Breifly Legal: The Battle of the Experts—and Beyond

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Increasingly in the area of malpractice litigation involving perinatal injury to the child, the deliberations go beyond the opinions of the experts to challenges to the bases of obstetrical care and the relationship of obstetrical events to the subsequent outcome. The comportment of the experts in lawsuits is governed by Federal Rule 702, which was created to codify standards for evidence and opinions presented by expert witnesses in legal proceedings. It states that a witness becomes "qualified" as an "expert" based on his / her knowledge, skill, experience, training, or education. This specialized knowledge, considered beyond the normal knowledge of the judge or jury, assists them in understanding the scientific or technical issues involved in the case. What makes the qualification so important is that the expert witness, unlike other witnesses, may provide testimony as an opinion. However, the expert's opinions must be based on sufficient facts or data and be the product of reliable principles and methods that the expert has meaningfully applied to the facts of the case.

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Most states have adopted or modified Federal Rule 702, including those portions covering expert testimony. These guidelines are governed by the Frye or Daubert Standard in individual states.

The Frye standard was based on a century-old 1923 court ruling (Frye v. United States) rejecting using lie detectors to discern "truth." At that time, the Court reasoned that there was insufficient general acceptance of the technology and offered guidelines for determining the admissibility of scientific examinations on determining when there is, "… experimental 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." In a trial alleging medical negligence, for example, the judge had to decide if a meaningful proportion of the relevant scientific community generally accepted the procedure, technique, or principles in question.

"In [the decision of Daubert v. Merrell Dow Pharmaceuticals, Inc.], the Court held that while the federal standard includes general acceptance (from Frye), it also looks at the more fundamental science and its application."

While this principle is still used as a benchmark for the admissibility of evidence in certain states, it has been supplanted by the Daubert rule established by the Supreme Court in 1993 in the case of Daubert v. Merrell Dow Pharmaceuticals, Inc. In that decision, the Court held that while the federal standard includes general acceptance (from Frye), it also looks at the more fundamental science and its application. In addition, the Daubert ruling made trial judges the "gatekeepers" of the admissibility of evidence and the acceptance of the opinions of an expert witness in their courtrooms. In this role, the judge should consider:

- What is the basic theory, and has it been tested?
- Are there standards controlling the technique?
- Has the theory or technique been subjected to peer review and publication?
- What is the known or potential error rate?
- Is there general acceptance of the theory?
- Has the expert adequately accounted for alternative explanations?
- Has the expert unjustifiably extrapolated from an accepted premise to an unfounded conclusion?

The Daubert court also ruled that concerns over questionable evidence or conclusions by the opposing expert could be scrutinized by opposing counsel through the presentation of contrary evidence

and pointed cross-examination of the expert. A "Daubert challenge" is made to request the Court to exclude certain testimony. The motion is made in limine, i.e., the deliberations are conducted outside the presence of the jury and decided by the judge. If conducted during the trial, the format creates the potential of a "trial within a trial" and demands careful instructions to the jury on the burden of proof. Thus, the admissibility of evidence may determine the case's outcome or even whether the case can be brought to Court. If the challenger prevails, the testimony is forbidden, and the case may be dismissed. The evidence may be presented if the challenger does not prevail but is subject to cross-examination. The decision to dismiss the challenge does not decide the outcome of the trial, only the matters that may be presented at trial. A Daubert challenge by the defense has a secondary gain in that in countering the challenge, the plaintiff's side will have disclosed the arguments made at trial.

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While being a physician may be sufficient to qualify as an expert in any particular case, it is usually insufficient to offer authoritative opinions on specialized issues that are commonplace during medico-legal cases alleging substandard care in Obstetrics. In these cases, a medical expert's credibility and qualification in brain-damaged children usually require considerable relevant experience. Research and publications are helpful, but so are common sense and the ability to communicate.

The case presentation below and the deliberations of a judge in a Daubert motion in limine before trial are designed to highlight the contemporary dispute over the role of mechanical factors during labor and delivery in the causation of perinatal injury and to illustrate the tortuous path some cases take, even before they get to trial.

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Facts of the case:

The patient is a 29 y/o primigravida who got pregnant while taking various medications for migraines and associated depression. During her pregnancy, she stated that she had asked her obstetrician if she was too small and if she should just have a cesarean section. She was 5 feet tall, "on a good day," and her pre-pregnant weight was 105 lbs. In discussing the options for delivery with her obstetrician, she commented that she was not committed to a "natural birth;" her most important concern was the baby's health. Her prenatal course was unremarkable.

"At 40 3/7 weeks' gestation, the patient was admitted to the hospital late afternoon for elective labor induction. An external monitor demonstrated a reassuring pattern with a stable baseline rate, intermittent accelerations, and absent decelerations with occasional contractions."

At 40 3/7 weeks' gestation, the patient was admitted to the hospital late afternoon for elective labor induction. An external monitor demonstrated a reassuring pattern with a stable baseline rate, intermittent accelerations, and absent decelerations with occasional contractions. A cervical exam reveals she is 1 cm dilated, 75% effaced at -1 station. After several hours of observation, Cervidil 10 mg is inserted vaginally. About 12 hours later, she was feeling cramps, and the Cervidil was removed. Oxytocin was started at 2 mU/min and increased progressively to 12 mU/min. Nubain 10 mg IV/ and Phenergan 6.25 mg were administered three hours later for pain. Twenty hours after admission, the cervix is only 3 cm dilated, 0 station, 85% effaced, and an epidural is begun with Fentanyl/bupivacaine 0.125%. At 24 hours, the patient is 6 cm dilated, 90% effaced, and -1 station. Because of excessive uterine activity, decreased maternal blood pressure, and late decelerations in response to the epidural, the Oxytocin is reduced to 6 mU/min, and ephedrine and oxygen are administered with relief of both the hypotension and the fetal decelerations.

"At 24 hours, the patient is 6 cm dilated, 90% effaced, and -1 station. Because of excessive uterine activity, decreased maternal blood pressure, and late decelerations in response to the epidural, the Oxytocin is reduced to 6 mU/min, and ephedrine and oxygen are administered with relief of both the hypotension and the fetal decelerations. "

Over the next several hours, progress to 8 cm of dilatation is very slow. Membranes rupture spontaneously, revealing a moderate amount of clear fluid. Despite the slow progress and evidence of excessive uterine activity, Oxytocin is again increased up to '14 mU/min, and at 27 hours, the patient is feeling rectal pressure. Examination reveals the cervix to be 8 cm dilated, +1 station, with moderate contractions every 3-4 minutes. In response to decelerations, the Oxytocin is reduced to 7 mU/min, and 02 is administered and remains with an IV bolus.

"It has taken 5 hours to go from 8 cm to full dilatation – an interval that usually requires less than 2 hours. "

An IUPC is inserted, and the Oxytocin progressively increases to 16 mU/min. For increasing pain, the patient receives several boluses of epidural anesthesia, and a fetal scalp electrode is applied 32 hours after admission. Ninety minutes later, the cervix is fully dilated with the head at +2 station – It has taken 5 hours to go from 8 cm to full dilatation – an interval that usually requires less than 2 hours. The patient is feeling increased pressure. With the onset of pushing, repetitive decelerations begin. After 2 hours of effort, the patient stops pushing. She is complaining of back pain and lower abdominal cramping. She is encouraged to resume pushing and take deep breaths during breaks in the contractions. With continued pushing, the FHR pattern deteriorates with decreased variability, multiple late and variable decelerations, and fetal tachycardia to 170 bpm. The physician is summoned to the delivery room when the decision is made to perform a vacuum-assisted delivery (VAD), and the scalp electrode and IUPC are discontinued. With the head still at +3 station, the vacuum is placed, and traction is applied. Within 4 minutes, there have been four pulls with the vacuum and three pop-offs. An episiotomy is performed, the vacuum is reapplied, and the fetus is delivered. The indication for delivery was "maternal exhaustion" and "non-reassuring fetal heart rate tracing."

"An EEG confirmed the presence of seizure activity, and a CT scan on that day revealed a skull fracture to the right parietal bone at the level of the lambdoid suture and evidence of bilateral ischemic infarcts...On follow-up, in addition to diplegia, the infant showed developmental delay with obvious physical, speech, and cognitive deficits requiring physical, occupational, and speech therapies."

The female infant weighs 3095 grams and receives Apgar scores of 8 and 9 at 1 and 5 minutes, respectively. There is obvious bruising and marked caput and molding of the head. The HC was 32.5 cm. (<10th %ile) the length was 51.5 cm. (There was no follow-up measurement of the HC. She was initially sent to the normal newborn nursery, but on DOL 2, she was found to have decreased alertness, episodes of cyanosis, apnea, and seizures. An EEG confirmed the presence of seizure activity, and a CT scan on that day revealed a skull fracture to the right parietal bone at the level of the lambdoid suture and evidence of bilateral ischemic infarcts. Phenobarbital was prescribed. A thrombophilia workup was negative. On follow-up, in addition to diplegia, the infant showed developmental delay with obvious physical, speech, and cognitive deficits requiring physical, occupational, and speech therapies.

The allegations

The failure to properly assess the feasibility of safe vaginal delivery

At no time during the labor did any provider consider an alternative to vaginal delivery, given the very protracted labor and the patient's small stature? This required an assessment of the pelvis, an estimate of the fetal weight, and an ongoing evaluation of the progress in cervical dilatation and descent of the presenting part. Pelvic size and estimation of fetal weight were not performed.

Failure to appreciate the abnormality of labor.

The patient made slow progress from 3 cm to 6 cm. From 6 cm to 8 cm, an interval that should have taken from 1 to 2 hours took 4 hours. She then made no progress for the next 5 hours – an arrest of labor in the active phase, from 8 cm to full dilatation, required 4 hours, an interval that should have taken about 1 hour (a protracted active phase). She was fully dilated for about 2 hours before her labor was abbreviated by a traumatic VAD despite the fetal head at +3 station. The labor abnormalities included the protracted active phase, arrest of the active phase, and protracted descent (and/or arrest of descent) in the 2nd stage of labor. The progress in descent is quite slow, and the true head was likely considerably higher in the birth canal than appreciated at the time of vacuum application, with a likely malposition of the fetal head, probably OP, suspected based on considerable back pain and rectal pressure.

"The caregivers should have recognized and responded to the excessive uterine activity and stopped the Oxytocin or at least refused to increase it further. They should also have notified the physician concerning the excessive uterine activity, the intermittent decelerations, and the lack of progress. "

The failure to maintain proper surveillance of uterine activity, The failure to properly and safely conduct the administration of Oxytocin, and the failure to timely recognize and respond to excessive uterine activity.

Increases in Oxytocin were contraindicated in light of the already excessive uterine activity, including the coupling of contractions and uterine hypertonus by IUPC. Efforts to diminish the effect of Oxytocin were insufficient as excessive uterine activity continued. The caregivers should have recognized and responded to the excessive uterine activity and stopped the Oxytocin or at least refused to increase it further. They should also have notified the physician concerning the excessive uterine activity, the intermittent decelerations, and the lack of progress.

The failure to timely recognize and respond to abnormal FHR patterns

The initial FHR started as reactive with absent decelerations. When combined with normal amniotic fluid volume, fetal growth, and behavior, these features bespeak both normal fetal responsiveness and the absent threat of hypoxia or ischemia. Over time, the baseline variability becomes flat with multiple decelerations, and changes in baseline rate and variability were not recognized or responded to appropriately by the moderation of pushing and reduction of Oxytocin.

"The required assessments of the patient at 8 cm of dilatation would have revealed the constellation of a mother of very short stature, quite prolonged labor with protracted active phase and an arrest of labor in the face of ruptured membranes, excessive uterine activity, high dosage of Oxytocin and malposition of the fetal head."

Failure to timely perform an atraumatic cesarean section.

The required assessments of the patient at 8 cm of dilatation would have revealed the constellation of a mother of very short stature, quite prolonged labor with protracted active phase and an arrest of labor in the face of ruptured membranes, excessive uterine activity, high dosage of Oxytocin and malposition of the fetal head. Under these circumstances, safe vaginal delivery was reasonably unlikely, and a cesarean section was required by the standards of care and would have resulted in a fetus free from a neurologic handicap. It also would have avoided the trauma and ischemia related to the prolonged non-progressive labor, excessive forces upon the fetal head, and traumatic delivery.

Failure to follow proper guidelines in the selection of patients and the use of vacuum devices

There was no assessment of the true station, the position of the presenting part, or the amount of molding or caput. The fetal head was noted to be at +3 station, but given the likely malposition of the head and the amount of molding and caput (confirmed at delivery), and the difficulty in effecting vacuum delivery, despite the mother's "pushing well," the true station of the fetal head was likely considerably higher in the pelvis than believed by the obstetrician.

From the outset, the likelihood of successful operative delivery was markedly diminished and preparations for cesarean section had to be made simultaneously in the event of failure. The vacuum delivery should not have been attempted without assessment of the several problems with the true station and position of the presenting part, as detailed above. It is highly improbable that there was true descent of the fetal head with each pull of the vacuum as required by the standard of care. The inappropriate operative delivery having been undertaken should have been abandoned with the failure of the first attempt. Failing to have the option for cesarean necessitated multiple attempts at vacuum and dramatically increased the risk of harm – exaggerated under the circumstances annotated above.

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Causation:

With regard to the neurological well-being of the fetus, the initial normal FHR patterns, combined with normal amniotic fluid volume, fetal growth, and behavior, bespeak both a normal fetal responsiveness and an absent threat of hypoxia or ischemia. Over time, there are changes in the baseline rate, variability, and the appearance of significant decelerations. Further, there is no clinical or radiological evidence of an earlier injury or some metabolic or genetic basis for injury. Nor is there evidence of significant umbilical acidemia or immediate depression in the newborn. The variable decelerations represent cerebral ischemia from impaired cerebral blood flow, not systemic hypoxia. {Ball, 1992 #21140} The traumatic efforts at vacuum delivery most likely provide the final blow to a baby set up for injury by severely protracted labor, with excessive uterine activity, including hypertonus and abnormalities of the fetal heart rate pattern.

The Daubert challenge:*

The review by the judge first produced a summary of the arguments.

"The Defendants and their experts made a Daubert motion in limine that any evidence regarding the Plaintiffs' causation theory, including the testimony of its witnesses, be excluded. Should the challenge prevail, the lawsuit would not go to trial."

The Defendants and their experts made a Daubert motion in limine that any evidence regarding the Plaintiffs' ***causation*** theory, including the testimony of its witnesses, be excluded. Should the challenge prevail, the lawsuit would not go to trial. In their motion, the defendants contended that Plaintiffs' theory that the baby's injuries were caused by mechanical forces acting on the fetal head had repeatedly been rejected by the obstetrics and medical communities as "junk science" and that none of the Plaintiffs' experts has a scientifically reliable basis to support the theory.

Plaintiff's experts opined that the physician's use of a vacuum extraction caused complications, leading to the baby suffering a perinatal stroke due to compression forces acting on the fetal head. Defendants argue that such a theory is inadmissible under Evidence Code 702 because it (1) has not been tested; (2) has not been subjected to peer review; (3) has no known or potential rate of error; and (4) perhaps most importantly, has gained **no general acceptance whatsoever** in the obstetrics and/or medical communities." Further, they argued that no Plaintiff expert could point out a single instance in which the theory has been tested and/or peer-reviewed in their expert reports. The experts agree that no controlled studies have tested (or could ethically test) the theory.

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Defendants' experts further testified that an article on which the plaintiff's expert relied during his deposition to support the theory (1) was not peer-reviewed in a journal accepted in the relevant medical and scientific communities and that the American College of Obstetrics and Gynecologists ("ACOG") has consistently rejected the head compression theory as unreliable and that it does not "reflect the generally accepted standard of care in the field of obstetrics."

Defendants also refer to several cases from other states which have precluded evidence of this theory from being introduced. Indeed, in a case in the state court of Georgia, the ACOG filed an amicus brief in support of a similar motion made to preclude the admission of the theory, which motion the Georgia court ultimately granted. Defendants, however, omitted the far more prevalent acceptance of the theory by many other courts.

"In response, the Plaintiffs contend that the causation theory that the baby suffered mechanical trauma during the patient's prolonged labor when the physician 'applied a vacuum extractor using multiple pulls after multiple pop-offs on a malpositioned fetal head resulting in a skull fracture, physical signs of trauma and a focal ischemic stroke.'"

In response, the Plaintiffs contend that the causation theory that the baby suffered mechanical trauma during the patient's prolonged labor when the physician "applied a vacuum extractor using multiple pulls after multiple pop-offs on a malpositioned fetal head resulting in a skull fracture, physical signs of trauma and a focal ischemic stroke."

"Plaintiffs assert that their experts' causation testimony is admissible under Evidence code 702(C) as other State courts have found "scientific support and scientific bases for the concept and theory that forces acting on the fetal head have the potential to cause ischemic injuries." "

Plaintiffs assert that their experts' causation testimony is admissible under Evidence code 702(C) as other State courts have found "scientific support and scientific bases for the concept and theory that forces acting on the fetal head have the potential to cause ischemic injuries."

Indeed, in many previous cases, the courts overruled motions from defendants seeking to exclude expert opinions that "trauma from abnormally excessive contractions caused decreased blood flow and oxygenation to the fetal brain resulting in brain injuries."

"Plaintiffs further claim that under Evidence code 702(C) analysis, a flexible inquiry determines whether the principles and methodology used to conclude are reliable."

Plaintiffs further claim that under Evidence code 702(C) analysis, a flexible inquiry determines whether the principles and methodology used to conclude are reliable. First, the Plaintiffs argue that their causation theory has been studied and tested to the extent ethically possible. For instance, the plaintiff's experts based their opinions on data and research from within their field and animal studies that tested fetal trauma and compression that they extrapolated to humans. Second, the Plaintiffs contend that "disruption of fetal cerebral circulation, infarction and stroke due to skull compression caused by excessive uterine activity and traumatic delivery" has been discussed and recognized in peer-reviewed literature. Additionally, such peer review is not necessary for an opinion to be admissible.

Third, Plaintiffs assert that State law does not require a rate of error for expert opinion testimony to be admissible as long as there is literature that includes a quantitative analysis of the background principles and methods used by the expert to reach his or her opinion.

Fourth, the Plaintiffs argue that the methods and principles used to reach the expert opinions that birth trauma is a cause of perinatal stroke have been generally accepted.

"In reply, Defendants contend that there is no methodologically sound evidence to support Plaintiffs' experts' opinions that mechanical forces to the fetal head during labor and delivery 'can cause sufficient disruption of cerebral blood flow in the fetus to cause hypoxic-ischemic injury and focal ischemic stroke.'"

In reply, Defendants contend that there is no methodologically sound evidence to support Plaintiffs' experts' opinions that mechanical forces to the fetal head during labor and delivery "can cause sufficient disruption of cerebral blood flow in the fetus to cause hypoxic-ischemic injury and focal ischemic stroke." According to Defendants, the only methodically sound scientific evidence is that mechanical labor and delivery forces can cause a global/watershed injury, not a focal ischemic stroke. Defendants reassert that Plaintiffs cannot meet any of the four requirements under Evidence code 702(C), meaning that the expert opinions are not admissible.

"Defendants reiterate that the Plaintiffs' causation theory has not been generally accepted, and their theory has not been tested. Specifically, Defendants contend that any studies relating to testing on sheep are not applicable because Plaintiffs have not established that humans are sufficiently similar to the tested animal (sheep)."

Defendants emphasize that the Plaintiffs' experts' causation theory extrapolates opinions based on the opinions of others, though these other opinions do not fit the Plaintiffs' experts' causation theory. In making this argument, Defendants rely upon the case of Valentine v. PPG Industries, Inc., 158 Ohio App.3d 615, 2004-Ohio-4521, 821 N.E.2d 580 (4th Dist.), which held that expert opinions that a specific type of brain cancer was caused by exposure to certain chemicals were not admissible because the experts extrapolated their opinions from studies that did not deal with specific cancer. Defendants also contend that the Second District Court of Appeals holds that experts "cannot extrapolate a causation opinion from the studies and publications of others if .. . those studies and publications do not reach the expert's conclusions and/or provide a scientifically reliable methodology for reaching the expert's conclusions." Additionally, Defendants state that a number of the publications relied upon by Plaintiffs do not support their specific causation theory and that Plaintiffs cannot meet their burden of proof to establish the admissibility of the expert testimony. Defendants reiterate that the Plaintiffs' causation theory has not been generally accepted, and their theory has not been tested. Specifically, Defendants contend that any studies relating to testing on sheep are not applicable because Plaintiffs have not established that humans are sufficiently similar to the tested animal (sheep).

The judge then offered an opinion about the prevailing law and its analysis

A. Legal Standards

Pursuant to Evidence code 702 (C), a witness may testify as an expert if all of the following apply:

(A) The witness' testimony either relates to matters beyond the knowledge or experience possessed by lay persons or dispels a misconception among lay persons;

(B) The witness is qualified as an expert by specialized knowledge, skill, experience, training, or education regarding the subject matter of the testimony;

(C) The witness' testimony is based on reliable scientific, technical, or other specialized information. Evidence code702.(C).

"The parties agree that the Defendants' challenge to the Plaintiffs' expert opinions on causation is raised solely under Evidence code 702(C). "In determining whether the opinion of an expert is reliable under Evidence code 702(C), a trial court examines whether the expert's conclusion is based on scientifically valid principles and methods.""

The parties agree that the Defendants' challenge to the Plaintiffs' expert opinions on causation is raised solely under Evidence code 702(C). "In determining whether the opinion of an expert is reliable under Evidence code 702(C), a trial court examines whether the expert's conclusion is based on scientifically valid principles and methods." The trial court is not tasked with determining whether the expert's ultimate conclusions are correct. To determine reliability, a court is to consider several factors: "(1) whether the theory or technique has been tested, (2) whether it has been subjected to peer review, (3) whether there is a known or potential rate of error, and (4) whether the methodology has gained general acceptance."

These factors aid in determining reliability and are meant to be flexible. When an expert draws inferences from bodies of work or extrapolates, this must be done in accordance with scientific principles and methods. If the Court determines that there is

"too great an analytic gap between the data and the opinion proffered," the opinion has no place in evidence. The determination of whether the expert opinion testimony is admissible is within the trial court's discretion, and the decision will not be disturbed absent abuse of discretion.

B. Analysis

1. Whether the theory or technique has been tested

The Court finds that Plaintiffs' experts' causation theory opinions have been tested. The causation theory is that increased intracranial pressure caused by mechanical forces, trauma during the baby's labor and delivery, and degrees of fetal hypoxia caused the baby's injuries. The theory that mechanical factors and excessive uterine activity cause hypoxic-ischemic cerebral injury has been tested and explained in medical literature and has been tested in animal studies. For example, Towner (2) et al. concluded that the "rate of intracranial hemorrhage is higher among infants delivered by vacuum extraction, forceps, or cesarean section during labor than among infants delivered spontaneously or by elective cesarean section. Plaintiffs provide several other journal articles summarizing various forms of testing performed after birth and reviews of trauma in hindsight, which have also tested the Plaintiffs' experts' causation theory that mechanical factors, along with excessive uterine activity, cause hypoxic-ischemic cerebral injury. The experts may base their opinions on a review of such professional literature.

"The Court finds that Plaintiffs' experts' causation theory opinions have been tested. The causation theory is that increased intracranial pressure caused by mechanical forces, trauma during the baby's labor and delivery, and degrees of fetal hypoxia caused the baby's injuries."

Plaintiffs rightly argue that the articles only address post-birth reviews and/or testing, as it would be unethical to test human fetuses before birth to determine whether mechanical factors, along with excessive uterine activity, can cause hypoxic-ischemic cerebral injury. Similar testing has been done on animals. Animal studies may be admissible to prove causation in humans if good grounds exist to extrapolate from animals to humans.

In the case at bar, the Plaintiffs provided examples of research performed on animals (3) in which pressure exerted on the skulls of lamb fetuses showed that the compression "of the fetal head by an externally applied force caused severe cerebral ischemia due to a marked reduction in cerebral blood flow." A similar study was conducted on monkey fetuses in the late 1960s in which the fetuses were subjected to asphyctic compromise. (4) The results showed that seven of the ten fetuses "exhibited mild to moderate degrees of brain swelling." Both the animals (sheep and monkeys) and this baby were fetuses who suffered from the same injury: pressure exerted on the skull during birth. In 1971, Myers (5) stated that in monkey fetuses, the "eventual long-term, static lesions closely compare to the lesions of human perinatal injury or cerebral palsy."

"It is not too great of an analytic gap for an expert to agree that mechanical forces, trauma during labor and delivery, and degrees of fetal hypoxia caused the baby's injuries. Thus, the Court finds that the literature and animal studies have tested the Plaintiffs' causation theory."

Defendants, though, argue that the Plaintiffs' experts' causation theory has not been tested because there is "too great of an analytic gap between the conclusions from the journal articles and animal test results and the expert conclusions." The Defendants contend that the opinion does not fit the Plaintiffs' case because the specific causation theory has not been tested. In considering this argument, the Court was persuaded by the opinion of a Judge in a similar case in this state who held that it is "not 'too great an analytic gap' in this case as Plaintiffs' have proffered literature to support the theory that pressure to the fetal head can produce injury." As in other cases, the Plaintiffs, in this case, have presented literature that the forces of labor, including mechanical forces used in labor and excessive uterine activity, can cause injury and have presented test results indicating that pressure to the fetal brain can cause severe cerebral ischemia by a marked reduction in cerebral blood flow. It is not too great of an analytic gap for an expert to agree that mechanical forces, trauma during labor and delivery, and degrees of fetal hypoxia caused the baby's injuries. Thus, the Court finds that the literature and animal studies have tested the Plaintiffs' causation theory.

2. Whether the theory or methodology has been subjected to peer review

The Court finds that Plaintiffs' experts' causation theory has been subjected to peer review. In this case, the Plaintiffs have submitted peer-reviewed publications and journal articles discussing labor forces that contribute to the type of injury the baby sustained. In making this determination, the Court did not focus on whether this causation opinion was correct or whether the opinion would satisfy the Plaintiffs' burden of proof at trial. If the evidence is questionable or confusing, it should not be excluded "since the experts' opinions would be subject to cross-examination and the credibility of their conclusions left to the trier of fact." Even if the theories which have been peer-reviewed have a contradictory conclusion, the theory should not be excluded, especially since it is the process of the peer review and not the conclusions that the Court must consider. Additionally, based on the above reasoning, the Court finds that it is not too great of an analytic gap for an expert to reach an opinion that increased intracranial pressure caused by mechanical forces and trauma during the baby's labor and delivery, along with degrees of fetal hypoxia, caused the baby's injuries. As such, the Court finds that Plaintiffs' causation theory has been subjected to peer review.

3. Whether there is a known potential rate of error

The parties do not dispute that there is not a known potential rate of error associated with the Plaintiffs' causation theory. A lack of a known error rate is not "fatal to the methodology's reliability because no one of the Daubert factors is dispositive of the inquiry, as the factors should be applied flexibly. Thus, the Court finds that Plaintiffs' causation theory is not unreliable based on the lack of a known potential rate of error.

"It is "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof [that] are the traditional and appropriate means of attacking shaky but admissible evidence.""

4. Whether the methodology has gained general acceptance

The Court finds that the methodology used to reach the experts' opinions has gained general acceptance. Defendants assert that the theory is at odds with the generally accepted cause of neonatal injuries being asphyxia or oxygen deprivation. Defendants also contend that there is a lack of general acceptance since ACOG has rejected the causation theory. Plaintiffs have provided many journal articles that support the general causation theory that brain injury can occur due to excessive intrauterine pressure and forces of mechanical extraction. For instance, in an article by Kumar entitled "Contralateral Cerebral Infarction Following Vacuum Extraction" (6), the authors summarized that "[m]echanical birth trauma has been recognized as a direct cause of intracranial arterial injury leading to ischemic or hemorrhagic stroke in the newborn." Further, it is unnecessary that scientific opinions "enjoy 'general acceptance' in the relevant scientific community to satisfy the reliability requirement of Evidence code 702." "Even if an expert's opinion has neither gained general acceptance by the scientific community nor has been the subject of peer review, these are not prerequisites to admissibility under Daubert"). It is "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof [that] are the traditional and appropriate means of attacking shaky but admissible evidence." Additionally, based on the above reasoning, the Court finds that it is not too great of an analytic gap for an expert to reach an opinion that increased intracranial pressure caused by mechanical forces and trauma during labor and delivery, along with degrees of fetal hypoxia, caused the baby's injuries. Accordingly, the Court finds that Plaintiffs' causation methodology has gained general acceptance, and even if it had not, this is not a prerequisite to its admissibility.

"The Court OVERRULED the Defendants' Motion in Limine to Exclude Testimony Regarding Plaintiffs' Causation Theory."

The Ruling and its impact

The Court **OVERRULED the** Defendants' Motion in Limine to Exclude Testimony Regarding Plaintiffs' Causation Theory. Shortly thereafter, their case was settled.

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