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Wisconsin Court Of Appeals
DISTRICT III

UNITY BAYER, BY HER GUARDIAN AD LITEM, VINCENT R. PETRUCELLI, LEAH BAYER, AND ANDREW BAYER,

PLAINTIFFS-RESPONDENTS,

AND

JOHN ALDEN LIFE INSURANCE COMPANY,

INVOLUNTARY-PLAINTIFF,

v

BRIAN D. DOBBINS, M.D., MMIC INSURANCE, INC., PREVEA CLINIC, INC., AND DEF INSURANCE COMPANY,

DEFENDANTS-APPELLANTS,

INJURED PATIENTS AND FAMILIES COMPENSATION FUND,

DEFENDANT-
CO-APPELLANT.

APPEAL NO: 2015AP001470
CIRCUIT COURT CASE NO: 13-CV-271
Code No. 30104

Appeal From The Circuit Court For Marinette County
Honorable David G. Miron, Presiding
Circuit Case No. 13-CV-271

Brief Of Plaintiffs-Respondents

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Statement On Oral Argument And Publication

This case warrants oral argument and publication. Complex scientific and legally disputed issues exist, and an oral presentation will likely answer questions not fully revealed by reviewing the parties' briefs and the record. Publication of the Court's opinion would benefit Wisconsin litigants since this will be the first appellant decision deciding the admissibility of expert medical causation testimony in the light of Wis. Stat. § 907.02(1).

Statement of the Case

A. Procedural Background Leading To The Appeal

1. Nature Of The Case

Unity Bayer, by her Guardian Ad Litem, Vincent R. Petrucelli, and her parents, Leah Bayer and Andrew Bayer, sued Brian D. Dobbins, M.D., Prevea Clinic, Inc., MMIC Insurance Inc., and the Injured Patients and Families Compensation Fund for medical negligence and lack of informed consent.

The complaint alleges:

(a) Dr. Dobbins negligently applied too much force and traction during his delivery of Unity Bayer after he diagnosed a shoulder dystocia, resulting in a severe and permanent complete right brachial plexus injury to her right arm, hand, and shoulder; and

(b) Dr. Dobbins should have counseled Leah Bayer of the risks of shoulder dystocia and a resulting brachial plexus injury prior to delivery. He breached the standard of care when he failed to obtain informed consent from Leah Bayer for delivery via cesarean section to avoid the risks of shoulder dystocia and fetal injury when he used a vacuum extractor in his attempt to deliver Unity Bayer.

The Plaintiffs contend Unity Bayer's shoulder dystocia rendered her susceptible to brachial plexus injury from the delivering physician applying lateral traction—a downward, upward, or rotational pulling force—to the baby's head and neck to dislodge her body and effectuate delivery. Because of Dr. Dobbins' actions, the plaintiffs contend Unity Bayer suffered a permanent brachial plexus injury. They allege that

Dr. Dobbins improperly utilized and applied excessive lateral traction to her neck and head to dislodge her shoulder.

2. The Plaintiffs' *Daubert* Motion

For over 100 years it was medically uncontested that a permanent brachial plexus injury in an otherwise healthy newborn who underwent a vaginal delivery resulted from physician applied lateral traction during a shoulder dystocia. Twenty years ago, defense experts hypothesized that such an injury sometimes occurred because of the maternal or natural "forces of labor." This term refers to both uterine contractions and maternal pushing. Not surprisingly, the defense retained experts who claimed Unity Bayer's permanent brachial plexus injury resulted from her mother's forces of labor.

The plaintiffs filed a *Daubert* motion to preclude the defense experts' causation opinion testimony.[1] R. 52. They argued that to satisfy Wis. Stat. § 907.02(1)'s admissibility requirements the defense experts first had to identify the mechanism of the injury, so a determination could be made whether an adequate foundation exists for the theory. R. 53. They claimed the defense theory remains poorly defined. *Id.* For instance, the experts claimed the injury occurred either before or after delivery of the baby's head. *Id.* None of the experts could identify exactly when the injury occurred, whether it was uterine contractions or maternal pushing, or the magnitude, direction, or rate of the force that caused the injury. *Id.* Precise identification of what caused the damage, according to the plaintiffs' motion, was a necessary predicate to even arguing a foundation existed for this undefined hypothesis. *Id.*

[1] In support of their motion, the Plaintiffs' filed both a brief and a reply. R. 53, 57 and 87.

A permanent brachial plexus injury is a stretch injury. Normal routine delivery, and shoulder dystocia delivery, both result in stretch to the brachial plexus because of the maternal forces of labor. *Id.* According to the plaintiffs' motion, the maternal forces of labor, in rare instances, causes temporary brachial plexus injury, but never causes permanent injuries. *Id.* They claimed there was no reliable scientific proof that a permanent brachial plexus can result from the maternal forces of labor in the face of shoulder dystocia. *Id.*

The plaintiffs contended the defense experts before their opinions were admissible, had to establish besides Unity Bayer's exposure to a harmful in-utero event, that the event can cause the injury (general causation) and that she was exposed to a sufficiently adverse event to cause the injury (specific causation). *Id.* Since the defense experts provided proof of neither, the plaintiffs claimed no foundation existed for the defense hypothesis that the maternal forces of labor caused Unity Bayer's permanent brachial plexus injury. *Id.* They asked the trial court to preclude the defense experts' causation testimony. *Id.*

3. The Circuit Court's Ruling

On 27 May 2015, the plaintiffs' *Daubert* motion was to be heard at the same time as the final pretrial conference and hearings on twenty-nine pretrial motions filed by the defendants. R.92. Given the number and complexity of the issues raised by the motions, the trial court adjourned the hearing and the jury trial set to begin on 2 June 2015. *Id.* The plaintiffs' *Daubert* motion, and the defense motions, were heard on 11 June 2015. R. 100.

At the hearing, Judge Miron first stated that he had read all briefs and supporting materials regarding the pending motions.

R. 100 at p. 5-6. The parties agreed the trial court would separately rule on each motion, and if the court had questions, counsel would address them. *Id.* at pp.6-7.

First, the court ruled inadmissible any testimony that directly or indirectly mentioned or relied upon the published case report of Henry M. Lerner & Eva Salamon, *Permanent Brachial Plexus Injury Following Vaginal Delivery Without Physician Traction or Shoulder Dystocia*, Am. J. of Obstetrics & Gynecology, Mar. 2008, at e7. *Id.* at p. 64. In that article, the authors claim "[T]his case demonstrates unequivocally that not all permanent brachial plexus injury at vaginal birth is due to physician traction." R. 51 Ex 1.

The plaintiffs' motion claimed the article was fraudulent and scientifically unreliable. *Id.* It was subject to a federal lawsuit. According to the lawsuit, "[T]he article's deceptive content has and will be used in medical malpractice trials as the article, in its present state is very favorable for doctor-defendants, causing prejudice to plaintiff-minors. If used in litigation proceedings, defense counsel will be relying on a blatantly false report and thus, will be misleading the court and tribunal as to the veracity of the case report." R. 51 Ex 2.

The First Circuit United States Court of Appeals in *A.G. v. Elsevier, Inc.*, 732 F.3d 77, 83 (1st Cir. 2013) suggested that the "*Daubert* doctrine presents the appropriate opportunity to raise, in a pretrial setting, concerns about the case report."

Next the trial court then ruled testimony or literature relied on by the defendants' experts that established the maternal forces of labor could cause transient brachial plexus injury inadmissible. R. 100 at pp. 64-66. The court reasoned this case involved a permanent brachial plexus injury in the face of shoulder dystocia. *Id.* Allowing causation evidence that proved

the maternal forces of labor in the face of shoulder dystocia caused something less than a permanent brachial injury was, according to the court, irrelevant evidence and would only serve to "confuse the jury." *Id.*

The court then stated the defense experts could offer opinion evidence that the maternal forces of labor caused Unity Bayer's permanent brachial plexus injury if they established the circumstances that caused her injury and that such force was sufficient to have caused the damage. R. 100 at pp. 66-80. The trial court then asked defense counsel, what the defense experts based their causation testimony upon other than the evidence ruled inadmissible. *Id.* Dr. Dobbins counsel did not cite one medical article or study in response to the court's inquiry. Instead, he claimed the defense experts were "board certified OB-Gyns with hundreds of years of experience" who knew "the forces that go into the delivery of a baby." *Id.* Without more, the trial judge ruled the defense experts maternal forces causation testimony did not meet the requirements of § 907.02(1). *Id.*

B. Statement Of The Facts Relevant To The Issue Raised For Review

1. Shoulder Dystocia Complicates Unity Bayer's Birth

Leah Bayer was admitted to St. Mary's Hospital in Green Bay, Wisconsin, for Unity's labor and delivery on 28 December 2006. R. 56 Ex. 1. Upon full dilation of her cervix, she pushed for one hour and fifteen minutes. *Id.* She became exhausted. Dr. Dobbins then attempted to deliver the baby with a vacuum extractor. *Id.* This attempted delivery failed. *Id.* Instead, shoulder dystocia occurred. *Id.* The baby's right shoulder became stuck on her mother's pubic bone. *Id.* Initially, the doctor tried the McRoberts' maneuver to relieve the shoulder dystocia. *Id.* Even with traction, he could not free Unity Bayer's

shoulder. *Id.* When these efforts proved unsuccessful, he used the Woods corkscrew maneuver — he put his fingers into the birth canal and rotated the infant's shoulders to achieve delivery. *Id.* From the diagnosis of the shoulder dystocia, it took two minutes to complete the delivery. *Id.*

Dr. Dobbins testified that it is a departure from accepted standards of medical care to apply any traction to a baby's head or neck during a shoulder dystocia unless maneuvers fail to deliver the baby. He testified:

> Q What circumstances would allow you -- if you had the baby's shoulder caught under the -- the anterior shoulder caught under the pubic symphysis, under what circumstances would you be allowed to apply traction to the baby's head or neck to deliver the baby?
>
> MS. WEBER: Objection, asked and answered.
>
> Q Go ahead and answer the question.
>
> A In life-threatening circumstances.
>
> Q Okay. And what would be life-threatening circumstances?
>
> A Well, a shoulder dystocia itself can be life-threatening, and if it's prolonged and it's not resolving

with other maneuvers, it potentially could be required.

Q So it has to be prolonged and maneuvers fail --

MR. GAYNOR: Object to form.

Q -correct?

A Maneuvers should have failed.

Q So before you can apply traction and comply with the standard of practice where you have the shoulders caught under the -- or the shoulder --or shoulder caught under the pubic symphysis, before you apply traction, it's your testimony that medical standard of care requires that you first use maneuvers, correct?

A Correct.

Q And if you don't do that, that's negligence, correct?

MR. GAYNOR: Object to the form. Go ahead.

A If I don't do maneuvers, is that what you're asking?

Q Right. If you apply traction before you use maneuvers, that's negligence, correct?

> A After shoulder dystocia is diagnosed, yes. R. 56 Ex. 5.

The family members present for the delivery, including the baby's father and aunt, both remembered Dr. Dobbins pulling and rotating Unity Bayer's head during the shoulder dystocia. R. 56 Exhibits 6 & 7.

2. Unity Bayer Suffered A Permanent Brachial Plexus Injury At Birth

Immediately after delivery, Unity Bayer had no spontaneous movement of her right arm and hand. R.56 Ex. 2. Her subsequent treating physicians found that she did not recover function to the arm and shoulder. *Id.* Doctors who examined her found that all nerves of the right brachial plexus had been injured ("a complete obstetric brachial plexus injury") along with a Horner's syndrome. *Id.* On 28 March 2007, Unity Bayer underwent a primary nerve repair procedure requiring a nerve transfer and nerve grafts. *Id.* The medical records indicate that despite surgery, she has continued to experience severe abnormalities in the movement of her right arm, hand, and fingers. *Id.* In the summer of 2008, Rahul Nath, M.D., performed a mod-quad procedure and six months later, a triangle tilt operation. *Id.*

Unity Bayer's right arm suffered paralysis at birth. *Id.* Her injury happened because the five nerves roots in her right brachial plexus were stretched to the point of being ruptured or avulsed during delivery. *Id.* The brachial plexus is a sheath of nerves which includes the lower four cervical nerve roots, and first thoracic nerve root (C5-T1) of the spine. *Id.* The nerves run from the spinal cord, through the neck, and into the arm. *Id.* These nerves innervate the upper extremities. *Id.*

Unity Bayer is left-handed for all activities. *Id.* She can use the right hand as a helping hand if the item is light. *Id.* She does not pick up anything in that hand; rather she will hold something light in the right hand if it is placed there. *Id.* Her level of strength is such that she cannot hold even a full can of soda. *Id.* She has "significant neurological disabilities as a result of a brachial plexus injury involving the right arm." *Id.* Her pattern of weakness demonstrates that the fifth, sixth, seventh and eighth cervical nerves of the brachial plexus were damaged. *Id.* The first thoracic nerve also suffered damage. *Id.* These neurological disabilities are permanent. *Id.*

3. The Defense Experts Claim That The Maternal Forces Of Labor Caused Unity Bayer's Permanent Brachial Plexus Injury

The defendants' causation hypothesis is that during labor the maternal forces of labor caused Unity Bayer's severe permanent brachial plexus injury to all five nerves, by stretching the brachial plexus to point it sustained the permanent injury. They rely on four expert witnesses to support this point. Three out of four, Drs. DeMott, Rouse, and Scher admit they have done no testing to prove this theory. None can cite the amount of maternal force that can cause such an injury. The defense also named Michele Grimm, Ph.D. — a biomechanical engineer— as a causation expert.

a. Dwight Rouse, M.D.'s Opinions

Dwight Rouse, M.D. is a practicing obstetrician with specialized training in maternal-fetal medicine. R. 56 Ex. 19 at pp. 21-22. He has never written on the cause of a permanent brachial plexus injury in the face of shoulder dystocia. *Id.* at p. 18. Nor has he done testing to determine the amount of stretch necessary to cause a neonate's permanent brachial plexus

injury. *Id.* at p. 20. During his career, he has never delivered a baby that suffered a permanent brachial plexus injury in the absence of traction during the delivery. *Id.* at pp. 97-98.

He claims that after Unity Bayer's right shoulder had become obstructed by her mother's pubic symphysis, (i.e., shoulder dystocia) the maternal forces of labor caused her injury. *Id.* at p. 81. He admits it was a "stretch injury." *Id.* at p 104. Nevertheless, he could not identify the time when the injury took place. *Id.* at pp. 112-114. He offered no evidence of how the maternal forces stretched the brachial plexus to where all five nerves were permanently damaged. *Id.* at p. 111-112. He did not even try to establish there was pushing or a contraction when he claimed the injury occurred. *Id.* at p. 111-113. Even if there were a contraction or pushing during the injury sequence, he could not quantify the strength of the force he claimed caused the damage. *Id.* at p. 112.

Dr. Rouse was clueless when pressed on the forces that caused Unity Bayer's brachial plexus injury. He testified:

> Q. I'm asking you if you have an opinion on how much, quantitatively, force was applied to the brachial plexus, in this particular case, that caused the injury?
>
> A. You might as well ask me what the stock market's going to be in two weeks. No one can know that.
>
> Q. So you don't know the answer to that --
>
> A. I don't know it and nobody else knows it.

> Q. When did the injury occur?
>
> A. Sometime before delivery of the body.
>
> Q. Before the delivery of the what?
>
> A. The body.
>
> Q. How much before?
>
> A. I don't know.
>
> Q. Was it 15 minutes before, 30 minutes before?
>
> A. I don't know.
>
> Q. Do you know what the forces of labor in this case were, in terms of a quantitative number?
>
> A. That's not a knowable number, so I don't know it. *Id.* at pp. 111-113.

When asked about the force necessary to cause a neonate's permanent brachial plexus injury, Dr. Rouse admitted he never studied the issue, has never tested the theory and claimed it was an unknown number. *Id.* at pp. 18-20, 116.

b. Robert DeMott, M.D.'s Opinions

Robert DeMott is a Green Bay, Wisconsin obstetrician. R. 56 Ex. 18 at p.6. He has never conducted scientific research on the cause of brachial plexus injuries. *Id.* at pp. 9-11. He has undertaken no research on brachial plexus injuries. *Id.* He has completed no study on the amount of maternal force generated during labor. *Id.* He has performed no animal study, cadaver studies or animations regarding the causes of brachial plexus injuries. *Id.*

Dr. DeMott admits the neurology textbooks state neonatal brachial plexus injuries in the face of shoulder dystocia result from physician-applied traction, except for a single recent book. *Id.* at pp.12-13. He also concedes all orthopedic textbooks state the same thing — physician-applied traction cause these injuries. *Id.*

In his opinion, Unity Bayer's injury occurred during the second stage of labor. *Id.* at pp. 26-27. According to him, the damage happened when the brachial plexus was stretched to the breaking point. *Id.* He found no evidence that the baby's injury resulted from any condition that made her susceptible to the injury she suffered. *Id.* at pp. 20-21. He concedes the damage is permanent. *Id.* at p. 63.

Despite his belief that the maternal forces of labor can cause a permanent brachial plexus injury, he does not know how much stretch is required to produce a permanent brachial plexus injury. *Id.* at p. 28. He is aware of Robert Allen, Ph.D.'s 2007 studies that scientifically tested and determined the maternal forces of labor could not stretch the neonate's brachial plexus sufficiently to cause a permanent brachial plexus injury. *Id.* at pp. 29-36. That study found the maternal forces only stretched the brachial plexus up to 25% of its normal length. *Id.*

Dr. DeMott could cite no scientific evidence that disproves Dr. Allen's findings. *Id.* Nor has he undertaken a study to refute them. *Id.* He admits to being unaware of how much maternal force is needed to cause a permanent brachial plexus injury in the face of shoulder dystocia. *Id.*

When asked to provide data that supports his theory that the maternal forces of labor caused Unity Bayer's injury, he drew a blank. *Id.* at pp. 38-40. First, he could not identify the extent of her nerve injuries since he had never reviewed her long-term pediatric records. *Id.* When asked to cite the quantitative forces responsible for her injury, he testified:

> Q Okay. Thank you. So you can't tell me the amount of force to do the damage that was done in this case, correct?
>
> MR. GAYNOR: Asked and answered. Go ahead.
>
> A Correct.
>
> Q You can't tell me the amount of force from the uterine contractions that caused this case quantitatively, correct, Doctor?
>
> A Correct.
>
> Q Can you tell me the force rate?
>
> A No.

> Q Can you tell us the amount of the stretch that was applied by the forces of delivery here?
>
> A No.
>
> Q Can you tell us the strength of the baby's brachial plexus nerves?
>
> A No.
>
> Q Was it -- was it contractions or was it the mother pushing that caused the injury in this case?
>
> A Well, it's a combination of the two during the second stage of labor.
>
> Q Well, which one was it? Or tell me the percentage of each here.
>
> A You can't separate that out. There's no way to know that. *Id.* at pp. 64-65.

c. Mark Scher, M.D.'s Opinions

Mark Scher, M.D., is a pediatric neurologist. R. 57 Ex. 1 at pp.9-10. He claims Unity Bayer's permanent brachial plexus injury occurred before the shoulder dystocia. *Id.* at pp. 99-100. According to him, she experienced temporary poor muscle tone and this condition along with the maternal forces of labor caused her "severe" permanent complete brachial plexus injury. *Id.* at p. 56.

Never having scientifically his theory of injury, Dr. Scher looked for medical literature that substantiated his claim. *Id.* at pp. 56-60. He could find none. *Id.* When asked when the injury

happened, Dr. Scher could not provide a time. *Id.* at. pp. 99-100. Likewise, he could not state how much force was necessary to cause Unity Bayer's injury. He testified:

> Q And so how much force would it have been --how much force was applied to cause this brachial plexus injury?
>
> A Well, by forces of labor, it had to be severe. But I don't know. I'm not a biomedical ex --biomechanical ex -- I'm not a bioengineer to know that quantitatively. *Id.* at pp. 101-102.

d. Michele Grimm, Ph.D.'s Opinions

Michele Grimm, Ph.D. claims to have proven that the maternal forces of labor are sufficient in the face of shoulder dystocia to cause a permanent brachial plexus injury. However, she testified that since she does not know the injury threshold of a newborn's brachial plexus trying to assess the forces that will cause a permanent brachial plexus injury during the birthing process is **nothing more than guesswork**.

> Q As far as you're concerned, trying to assess the forces that cause brachial injury, quote, would be little more than guess work, unquote?
>
> A Can you tell me what that quote is from, please?
>
> Q From your -- from your prior testimony and from your textbook.

MR. SIMERSON: You've got to give us more context than that.

THE WITNESS: Yeah. I mean that's.

Q (By Mr. Petrucelli) Do you agree that trying to assess the forces that would cause a brachial plexus injury would be little more than guesswork in a particular case?

A Okay.

MR. SIMERSON: Objection. Vague.

THE WITNESS: For -- so assessing how much force for any given infant was required to cause a particular pattern of injury would simply be guesswork, yes.

Q (By Mr. Petrucelli) **You wrote in your textbook, quote, there are a significant number of questions still to be answered. Number one, unparen, what is the injury corridor for the neonatal brachial plexus and what factors affect variation? Your statement, Doctor?**

A Yes. [Emphasis Added.] R. 56 Ex. 17 at pp. 127-128.

She concedes the greatest risk of a permanent shoulder dystocia during a vaginal delivery is physician applied lateral traction, and her modeling provides no basis for concluding that the

maternal forces of labor can cause a permanent brachial plexus injury.

Q And you still believe that physician-applied lateral traction forces is the greatest risk of injury and should be avoided at all costs.

A Yes.

Q True statement, Doctor?

A Correct.

Q Your data on brachial plexus strain cannot be directly related to a brachial plexus injury occurrence or severity in an actual obstetrical case. True statement, Doctor?

A Because we don't know what that particular infant's threshold for injury is, that statement is true.

Q Your modeling cannot provide any factual, actual or specific conclusions about a specific delivery. True statement, Doctor?

A True.

Q I didn't hear your answer.

A True.

> Q So, Doctor, it's true that you cannot draw any factual, accurate or specific conclusions from your MADY --
>
> A MADYMO.
>
> Q -- M-A-D-Y -- thank you, Doctor. Let me start it again. So it's true you cannot draw any factual, accurate or specific conclusions from your M-A-D-Y-M-O model about Unity Bayer's specific delivery, correct?
>
> MR. SIMERSON: Objection. Form.
>
> THE WITNESS: Correct. As would be true for any modeling, we cannot apply it specifically to Unity Bayer's delivery. [Emphasis Added.] *Id.* at pp. 131-132.

Nonetheless, Dr. Grimm claims a research paper entitled *Mechanical Properties of Spinal Nerve Roots Subjected to Tension at Different Strain Rates* establishes the injury threshold for a permanent brachial plexus injury in a newborn however, the research reported in that article did not study newborns, or even adult human beings. It involved the evaluation of the mechanical properties and failure thresholds of adult rats' spine nerves. R. 56 Ex. 9 at pp. 57-61.

The study involved nerve failure in four spinal nerves of the adult rats, with each level tested at both a slow rate of stretch (.01 mm/ second), and a faster rate of stretch (15 mm/ second). Dr. Grimm, however, has repeatedly admitted no data establishes any relationship between the nerves of adult rats and those of human newborns. She testified there is no validation or

scientific basis for concluding that the nerves of adult rats are similar to a neonate's brachial plexus.

> Q You can point to no study that can show us -- that compares the tensile strength, the stretch capacity and the stretch capacity of the human baby's brachial plexus or any of its nerves within it to an adult rat's spinal nerves, correct?
>
> A There is no data on human infant brachial plexus or any of the components of the human infant brachial plexus in terms of mechanical properties so no comparisons have been done. R. 56 Ex. 17 at p. 105.

Dr. Grimm's reliance on the Singh article as a basis for making the claim it proves the maternal forces of labor can cause a permanent brachial plexus injury came only after she superimposed the data from the adult rat study on the applied data from a different study she did in 2003 — the one studying the injury threshold of an adult rabbit's tibial nerve. The injury threshold data from the rabbit study, however, is at significant variance with the adult rat study. She essentially, and without explanation, combined the two studies to reach her conclusion regarding the injury threshold for a neonate brachial plexus. R. 56 Ex. 9 at pp.62-71.

Grimm's modeling utilizes a preexisting program called Mathematical Dynamic Model ("MADYMO"). MADYMO, produced by Tass International, is described as the "Worldwide Standard in Occupant Safety." Its applications assess injury and

vehicular damage from automotive crashes. Dr. Grimm is the only person in the world using this program for modeling human birth. R. 56 Ex. 17 at pp. 80-81. In her 2003 paper, she claimed to have added a "brachial plexus" to the MADYMO program. The simulated brachial plexus is based on what she calls the "stiffness" of an adult rabbit tibial nerve. "Stiffness" describes how the simulated structure responds to an increasing load or force being applied to it, and at what point it fails, i.e. the "injury threshold." In her 2003 computer simulation, Dr. Grimm claims to have used the stress/strain curve from an article entitled *An in vitro Mechanical and Histological Study of Acute Stretching on Rabbit Tibial Nerve*. R. 56 Ex. 9 pp.62-66. However, she admits that the rabbit study had no validation either:

> Q Excuse me. You have no test validation -- no study validation that a rabbit tibial nerve has the same properties as a neonate's brachial plexus, correct?
>
> MR. SIMERSON: Objection. Asked and answered. Argumentative.
>
> THE WITNESS: As the data on the human neonatal brachial plexus does not exist, no, I cannot do a one-to-one assessment of that. There is substantial scientific validation for the use of animal nerves as surrogates for human nerve. R. 56 Ex. 17 at pp. 95-96.

Dr. Grimm in her 2010 attempt to establish the permanent injury threshold for the neonate's brachial threshold injury goes further. She sets aside the injury threshold contained in Rydevik's tibal rabbit nerve article that she used as the basis of her 2003 simulation of the brachial plexus and its stretching when force/load is applied. Instead, and without explanation, in 2010 she superimposed the injury threshold by Singh (adult rat's spinal nerves), on Rydevik's data (adult rabbit tibial nerve). *Id.* at pp. 97-107.

The adult rat study had a low overall average injury threshold for the slow motion stretch group (29%), which is the data she arbitrarily used from that study, and a large standard deviation (8.9%). The adult rabbit study had a higher injury threshold (38.5%) and a much lower standard deviation (2%). Even at two standard deviations from the mean, the injury threshold based on the data from the rabbit study would be 34.5%. This estimate is well beyond the 15% to 18% stretch Dr. Grimm claims can cause injury due to the maternal forces of labor. She contends this mixing and matching approach — using the characteristics of adult rabbit tibial nerves to simulate the response of the brachial plexus to the maternal forces of labor in her simulations and her data, and then superimposing upon the results the failure threshold from an entirely different study involving adult rats — is a reliable foundation for establishing an injury threshold. *Id.*

As to data from Unity Bayer's delivery that supports her theory the maternal forces of labor caused the damage, Dr. Grimm believes contractions primarily stretched the right brachial plexus resulting in permanent damage to all five nerves. *Id.* at pp. 135-136. However, she has no idea when the contraction occurred, how long it stretched the right brachial nerves or the force it produced. *Id.* at pp133-138. She concedes it is

impossible to quantify how much force Leah Bayer produced during any of her contractions. *Id.,* R.84 Ex.1 pp.156-159. She testified the injury occurred after the shoulder dystocia, but admits the defendant doctor's downward bending of Unity Bayer's neck could equally explain the injury. R.84 Ex.1 at pp. 173-175.

4. Dr. Grimm Concedes No Medical Study Exists Supporting The Defense Hypothesis That The Maternal Forces Of Labor Can Cause A Permanent Brachial Plexus Injury In The Face Of Shoulder Dystocia — Except The "Lerner Article."

In 2012, Dr. Grimm testified in a lawsuit where she served as a defense expert witness. She admitted during her testimony that the published case report by Lerner (the same article the trial court excluded from evidence) was the only medical publication supporting the theory that the maternal forces of labor are sufficient to cause a permanent brachial plexus injury. R. 56 Ex. 12.

Standard Of Review

This case requires this Court to interpret and apply Wis. Stat. § 907.02(1). Interpretation of a statute is a question of law, which is reviewed de novo. *State v. Steffes*, 2013 WI 53, ¶ 15, 347 Wis.2d 683, 832 N.W.2d 101. Interpreting § 907.02(1) is also guided by cases interpreting and applying Federal Rule of Evidence 702, which adopted the standard for the admissibility of expert opinion testimony in *Daubert* and its progeny. *Siefert v. Ballink*, 2015 WI App 59, ¶14, 364 Wis.2d 692, 869 N.W.2d 493 (rev. granted __N.W.2d __, Wis., Nov. 04, 2015)

After independently considering the applicable legal framework governing the admission of expert testimony, appellate courts review "a circuit court's decision to admit or exclude expert

testimony under an erroneous exercise of discretion standard." *State v. Giese*, 2014 WI App 92, ¶ 16, 356 Wis.2d 796, 854 N.W.2d 687. The discretionary decision of the circuit court stands "if it has a rational basis and was made in accordance with accepted legal standards in light of the facts in the record." *Id.*

A decision to admit or exclude expert scientific testimony is not an abuse of discretion unless it is "manifestly erroneous." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 142, 118 S.Ct. 512, 139 L.Ed.2d 508 (1997). Significantly, the abuse of discretion standard "applies as much to the trial court's decisions about how to determine reliability as to its ultimate conclusion." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152, 119 S.Ct. 1167, 143 L.Ed.2d 238 (1999). In analyzing the admissibility of expert evidence, the circuit court must be afforded broad discretion to determine what method is appropriate for evaluating reliability under the circumstances of each case.

Argument

I. The Circuit Court Properly Excluded The Defense Experts' Opinions That The Maternal Forces Of Labor Caused Unity Bayer's Permanent Brachial Plexus Injury Since Those Opinions Were Unreliable And Bore No Scientific Connection To The Causation Issue Present In The Case

This case illustrates the continuing importance of the Supreme Court's observation in *Daubert v. Merrell Dow Pharmaceuticals, Inc.,* 509 U.S. 579, 113 S.Ct. 2786, 125 L.Ed.2d 469 (1993):

> [T]here are ... differences between the quest for truth in the courtroom and the quest for truth in the laboratory.

> Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment often of great consequence about a particular set of events in the past. We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.

Daubert, 509 U.S. at 596–97, 113 S.Ct. 2786. In Judge Posner's words, "the courtroom is not the place for scientific guesswork, even of the inspired sort. Law lags science; it does not lead it." *Rosen v. Ciba–Geigy Corp.*, 78 F.3d 316, 319 (7th Cir.1996).

Judge Miron characterized the defense experts' maternal forces causation evidence as guesswork, and the record supports his

conclusion. Although the defendants' evidence provided support for the proposition those forces could cause a temporary brachial plexus injury in the face of shoulder dystocia; however, the record failed to show such a force could or caused the permanent injury Unity Bayer sustained. Therefore, the trial court did not abuse its discretion in ruling that the defense experts' opinions failed to satisfy § 907.02(1)'s standard of reliability.

A. The Circuit Court Appropriately Applied Wis. Stat. § 907.02(1) To Determine The Admissibility Of The Defense Experts' Causation Opinions

The defendants contend the trial judge misapplied § 907.02(1) four different ways. They argue any of one of the claimed transgressions constitutes an abuse of discretion mandating reversal. However, an examination of Judge Miron's rationale for excluding the defense experts' maternal forces causation testimony shows his opinion has a sound basis and comports with how he was to apply the statute. Consequently, he did not abuse his discretion in ruling as he did.

First, the defense complains Judge Miron's ruling is erroneous since he failed to "describe or refer to the *Daubert* test in any way." In determining the admissibility of expert testimony under § 907.02(1), a trial court need not "recite the *Daubert* standard as though it were some magical incantation." *Ancho v. Pentek Corp.*, 157 F.3d 512, 518 (7th Cir.1998). Nor need it apply all of the reliability factors suggested in *Daubert* and *Kumho*. *Id.* All the trial court must do is to demonstrate it has performed its duty as a gatekeeper. *Id.* Judge Miron's order must be read in its totality, and when done so, it is sufficiently clear that he relied on the *Daubert* standard when he rendered his oral ruling.

The second and third complaints the defense raise claim the trial judge refused to accept "peer-reviewed literature relied on by their experts and failed to the "accept the breadth of evidence" submitted to support the defense causation theory. Regarding his exclusion of the defendants' experts' general causation testimony, Judge Miron conducted a thorough review of the scientific literature submitted by the parties and which the defendants' experts relied. He found, as Dr. Grimm admitted, there is insufficient scientific that supports the theory the maternal forces of labor can cause a permanent brachial plexus injury, and the controversial Lerner single case report does not provide the necessary data to bridge the gap. Judge Miron's evaluation of the fit between the defense experts' opinions and the scientific literature on which they relied was within the broad discretion afforded to him under § 907.02(1). It is precisely such an undertaking that assures that an expert, when formulating an opinion for use in the courtroom, will employ the same level of intellectual rigor as would be expected in the scientific community.

What the defense postulates is that since their experts say the science and the medical literature proved the maternal forces of labor can and did cause Unity Bayer's permanent injury, the court is prevented from questioning the conclusions their experts reached. Such a view is contrary to what the United Supreme Court recognized in *Joiner*,

> [B]ecause it was within the District Court's discretion to conclude that the studies upon which the experts relied were not sufficient, whether individually or in combination, to support their conclusions that Joiner's exposure to PCB's contributed to his

> cancer, the District Court did not abuse its discretion in excluding their testimony.

Joiner, 522 U.S. at 146–47. Thus, when an expert opinion is based on data, a methodology, or studies that are simply inadequate to support the conclusions reached, *Daubert* mandates the exclusion of that unreliable opinion testimony. *See Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 153 (3d Cir.1999) ("[A] district court must examine the expert's conclusions to determine whether they could reliably follow from the facts are known to the expert and the methodology used.").

Judge Miron did as he was supposed to have done. As *Joiner* teaches "[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered." 522 U.S. at 146. Accordingly, for the reasons stated in its opinion, the trial court did not abuse its discretion in excluding the defense experts' testimony when it that concluded the analytical gap between the studies on which they relied and their conclusions were simply too great rendering their opinions unreliable.

Finally, the defense contention that the trial court's decision excluding its expert causation testimony usurped the "adversarial process" ignores that the result reached by the trial court is exactly what the legislature intended when it amended § 907.02(1). Had the legislature just wished to allow juries to decide what expert theory to accept it would have left in place the former relevancy standard. As Judge Miron explained, § 907.02 mandates that before a jury may consider expert

testimony, it must first meet the foundation required by the § 907.02. Since the defense experts' maternal forces of labor opinions did not meet the bar set by § 907.02(1), the trial judge's decision constituted no usurpation of the jury's and experts' roles.

B. The Circuit Court Properly Excluded The Defense Experts' Maternal Forces Of Labor Causation Opinions Under Wis. Stat. § 907.02(1)

The defense expert opinions can be broken down into two components — general causation and specific causation. The first is concerned with whether the injury at issue can theoretically be caused by the mechanism in issue (can x cause y); while "specific causation" is concerned with whether the injury was so caused (did x cause y in this case). *Ambrosini v Labarraque*, 101 F3d 129, 130 (CA DC 1996), *Ruggiero v Warner-Lambert*, 424 F3d 249, 254 (CA 2 2005). Here, for reasons explained below, the trial court acted within its discretion in precluding the defense causation opinions under §907.02(1) since they lacked "sufficient facts or data" to support them.

1. Since No Reliable General Causation Evidence Was Presented That Proved The Maternal Forces Of Labor Can Cause A Permanent Brachial Plexus Injury In the Face Of Shoulder Dystocia, The Circuit Court Acted Within Its Discretion In Excluding The Defense Experts' Causation Opinions

The trial court recognized medical science had only established a link between temporary brachial plexus injuries in the face of shoulder dystocia and the maternal forces of labor. This finding is consistent with Dr. Grimm's admission that other than the Lerner single case report there is no medical literature or study

supporting the theory that the maternal forces of labor are sufficient to cause a permanent brachial plexus injury. Without more, which the defense never provided to the court, Judge Miron rationally found there was an absence of proof that the maternal forces of labor were sufficient to cause a permanent brachial plexus injury in the face of shoulder dystocia.

Nor did Dr. Grimm's animal studies provide the missing link. She admitted there is no human data with which to correlate their results, and, therefore, the trial court implicitly found any attempted correlation was nothing more than speculation. Courts have not hesitated to exclude expert causation opinions relying on animal studies where the expert fails to explain how and why the results of the animal studies can be extrapolated to humans. *See, Newkirk v. Conagra Foods, Inc.,* 727 F. Supp. 2d 1006, 1025-26 (W.D. Wash. 2010) citing *Joiner*, at 522 U.S. 143-45 (1997) (plaintiff's proffered expert testimony relying on animal studies was excluded because the expert offered "no explanation for how and why the results of those studies can be extrapolated to humans"). Therefore, Judge Miron acted within his discretion in rejecting the Grimm studies as a basis for the defense causation opinions that the maternal forces of labor were sufficient to cause a permanent brachial plexus injury in the face of shoulder dystocia.

In the end, the medical literature on brachial plexus only speculates that the maternal forces of labor can cause a permanent injury. It offers no answers beyond the theories they describe. As it turns out, there is still much mystery surrounding infant development and the birth process. The fact that our society's moral and ethical constraints and the current limits of our technology prevent obtaining the data that might establish defendants' causation theory does not mean that the trial court

abused his discretion in not overlooking the analytic gap that exists.

C. The Circuit Court Did Not Abuse Its Discretion In Excluding The Defense Experts' Maternal Forces Causation Opinions When He Choose Not To Follow Case Law That Was Nonbinding, Unpersuasive, And Involved Different Evidence

Defendants cite cases where other courts have allowed the maternal forces of labor causation defense. However, it failed to cite the most thorough and recent cases that find the defense inadmissible. In *Muhammad v. Fitzpatrick*, 91 A.D.3d 1353, 937 N.Y.S. 2d 519 (2012) the Appellate Division precluded the same theory of causation offered in this case in part because of the inability of the defendant to establish evidence of general or specific causation. *See also, Nobre v. Shanahan,* 42 Misc. 3d 909, 976 N.Y.S. 2d 841 (Orange Co. Sup. Ct, 2013).

The defense argues that by refusing to march in lockstep with other nonbinding court decisions that admitted the maternal forces of labor defense, the trial court abused its discretion in excluding the defense expert's causation opinions. However, such argument ignores that the trial court may consider many factors in assessing reliability under § 907.02(1) and because of that discretion appellate review is limited to determining whether the trial court's application of § 907.02(1) manifests a clear error of judgment or exceeds the bounds of permissible choice in the circumstances. When coupled with this deferential standard of review, *Daubert's* effort to safeguard the reliability of science in the courtroom may produce a counter-intuitive effect: different courts relying on the virtually the same science may reach different results. *See generally* Federal Judicial Center*, Reference Manual on Scientific Evidence 25 (3d ed. 2011)* (observing that, because of the abuse of

discretion standard of review for *Daubert* determinations of reliability, "in theory judges are free to select different procedures and apply different factors to a particular expert or type of expertise than their colleagues do in the same district or circuit" and that "[a]s a consequence, similar cases could be resolved differently on the basis of inconsistent determinations about admissibility"). Thus, the exclusion of the maternal forces of labor evidence as unreliable does not establish that an inconsistent holding by the trial court compared to other opinions constituted an abuse of discretion.

The review here is whether the trial court acted within its discretion in ruling that the maternal forces of labor evidence was unreliable in light of the record and § 907.02(1). Since the court acted within its discretion, even thou there is disagreement with the cases cited by the defense, the trial court's ruling must stand.

D. It is Not Enough That The Defense Experts' Maternal Forces Of Labor Causation Opinions Are Merely Possible And Since That Is All They Are, The Circuit Court Acted Within Its Discretion In Excluding Them From Trial

The defense claims that if their experts' causation opinions are possible, they are admissible. Therefore, since their experts' maternal forces of labor opinions were possible, they contend the trial court abused its discretion in disallowing them. This argument misstates Wisconsin case law both before the adoption of the current version of § 907.02(1) and the amended statute itself.

Wisconsin law is clear that "a verdict cannot stand on conjecture, unproved assumptions or mere possibilities." *Schwalbach v. Antigo Elec. & Gas. Inc.*, 27 Wis. 2d 651, 655,

135 N.W.2d 263 (1965). Wisconsin law is equally clear that the defendants have the burden to introduce evidence to support any alternative cause of Unity Bayer's injuries before they may assert such a defense.

Clearly, alternative causes for Unity Bayer's injuries requires expert testimony because it "involves technical [and] scientific ... matters beyond the common knowledge and experience of jurors." *City of Cedarburg Light & Water Comm'n v. Allis-Chalmers Mfg. Co.*, 33 Wis. 2d 560, 568, 149 N.W.2d 661 (1967); *Bruss v. Milwaukee Sporting Goods Co.*, 34 Wis.2d 688, 696, 150 N.W.2d 337 (1967) ("[T]he lack of expert testimony on the question of causation results in an insufficiency of proof...."). Where expert testimony is required, experts must testify to a reasonable professional "certainty" or "probability." *McGarrity v. Welch Plumbing Co.*, 104 Wis. 2d 414, 429-30, 312 N.W.2d 37 (1981*); Pucci v. Rausch*, 51 Wis. 2d 513, 519-20, 187 N.W.2d 138 (1971). That is, "an expert opinion expressed in terms of possibility or conjecture is insufficient...." *McGarrity*, at 430.

The defendants overstate the holdings of *Hernke v. Northern Insurance Co.*, 20 Wis. 2d 352, 360, 122 N.W.2d 395 (1963) and *Peil v. Kohnke*, 50 Wis.2d 168, 183, 184 N.W.2d 433 (1971), which they claim entitles them to have their experts testify during direct examination regarding possibilities rather than probabilities. This argument fails for two reasons. First, in *Hernke*, the issue was whether the plaintiff's medical doctors could be cross-examined on other possible causes of the plaintiff's injuries. The court held that "it is proper to cross-examine a plaintiff's medical witness on matters which do not rise to the dignity of 'reasonable medical probability." Similarly, in *Peil v. Kohnke*, 50 Wis. 2d 168, 183, 184 N.W.2d 433 (1971), the Wisconsin Supreme Court cited *Hernke* as support

for the proposition that "it is proper to cross-examine a plaintiff's medical witness on matters which do not rise to the dignity of 'reasonable medical probability.' " Thus, it is proper to cross-examine experts on possibilities because it tests the strength of the expert's opinion.

Second, the Wisconsin Court of Appeals rejected the contention that defendants can introduce alternative causes for the plaintiff's injuries couched in terms of possibilities in *Estate of Hegarty ex rel. Hegarty v. Beauchaine*, 2006 WI App 48, 249 Wis.2d 142, 638 N.W.2d 355. *Hegarty* was a medical malpractice case where the plaintiffs alleged that the defendant physician negligently diagnosed and treated the decedent. *Id.* at ¶¶ 9-13. The defendants asserted two alternative causes for the plaintiff's injuries: (1) the failure of other physicians to perform surgery later in the morning on the day in question "possibly" caused the injuries; or, (2) the failure of other physicians to perform surgery one month before the day in question "possibly" caused the injuries. *Id.* at ¶¶ 161 & 170. Before trial, the plaintiffs moved in limine to preclude the defendants from introducing evidence of "possible negligence... that was not causal and that was not established by expert testimony." *Id.* at ¶ 157. The trial court granted the motion. *Id.* at ¶ 158.

On appeal, the defendants argued that *Hernke* allowed them to introduce testimony on alternative theories of negligence or cause, even if couched in terms of possibilities:

> Relying on *Hernke v. Northern Insurance Co.*, 20 Wis.2d 352, 360, 122 N.W.2d 395 (1963), Beauchaine/OHIC begin by asserting that in medical malpractice cases, the plaintiff must produce testimony based on reasonable medical probabilities, while the defendant may weaken the

> plaintiff's claim by showing mere possibilities.

Id. at ¶ 159. In affirming the trial court's exclusion of testimony regarding alternative possibilities, the Court of Appeals stated, "Beauchaine/OHIC are mistaken." *Id.* (emphasis added). It went on to say that "[w]hile it is true that a party need not rise to a level of medical probability when cross-examining an opposing party's expert witness regarding matters on which the opposing party bears the burden of proof...," introducing evidence of alternative theories "would have invited speculation by the jury and would have been inconsistent with the proper standard; that is, that the jury must be satisfied 'by the greater weight of the credible evidence, to a reasonable certainty, that 'yes' should be [the] answer to the verdict questions.' WIS JI--CIVIL 200." *Id.* at ¶ 160.

Any doubt about whether a defense expert can introduce alternative theories of causation couched in possibilities was wiped away with the 2011 amendment to § 907.02(1). The statute applies to all expert testimony. It prohibits expert opinion testimony based on a possibility. Had the trial court measured the defense's maternal forces of labor theory based on whether it was possible to have caused Unity Bayer's injury that would have been an erroneous application of the statute. Instead, the trial court properly refused to use the possibility standard when it ruled on the plaintiffs' *Daubert* motion. Had the trial court used the possibility standard, he would have committed error. Instead, his ruling comported with the mandates of § 907.02(1).

Conclusion

The plaintiffs request that this Court find the trial court acted within its discretion when it found that under Wis. Stat. § 907.02(1) the defense experts' maternal forces of labor

causation testimony was unreliable and inadmissible. They ask that the trial court's order be affirmed.

Dated this 26th day of January 2016.

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Certifications

Form And Length Certificate

I certify this brief meets the form and length requirements of Wis. Stat. § 809.19(8)(b) and (c) as modified by the court's order. It is in proportional serif font, minimum printing resolution of 200 dots per inch, l3-point body text, leading of minimum 2-point and maximum 60-character lines. The length is 8,242 words.

Dated this 26th day of January 2016.

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Certificate Of Compliance With Wis. Stat. § 809.19(12)

I certify that I submitted an electronic copy of this brief which complies with requirements of Wis. Stat. § 809.19(12). I further certify this electronic brief is identical in content and format to the printed form filed as of this date. A copy of this certificate had been served with the paper copies filed with the Court and served on all opposing parties.

Dated this 26th day of January 2016.

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Certificate Of Service

I certify that on the 26th day of January 2016 I caused copies of the foregoing brief to be deposited in the United States' Mail for delivery to counsel for the parties by first-class mail at these addresses:

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