appellant was prescribed and that, if such oral contraceptives had a stronger concentration of estrogen, Tegretol would likely have had no curtailing effect on the oral contraceptives. Though some of the articles upon which Brown relies state that Carbamazepine, another name for Tegretol, *may* decrease the efficacy of oral contraceptives, numerous other sources state that Tegretol *does* decrease the efficacy of oral contraceptives.[3] Brown

---

[3] Specifically, we note that the following trial exhibits support Brown's conclusion that Tegretol reduced the efficacy of the oral contraceptives: Micromedex(R) (stating "Adverse Effect: decreased contraceptive effectiveness"), Epilepsia, April 2002, "The importance of drug interactions in epilepsy therapy" (stating "[antiepileptic drugs] also enhance the metabolism of many other drugs (e.g., oral contraceptives, antidepressants, and warfarin) so that therapeutic efficacy of coadministered drugs is lost unless the dosage is increased"), Clinical Pharmacokinetics, 2002, "Treatment of epilepsy in women of reproductive age: pharmacokinetic considerations" (stating "[d]rug interactions between enzyme-inducing [antiepileptic drugs] and contraceptives are well documented"), Drug Safety, January-February 1991, "Risk-benefit assessment of anticonvulsants in women of child-bearing potential" (stating "[a]nticonvulsants which are liver enzyme inducers (phenytoin, phenobarbital, primidone and carbamazepine) reduce the efficacy of the oral contraceptive pill"), Advances in Contraception, December 1991, "Oral contraceptive steroids–pharmacological issues of interest to the prescribing physician" (stating "[e]nzyme-inducing agents such as rifampicin, phenobarbitone, phenytoin and carbamazepine reduce blood levels of the [oral contraceptive steroids] leading to contraceptive failure"), (continued...)

testified that many of the articles and abstracts themselves have been published and subjected to peer review. Brown further stated that the interaction between Tegretol and oral contraceptives has been widely known and generally accepted for years. After ruling out the possibility of pill failure or gastrointestinal problems, which affect the body's ability to absorb the oral contraceptives properly, and assuming that Appellant properly took her medication, Brown concluded that, after conducting his research, the Tegretol prescription compromised the therapeutic effects of the oral contraceptives.

Further, Appellant presented the testimony of Dr. Block, an OB/GYN, in order to establish the element of causation. Block explained that oral contraceptives suppress ovulation and produce a cervix mucus which is hostile to sperm penetration. Block further testified that oral contraceptives have a failure rate of less than one percent and that the other notable causes of contraception failure are gastrointestinal problems, such as vomiting or diarrhea, and drug interactions. He stated that it was widely disseminated in the medical community that Tegretol reduces the efficacy of oral contraceptives. Block further stated that, based on his own knowledge, any amount of Tegretol, more likely than not, had an effect on Appellant's oral contraceptives. After ruling out the possibilities of the less than one percent failure rate, which is minimal, and gastrointestinal problems, of which there was no evidence, Block concluded that the Tegretol prescription was more likely than not the cause of Appellant's unplanned pregnancy. *See Wilson v. CSX Trans., Inc.*, No. E2002-00291-COA-R9-CV, 2003 WL 1233536, at *7-8 (Tenn. Ct. App. Mar. 18, 2003) (discussing the testimony of Dr. Nassetta, who determined the most likely source for the cause of a brain tumor). After considering the record as a whole, the qualifications of the expert witnesses, and the data and research upon which they relied, we hold that the trial court erred when it decided to exclude Brown's and Block's testimony relating to causation on the grounds that it would not substantially assist the trier of fact or was untrustworthy.

We note that the trial court awarded summary judgment to Walgreen's on the same basis as Haykal and Sauter: the fact that Appellant failed to establish the element of causation. This Court is mindful that, once a duty has been established, the scope of the duty for a pharmacist is a question

---

[3](...continued)
Mayo Clinic Proceedings, October 1996, "Epilepsy in women" (stating "the contraceptive failure rate increases fourfold if patients are being treated concurrently with enzyme-inducing antiepileptic drugs"), Clinical Pharmacokinetics, June 1990, "Pharmacokinetic Drug Interactions with Oral Contraceptives" (stating "[a] number of anticonvulsants (phenobarbital, phenytoin, carbamazepine) are enzyme-inducing agents and thereby increase the clearance of the oral contraceptive steroids" and "[t]here are pharmacokinetic drug interactions with oral contraceptives of definite clinical relevance (anticonvulsants, rifampicin) because, in the majority of subjects who take the 2 drugs, interaction will occur"), The Journal of the American Medical Association, July 11, 1986, "Use of Oral Contraceptives by Women With Epilepsy" (stating "[f]ailure of oral contraceptives, normally 0.7 per 100 woman-years, increases to 3.1 per 100 woman-years in women taking antiepileptic drugs, which is equivalent to the failure rate for intrauterine devices"), Neurologic Clinics: Epilepsy, May 2001, "Treatment Issues For Women With Epilepsy" (stating "[p]henobarbital, primidone, phenytoin, and carbamazepine also induce the production of sex hormone-binding globulin, further reducing the concentration of unbound (free) progesterone and the likelihood of suppressing ovulation"), Epilepsia, 2002, "The Importance of Drug Interactions in Epilepsy Therapy" (stating "Numerous [antiepileptic drugs] (for example, [carbamazepine], PHT, PB, FBM, OXC, and TPM) increase the metabolism and clearance of oral contraceptives, reducing their contraceptive efficacy, with the potential for unwanted pregnancy").

of fact. *Dooley v. Everett*, 805 S.W.2d 380, 386 (Tenn. Ct. App. 1990). Because the trial court addressed only the element of causation for Haykal, Sauter, and Walgreen's, we are unable to determine whether summary judgment is appropriate on other grounds. Therefore, we reverse the trial court's grant of summary judgment.

Conclusion

For the aforementioned reasons, we reverse the grant of summary judgment in favor of Appellees and remand this case for further proceedings consistent with this opinion. Costs of this appeal are taxed to Appellees, Dr. Radwan Haykal, the estate of Dr. Robert Sauter, and Walgreen Co., for which execution may issue if necessary.

_____

ALAN E. HIGHERS, JUDGE