KIMMIE SERIGNE, INDIVIDUALLY AND LISA SERIGNE, INDIVIDUALLY AND AS NATURAL TUTORS OF THEIR MINOR CHILD, KRISTAL SERIGNE	*	**NO. 2000-CA-0758**
	*	**COURT OF APPEAL**
	*	**FOURTH CIRCUIT**
	*	**STATE OF LOUISIANA**
VERSUS	*	
FRANCES B. IVKER, M.D., BARR LABORATORIES, INC., HENRY SCHEIN, INC., POYTHRESS LABORATORIES, INC., ROXANE LABORATORIES, INC., DANBERRY PHARMACOL, INC., SMITH, KLEIN & FRENCH LABORATORIES, MENLEY & JAMES LABORATORIES, UNITED RESEARCH LABORATORIES, ET AL.,	*	
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<u>CONSOLIDATED WITH:</u>		**<u>CONSOLIDATED WITH:</u>**
KIMMIE SERIGNE, INDIVIDUALLY AND LISA SERIGNE, INDIVIDUALLY AND AS NATURAL TUTORS OF THEIR MINOR CHILD, KRISTAL SERIGNE		**NO. 2000-CA-0759**
VERSUS		
FRANCES B. IVKER, M.D., BARR LABORATORIES, INC., ET AL.		

APPEAL FROM
CIVIL DISTRICT COURT, ORLEANS PARISH
NOS. 86-14778 c/w 88-15339, DIVISION "N-8"
Honorable Ethel Simms Julien, Judge
* * * * * *
Judge Terri F. Love
* * * * * *

(Court composed of Judge Michael E. Kirby, Judge Terri F. Love, Judge Max N. Tobias, Jr.)

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AFFIRME

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Plaintiffs Lisa Serigne, her husband, Kimmie, and their daughter, Kristal, appeal after a trial court judgment in favor of the defendant, Dr. Frances Ivker. For the following reasons, we affirm.

STATEMENT OF THE CASE

On February 5, 1985, Lisa Serigne (Mrs. Serigne) presented to obstetrician-gynecologist Dr. Frances Ivker's (Dr. Ivker) New Orleans East Office. Dr. Ivker determined that Mrs. Serigne was roughly ten to eleven weeks pregnant on her initial visit. During this visit, Mrs. Serigne filled out a form in which she described her medical history. This form contained a checklist for the patient to indicate any existing diseases or conditions. The box in front of epilepsy was checked and Mrs. Serigne wrote in that she had previously taken Dilantin. In addition, Mrs. Serigne stated on the form that she was a smoker. Dr. Ivker then went on to gain further history from the patient and conducted a physical exam. She advised the patient on the harms of smoking and scheduled a second visit to take place four weeks later. These facts are not in dispute.

There is a dispute, however, over what other information was conveyed to the doctor during that initial visit. The plaintiffs contend that Mrs. Serigne gave the following history. Mrs. Serigne was treated as a child

for four or five “fainting spells” between the fourth grade and age sixteen. At age sixteen, Mrs. Serigne saw an internist and later a neurologist for treatment of the spells. She was given an EEG which indicated some abnormal electrical activity in the brain. The plaintiffs further claim that although there was no diagnosis of epilepsy, she was placed on Dilantin in an abundance of caution.

Mrs. Serigne took the Dilantin initially, but stopped taking the medication after only two months because of the side effects. She was not taking medication during her first pregnancy, which was without complications. She was, also, not taking medication at the time of her February 1985 visit to Dr. Ivker. Mrs. Serigne contends that she informed the doctor that she had an “incident” after being struck on the head by her son. She became light headed and then collapsed. With this history as the basis, Dr. Ivker prescribed phenobarbital to Mrs. Serigne during her second visit. Mrs. Serigne claims that Dr. Ivker did not disclose the risks of birth defects to her at that time.

The defendant, Dr. Ivker, acknowledges that Mrs. Serigne discussed taking Dilantin with her, but presents the following facts. Dr. Ivker claims that Mrs. Serigne told her that she stopped taking the Dilantin in 1981, at age 18. She stopped because of her first pregnancy at the request of her OB-

GYN because of the risks of the medication to the baby. Though she had a normal pregnancy, Mrs. Serigne reported to Dr. Ivker that she had experienced palpitations and parathesis (numbness of the limbs) during this first pregnancy. When asked when her last seizure was, the patient responded that it was in September of 1984, six months before she reported to Dr. Ivker for her second pregnancy.

Dr. Ivker testified that it was necessary to treat the patient with medication for the epilepsy. After conducting a risk/benefit analysis, she determined it was necessary to wait until a subsequent visit so that organogenesis (primary organ development) would have occurred in the fetus and there would be no threat to the baby. Dr. Ivker contends that she discussed the risks with Mrs. Serigne during her second visit, which was at fourteen weeks. Mrs. Serigne demonstrated concern because she had previously been on Dilantin. Dr. Ivker informed Mrs. Serigne that phenobarbital was safer than Dilantin and that there was no known threat of abnormalities in humans. The doctor then placed Mrs. Serigne on a low, but therapeutic dose of phenobarbital.

The parties do not dispute that in June 1985, Mrs. Serigne was admitted into the emergency room after reporting to Dr. Ivker that she had experienced dizziness and tightness in her chest. Mrs. Serigne had stopped

taking the medication two weeks prior because she was afraid of the effect it would have on the baby. Dr. Ivker met her in the emergency room and determined that Mrs. Serigne required a double dose of phenobarbital and informed her that with time, her symptoms would be relieved.

Several days after the visit to the emergency room, Mrs. Serigne went to her regularly scheduled appointment with Dr. Ivker. During that visit, Dr. Ivker found Mrs. Serigne to be anemic and therefore gave her iron shots and increased her dosage of folic acid. Dr. Ivker continued to see the patient regularly and measured the fundal height of the fetus during each visit. Between the 34th and 37th weeks the fundal height had decreased by two inches. Concerned about the change in height, Dr. Ivker conducted a vaginal exam. She found that the baby's position had shifted, thus, the drop in fundal height was normal. At 39 weeks, the fundal height had increased showing that the baby was still growing.

When Kristal was born on August 17, 1985, the hospital reported her as being small, but normal, at birth. However, Kristal did not open her eyes or eat for three days and did not cry for three months. Furthermore, in the months following her birth, Kristal was not growing. Following testing, it was discovered that Kristal was missing a portion of her cerebellum. Consequently, she was diagnosed as mentally retarded.

In accordance with the requirements of the Louisiana Medical Malpractice Act, the plaintiffs convened a medical review panel in April of 1988. After hearing the evidence presented by both sides, the review panel found in favor of the defendant. The panel found that that Dr. Ivker had not breached the standard of care for an obstetrician-gynecologist in the area in the manner in which she treated Mrs. Serigne. The plaintiffs then filed the instant lawsuit.

At the conclusion of trial, the judge found in favor of the defendant. The judge determined that the plaintiffs did not show by a preponderance of the evidence that phenobarbital caused Kristal's abnormalities, but that there was significant evidence in the record to support the fact that Kristal's problems were genetic.

DISCUSSION

Louisiana has set out the requirements to sustain a cause of action in medical malpractice in Louisiana Revised Statute 9:2794. The plaintiff must initially demonstrate what degree of knowledge or skill is required by doctors in the same practice area in a similar locale. La. Rev. Stat. 9:2794 (A)(1). The plaintiff must then show that the defendant lacked or failed to utilize that standard of care. La. Rev. Stat. 9:2794(A)(2). Finally, the plaintiff must show that the defendant's conduct was the proximate cause of

the plaintiff's injury. La. Rev. Stat. 9:2794(A)(3). Giammanchere v. Ernst, 96-2458 (La. App. 4 Cir., 05/19/99), 742 So.2d 572, 575. Each element must be proven by a preponderance of the evidence. Martin v. East Jefferson General Hospital, 582 So.2d 1272, 1276 (La. 1991).

Determinations of the requisite level of skill required, whether there has been a breach and causation, are findings of fact and should only be reversed upon a finding of manifest error. Martin, 582 So.2d at 1276. The appellate court may only reverse if "(1) the record reflects no reasonable factual basis for the trial court's finding, and (2) the record establishes that the finding is clearly wrong." Giammanchere, 742 So.2d at 575 (citing Baumeister v. Plunkett, 95-2270 (La. 5/21/96), 673 So.2d 994, 998).

STANDARD OF CARE

The plaintiffs first argue that the trial court erred by finding that the defendant did not breach the standard of care. This court has set out the standard as follows:

> "A physician's duty is to exercise the degree of skill ordinarily employed by his professional peers under similar circumstances. The law does not require absolute precision in medical diagnoses. Acts of professional judgment are evaluated in terms of reasonableness under the circumstances then existing, not in terms of the result or in light of subsequent events."

Slavich v. Knox, 99-1540 (La.App. 4 Cir. 12/28/99), 750 So.2d 301,

303; Soteropulos v. Schmidt, 556 So.2d 276, 278 (La. App. 4 Cir. 1990); Jackson v. Huang, 514 So.2d 727 (La. App. 2 Cir. 1987).

Expert testimony of professionals in the field is necessary to help the court determine what the standard was at the time in question and whether there has been a breach. Descent v. Administrators of Tulane Educational Fund, 95-2127 (La. App. 4 Cir. 1/21/98), 706 So.2d 618, 628. Expert witnesses often disagree as to the standard of care applicable to a case. The amount of weight given to a particular expert's testimony depends on the qualifications and experience of the expert and on any studies used by the expert to render an opinion. Williams v. Robinson, 98-3016 (La. App. 4 Cir. 5/31/00), 765 So.2d 400, 407 (citing Moore v. Willis-Knighton Medical Center, 31,203 (La. App. 2 Cir. 10/28/98), 720 So.2d 425, 428, 429). When such a disagreement occurs, the trial court's determination is given a great deal of deference. Jackson v. State Through Charity Hosp. of Louisiana at New Orleans, 94-2090 (La.App. 4 Cir. 5/16/95), 655 So.2d 795, 797.

The plaintiffs assert that the defendant breached the standard of care in several ways. First, the plaintiffs claim that Dr. Ivker should have obtained Mrs. Serigne's previous medical records and then referred her to a neurologist for a determination of epilepsy. Plaintiffs called Dr. Grant Bagley, an OB-GYN, and Dr. Brian Bertucci, a family practice specialist, to

establish the standard of care requisite in relying on patient history and patient referral. Dr. Bagley testified that a prudent OB-GYN would not rely completely on the history given by the patient. He claimed that it was necessary to conduct further inquiry by consulting the previous medical records and/or contacting the diagnosing physician. Dr. Bagley further opined that he would be inclined to advise the patient to see a specialist. Dr. Bertucci testified that it would be necessary to refer the patient to a neurologist if she had not been on medication and had not had a seizure in quite some time. Dr. Bertucci testified, however, that ninety percent of diagnosis in the medical profession is made strictly using the patient history. He further testified that a doctor is justified in a belief of the patient's characterizations of his or her disease and his or her symptoms.

The defendant called two experts in obstetrics-gynecology and maternal fetal medicine, both of whom stated that it was not the standard of care to procure records from previous doctors, to contact them, or to refer the patient under the circumstances presented. Dr. Joseph Miller testified that OB-GYNs are primary care doctors and therefore are trained in various areas of medicine. Dr. John Morrison testified that most doctors would not have attempted to obtain medical records with such a specific diagnosis history given by the patient. He also stated that he would not have the

patient go through the unnecessary time and expense of seeing a neurologist.

The plaintiffs next argue that the defendant did not explain the risks associated with ingesting phenobarbital during pregnancy. According to the Louisiana informed consent doctrine, a doctor is required to inform a patient of any of the potential harms of a course or treatment so that the patient can make an informed decision to deny or accept the course of treatment. La. Rev. Stat. 40:1299.40. Morris v. Ferris, 95-1790 (La. App. 4 Cir. 2/15/96), 669 So.2d 1316, 1327. Both Dr. Ivker and Mrs. Serigne testified that there was a discussion of the risks involved with the phenobarbital. Dr. Ivker believed that there were none after the first trimester and withheld the medication until such time as organogenesis had passed. Dr. Ivker further explained that the risk of having a seizure was much more dangerous than any possible effects of the drug after the first trimester. A seizure increases the chance of falling or fainting. Fainting would cause a decrease in the mother's blood flow and cause a lack of oxygen to be sent to the baby. Neither side disputes that this conversation occurred or that Mrs. Serigne decided to take the medicine thereafter.

The thrust of plaintiffs' argument is that Dr. Ivker was unaware of the risks associated with the phenobarbital and as a result, failed to inform them of the potential consequences of taking the drug. The plaintiffs contend that

it was widely known in 1985 that phenobarbital was a significant factor in causing birth defects. Plaintiffs, first, placed into evidence the package insert, which states that the drug should not be used in pregnant women. The plaintiffs also placed into evidence information from the Physician's Desk Reference that the Food and Drug Administration (FDA) warned that there was positive evidence of birth defects in children born of mothers taking phenobarbital. The FDA, however, approved the use of the medication for use in life-threatening situations despite the risk.

Toxicologist Thomas Schrager testified for the plaintiffs that there was some clinical data in 1985 reflecting the possibility of developmental toxicity and the threat of teratogenic effects posed by exposure to phenobarbital. He believed that phenobarbital could cause developmental defects throughout the development of the fetus. Because of the potential for harm to the fetus, Dr. Schrager testified that it is necessary for the treating doctor to perform a risk analysis before prescribing the medication.

The plaintiffs, also, argue phenobarbital should not have been prescribed because it was unnecessary. Both sets of experts agree that phenobarbital should not have been prescribed if there was no seizure activity within two years. There is much controversy as to whether the September 1984 incident was actually a seizure. Regardless of whether it

was or not, Mrs. Serigne characterized it as such. Relying upon Mrs. Serigne's characterization of the incident, Dr. Ivker believed that Mrs. Serigne was actively seizing and there was a potential for risk of a seizure during pregnancy.

Toxicologist David Benjamin, testifying on behalf of the plaintiffs, stated that it would be necessary to perform a risk-benefit analysis because no medication should be prescribed during pregnancy unless essential. Dr. Benjamin also believed that women who receive phenobarbital during pregnancy have a two- to three-fold increase in the relative risk of the child being born with malformations. He testified that there were studies available in 1985 to show that anti-convulsants were not safe to be taken during pregnancy. Most of these studies lumped together many of the anti-convulsant drugs and there was no showing that by 1985 sufficient studies had been conducted isolating the effects of phenobarbital.

Dr. Ivker testified that she conducted a risk-benefit analysis. She believed that the risk associated with a possible seizure would be greater to the mother and child than exposure to phenobarbital after organogenesis. The defendant decided to use phenobarbital as opposed to another anti-convulsant because it was believed in the industry that the drug was the safest on the market for pregnant women.

The plaintiffs finally argue that Dr. Ivker breached the standard of care in her follow-up of Mrs. Serigne during her pregnancy. Dr. Bagley testified that he would have more closely monitored the patient after placing her on phenobarbital because her pregnancy was a high-risk. He relayed that it was standard practice to prescribe a large dose of folic acid to replace the deficiency created by the medication. He was unsure, however, about the standard practice for conducting an ultrasound.

Dr. Miller, defendant's expert, testified that he would not have considered Mrs. Serigne a high-risk pregnancy. She showed no signs of distress during her pregnancy, so the fact that she was on medication would not elevate her to high risk. Dr. Miller also testified that he believed that Dr. Ivker adequately compensated for the folate deficiency created by the phenobarbital. She prescribed prenatal vitamins, which contained 1-mg of folic acid. In addition, she prescribed an additional dose of 1-mg, which she later increased to 2-mg. Finally, Dr. Miller testified that although ultrasounds are conducted regularly now, this was not the case in 1985.

The trial court's determination that there was not a breach of the standard of care is a factual finding subject to the manifest error standard. Barre v. Nadell, 94-1883 (La. App. Cir. 4 06/07/95), 657 So.2d 514. If the trial court's determination is reasonable in light of testimony adduced at

trial, the appellate court may not reverse, even if it would have come to a contrary result. Martin v. East Jefferson Hospital, 582 So.2d 1272, 1277 (La. 1991) (quoting Sistler v. Liberty Mutual Ins. Co., 558 So.2d 1106, 1112 (La. 1990)).

The trial judge listened to nine days of testimony and also had the opportunity to observe the demeanor of the witnesses over a nine-day period. In all, the trial judge listened to the testimony of 15 expert witnesses and ultimately concluded that Dr. Ivker did not breach the standard of care. When evaluating expert testimony, the trial court judge measures the value of such based upon the qualifications and experience of the expert. See Moore, 720 So.2d 425,428. As a court of review, we are obligated to defer to the judgment of the trial court judge in his assessment of expert testimony. See Jackson, 655 So.2d 795, 797. Furthermore, in reviewing the trial court judge's determinations, we are further bound by the guidelines that a court of appeal may not set aside a trial court's finding of fact in the absence of "manifest error" or unless it is "clearly wrong." Rossell v. ESCO, 549 So.2d 840 (La. 1989). Thus, in order to reverse a trial court's finding of facts, an appellate court must first determine, after reviewing the record in its entirety, that a reasonable factual basis does not exist for the finding and that the record establishes that it is clearly wrong. Mart v. Hill, 505 So.2d 1120 (La.

1987). Abiding by the foregoing precepts, we cannot say that the trial court was in error for making a factual determination that Kristal's ailments were not caused by the phenobarbital. The trial judge was presented with testimony and evidence supporting two contradictory opinions about Dr. Ivker's medical service. Justifiably, the trial court judge merely determined that the testimony and evidence submitted at trial supported one viewpoint more than the other – that Dr. Ivker did not violate the acceptable standard of care. We fail to find that there was an absence of factual support for this determination. Notably, the testimony in the record supporting the trial judge's decision revealed that it was not the standard of care to obtain records from previous doctors or to refer a patient in Mrs. Serigne's condition to a specialist. Furthermore, additional testimony also elicited that Dr. Ivker sufficiently informed Mrs. Serigne of the risks associated with phenobarbital. Accordingly, we find nothing in the record to demonstrate that the trial judge's finding was clearly wrong, as there exists ample testimony and evidence to support this determination.

CAUSATION

The plaintiffs additionally assign error to the judge's finding there was a genetic link to Kristal's disorder and therefore phenobarbital was not the cause. Plaintiffs argue in their brief that the defendant did not prove that

Kristal's condition was genetic. As stated previously, the plaintiffs have the burden of proof in causation, not the defendant. The plaintiffs were required to show that it was more probable than not the defendant's actions caused her injury. Bartley v. Pailet, 527 So.2d 430 (La. App. 4 Cir. 1988) (citing Coleman v. Touro Infirmary of New Orleans, 506 So.2d 571 (La. App. 4 Cir. 1987)). Therefore, the plaintiffs had the burden to prove that phenobarbital was more probable than not the cause of Kristal's condition.

Dr. Schrager opined that something is the cause when the removal of a certain agent reduces the presence of a certain affect. That agent would be considered a causal agent. Doctors base their opinions on personal experience and research and different doctors often disagree. However, opinions over time become so widely accepted in the medical community that they are considered fact. Obiago v. Merrell-National Laboratory, Inc., 560 So.2d 625 (La. App. 4 Cir. 1990).

After conducting a hazard assessment and a review of the literature, Dr. Schrager concluded that phenobarbital caused Kristal's illness. The literature he relied upon gave a list of conditions that have been associated with phenobarbital exposure. On cross-examination, Dr. Schrager listed a short nose, low set ears and distal digital hypoplasia as examples of such conditions. He noted that Kristal Serigne does not suffer from any of these

features.

The defendant called clinical geneticist, Dr. Yves Lacassie. Kristal's parents brought her in to see Dr. Lacassie in 1991 to determine the cause of Kristal's condition. He informed the Serignes that phenobarbital was likely not the cause of Kristal's condition. He believed she suffered from a genetic disorder and wanted to conduct more tests. The plaintiffs did not return until 1998. Kristal's pediatric neurologist suggested they return for more testing because she believed Kristal suffered from a form of congenital microcephaly and retardation. Dr. Lacassie testified that he continued to believe that Kristal's symptoms more closely resembled a genetic disorder, Dandy-Walker syndrome. Though the doctor could not pinpoint the exact genetic nature of the condition, he continued to believe phenobarbital could not be the cause.

The plaintiffs called a rebuttal witness, Dr. William Dobyns. Dr. Dobyns testified by deposition that he believed that Kristal likely suffered from pontocerebellar hypoplasia, a non-genetic form of the disorder. After reviewing the medical records, Dr. Dobyns concluded that phenobarbital was the best explanation of the possibilities given and was in fact the cause.

In order to show causation, the plaintiff has to prove that the defendant's conduct increased the risk of harm such that it is a substantial

factor causing the injury. Hastings v. Baton Rouge General Hospital, 498 So.2d 713, 720 (La. 1986). The trial judge determined that Dr. Ivker's conduct was not a substantial factor in the harm to Kristal. Causation is also a fact finding that cannot be reversed unless there is manifest error. Martin, 582 So.2d 1272.

After hearing the testimony and reviewing the testimony of Dr. Dobyns, the trial court found the defendant's expert more convincing. In the reasons for judgment, the trial judge stated that there was more evidence of a genetic source as opposed to the phenobarbital source of Kristal's condition. It is well settled that a trial court's findings of fact will not be disturbed unless the record establishes that a factual, reasonable basis does not exist and the finding is clearly wrong or manifestly erroneous. Syrie v. Schilhab, 96-1027 (La. 5/20/97), 693 So.2d 1173, 1176. After a review of the record, we are not convinced that the trial court was manifestly erroneous in her determination that the plaintiffs failed to prove by a preponderance of the evidence that phenobarbital was the cause.

CONCLUSION

Upon review of the record, we conclude that the trial court judge did not commit manifest error. Therefore, we affirm the judgment of the trial court finding that Dr. Ivker did not commit medical malpractice and that

Kristal Serigne’s condition was not caused by phenobarbital.

AFFIRMED