**Supreme Court of Kansas**

**Gail KUHN, as Special Administrator of the Estate of Jennifer Jean Kuhn Bishop, deceased; Jerry Bishop, Individually as Heir-at-Law of Jennifer Jean Kuhn Bishop, deceased; and Jerry Bishop, as Parent, Natural Guardian and Next Friend of Ryan Thomas Kuhn Bishop, a Minor, Heir-at-Law of Jennifer Jean Kuhn Bishop, deceased, Appellants,**

**v.**

**SANDOZ PHARMACEUTICALS CORPORATION, a Delaware Corporation; Sandoz Ltd., a Foreign Corporation; and Sandoz Pharma Ltd., a Foreign Corporation, Appellees**

**No. 83,226**

Decided Dec. 15, 2000.

Counsel:

Channel P. Townsley, of Hutton & Hutton, of Wichita, argued the cause, and Andrew W. Hutton, of the same firm, was with him on the briefs for appellants.

Joe G. Hollingsworth, of Spriggs & Hollingsworth, of Washington, DC, argued the cause, and Katharine R. Latimer, of the same firm, Wyatt M. Wright, of Foulston & Siefkin L.L.P., of Wichita, and Grant J. Esposito, of Mayer, Brown & Platt, of New York, NY, were with him on the brief for appellees.

SIX, J.:

This case reviews the district court's use of the Frye test, Frye v. U.S., 293 F. 1013 (D.C.Cir.1923), to strike plaintiffs' expert causation opinions advanced to explain a mother's death 3 days after the delivery of her baby. Summary judgment was entered for defendant Sandoz Pharmaceuticals Corporation (Sandoz). The plaintiffs, Gail Kuhn, the mother of Jennifer Kuhn Bishop, deceased, and as Special Administrator of her Estate; Jerry Bishop, the deceased's husband; and Ryan Thomas Kuhn Bishop, the deceased's minor son, appeal.

The plaintiffs' underlying product liability/ negligence suit asserts wrongful death and survivor claims. The plaintiffs contend that the drug Parlodel, manufactured by Sandoz, caused or contributed to Jennifer's death. The district court reasoned that all of plaintiffs' experts' causation opinions and all studies, literature, and other evidence on which plaintiffs' experts relied was unreliable as a matter of law.

Our jurisdiction is under K.S.A. 20-3018(c), a transfer on our order from the Court of Appeals.

We review whether the district court committed error by: (1) granting summary judgment in favor of Sandoz based on the failure of medical causation proof and (2) reasoning that the opinions on causation expressed by plaintiffs' experts failed the Frye test.

Genuine issues of material fact remain. We reverse and remand. The Frye test is not applicable to the expert causation opinions at issue here.

FACTS

Jennifer Bishop gave birth to a baby boy at 7:47 a.m. on July 25, 1993, in the Hays, Kansas, hospital. Because Jennifer had decided not to breast-feed her baby, she received a 2.5 mg. tablet of Parlodel at 5:30 p.m. during dinner on that day to prevent postpartum lactation (the production of breast milk.) She vomited at 6:15 p.m., was overcome by nausea at 6:30 p.m., experienced chills and elevated blood pressure at 6:40 p.m., and vomited again at 7 p.m. By 7:30 p.m., Jennifer's temperature increased to 102.3 degrees Fahrenheit. She vomited again at 7:40 p.m. and continued to complain of a headache and chilling. At 9 p.m., she was drowsy and could not open her left hand on request. At 9:30 p.m., she screamed and became stiff and less responsive. Jennifer remained rigid over the next 30 minutes, relaxing only when she was given Benadryl at 10:13 p.m. At 10:45 p.m., she was transferred to the intensive care unit, suffered a respiratory arrest, and lapsed into a coma. She was

pronounced dead at 3:30 p.m. on July 28, 1993.

The autopsy reported that the probable cause of the death was "related to postpartum eclampsia" or "possible bacteremia." Definitions are appropriate here to assist the reader: "postpartum" ("[a]fter childbirth"), "eclampsia" (the "[o]ccurrence of one or more convulsions, not attributable to other cerebral conditions such as epilepsy or cerebral hemorrhage, in a patient with preeclampsia"), and "bacteremia" (a condition characterized by "viable bacteria in the circulating blood"). Stedman's Medical Dictionary (26th ed.1995), pp. 1413, 540, 181.

The autopsy description of Jennifer's central nervous system stated that sections of the cerebrum and cerebellum showed "hyperemia and some diffuse edema and possible petechial hemorrhage" and that sections of the brain stem "demonstrate[d] softening and mild edema with hyperemia." The following definitions apply: "hyperemia" ("[t]he presence of an increased amount of blood in a part or organ"), "edema" ("[a]n accumulation of an excessive amount of watery fluid in cells, tissues, or serious cavities"), and "petechial" (a condition characterized by "[m]inute hemorrhagic spots, of pinpoint to pinhead size, in the skin"). Stedman's at 824, 544, 1337.

Jennifer's discharge summary listed the final diagnosis regarding her death as "Bacteria with Strep Group D," a condition that brought about "cerebral edema and probable herniation of the brain stem secondary to postpartum toxemia." ("Toxemia" refers to the "[c]linical manifestations observed duringcertain infectious diseases, assumed to be caused by toxins and other noxious substances elaborated by the infectious agent.... A lay term referring to the hypertensive disorders of pregnancy." Stedman's at 1826.) The plaintiffs sued Sandoz, the manufacturer of Parlodel, on July 16, 1996.

DISCUSSION

The FDA Report

Plaintiffs' claim was presented in the context of a decade-long disagreement between Sandoz and the Food and Drug Administration (FDA) concerning the use of Parlodel for the prevention of physiologic lactation. (Parlodel's generic name is bromocriptine.) The FDA originally approved the use in 1980. By 1983, however, both Sandoz and the FDA began receiving reports relating the drug to hypertension or related effects. As a result of these reports, FDA staff members requested in both May 1983 and March 1985, that Sandoz place a warning of the adverse experiences in its labeling.

Initially, Sandoz would not agree to place the requested warning. In February 1987, however, Sandoz agreed to both make the requested labeling changes and to send a letter to doctors alerting them to the potential hazards of using Parlodel for the prevention of lactation.

The FDA continued to receive reports over the next few years of negative side effects associated with the use of Parlodel for the prevention of lactation. The FDA's Fertility and Maternal Health Drugs Advisory Committee considered a comprehensive study by Sandoz on the drug (the ERI study) that downplayed the relationship between Parlodel and the asserted harms. However, the FDA determined that the ERI study: (1) failed to allay concerns regarding the drug's association with seizures and (2) was too small in size to adequately characterize the risk of stroke.

The FDA committee recommended that drugs (including Parlodel) not be used for lactation suppression. The possibility that the products might cause serious adverse experiences in some patients outweighed the limited benefits associated with their use. The FDA agreed with its committee's recommendation and asked that all manufacturers remove the indication for lactation suppression from their drug products.

The FDA met with Sandoz on June 2, 1989, and informally requested a voluntary withdrawal of the lactation suppression indication from Parlodel's labeling. Sandoz declined. Sandoz met again with the FDA on September 7, 1989, to discuss "alternatives" to withdrawal of the indication. The FDA issued a letter on September 13, 1989, that reaffirmed its original withdrawal request.

On October 25, 1989, Sandoz declined the FDA request for withdrawal and announced its position that "Parlodel should not be used routinely but should remain available for specific circumstances under which the physician and the patient decide that the drug is indicated." On March 2, 1990, the FDA advised Sandoz that attempts to gain approval for revised package inserts and a draft patient brochure were "not approvable." The FDA had not changed its opinion "that there is no need for pharmacologic agents to prevent postpartum lactation."

On August 17, 1994, the FDA issued a talk paper stating that it had initiated procedures

for withdrawing approval for the indication. A day later, Sandoz withdrew the Parlodel indication for the prevention of lactation in the United States.

The Plaintiffs' Contentions

The plaintiffs argue that the FDA case reports and Sandoz' history with the FDA tend to show that the 2.5 mg. dose of Parlodel ingested by Jennifer Bishop was a contributing factor as a "direct and proximate cause" of the serious bodily injuries culminating in her death. In support of their contention, plaintiffs refer to the opinions and deposition testimony of four medical experts, each of whom claimed that Parlodel caused or contributed to Jennifer's death. Plaintiffs' counsel stated in the district court and on appeal that the opinion of Dr. Leslie Iffey (one of the four) would not be relied on for causation. Our discussion focuses on the causation opinions of the other three experts.

Plaintiffs' Experts

The qualifications for plaintiffs' causation experts are summarized below.

Dr. Al Davies received his M.D. degree from the University of Utah in 1975. He is Board Certified in internal medicine and in the sub-specialities of endocrinology and metabolism and critical care medicine. Dr. Davies was associated with the Duke University Medical Center from 1975 to 1984. While at Duke, he served as an Associate in Medicine; Assistant Professor of Medicine, Division of Allergy, Critical Care, and Pulmonary Medicine; and Director of the Medical Intensive Care Unit. He currently is Associate Professor in Pulmonary and Critical Care Medicine, Department of Internal Medicine at the Baylor College of Medicine, Houston, Texas (Baylor). He became Assistant Professor of Medicine, Section on Hypertension and Clinical Pharmacology at Baylor. He has concurrent Attending Physician positions in the Critical Care Medicine Group and Pulmonary Medicine Service at The Methodist Hospital (Methodist), Ben Taub General Hospital all located in Houston. He was Attending Physician in the Hypertension and Clinical Pharmacology Service at Methodist and Baylor from 1984 to 1989. He also held the position of Director of the Clinical Pharmacology Invasive Laboratory at Methodist and Baylor until 1987.

In 1990, Dr. Davies became Director of the Critical Care Medicine Training Program at Baylor, as well as Director of the Medical Intensive Care Unit at Methodist. He retains both positions. In 1986, he began an Assistant Professorship in Physiology and Molecular Biophysics in the Department of Physiology and Molecular Biophysics at Baylor, a position he still holds. He is an invited reviewer of articles for a number of medical publications. In 1977, he gave a presentation on Parlodel and its use in microadenomas and associated pituitary illness.

Dr. George R. Saade received his M.D. from the American University of Beirut Medical School in 1985. He began his residency in Obstetrics and Gynecology at the American University of Beirut. Dr. Saade was at Union Memorial Hospital in Baltimore, for 4 years, as a Resident in Obstetrics and Gynecology. He was a Fellow in Maternal Fetal Medicine from 1991 to 1994 at Baylor. In 1993, Dr. Saade accepted a position as Director of the Obstetrical Clinic at Ben Taub General Hospital in Houston. He began directing the Obstetrical Outpatient Services at Baylor in 1994. Also in 1994, he accepted an appointment as Assistant Professor of Obstetrics and Gynecology, Division of Maternal Fetal Medicine at Baylor. In 1995, he began working as Assistant Professor of Pharmacology at Baylor. In 1993, he became eligible for Board Certification in Maternal-Fetal Medicine. Dr. Saade is a member of the Society for Obstetric Anesthesia and Perinatology. He is a member of the North American Society for the Study of Hypertension in Pregnancy. He is also a Junior Fellow for the American College of Obstetricians and Gynecologists.

Dr. Saade has received awards for research excellence from the Society of Perinatal Obstetricians. He retains editorial positions for "Reviews in Maternal-Fetal Medicine," a publication of the Division of Maternal Fetal Medicine at Baylor, and for "Guidelines for the Antepartum Management of the Pregnant Patient with Medical Complications" published by the Division of Maternal-Fetal Medicine of Baylor. He is also a reviewer for the Obstetrics and Gynecology Journal and for the American Journal of Obstetrics and Gynecology. Dr. Davies, when deposed in this case, responded, "Yes, sir," when asked if he was aware that 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."

Dr. Jill Gould received her M.D. degree from the University of Kansas in 1981. She then served an internship and a residency in Pathology at the University of Colorado Health Services Center. She finished her post- graduate training in a fellowship in Forensic Pathology for the Denver County Coroner's Office in Denver, Colorado, and received Board Certification in

Anatomical and Clinical Pathology in 1985 and Board Certification in Forensic Pathology in 1986.

Following her fellowship, between 1986 and 1993, Dr. Gould was employed as a Forensic Pathologist by the County Coroner's Office in three Colorado counties. She also was Medical Examiner and Coroner for Arapahoe County, Colorado. She was Assistant Clinical Professor of Pathology at the University of Colorado Health Sciences Center. In 1994, she was Clinical Assistant Professor in Pathology and Laboratory Medicine for the University of Kansas Medical Center. She later served as Coroner for Douglas, McPherson, and Harvey Counties in Kansas. At the time of her deposition she was employed as Deputy Coroner for Sedgwick County and also was a consultant pathologist in Colorado, Nebraska, Missouri, Wyoming, California, Texas, and Arizona.

The Causation Opinions

We next set out a summation of the causation opinions expressed by plaintiffs' three experts in their reports and depositions. Our ultimate inquiry is, how do the opinions play at the procedural stage of summary judgment?

Dr. Gould opined in her report that Jennifer had been in an "unrecognized, unstable, preeclamptic state characterized by elevated blood pressure, proteinuria, and hyperreflexia," 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."

In Dr. Saade's opinion Parlodel "increased peripheral and intracranial pressures in a patient who already had preeclampsia and precipitated the cerebral edema and its consequences."

Dr. Davies emphasized that "there was sufficient time for the bromocriptine [Parlodel] to have participated in exacerbating [Jennifer's] pregnancy-induced hypertension," concluding that "in reasonable medical probability, Parlodel contributed to Ms. Bishop's death."

The plaintiffs assert that the conclusions of Drs. Gould, Saade, and Davies were based upon the standard medical methodology of "differential diagnosis." Differential diagnosis is defined as "[t]he 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." Stedman's at 474. According to plaintiffs, each of the three experts compared symptoms of different conditions and excluded alternative causes of the cerebral edema during their depositions.

Dr. Gould compared symptoms of various conditions and ruled out various bacteria as the likely cause of Bishop's death, including pneumonia, uterine infection, and infectious meningitis. She reported that: (1) stains revealed no bacteria capable of causing disease, (2) minor signs of an infection were more likely attributable to the respirator than to pneumonia, (3) evidence of a uterine infection was inconsistent with the sort of infection that is usually the cause of a patient's death, and (4) the existence of "pinpoint hemorrhages" in the meninges ruled out the possibility of infectious meningitis.

Dr. Saade compared symptoms of different conditions and excluded both eclampsia and infection from his differential diagnosis. He noted that eclampsia will usually look different from the type of seizure suffered by Jennifer, while the presence of an infection was doubtful because her uterus (the likely source of an infection) evidenced no signs of an infection. Finally, Dr. Davies compared symptoms from different diseases and ruled out bacteremia, sepsis, meningitis, an alternative medication, and a preexisting seizure disorder as the causes of Jennifer's death.

The Sandoz Cross-examination

Sandoz, in countering plaintiffs' causation testimony, claims that plaintiffs' experts: (1) are unable to identify any human study to support their hypotheses, (2) admit that no epidemiological evidence concludes that Parlodel causes cerebral edema; (3) are not aware of any study demonstrating a statistically significant rise in blood pressure associated with the use of Parlodel; (4) admit that there is no epidemiological evidence that a single dose of Parlodel can cause seizure, hypertension, or death; (5) admit there is no statistically significant epidemiology demonstrating an increased incidence of stroke, seizure, myocardial infarction, or hypertension with Parlodel use; and (6) are not aware of any epidemiological studies associating Parlodel with any cardiac events.

Sandoz emphasizes that Jennifer Bishop ingested only a single tablet of Parlodel.

The District Court's Ruling

The district court, in ruling that the plaintiffs failed in their proof of medical causation, observed that plaintiffs' experts testified "using the correct 'magic words' of probability, plaintiffs' expert witnesses improperly offer medical causation opinions concerning Parlodel without general acceptance of the bases for those opinions within the relevant scientific community as required by Canaan and Frye." See State v. Canaan, 265 Kan. 835, 848- 49, 964 P.2d 681 (1998); Frye v. United States, 293 F. 1013 (D.C.Cir.1923).

The district court emphasized a lack of evidentiary support for the methodology and conclusions of plaintiffs' experts' opinions concerning general causation. Thus, plaintiffs were prevented from meeting their burden of establishing that the opinions were "generally accepted as reliable within the relevant scientific community." In addition, the district court noted that "the studies, literature and other evidence upon which plaintiffs' experts purport to rely for their general causation opinions concerning the alleged causal relationship between Parlodel and serious injuries are not sufficient legally reliable support for such opinions." The district court decided that a lack of evidentiary support for the experts' opinions concerning a specific causation prevented the plaintiffs from sustaining their burden of proving that these opinions were "generally accepted as reliable within the relevant scientific community."

The district court acknowledged, in dismissing plaintiffs' case with prejudice, that several pending motions were rendered moot by the causation ruling.

Summary Judgment

Before moving onto our analysis of Frye's application here, a comment on summary judgment is in order. Summary judgment is appropriate if there are no genuine issues of material fact and the movant is entitled to judgment as a matter of law. K.S.A. 60-256(c). Summary judgment decisions are reviewed de novo. See Mark Twain Kansas City Bank v. Kroh Bros. Dev. Co., 250 Kan. 754, Syl.§ 2, 863 P.2d 355 (1992). We resolve all facts and inferences which may reasonably be drawn from the evidence in favor of the party against whom the ruling is sought. Bergstrom v. Noah, 266 Kan. 847, 871, 974 P.2d 531 (1999).

The essential facts here are documented in the parties' summary judgment submissions. Our standard of reviewing summary judgment is well established. See e.g., Mitzner v. State Dept. of SRS, 257 Kan. 258, 260-61, 891 P.2d 435 (1995). We conclude that genuine issues of material fact regarding the cause of Jennifer's death remain.

The Frye Test

In Kansas, the admissibility of expert testimony is subject to K.S.A. 60-456(b). The Frye test, however, acts as a qualification to the 60-456(b) statutory standard. Frye is applied in circumstances where a new or experimental scientific technique is employed by an expert witness. Canaan, 265 Kan. at 848, 964 P.2d 681.

We next undertake the analysis that leads us to the conclusion that Frye is not applicable here.

We adopted the Frye test in State v. Lowry, 163 Kan. 622, 629, 185 P.2d 147 (1947). Frye requires that before expert scientific opinion may be received into evidence, the basis of the opinion must be shown to be generally accepted as reliable within the expert's particular scientific field. If a new scientific technique's validity has not been generally accepted or is only regarded as an experimental technique, then expert testimony based upon the technique should not be admitted. Canaan, 265 Kan. at 848, 964 P.2d 681. In State v. Washington, 229 Kan. 47, 54, 622 P.2d 986 (1981), we identified the purpose of the Frye test:

" 'Frye was deliberately intended to interpose a substantial obstacle to the unrestrained admission of evidence based upon new scientific principles.... Several reasons founded in logic and common sense support a posture of judicial caution in this area. Lay jurors tend to give considerable weight to "scientific" evidence when presented by "experts" with impressive credentials. We have acknowledged the existence of a "... misleading aura of certainty which often envelopes a new scientific process, obscuring its currently experimental nature." ' " (Quoting People v. Kelly, 17 Cal.3d 24, 31-32, 130 Cal.Rptr. 144, 549 P.2d 1240 [1976].)

The district court here determined that: (1) Frye applied, and (2) plaintiffs' expert's opinions failed to meet Frye's foundational requirements. The experts' opinions failed to prove both general causation (the relationship between Parlodel and cerebral edema) and specific causation (the relationship between Parlodel and Jennifer's death).

The district court's use of Frye to dismiss plaintiffs' case with prejudice generates four questions: (1) What is our standard of review? (2) Does the expert testimony here fall under the "pure opinion" exception to the Frye test? (The term "pure opinion" was used in

Florida Power & Light Co. v. Tursi, 729 So.2d 995, 997 [Fla. Dist.App.1999], discussed later in our opinion.) (3) Is differential diagnosis a "generally accepted" means of determining legal causation within the relevant scientific community? (4) Did the district court err in excluding all studies, reports, and literature upon which the plaintiffs' experts relied?

Our review of these four inquiries leads to the conclusion that plaintiffs' expert causation testimony is not subject to the Frye test. Our conclusion moots the need to reach a detailed discussion of differential diagnosis.

The Standard of Review

We first examine the appropriate standard for reviewing the district court's decision to strike plaintiffs' expert causation testimony. Sandoz correctly asserts that Kansas law has traditionally called for an abuse of discretion standard in reviewing the legal admissibility of expert testimony under the Frye test. Sandoz relies on Canaan, 265 Kan. at 848-49, 964 P.2d 681. In Canaan, we said that the district court's decision regarding the admissibility of expert testimony "will not be reversed on appeal absent a showing of abuse of discretion." 265 Kan. at 848, 964 P.2d 681.

The plaintiffs concede that an abuse of discretion standard is used in most cases involving the admissibility of scientific evidence, but they argue that de novo review is appropriate here because the district court's failure "to correctly apply the Frye standard" presents an "abstract question of law." We agree. See Baker v. Dalkon Shield Claimants Trust, 156 F.3d 248, 252 (1st Cir.1998).

The parties' disagreement on the standard of review seems rooted in an understandable debate over the nature of the abuse of discretion standard. Although abuse of discretion describes a highly deferential standard, it can refer to questions of law warranting independent appellate review. Questions of law are presented when an appellate court seeks to review the factors and considerations forming a district court's discretionary decision.

We observe that the United States Supreme Court in discussing labels for a standard of review has said:

"Little turns, however, on whether we label review of this particular question abuse of discretion or de novo, for an abuse-of-discretion standard does not mean a mistake of law is beyond appellate correction. A district court by definition abuses its discretion when it makes an error of law. [Citation omitted.] That a [sentencing guideline] departure decision, in an occasional case, may call for a legal determination does not mean, asa consequence, that parts of the review must be labeled de
novo while other parts are labeled an abuse of discretion. [Citation omitted.] The abuse-of- discretion standard includes review to determine that the discretion was not guided by erroneous legal conclusions." Koon v. United States, 518 U.S. 81, 100, 116 S.Ct. 2035, 135 L.Ed.2d 392 (1996).

One commentator, however, seems less convinced that the distinction between the labels is without meaning. Davis, Standards of Review: Judicial Review of Discretionary Decisionmaking; The Journal of Appellate Practice and Process Vol. 2, No. 1, 47, at 70 (Winter 2000). Here, we have a first impression issue on the admission of medical causation proof that warrants our unlimited review. The appropriate label for the standard of review in this case is "de novo."

The "Pure Opinion" Exception

We use the term "pure opinion" to characterize an expert opinion developed from inductive reasoning based on the expert's own *457 experience, observation, or research. See, Florida Power & Light Co., 729 So.2d at 997. The Frye test does not apply to pure opinion testimony. The Frye test does apply when an expert witness reaches a conclusion by deduction from applying a new or novel scientific principal, formula, or procedure developed by others.

The validity of pure opinion is tested by cross-examination of the witness. The validity of an opinion subject to Frye is tested by inquiring into general acceptance as reliable within the expert's particular scientific field. See Logerquist v. McVey, 196 Ariz. 470, 320 Ariz. Adv. Rep. 15, 1 P.3d 113, 132-33 (2000).

We next consider the Frye test's applicability to the testimony of Drs. Gould, Saade, and Davies. The Frye test is concerned with whether the expert's opinion is based on a technique that has earned general acceptance in the expert's scientific field as reliable. Expert testimony based on results of an experimental technique should not be admitted into evidence. Canaan, 265 Kan. at 848, 964 P.2d 681.

A critical question, however, in deciding if Frye applies to expert testimony concerns the precise meaning of the term "technique" for the purposes of applying the test. Sandoz adopts the district court's reasoning and

takes a broad view of the term "technique." The district court, for example, concluded that "the studies literature and other evidence upon which plaintiffs' experts purport to rely" for both their general and specific causation opinions were "not sufficiently legally reliable support for such opinions." Sandoz similarly assumes that the Frye test is applicable without a measured discussion of whether the plaintiffs' experts employed a technique that is subject to the Frye test.

Two foreign cases are of interest in resolving whether the expert opinions at issue here employed a technique or methodology to which the Frye test applies. In the first, Florida Power & Light Co., 729 So.2d 995, an electrical transformer from a utility pole leaked liquid containing a harmful toxin known as polycholorinated bipheyles (PCB's) into the eye of Tursi, a man who happened to be standing under the pole. Tursi developed conjunctivitis, experienced irritation under his skin 6 months later, and developed a cataract 4 years after the incident. Tursi's causation expert, an ophthalmologist who had experience treating thousands of cataract patients, testified that: (1) there were many causes of cataracts, including aging, congenital, x- rays, radiation, exposure to chemicals, and other trauma, (2) chemical agents can cause cataracts, and (3) cataracts can take from weeks to years to develop. The ophthalmologist ruled out a number of other causes of Tursi's cataract because of Tursi's young age (60) and the fact that the cataract only developed in one eye. The expert concluded that within a reasonable medical certainty, the transformer liquid was the cause of Tursi's cataract.

Florida Power and Light Co., the defendant, advancing the Frye test, challenged the district court's decision to admit the ophthalmologist's testimony. The district court determined that the expert testimony had been pure opinion and that the ophthalmologist had not relied on a scientific principle or test; thus, there was no Frye requirement. 729 So.2d at 997. The Florida Power and Light Co. court affirmed and distinguished between pure opinion testimony and testimony relying upon a scientific method or principle:

"[P]ure opinion testimony, such as an expert's opinion that a defendant is incompetent, does not have to meet Frye, because this type of testimony is based on the expert's personal experience and training. While cloaked with the credibility of the expert, this testimony is analyzed by the jury as it analyzes any other personal opinion or factual testimony by a witness." 729 So.2d at 997.

Sandoz argues that Florida Power & Light Co. actually supports the district court's decision here. According to Sandoz, although that opinion determined that pure opinion testimony does not have to meet the Frye test, the expert testimony offered by plaintiffs here must. We disagree.

Like the ophthalmologist in Florida Power & Light Co., plaintiffs' causation experts here relied on their experience and training. The experts opined that alternative causes of Jennifer's death could be excluded from speculation as the likely cause of the cerebral edema.

A similar distinction between opinion testimony and testimony involving scientific methods or procedures is evident in the Arizona Supreme Court's recent decision in Logerquist, 196 Ariz. 470, 1 P.3d 113. Logerquist alleged that her pediatrician, Dr. Danforth, sexually abused her on several occasions between 1971 and 1973, when she was 8 to 10 years old. She contended that she had amnesia about the abuse until 1991, when her memory was triggered by watching a television commercial featuring a pediatrician.

Logerquist sought to introduce evidence that severe childhood trauma can cause a repression that can later be recalled with accuracy. The district court granted the defendant's (Dr. Danforth) motion to subject the evidence to a Frye test hearing. At the hearing, Logerquist's expert witness testified that his experience and observations over many years and the extensive literature on the subject led him to conclude that the repressed memory phenomenon existed in some patients. Dr. Danforth's expert countered that there were serious flaws in the many studies supporting repressed memory. The Danforth expert witness cited other studies finding that trauma usually enhances memory rather than causing amnesia. The district court, applying Frye, excluded Logerquist's expert testimony. According to the district court, the theories advanced by Logerquist's expert were not generally accepted within the relevant scientific community.

The Arizona Supreme Court reversed. Relying on an extensive review of relevant case law, the Supreme Court concluded that Frye is not applicable when a qualified witness offers relevant testimony or conclusions based on experience and observation of human behavior for the purpose of explaining that behavior. 1 P.3d at 123. The Logerquist court said: " 'Although compliance with Frye is necessary when the scientist reaches a conclusion by applying a scientific theory or process based on the work or discovery of

others, under Rules 702 [Rule 702, Arizona Rules of Evidence, governs the admission of opinion testimony] and 703 experts may testify concerning their own experimentation and observation and opinions based on their own work without first showing general acceptance.' " 1 P.3d at 123 (quoting State v. Hummert, 188 Ariz. 119, 127, 933 P.2d 1187 [1997]). We agree. At issue in Logerquist was whether Arizona would abandon the Frye test and apply Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993). A divided court reaffirmed Frye. The dissenters in Logerquist would adopt Daubert and exclude the testimony of Logerquist's expert. 1 P.3d at 134.

The distinction between pure opinion testimony and testimony based on a scientific method or procedure is rooted in a concept that seeks to limit application of the Frye test to situations where there is the greatest potential for juror confusion.

We have yet to articulate a distinction between pure opinion testimony and testimony relying upon a scientific technique. Such a distinction, we believe, has advantages. The distinction would be consistent with Kansas appellate decisions applying the Frye test, almost all of which have involved devices or tests surrounded by an "aura of infallibility" to which a trier of fact might tend to ascribe "an inordinately high degree of certainty." See People v. McDonald, 37 Cal.3d 351, 372-73, 208 Cal.Rptr. 236, 690 P.2d 709 (1984), overruled on other grounds People v. Mendoza, 23 Cal.4th 896, 98 Cal.Rptr.2d 431, 4 P.3d 265 (2000).

Kansas Frye test cases have addressed a variety of scientific techniques. See State v. Shively, 268 Kan. 573, 584-87, 999 P.2d 952 (2000) (polygraph evidence); State v. Valdez, 266 Kan. 774, 787-88, 977 P.2d 242 (1999) (statistical evidence accompanying a type of DNA testing known as polymerase chain reaction [PCR] testing); State v. Heath, 264 Kan. 557, 577-78, 957 P.2d 449 (1998) (battered child syndrome); State v. Chastain, 265 Kan. 16, 22-23, 960 P.2d 756 (1998) (the horizontal gaze nystagmus sobriety test); State v. Canaan, 265 Kan. 835, 852, 964 P.2d 681 (1998) (the luminol test for the presence of blood); State v. Isley, 262 Kan. 281, 290, 936 P.2d 275 (1997) (statistical evidence accompanying PCR testing); State v. Haddock, 257 Kan. 964, 985, 897 P.2d 152 (1995) (PCR testing); State v. Hill, 257 Kan. 774, 785, 895 P.2d 1238 (1995) (PCR testing); State v. Colbert, 257 Kan. 896, 910, 896 P.2d 1089 (1995) (DNA print testing and the process of restriction fragment link polymorphism [RFLP] analysis); State v. Witte 251 Kan. 313, 329, 836 P.2d 1110 (1992) (the horizontal gaze nystagmus sobriety test); Smith v. Deppish, 248 Kan. 217, 238-39, 807 P.2d 144 (1991) (DNA print testing and the process of RFLP analysis); State v. Butterworth, 246 Kan. 541, 550, 556, 792 P.2d 1049 (1990) (hypnosis); State v. Hodges, 241 Kan. 183, 187, 734 P.2d 1161 (1987) (theory and methodology underlying the battered woman syndrome); State v. Miller, 240 Kan. 733, 735-38, 732 P.2d 756 (1987) (the Dequenois-Levine test for determining whether a substance is marijuana); State v. Haislip, 237 Kan. 461, 481-82, 701 P.2d 909 (1985) (use of hypnosis to induce witness testimony); Neises v. Solomon State Bank, 236 Kan. 767, 774, 696 P.2d 372 (1985) (a voice lie detector test called the PSE); State ex rel. Hausner v. Blackman, 233 Kan. 223, 228, 662 P.2d 1183 (1983) (human leukocyte antigen [HLA] test); State v. Marks, 231 Kan. 645, 654, 647 P.2d 1292 (1982) (psychiatric diagnosis on rape trauma syndrome admissible); State v. Washington, 229 Kan. 47, 53-54, 622 P.2d 986 (1981) (the Multi System method of blood analysis of polymorphic enzymes; also lists examples of the application of the Frye test from other jurisdictions); State v. Lowry, 163 Kan. 622, 628-29, 185 P.2d 147 (1947) (the admissibility of a lie-detector test); State v. Fuller, 15 Kan.App.2d 34, 36, 802 P.2d 599 (1990) (a technique for identifying marijuana); Tice v. Richardson, 7 Kan.App.2d 509, 510, 644 P.2d 490 (1982) (the admissibility of HLA test in a paternity suit). See also cases in which Frye did not apply, State v. Warden, 257 Kan. 94, 106, 891 P.2d 1074 (1995) (facilitated communication); State v. Tran, 252 Kan. 494, 502, 847 P.2d 680 (1993) (testimony of a "gang expert"); State v. Barker, 252 Kan. 949, 958, 850 P.2d 885 (1993) (the use of narcotics dog).

The distinction between pure opinion testimony and testimony relying on scientific technique promotes the right to a jury trial. Judges generally are not trained in scientific fields and, like jurors, are lay persons concerning science. A Kansas jury has a constitutional mandate to decide between conflicting facts, including conflicting opinions of causation. Kansas Constitution Bill of Rights, § 5; see K.S.A.1999 Supp. 60-238. The district judge under K.S.A. 60-456(b) controls expert opinion evidence that would unduly prejudice or mislead a jury or confuse the question for resolution. Cross-examination, the submission of contrary evidence, and the use of appropriate jury instructions form a preferred method of resolving a factual disputes.

The nature of the testimony of Drs. Davies, Saade, and Gould differs from scientific evidence that is usually subject to the Frye test. Plaintiffs' expert testimony here is distinguished from expert testimony where a scientific principal, device, test, or procedure,

developed by another, is employed that purports to offer a definitive conclusion as to causation. The weight of the expert opinions here will not hinge on the validity of a scientific principal, device, test, or procedure developed by another. Weight will depend on the accuracy of observation, the extent of training, and the reliability of the experts' interpretations.

Plaintiffs assert that the district court determined that the experts' opinions were inadmissible simply due to the fact that their conclusions were neither the majority opinion nor generally accepted. It is well-established that the Frye test is exclusively concerned with the methodologies underlying expert testimony, rather than the conclusions of that testimony. The very wording of Frye demonstrates that the focus is on the underlying scientific principles from which the conclusions are deduced:

"Just when a scientific principle or discovery crosses the line between the experimental and demonstrable stages is difficult to define. Somewhere in this twilight zone the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs." Frye v. United States, 293 F. 1013, 1014 (D.C.Cir.1923).

An illustrative case is Osburn v. Anchor Lab., Inc., 825 F.2d 908 (5th Cir.1987). Anchor, a pre-Daubert case, admitted opposite conclusions of testimony derived from the same scientific methodology. 825 F.2d at 916. "[M]edical expert opinion testimony that is controversial in its conclusions can support a jury finding of causation as long as the doctor's conclusory opinion is based upon well-founded methodologies." 825 F.2d at 915.

The logical corollary of the Frye test's focus on methodology rather than conclusions is that even unpopular conclusions are admissible so long as they are based upon generally accepted methodologies. Sandoz correctly points out that an unpopular conclusion by a scientist can be evidence that a method has not been faithfully applied. (citing Lust v. Merrell Dow Pharmaceuticals, Inc., 89 F.3d 594, 598 [9th Cir.1996] [applying Daubert]). However, unpopular conclusions alone are insufficient to render testimony inadmissable. See Douglas v. Lombardino, 236 Kan. 471, 693 P.2d 1138 (1985).

Lombardino, a significant case in our analysis, is a medical malpractice action resulting in a jury verdict for the defendant, Dr. Lombardino. A patient of Dr. Lombardino's died shortly after giving birth. In his defense, Dr. Lombardino offered expert testimony from two M.D.'s who opined that the cardiotoxic effects of the drug Marcaine led to the patient's death and that Lombardino had followed acceptable medical practice in caring for his patient. Although the conclusions of Dr. Lombardino's two experts were not generally accepted within the relevant scientific community, we ruled that the opinions were admissible. We concluded:

"There was no abuse of discretion in allowing testimony of the cardiotoxic nature of Marcaine even though the theory was not as yet widely accepted in the field. We note that along with the 'cardiotoxic' testimony, the jury also heard testimony and opinions of other experts who disagreed with the validity of this theory. The fact that this theory was a minority view goes only to the weight the jury may give it, and not its admissibility." 236 Kan. at 486-87, 693 P.2d 1138.

Lombardino clearly establishes that lack of popularity is not a sufficient reason to block admission. We said: "Under K.S.A. 60-456(b) there is no requirement that before an expert witness may give an opinion he must demonstrate that most, or all, or many other experts would agree with his opinion." 236 Kan. 471, Syl. § 5, 693 P.2d 1138.

During the proceedings here, the district judge said: "The plaintiffs would distinguish between methodology and ultimate conclusions. In the Court's opinion, if that's a distinction, it's a distinction without a difference for this purpose in that however you label those parts, when they come together, the same test applies."

The methodology underlying expert testimony and the conclusions of that testimony do not constitute "the same test." As the Fifth Circuit observed in Osburn, employment of the same generally accepted methodology can lead to different conclusions with markedly different degrees of acceptance within the scientific community. Osburn, 825 F.2d at 915.

The Third Circuit Court of Appeals in Heller v. Shaw Indus. Inc., 167 F.3d 146, 156 (3d Cir.1999), quoted Prof. Capra, Reporter to the Advisory Committee on the Federal Rules of Evidence:

" '[T]o require the experts to rule out categorically all other possible causes for an injury would mean that few experts would ever be able to testify.... Obvious alternative causes need to be ruled out. All possible causes, however, cannot be and need not be eliminated before an expert's testimony will be admitted.' "

We now turn to general and special causation, two toxic tort concepts that surfaced in the summary judgment proceedings below. Linked to the general/ special causation argument is Sandoz' emphasis on the absence of epidemiological studies supporting plaintiffs' claims. We disagree with the district court's application of the requirements of general and special causation to the facts here. The district judge said: "More particularly, plaintiffs must prove both general medical causation--that the substance can cause the injury at issue--and specific medical causation--that the substance did cause the injury at issue."

The need for separate evidence of general causation to admit testimony of specific causation apparently has not been addressed by Kansas appellate courts. Kansas Pattern Instruction, (PIK) Civ. 128.18, regarding products liability, does not refer to a general causation requirement. The instruction states that the "defect in the product was the cause or contributed to cause plaintiff's injuries and damages" without any mention of general causation. PIK Civ. 104.01, regarding causation, explicitly recommends that "no instruction be given defining causation." See also Southgate Bank v. Fidelity & Deposit Co., of Maryland, 14 Kan.App.2d 454, 459, 794 P.2d 310 (1990) (concluding that a district court's use of the phrase "direct result" needs no definition and is not a difficult term for a jury to understand).

No Kansas cases have required a finding of general causation in order to admit evidence pertaining to specific causation under the Frye test. The cases on which Sandoz relies to establish the need for both general and specific causation are distinguishable based upon the different legal standards employed in their respective jurisdictions; See Keene Corp., Inc. v. Hall, 96 Md.App. 644, 659, 626 A.2d 997, cert. granted Hall v. Keene Corp., 332 Md. 741, 633 A.2d 102 (1993) (the Frye test excluded the use of polarized light microscopy [PLM] to detect asbestos fibers in human tissue; PLM had been used to identify asbestos in building material); Blum v. Merrell Dow Pharmaceuticals, Inc., 705 A.2d 1314, 1322-25 (Pa.Super.1997), appeal granted 558 Pa. 597, 735 A.2d 1267 (1999) (the trial judge as a " gatekeeper decides whether the expert is offering sufficiently reliable, solid, trustworthy science;" a birth defect allegedly caused by taking Benedectin during pregnancy "[r]eplicated epidemiological studies consistently finding a strong association are necessary to establish causation" under the Frye/ Topa standard; the

We do not foreclose, by our holding here, that a future case with appropriate facts may require a finding of general and special causation. However, the facts here distinguish this case from cases that have employed a general causation requirement. First, general causation requirements (requiring plaintiffs to present confirming epidemiological evidence to make out a prima facie case) have typically been applied in cases involving mass exposures:

"Cases that have not imposed this requirement [general causation] typically involve injuries that may be placed in the 'sporadic accident model of tort law.' In [these] cases, where only a single plaintiff or a few plaintiffs have allegedly suffered an injury due to some exposure, a medical doctor will be permitted to render an opinion as to whether the exposure caused the plaintiff's injury solely on an examination of the plaintiff and a differential diagnosis of the source of the plaintiff's injury, sometimes supplemented with toxicological evidence....

"In many of these cases there is relatively little epidemiological data available and the courts are reluctant to burden 'first plaintiffs' with the task of using epidemiology to prove general causation." 2 Faigman, Keye, Saks & Sanders, Modern Scientific Evidence: The Law and Science of Expert Testimony: The Role of Epidemiological Evidence in Toxic Tort Cases. § 28-1.3.2, pp. 307-08 (Citing Boston, A Mass Exposure Model of Toxic Causation: The Content of Scientific Proof and the Regulatory Experience, 18 Colum.J.Envtl. L. 181, 188 [1993].)

The scope of plaintiffs' case here does not approach that of mass tort litigation. In addition, general causation requirements are usually imposed in cases with large existing epidemiological records. Richardson v. Richardson-Merrell, Inc., 857 F.2d 823, 832 (D.C.Cir. 1988), justified employing a general causation requirement on these grounds:

"Indeed, we are at the other end of the spectrum, a great distance from the 'frontier of current medical and epidemiological inquiry.' And far from a paucity of scientific information on the oft-asserted claim of causal relationship of Bendectin and birth defects, the drug has been extensively studied and a wealth of published epidemiological data has been amassed, none of which has concluded that the drug is teratogenic. Uniquely to

this case, the law now has the benefit of twenty years of scientific study, and the published results must be given their just due."

A federal appeals court, in a case considering whether dermal exposure to dilute solutions of paraquat could cause pulmonary fibrosis, concluded: "Thus, a cause-effect relationship need not be clearly established by animal or epidemiological studies before a doctor can testify that, in his opinion, such a relationship exists." Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1535 (D.C.Cir.1984) cert. denied, 469 U.S. 1062, 105 S.Ct. 545, 83 L.Ed.2d 432 (1984). See also Earl v. Cryovac, 115 Idaho 1087, 1095, 772 P.2d 725 (1989) (pulmonary disease allegedly caused by exposure to fumes from plastic film used in meat packing room; summary judgment for defendant reversed; "plaintiff's claim

in a toxic tort case does not fail merely because the circumstantial evidence and the expert opinions are unsupported by animal or epidemiological studies confirming the existence of a cause-and-effect relationship").

Sandoz cites three studies tending to downplay the negative effects of Parlodel for the purposes of preventing postpartum lactation. This research, however, was insufficient to deter the FDA from issuing a formal recommendation that Sandoz withdraw the indication. Moreover, further studies are precluded by the potential harm of the drug on prospective study participants.

Exclusion of Plaintiffs' Studies, Reports, and Literature

The plaintiffs also argue that the district court abused its discretion in deciding to exclude all of the "studies literature, and other evidence" upon which their experts relied. The plaintiffs argue that "[t]he trial court gave no evidentiary basis, such as hearsay, failure of foundation, privilege, relevance, prejudice, or unfair surprise, to support the exclusion; and the Court did

not distinguish any individual document or group of documents for exclusion." The "studies, literature, and other evidence" excluded by the district court were not identified. We have no findings, analysis, or rationale for the district court's conclusion that they "are not sufficient legally reliable support for such opinions." What studies, literature, and other evidence is the district court referring to? Why are the studies, literature, and other evidence not "legally reliable"? If materials are to be excluded, findings identifying the excluded items and the reason for exclusion should be made. Otherwise, we have no basis for a meaningful review.

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 factfinder. The factfinder will have the benefit of cross-examination and, we assume, contrary evidence from the Sandoz experts.

Reversed and remanded with directions.