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Daubert, Kumho Tire, Frye, and *Sandoz*: Expert Opinion in Kansas Courts

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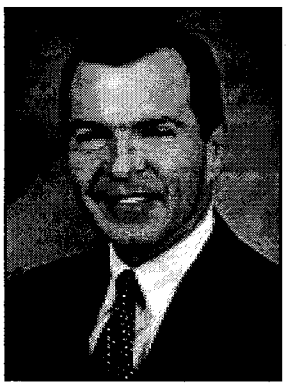

Kansas federal courts deal with expert opinion evidence much differently than do our state district courts. The following discussion, which was first presented at the 2001 Annual Meeting of the Kansas Bar Association, identifies the key elements of the several approaches and comments upon their implications for Kansas defense counsel.

I. The Federal Approach

A. The *Daubert* Factors:

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the United States Supreme Court focused upon the admissibility of scientific expert testimony. Rejecting the *Frye* test, the Court found that Rule 702 requires "evidentiary reliability" before expert testimony may be admitted. The Court identified several factors to be considered: (1) can the theory or technique be tested, and has it been; (2) has the theory or technique been subjected to peer review and publication; (3) in the case of a particular scientific technique, what is the known or potential rate of error and do there exist standards controlling the technique's operation; and (4) does the theory or technique exist within a relevant scientific community, and has it achieved acceptance within that community? The Supreme Court emphasized that the inquiry was to be "a flexible one"; and that the focus "must be solely on principles and methodology, not on the conclusions that they generate." 509 U.S. at 594, 595.

B. Kumho Tire Expands the Reach of *Daubert*

In *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137 (1999), the Supreme Court ruled that the gate keeping obligation articulated in *Daubert* applies not only to "scientific" testimony but to all expert testimony. The Court concluded that a trial court may consider one or more of the *Daubert* factors when doing so will help determine the reliability of the expert testimony. But the Court repeated that the test was "flexible"; and it went on to say that the *Daubert* list of factors "neither necessarily, nor exclusively, apply to all experts or in every case." 526 U.S. at 141.

In *Kumho*, the Plaintiffs rested their case principally upon an expert in tire failure analysis named Dennis Carlson. The Plaintiffs' expert had broad qualifications, including a masters degree in mechanical engineering, ten years work at Michelin, and had testified as a tire failure consultant in other tort cases. The expert's testimony assumed certain background facts about the tire in question - - that the tire had traveled a long way, that its tread depth was significantly warn, and that the tread had at least two punctures which had been inadequately repaired.

Despite the tire's age and history, the plaintiffs' expert opined that a defect in manufacture or design caused the blowout. The expert's conclusion was based upon several things not in dis-

Continued on page 3

Continued from page 1

pute, among them that the tread of the tire had separated from the steel-belted carcass prior to the accident and that the separation caused the blow-out, which lead to the serious injuries of several passengers and the death of another.

The plaintiffs' expert's conclusion that a defect caused the separation rested upon other propositions. Carlson contended that if a separation were not caused by "overdeflection" - - tire misuse involving either under inflating the tire or causing it to carry too much weight, then, ordinarily, the cause was a tire defect. If a tire had been subject to sufficient misuse to cause a separation, it should reveal certain physical symptoms, including: (1) tread wear on the tire's shoulder greater than tread wear along the tire's center; (2) signs of a "bead groove," where the beads have been pushed too hard against the bead seat on the inside of the tire's rim; (3) sidewalls of the tire with physical signs of deterioration, such as discoloration; and/or (4) marks on the tire's rim flange. According to the plaintiffs' expert, if at least two of the four physical signs were not present, a manufacturing or design defect caused the separation.

When Carlson inspected the tire at issue, he found greater wear on the shoulder than in the center, some signs of "bead groove," some discoloration, a few marks on the rim flange, and inadequately filled puncture holes. Nevertheless, Carlson believed that the symptoms were not significant and attempted to explain why they did not reveal "overdeflection." Because he ultimately concluded that the tire did *not* have at least two of the four overdeflection symptoms, and since neither overdeflection nor the punctures caused the blow-out, he concluded a defect must have done so.

The trial court examined the Carlson's methodology in light of the four *Daubert* reliability factors: the theory's testability; whether it was subject to peer review or publication; known or potential rate of error; and the degree of acceptance within the relevant scientific community. The trial court found all four factors argued against the reliability of Carlson's methods, and granted the defendant's motion to exclude the testimony as well as the defendant's accompanying motion for summary judgment.

The Eleventh Circuit reviewed *de novo* what it described as the "district court's legal decision to apply *Daubert*." *Carmichael v. Samyang Tire, Inc*., 131 F.3d 1433, 1435 (1997). It believed the Supreme Court limited its holding in *Daubert* to scientific cases, observing that a *Daubert* analysis applies only where an expert relies on the application of scientific principles rather than on skill or experience-based observation. The Eleventh Circuit concluded that Carlson's testimony, which relied on experience, fell outside the scope of *Daubert*. Therefore, the district court erred as a matter of law in applying *Daubert* to the case. *Id.* at 1436.

In reversing the Eleventh Circuit, the Supreme Court ruled that *Daubert* applied to *all* expert testimony. Turning then to the evidence of the case before it, the Court determined that the expert's testimony was not reliable. It found no indication that other experts in the industry used Carlson's two-factored test or that other tire experts normally made the very fine distinctions about the symmetry of comparatively greater shoulder tread wear that were necessary to support the expert's conclusions. The Court found no articles or papers that validated the expert's approach. Although the expert claimed that his method was accurate, the Court observed that nothing in *Daubert* or the Federal Rules of Evidence required a district court to admit opinion evidence "that is connected to existing data only by the *ipse dixit* of the expert." 526 U.S. at 157. The Court ultimately found that the conclusion reached by the trial court was within its discretion.

II. The Kansas Approach: *Frye* and *Sandoz*

A. *Kuhn v. Sandoz Pharmaceuticals Corporation*, 270 Kan. 443, 14 P.3d 1170 (2000)

THE FACTS

The *Sandoz* case involves a review of the trial court's use of the *Frye* test to strike the plaintiffs' expert causation opinions advanced to explain Jennifer Bishop's ("Bishop) death three days after the delivery of her child. The plaintiffs brought suit against Sandoz Pharmaceuticals Corp. ("Sandoz"), contending that the drug Parlodel, manufactured by Sandoz, caused or contributed to Bishop's death.

In *Sandoz*, Jennifer Bishop gave birth to a son on July 25, 1993, at 7:47 in the morning. Bishop had decided not to breast-feed her baby, and received a tablet of Parlodel at 5:30 p.m. to prevent postpartum lactation. Bishop ran into immediate difficulty. Within 45 minutes of taking Parlodel, Bishop began vomiting, experiencing chills and elevated blood pressure. Within two hours of consuming Parlodel, her temperature increased to 102.3 degrees. By 9:00 p.m., Bishop was drowsy and could not open her left hand on request. At 9:30 p.m., Bishop screamed and then became stiff and less responsive. She remained rigid over the next 30 minutes and only relaxed when given Benadryl. At 10:45 p.m., Bishop was transferred to ICU, where she suffered respiratory arrest and lapsed into a coma. On July 28, Jennifer Bishop died, just days three days after giving birth to a son.

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The plaintiffs contend that the FDA case reports and Sandoz's history with the FDA evidence that the Parlodel ingested by Bishop was the "direct and proximate" cause of the serious bodily injuries resulting in her death.

"THE FDA CONTEXT"

Plaintiffs presented their claim in the context of a decade-long dispute between Sandoz and the FDA concerning the use of Parlodel for the prevention of physiological lactation. The drug Parlodel was first released in 1980. Within three years of its release, Sandoz and the FDA began receiving reports relating the drug to hypertension. As a result of these reports, the FDA requested in 1983 and again in 1985 that Sandoz warn of these adverse experiences. Initially, Sandoz refused. In 1987, however, Sandoz agreed to make the requested labeling changes and to send a "dear doctor letter" alerting doctors to the potential hazards of using Parlodel to prevent lactation. Over the next few years, the FDA continued to receive reports of negative side effects associated with the use of Parlodel in the preven tion of lactation. The FDA committee eventually recommended that Parlodel not be used for lactation suppression and asked that all manufacturers remove the indication from the products. In 1989, the FDA met with Sandoz and informally requested a voluntary withdrawal of the lactation suppression indication, but Sandoz refused. In September 1989, the FDA sent a letter reaffirming its withdrawal request. In October 1989, Sandoz again declined the request for withdrawal. In March 1990, the FDA advised Sandoz it would not approve revised packet inserts and a draft patient brochure concerning lactation suppression. On August 17, 1994, the FDA issued talk paper advising it had initiated procedures for withdrawing approval for the indication. The following day, Sandoz withdrew the Parlodel indication for the prevention of lactation.

THE PLAINTIFFS' CONTENTIONS

The plaintiffs contend that the FDA case reports and Sandoz's history with the FDA evidence that the Parlodel ingested by Bishop was the "direct and proximate" cause of the serious bodily injuries resulting in her death. To support this claim, the plaintiffs rely on the opinions of four medical experts, each of whom opined that the drug Parlodel either caused or contributed to Bishop's death.

THE QUALIFICATIONS OF PLAINTIFFS' EXPERTS

Dr. Al Davies received his M.D. degree from the University of Utah and is Board Certified in internal medicine, and in the sub-specialties of endocrinology and metabolism, and critical care medicine. At that time, Dr. Davies was an Associate Professor in pulmonary and critical care medicine at Baylor College of Medicine, Houston and an Attending Physician in critical care medicine and pulmonary medicine at the Methodist Hospital and Ben Taub General Hospital, Houston. Dr. Davis was an invited reviewer of articles for a number of medical publications, and in 1977, he gave a presentation on Parlodel and its use in microadinoma.

Dr. George R. Saade was a fellow in Maternal Fetal Medicine from 1991 to 1994 at Baylor. Dr. Saade also served as Director of the Obstetrical Clinic at Ben Taub General Hospital in Houston. He was a member of the North American Society for the Study of Hypertension in Pregnancy. According to Dr. Davies, Dr. Saade is one of the people "in the country and, in fact, in the world who knew more about hypertensive disorders in pregnancy than a lot of other doctors and has published on it."

Finally, Dr. Jill Gould received her M.D. degree from the University of Kansas and her post-graduate training focused on forensic pathology. Dr. Gould is Board Certified in anatomical and clinical pathology and in forensic pathology. At the time of her deposition, Dr. Gould was employed as Deputy Coroner for Sedgwick County, Kansas.

THE CAUSATION OPINIONS

In Dr. Gould's opinion, Ms. Bishop had been in an unrecognized, unstable state characterized by elevated blood pressure, proteinuria and hypereflexia, a condition that had been markedly exacerbated by the administration of Parlodel, setting off a chain of events consisting of vasospasm, exacerbation of hypertension, seizures, and resulting cerebral edema.

Dr. Saade opined that Parlodel increased peripheral and intracranial pressures and precipitated the cerebral edema. Dr. Davies concluded that the Parlodel exacerbated a pregnancy-induced hypertension and "in reasonable medical probability" contributed to Ms. Bishop's death.

According to the plaintiffs, the opinions of the experts were based upon the standard medical methodology of "differential diagnosis." Differential diagnosis is defined as "the determination of which of two or more diseases with similar symptoms is the one from which the patient is suffering, by a systematic comparison and contrasting of the clinical findings." *Id.* at 452, 14 P.3d at 1177.

In reaching these opinions, Dr. Gould ruled out bacteria as the likely cause of death. Dr. Saade excluded eclampsia [the occurrence of one or more convulsions, not attributable to other cerebral conditions such as epilepsy or cerebral hemorrhage, in a patient with pre-eclampsia] and infection. Dr. Davies compared symptoms from different diseases and ruled out bacteremia, sepsis, meningitis, an alternative medication, and pre-existing seizure disorder as the causes of death.

Sandoz challenged the causation testimony of the plaintiffs' experts by pointing out that the experts were unable to identify any human study to sup-

port their hypothesis. No epidemiological evidence concluded Parlodel caused cerebral edema. The experts were not aware of any study demonstrating a statistically significant rise in blood pressure associated with the use of Parlodel. The experts admitted there was no epidemiological evidence that a single dose of Parlodel can cause seizure, hypertension or death. And the experts admitted there is no statistically significant epidemiology demonstrating an increased incidence of stroke, seizure, myocardial infarction and hypertension with Parlodel use.

THE DISTRICT COURT'S RULING

The district court granted the defendant's motion for summary judgment because the plaintiffs were unable to establish a general acceptance of the bases for their opinions within the scientific community, as required by the *Frye* test. In reaching this opinion, the district court emphasized a lack of evidentiary support for the methodology and conclusions concerning general causation (i.e., the relationship between Parlodel and cerebral edema). The district court also found that the plaintiffs' experts' opinions failed to establish specific causation - - the relationship between Parlodel and this patient's death.

THE KANSAS SUPREME COURT'S DISCUSSION

The Kansas Supreme, in reversing the trial court, concluded that the *Frye* test was not applicable. According to the court, in Kansas, *Frye* applies "when an expert witness reaches a conclusion by deduction from applying a new or novel scientific principle, formula, or procedure *developed by others*." *Id.* at 457, 14 P.3d at 1179 (emphasis supplied). If a new scientific technique's validity has not been generally accepted or is regarded as experimental, then expert testimony based upon the technique should not be admitted. The validity of an opinion subject to *Frye* is tested by inquiring into its general acceptance within the expert's scientific field. *Id.* at 457, 14 P.3d at 1179-80 (citing *Logerquist v. McVey*, 1 P.3d 113, 132-33 (Ariz. 2000)). Here, the *Frye* test did not apply because the expert testimony was "pure opinion."

"Pure opinion" is a term used by the Kansas Supreme Court to "characterize an expert opinion developed from inductive reasoning based on the expert's own experience, observation, or research." *Id* at 457, 14 P.3d at 1179. A person challenges pure opinion testimony by cross-examination. Considering the applicability of *Frye* to the testimony of Drs. Gould, Saade and Davies, Justice Six repeatedly noted that the plaintiffs' experts in this case "relied on their experience and training." Along the way, the Kansas court gave considerable attention to the Arizona Supreme Court's recent decision in *Logerquist*.

IMPORTANCE OF EPIDEMIOLOGICAL STUDIES

The Kansas Supreme Court chided Sandoz's insistence upon epidemiological results. The court noted that the studies cited by Sandoz as tending to downplay the negative effects of Parlodel were "insufficient to deter the FDA from issuing a formal recommendation that Sandoz withdraw the indication." The court went on to note that "further studies are precluded by the potential harm of the drug on prospective study participants. *Id.* at 466, 14 P.3d at 1185.

KANSAS POLICY CONSIDERATIONS

a. A Kansas jury has a constitutional mandate to decide between conflicting facts, including conflicting opinions of causation. *Kansas Constitution Bill of Rights*, §5.

b. Judges generally are not trained in scientific fields. Like jurors, they are lay persons concerning science.

c. The distinction between pure opinion testimony and testimony relying on scientific technique promotes the right to a jury trial.

Ultimately, as it relates to "pure opinion" testimony, the Kansas Supreme Court believes the jury should deal with it:

"In conclusion, we believe that the adversary process can be trusted to sort out reliable from unreliable evidence. The weight of the evidence is left to the fact finder." *Id.* at 466, 14 P.3d at 1185.

III. *Kumho Tire* Tried In A Kansas District Court

The opinion that Dennis Carlson, Jr. offered against Kumho Tire would have been admitted by a Kansas court following *Sandoz*. The Eleventh Circuit's handling of the trial court decision followed the *Sandoz* approach precisely. It ob-

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served that the testimony relied upon experience-based observation; accordingly, the expert testimony fell outside the scope of *Daubert*.

In his opinion for the court in *Kumho Tire*, Justice Breyer took issue with the 11th Circuit and noted that some of *Daubert's* questions could help to evaluate the reliability "even of experience-based testimony." 526 U.S. at 151. He identified the following questions that would be appropriate for the trial court to ask:

a. How often does the expert's experience-based methodology produce erroneous results?

b. Is the method generally accepted in the relevant engineering or other community?

c. Even if the expertise is based purely on experience ["say, a perfume tester able to distinguish among 140 odors at a sniff"] - - was his preparation of a kind that others in the field would recognize as acceptable? *Id.*

The handling of the evidence in *Kumho Tire* thus stands in stark contrast to the approach taken in Kansas (and in Arizona). The *Logerquist* court in Arizona strongly criticized *Daubert* and *Kumho* in the following language:

Daubert and *Kumho* give the judge authority to preclude evidence because the judge disagrees with the methodology used by the witness or believes the methodology is unreliable or the witness is less credible than the witness produced by the other side. *Kumho*, in other words, permits the judge to engage in the weighing factor. Neither the common law of evidence nor the Federal Rules of Evidence permitted this type of judicial activism. *Logerquist v. McVey*, 196 Ariz. 470, 1 P.3d 113, 132 (2000).

See also *Weisgram v. Marley Co.*, 169 Fed.3d. 514, 525 (8th Cir. 1999): "The plaintiffs' experts base their opinions on personal inspection of the evidence and applying knowledge acquired from training and experience. Their opinions rested on factual support. The district court did not abuse its discretion in determining that their opinions were reliable and could be considered by the jury." (Bright, J., dissenting.) *Weisgram* was later affirmed by the United States Supreme Court at 528 U.S. 440 (2000).

IV. Conclusion

Where does this leave defense counsel in Kansas? We must certainly expect very different results depending upon which court considers the expert opinion. A federal trial court can be counted on to be more demanding. At the beginning, therefore, defense counsel must think much more critically about removal. Not removing will continue to affect convenience for the clients and witnesses, time to trial, the jury pool, time for appeal, cost, and the variety of issues we are familiar with. After *Sandoz*, however, not removing may well make the entire difference between a case that survives summary judgment and one that does not.

Defense counsel can also expect their adversaries to tout *Sandoz* as requiring most expert opinions to go to the jury. It does not, of course; but that will be the argument. The facts of *Sandoz* were compelling, but unusual. A solid familiarity with the *Sandoz* facts will enable a contrast with the facts of the case at issue; and that will assist the court in responding appropriately to opinions that are, at bottom, unreliable. Whether reached through induction, deduction, or alchemy, unreliable opinions have no business in a Kansas courtroom, and we should urge our judges to keep them out.