IN THE SUPREME COURT OF THE STATE OF MISSISSIPPI

CASE NO. 2009-TS-01037

ATRAVIUS COLEMAN, BY AND THROUGH HIS MOTHER AND NEXT FRIEND, ANGELIA PATTERSON, ON BEHALF OF THE WRONGFUL DEATH BENEFICIARIES AND AS ADMINISTRATRIX OF THE ESTATE OF ATRAVIUS COLEMAN, DECEASED **PLAINTIFF/APPELLANT**

VS.

BOB TIBBS, M.D., WILLIAM McARTHUR, M.D. and BOLIVAR MEDICAL CENTER **DEFENDANTS/APPELLEES**

BRIEF OF APPELLEE BOLIVAR MEDICAL CENTER

Appeal from the Circuit Court of Bolivar County, Mississippi
Second Judicial District
Civil Action Nos. 2002–0150 & 2002-0151
Honorable Charles E. Webster, Circuit Court Judge

ORAL ARGUMENT REQUESTED

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CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons have an interest in the outcome of this case. These representations are made in order that the Justices of the Mississippi Supreme Court and/or the Judges of the Court of Appeals Court may evaluate possible disqualification or recusal:

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10. Honorable Charles E. Webster
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SO CERTIFIED, this, the 10 day of September, 2010.

KIMBERLY N. HOWLAND

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STATEMENT OF THE ISSUES

I. The trial court correctly concluded that the opinion testimony of Plaintiff's experts was not the product of reliable scientific methodology in that Plaintiff's experts failed to provide a scientific basis for their opinions (1) regarding the half-life of Demerol in a neonate and (2) failed to support their opinions that post-mortem redistribution does not apply to Demerol, making their opinions regarding the cause of death of Atravius Coleman being Demerol toxicity/overdose scientifically unreliable. The trial court thus correctly excluded these opinions pursuant to Mississippi Rule of Civil Procedure 702.

II. The trial court did not err in granting judgment for the Defendants as Plaintiff did not argue to the trial court the ability to prove medical causation without the testimony of Dr. Shukan and Dr. Hayne, and Plaintiff did not oppose the entry of summary judgment and dismissal in favor of the Defendants.

STATEMENT OF THE CASE

I. General Nature of the Case and Proceedings Below

This is a wrongful death case arising from the demise of newborn baby, Atravius Coleman, on February 23, 2002, at Bolivar Medical Center (sometimes hereinafter referred to as "BMC"). Angelia Patterson, the mother of Atravius Coleman, brought suit against BMC, the obstetrician who delivered Atravius – Dr. William McArthur, M.D., and the pediatrician who cared for Atravius, Dr. Robert Tibbs, M.D. During the course of discovery Plaintiff designated Steven Shukan, M.D., as a retained expert in the field of pediatrics and also designated pathologist Steven Hayne, M.D. Dr. Hayne performed the post-mortem examination of Atravius Coleman. Defendants deposed Dr. Shukan and Dr. Hayne to discover their opinions relating to the cause of death of Atravius Coleman, and subsequently challenged the reliability of those opinions pursuant to Mississippi Rule of Evidence 702, *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) and its Mississippi progeny. After a lengthy two day *Daubert* hearing which included testimony of numerous experts, the Honorable Charles Webster issued a well reasoned opinion holding that the opinions of Doctors Shukan and Hayne regarding Demerol toxicity/overdose as the cause of death of Atravius Coleman, which were based upon application of the theory of retrograde or back extrapolation, lacked the requisite scientific reliability. Accordingly, the trial court correctly excluded those opinions. Plaintiffs then conceded that without the excluded testimony of Doctors Shukan and Hayne they could not meet their burden of proof as to medical causation, and allowed judgment to be entered for the Defendants without objection. Plaintiffs now appeal to this Court seeking the reversal of the trial court's

ruling excluding the testimony of Doctors Shukan and Hayne and the subsequent entry of judgment in favor of the Defendants.

II. Statement of Relevant Facts

Atravius Coleman was born at BMC February 22, 2002 at 4:35 a.m. His mother, Angelia Patterson, was a patient of Dr. McArthur and Dr. McArthur attended Patterson during her labor and delivery. Patterson was admitted to the BMC labor and delivery unit on the afternoon of February 21, 2001. (D7, BMC-50-51)[1] As is commonly done in childbirth labor, Dr. McArthur ordered that the narcotic pain reliever, Meperidine, commonly known as Demerol, be administered to Patterson as needed for pain relief. (D7, BMC-0069) Per item 10 of Dr. McArthur's standing labor and delivery orders, the BMC labor and delivery nursing staff was authorized to administer 50 milligrams of Demerol either intravenously or intramuscularly every two hours as needed. The BMC labor and delivery progress notes and the BMC labor and delivery narcotics log document that Patterson received 50 milligram doses of Demerol at 20:10 (8:10 p.m.) and at 23:00 (11:00 p.m.). (D7, BMC 60-61, D8, BMC 212-213, R861) It is not contended by any party that these two doses of Demerol would violate any medical standard of care. After an uneventful labor, Atravius Coleman was delivered at 4:35 a.m. on February 22, 2002, and admitted to the well-baby newborn nursery. (D7, BMC 77; D6, BMC 11, 36) Dr. Tibbs' newborn admission assessment on the 22nd found Atravius to be "doing well." (D6, BMC 6)

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[1] "R." refers to the main record of Clerk's papers and "T." to the *Daubert* hearing transcript. "P#" and "D#" refers to the exhibits of the *Daubert* hearing.

As Atravius had no medical contra-indications, he was circumcised by Dr. McArthur at 1:45 p.m. that afternoon. (D6, BMC 16) The nurse who attended the circumcision, Natalie Tolbert, LPN II, noted, "13:45 - circ. [circumcision] done per Dr. McArthur. Light bleeding noted. Neosporin ointment with adaptec dressing applied." (D6, BMC 16) It is established by unrefuted sworn testimony that male infants born at BMC do not receive oral or intravenous medication of any kind for pain relief for circumcision, and the uncontradicted testimony of Dr. McArthur and the BMC personnel was that Atravius Coleman did not receive Demerol at the time of his circumcision, or at any time after his birth by direct administration. (R 438-451) It is further undisputed that Demerol crosses the placental barrier when administered to laboring mothers, and that newborns whose mothers receive Demerol during labor will have blood concentrations containing Meperidine/Demerol.

At 3:30 p.m. the BMC nursery RN, Shelley Bays, noted Atravius to pale and with lower than normal oxygen saturation. (D6, BMC 15) Lab tests, blood cultures, aterial blood gases were ordered and performed. (D6, BMC 8) At 17:30 Dr. Tibbs ordered that an echocardiogram be performed "STAT" or as soon as possible. (D6, BMC 8) The findings of the echocardiogram were:

> There is indistinct separation of the right and left ventricles. There is suggestion of hypoplastic appearance of what should be the left ventricle . . . . Congenital anomalous appearance of the heart. Findings are suspicious for hypoplastic left heart syndrome or Type III persistent truncus arteriosus.

(D4, Exhibit 6) These cardiac conditions negatively effect the heart's ability to pump blood, and unless the baby is born in, or is able to be quickly transferred to, a cardiac surgery specialty center, usually result in death. (T. 153)

Despite resuscitative measures, Atravius Coleman died at 00:05 a.m., February 23, 2002. His body was taken to Jackson for autopsy, which was performed by Dr. Steven Hayne. Dr. Hayne did not have Atravius Coleman's BMC medical record at the time of the autopsy and did not review the echocardiogram report until one to two years after he performed the actual autopsy. (D4, pp. 80, 121) Dr. Hayne's autopsy did not find a hypoplastic left ventricle or other serious heart defect. Toxicological studies performed upon blood samples of ventricular heart blood drawn by Dr. Hayne at autopsy revealed that Atravius Coleman's blood contained caffeine, Meperidine/Demerol and the metabolite of meperidine, normeperidine, all within expected analgesic ranges. The blood serum concentration of Demerol found post-mortem in Atravius Coleman was .17 micrograms per milliliter, a "normal" finding according to the performing laboratory. (R. 924, D10-PME 0016).

During the litigation Plaintiff designated as experts Dr. Steven Shukan, pediatrician, and Dr. Steven Hayne, pathologist, who, by using the process of back extrapolation, a mathematical computation by which a determination of blood level content at an earlier time is reached by calculating back from a later known level using *known properties* of the drug or chemical and how it is eliminated from the body over time, opined that if Atravius Coleman's blood concentration of Demerol was .17 micrograms per milliliter at the time of death, he would have had a higher blood concentration of Demerol during his twenty hour life. Doctors Shukan and Hayne, using the process of back extrapolation, opined that Atravius Coleman's cause of death was Demerol toxicity/overdose. In order to engage in the process of back extrapolation, Plaintiff's experts necessarily had to utilize the concept of the "half-life" of Demerol,

which is the time it takes for the blood concentration of a substance to become reduced by half in the blood stream and then continues to be eliminated until it is no longer present. They also had to rely upon the accuracy of the .17 micrograms per milliliter blood concentration of Demerol found post-mortem as being the level of Demerol in Atravius Coleman's blood stream *prior* to death in order to attempt to back extrapolate from that number. Both of these points are critical to Dr. Shukan and Dr. Hayne's opinions in this case.

DR. SHUKAN'S OPINION

Despite an initial opinion that discounted the role of Demerol in Atravius' death and questioned Dr. Hayne's cardiac/heart autopsy findings (R 65), Dr. Shukan later opined that massive Demerol overdose was the cause of death of Atravius Coleman. This opinion was given in spite of the fact that the medial record is devoid of any physician order for Demerol to be given to Atravius, despite the testimony of Dr. McArthur, the physician who performed the circumcision, that no medication was given to Coleman in preparation for his circumcision, and despite the unrefuted affidavits of the BMC nursery and lab personnel establishing that Demerol was not ordered or given to Atravius Coleman at any time he was in the BMC nursery. (R. 438-451) Indeed, Dr. Shukan opined that he was able to determine *with specificity* the time this phantom dose of Demerol was administered to Atravius and the amount given. Dr. Shukan testified at his deposition that he had not used Demerol in his practice in many years, but that he "refreshed" himself on the properties of Demerol using the PDR and WebMD. (D3, pp. 42-43) He then testified that an unidentified person administered 100 milligrams of Demerol to Atravius Coleman at 1:30 p.m. on February 22, 2002, as

analgesia for the circumcision procedure. (D3, p. 107-108; 38-39) This would be twenty times the appropriate dose of Demerol for a neonate of Atravius Coleman's weight! Using a three hour half-life for Demerol, Dr. Shukan simply doubled the .17 microgram per milliliter concentration found post-mortem every three hours until he reached a value approaching 100 mgs., which according to his timeline would be 1:30 p.m, the time of the circumcision. He testified as follows:

> And a very important part of Demerol, a very important part is its half-life. And its half-life is what I explained approximately three hours in a child. And now I am showing the jury what the half-life means, because it is a concept that people don't deal with and that people don't readily know.
>
> If we took a dose of 100 milligrams, three hours later in the body that would be 50 milligrams; three hours after that, 25 milligrams; three hours after that 12, 12½ milligrams; and three hours after that, 6 milligrams. Six milligrams is as close as we can come in a dose to the dose (sic) that -- remember we just told you Atravius Coleman's would be close to 5 milligrams, and in all honesty, in medicating 5 and 6 milligrams are very close to each other. But this is about the dose that could easily give a therapeutic – that is, at this dose we would expect to find blood levels that are safe and would take away pain.
>
> So, very frankly, this could give us a dose level of .17 micrograms. It can give us a dose level of between and 1 and 3 -- .1 and .3 micrograms, which is pretty much the normal of Demerol. So that's about what I wanted you to know there. . . . If we go back and take this back, we'll notice that to get to this dose, it took approximately twelve hours to go from 100 milligrams to 6 milligrams, and that is very important to know. Twelve hours.
>
> We will show you that when this was given to Atravius, it was approximately 12 hours before the blood was taken from him that gave us a normal blood level. The laboratory [Dr. Hayne] recognized it because they called it a toxic level, even though that it was right in their normal therapeutic levels that they would expect in a person who is getting the right dose. They recognized how old the blood was and that this would have to have been a much larger dose. So they called it a toxic dose.

(R. 1068). Essentially, Dr. Shukan determined that the half-life of Demerol in a neonate was three hours, and his back extrapolated using a specific three hour half-life from the

amount of Demerol discovered in the blood samples taken from the body of Atravius Coleman post-mortem, to the time of the circumcision.

The *Daubert* hearing was held ten months after Dr. Shukan was deposed and gave his opinion based upon back extrapolation using the three hour half-life. Dr. Shukan did not testify at the *Daubert* hearing. At the hearing Plaintiff failed to provide any scientific literature to support the use of a specific three hour life of Demerol in a neonate, or to address the medical literature provided by the Defendants that contradicts the categorical use of a three hour half-life for a neonate.

DR. HAYNE'S OPINION

Dr. Hayne also gave an opinion that Atravius Coleman's death was related to a Demerol overdose using the process of back extrapolation applied to the values found in post-mortem toxicology results. Dr. Hayne, however, used a 4.5 to 5 hour half-life for Demerol and he back extrapolated to the time of Atravius Coleman's birth, some 21 hours prior to death. (D4, pg. 119) Contrary to Dr. Shukan, who contended that a massive dose of Demerol was directly administered to baby Coleman, Dr. Hayne believed the Demerol found in Atravius' blood stream post-mortem was the result of the Demerol administered to his mother during labor. (D4, pg. 119) Dr. Hayne's use of a 4.5 to 5 hour half-life was based upon phone calls to employees of the State Crime Lab. (D4, 126, 157-58) Those employees did not testify before the trial court in the *Daubert* hearing, and the information upon which they relied upon was never disclosed.

It is undisputed that both Dr. Shukan and Dr. Hayne were only aware of, and therefore utilized, the general two to five hour half-life for Demerol that is applicable to

adults, and were not aware of the medical literature establishing the half-life of Demerol in neonates, such as Atravius Coleman.

TESTIMONY AND LITERATURE REGARDING THE PHARMACOKINETICS OF DEMEROL AND POST-MORTEM REDISTRIBUTION

The only medical literature submitted to the Court regarding the pharmacokinetics and half-life of Demerol in neonates was put forth by Defendants. (R. 1168-69, 1198-99). That literature stands uncontradicted as follows:

P16 Robert J. Roberts, M.D., Ph.D., *Drug Therapy in Infants*, p. 303, "For meperidine, the reported plasma half-life in newborns ranges form 6.5 to 39 hours."

P14 Betty R. Kuhnert, Ph.D., et al, *Disposition of Meperidine and Normeperidine Following Multiple Doses During Labor,* American Journal of obstetrics and Gynecology, p. 414: Showing a median half-life of 13.24 hours with a 2.6 hour standard deviation.

P15 Marja-Leena Pokela, M.D., et al, *Pharmacokinetics and Pharmacodynamics of Intravenous Meperidine in Neonates and Infants*, Clinical Pharmacology Therapy, p. 342: "The pharmacokinetics of meperidine varied greatly between the subjects, with a median elimination half-life of 10.7 hours. Impaired meperidine metabolism is believed to be limited to newborns . . . . The great interindividual variability in meperidine pharmacokinetics should be taken into consideration when meperidine is administered to neonates."

D30 P. L. Morselli, et al, *Placental Transfer of Pethidine and Norpethidine and their Pharmacokinetics in the Newborn.* "In the neonate, the apparent pethidine [meperidine] half-life is 2 to 7 times longer than in adults with values ranging from 7 to 32 hours."

D31 WikiAnswers – *What are the Pharmacokinetics of Demerol?* p. 5, 6 "In the neonate, the half-life of Meperidine has been variously reported as 7 to 40 hours (Kuhnert) or 4.9 to 16-8 hours (Poleka) in term infants less than one week of age." (emphasis added)

Dr. Cleary, a board certified pharmacotherapist, with the University of Mississippi Medical Center, testified on behalf of the Defendants regarding the pharmacokinetics of

Demerol and the well recognized scientific phenomenon of post-mortem redistribution. Unlike Dr. Shukan and Dr. Hayne, who did not produce any literature or information applicable to the use of Demerol in neonates, Dr. Cleary provided the trial court with a body of literature specifically applicable to neonates, which anyone purporting to engage in back extrapolation calculations for Atravius Coleman should have located and considered. It is undisputed that Plaintiff's experts did not locate or even consider the scientific literature applicable to neonate patients such as Atravius Coleman, but rather, relied upon generic information for adults, which for firmly established, well known medical/scientific reasons simply does not apply to Atravius Coleman. Explaining the relevant and applicable literature, Dr. Cleary testified the reason Demerol is eliminated from a neonate at a much slower rate is that in the first few hours of life, a neonate's liver, which has only just begun to function independently of the mother, does not work as efficiently as an adult liver and cannot clear serum concentrations from the bloodstream in the same period of time as an adult. Dr. Clearly testified unequivocally that he could find no scientific basis for the premise that the half-life of Demerol in a neonate is comparable to the half-life of Demerol in an adult, which mis-information is the very basis of the back extrapolation calculations of Dr. Shukan and Dr. Hayne. (T. 237-38)

In addition to using inapplicable literature to base their opinions regarding back extrapolation, Plaintiff's experts also failed to take into account the known high rate of error which the scientific community recognizes when one attempts to utilize a post-mortem blood concentration in order to estimate what a pre-death blood serum concentration would have been. This known high rate of error is brought about by a

process called post-mortem redistribution, which is the process of which drugs and other chemicals that have been absorbed into the tissues of a living body leach from those tissues back into the blood stream or collect in certain organs of the body at death. Dr. Cleary's testimony before the trial court analyzed the medical literature on post-mortem redistribution and demonstrated, based upon the peer reviewed scientific literature, the large degree of variability between drug concentrations tested at autopsy to pre-death levels. (T. 245-252) Specifically, Dr. Cleary utilized a text book accepted by Dr. Christopher Long, the only witness who testified for the Plaintiff at the *Daubert* hearing, which states, "Meperidine may be subject to post-mortem redistribution; heart/femoral blood concentration ratios averaged 2.1 (range 1.2 - 3.2) in five autopsy cases, but averaged 1.1 (range 0.8 - 1.5) in additional six cases. (P. 9, Randall Baselt, PhD., *Disposition of Toxic Drugs and Chemicals in Man* (7th Ed.), pg. 658) Dr. Cleary was then asked:

> Q. And does that give support to the scientific finding that you had in these other articles that you cannot rely upon scientifically at post-mortem a finding of a drug in the blood and apply it backwards to life, what was in the blood at life?
>
> A. What it tells me is that it would only be a rough estimate if I was going to use those concentrations. It is not sound in mathematics and sound in being able to go forward and make a prediction about it.

(T. 252)

The trial court found significant the peer reviewed article from the Journal of Clinical Pathology, P-13, *Estimating Antemortem Drug Concentrations from Post-Mortem Blood Samples: The Influence of Post-Mortem Redistribution*, pg. 284, which states, "Our study shows a high degree of error can arise from attempting to predict

antemortem concentrations from post-mortem concentrations, and emphasizes the need for continued research in this area of pathology practice. **In the absence of such data, estimates of circulating drug concentrations during life should not be made. In borderline cases where drugs might be involved, the toxicological finding should only be used to support known clinical or pathological findings.**" (emphasis added) What has occurred in this case is exactly what the authors of P-13 warn against, using toxicological findings which are known to have a high degree of error when there is no known clinical basis for the conclusions.

TESTIMONY OF PLAINTIFF'S WITNESS CHRISTOPHER LONG, M.D.

It is undisputed that neither Dr. Shukan nor Dr. Hayne testified before the trial court to support their opinions and did not make submissions of any type to bolster their challenged opinions. Instead, Plaintiff attempted to shore-up Dr. Shukan and Dr. Hayne's opinions by the testimony of Dr. Christopher Long, toxicologist. With regard to the issue of post-mortem redistribution and that phenomenon's effect upon the accuracy of the post-death blood concentration levels as reflecting pre-death levels, Dr. Long opined that post-mortem redistribution does not occur when the administration of the drug at issue occurs within 24 hours of the death, which is referred to as an "acute dose." (Relying upon P-8, *Toxicology, The Basic Science of Poisons*, pg. 14, "Acute exposure is defined as exposure to a chemical for less than 24 hours.") However, the definition of "acute dose" was not the issue. With regard to whether post-mortem redistribution made the .17 micrograms per milliliter finding a questionable foundation upon to further speculate using back extrapolation, Dr. Long admitted repeatedly that

he had no scientific literature upon which to base his assertions that post-mortem redistribution does not occur with acute drug exposure. (T. 116, 78-79)

With regard to the issue of the half-life of Demerol in neonates, Dr. Long had done no research with regard to the half-life of Demerol applicable in neonatal patients and openly testified to the court that if such literature did exist, he was not aware of it. (T. 63) Dr. Long was content to utilize the half-life Demerol applicable in adult patients as he did not find the utilization of any particular half-life figure significant. According to Dr. Long, "The fact that it is in the range that's used or has been reported as acceptable is really the key." (T. 36) However, Dr. Long could not support or explain why it would be reliable to use only the shortest half-life value ever recorded from which to back extrapolate, and ignore the longer half-life ranges established by the peer reviewed medical literature. Indeed, Dr. Long was forced to admit that a three hour half-life is the only figure that Dr. Shukan could have used to make his calculations "work" to prove that Demerol was administered to Atravius Coleman at the time of the circumcision. (T. 106) Thus Dr. Long did not validate the methodology of Drs. Shukan and Hayne, and in fact opined that if Atravius Coleman had been administered 100 milligrams of Demerol at the time of the circumcision, he would have exhibited symptoms of distress at 1:30 p.m., and would have expired very quickly without the aid of mechanical ventilation (which was not given), none of which comports with the known facts of Atravius Coleman's clinical course. (T. 93-95)

SUMMARY OF THE ARGUMENT

In support of their Motion to Exclude the Testimony of Dr. Shukan and Hayne, the Defendants' produced testimony of multiple experts, along with a body of peer reviewed literature, definitively demonstrating that the opinions of Doctors Shukan and Hayne were not based upon the appropriate and applicable half-life of Demerol in a neonate, which literature should have been the very foundation of any opinion attempting to utilize the process of back extrapolation in this case. To the contrary, Doctors Shukan and Hayne relied upon half-life values applicable to adult patients, which values are vastly different from those for neonates, such that their opinions regarding back extrapolation lacked the requisite scientific reliability and validity. In response to the overwhelming testimony and on-point medical literature, Plaintiff failed to provide any support for the opinions of Doctors Shukan and Hayne as regards the applicable life of Demerol in a neonate. Additionally, Plaintiff failed to meet the evidence produced by the Defendants that the phenomenon of post-mortem redistribution makes the blood serum Demerol concentration found post-mortem an unreliable platform from which to attempt to determine his pre-death blood concentration of Demerol. Thus Plaintiff's experts failed to demonstrate a reliable scientific basis for both their starting point, the .17 micrograms per milliliter as an accurate reflection of Atravius Coleman's pre-death Demerol blood concentration, and the methodology of how to back extrapolate in this scenario, when the patient is a neonate whose ability to metabolize and rid itself of drugs is markedly different from an adult.

The law of Mississippi mandates the exclusion of expert opinion which has been shown to be scientifically unreliable and also unreliably applied to the facts of the case. The circuit court did not abuse its discretion in excluding the testimony of Dr. Shukan and Dr. Hayne as regards to the process of back extrapolation as those opinions were demonstrated by the Defendants to be based upon insufficient facts and data, not to be the product of reliable principles and methods, and that the principles and methods utilized by Plaintiff's experts were not reliably applied to the known facts of the case. As the trial court did not rule in an arbitrary and clearly erroneous manner, this Court should uphold the ruling excluding the testimony of Dr. Shukan and Dr. Hayne.

Further, Plaintiff did not oppose entry of judgment for the Defendants after the trial court's ruling excluding Dr. Shukan and Dr. Hayne's opinions as related to back extrapolation. Plaintiff did not contend to the trial court that she had sufficient proof of medical causation to avoid the entry of summary judgment for the Defendants, and argues this for the first time on appeal. Plaintiff has waived this argument and cannot be heard to complain for the first time on appeal that summary judgment and entry of judgment for the Defendants was improper.

ARGUMENT

I. STANDARD OF REVIEW AND STANDARD FOR EXCLUSION OF EXPERT TESTIMONY

A trial court's admission or exclusion of expert testimony is reviewed for abuse of discretion. *Miss. Transp. Comm'n v. McLemore*, 863 So. 2d 31 (Miss. 2003). The trial court's decision must stand unless the reviewing court concludes that the decision was arbitrary and clearly erroneous, amounting to an abuse of discretion. *Id.*

In *Miss. Transp. Comm'n v. McLemore*, the Mississippi Supreme Court adopted the "*Daubert*/Kumho" rule as the standard for assessing the reliability and admissibility of expert testimony. *McLemore*, 863 So. 2d at 35. Of primary importance in assessing the admissibility of expert testimony is Rule 702 of the Mississippi Rules of Evidence, which states:

> If scientific, technical or other specialized knowledge will assist the trier of fact to understand or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principals and methods, and (3) the witness has applied the principals and methods reliably to the facts of the case.

Miss. R. Evid. 702.

Trial courts have authority to review scientific evidence to determine admissibility, and authorities are clear that it is the trial court that is vested with this gatekeeping responsibility. *McLemore,* 863 So. 2d at 36. The trial court must engage in a two pronged inquiry, determining whether the expert testimony rests on a reliable foundation and is relevant to the matter. *Id.* Regarding the "reliability prong" – which is at issue in the present case, the testimony must be grounded in the methods and procedures of science, and must not be merely subjective belief or unsupported

speculation. *McLemore,* 863 So. 2d at 36 (citing *Daubert*, 509 U.S. at 590). The *Daubert* court adopted a non-exhaustive, illustrative list of reliability factors for determining the admissibility of expert testimony. These factors include: whether the theory or technique can be or has been tested; whether it has been subjected to peer review and publication; whether in respect to a particular a technique, there is a high known or potential rate of error; whether there are standards controlling the technique's operation; and whether the theory or technique enjoys general acceptance within a relevant scientific community. *McLemore,* 863 So. 2d at 37 (citing *Daubert*, 509 U.S. at 592-94).

The importance of the gatekeeping function of the trial court cannot be exaggerated. Once a witness is deemed by the trial court to be an expert, he is equipped with a tremendous power to influence a jury. As noted by the trial court:

> Juries are often in awe of expert witnesses because, when the expert witness is qualified by the court, they hear impressive lists of honors, education and experience. An expert witness has more experience and knowledge in a certain area than the average person. Therefore juries usually place greater weight on the testimony of a expert witness than that of a law witness.

(Citing *Watts v. Radiator Specialty Co.*, 990 So. 2d 143, 146-147 (Miss. 2008)).

Because a jury is ill-equipped to evaluate expert testimony, it will often accept the expert's testimony as truth. Accordingly, the court, in its role as gatekeeper, should exclude all expert testimony that is unreliable according to Rule 702 and the applicable case law interpreting the Rule, because the jury is limited in its ability to perceive fundamental flaws in the methodology and direct contradictions within the experts' testimony.

Although it is always important that the trial court apply the principles of Rule 702 to ensure expert reliability, it is of heightened importance in the instant case due to the complex nature of the testimony as to the cause of Atravius Coleman's death and the fact that the jury is wholly dependent upon expert testimony for the element of causation in this medical malpractice/wrongful death action. That the Plaintiff's experts' back extrapolation theory, and ultimately their opinions as to causation, are unreliable because they depend on an unreliable and uninformed choice as to the half-life of Demerol in a neonate and wholly failed to account for post-mortem redistribution is not something that a jury can likely discern and understand, even with the most rigorous cross-examination.

II. THE TRIAL COURT CORRECTLY RULED THAT THE SUBJECT EXPERT OPINIONS WERE NOT BASED UPON SUFFICIENT DATA.

The trial court correctly determined that, "[t]he significance of the half-life of meperidine in *this* case is that both Dr. Shukan's and Dr. Hayne's mathematical back extrapolation and their determinations as to the pre-death concentration of meperidine in the infant's body is significantly dependent upon the use of a reliable half-life." This is because the back extrapolation process by definition requires working from a known value to an earlier unknown value based on scientific knowledge of how the particular drug is eliminated from the body. Thus, if what is known is that the elimination half-life of the drug is greatly variable, it follows that any back extrapolation calculation which utilizes only numbers at one extreme of the spectrum and fails to even consider the body of scientific literature applicable to the specific subject matter is not scientifically sound. This is the situation in the instant case. What is established by the medical literature is the half-life of Demerol in neonates is much longer than in adults, and the

half-life of Demerol in neonates covers a very wide range of time – from 3.3 hours at the very shortest end to 59.4 hours at the longest. Doctors Shukan and Hayne, not being aware to the applicable literature regarding the Demerol half-life in neonates, based their extrapolation calculations only upon the short half-life values from literature applicable to adults and did not consider the ranges supported by literature specific to neonates.

Given the proof before it, the court correctly understood and fulfilled its role. Contrary to Appellee's argument, the trial court did not choose a "correct" half-life or determine that a particular expert's opinion on the applicable half-life was preferable to others. To the contrary, a reading of the careful, well reasoned opinion of the Court reveals the Court determined that due to the great variability in the elimination half-life of Demerol in neonates, *no one* could say with a reasonable degree of medical certainty, (which is the Plaintiff's burden of proof) what the pre-death level of Demerol was for Atravius Coleman. As clearly articulated by the Court:

> Depending on the scientific literature one reads, the half-life of meperidine in a neonate can range from 6.5 to 39 hours, or from 3.3 to 59.4 hours. A testing of five neonates whose mothers had been administered multiple doses of meperidine during labor reflected that the half-life of the meperidine that entered the neonates' blood stream *via* seminal transmission ranged from 11.55 hours to 17.33 hours with a mean of 13.24 hours. As is readily apparent, the ranges given for the half-lives of drugs in a neonate are wide. It appears that the breadth of such ranges are limited only by the number of medical journals one reads. No evidence was presented explaining exactly how Dr. Shuken came to choose three (3) to three and one-half (3½) hours as the half-life of meperidine to be used in his back extrapolation calculations. It seems to this court that arbitrarily choosing a half-life from the panoply of half-lives available when dealing with a neonate is tantamount to choosing a half-

> life by throwing darts at a medical dartboard. While one may occasionally hit the proper number, it is not a process that instills confidence in the result.

(R. 1216-17)

The trial court did not accept either the Plaintiff *or* the Defendant's experts' opinions or conclusions regarding a "correct" half-life of Demerol in neonates. Rather, the trial court appropriately considered and analyzed the medical literature and testimony presented and concluded that, " the evidence presented and the scientific and/or medical literature offered describing the ranges of half-lives of meperidine and/or normeperidine in a neonate are so wide that pre-death levels and/or concentrations of such drug *in a neonate* cannot be determined with any reasonable degree of medical or scientific certainty by the process of back extrapolation." (R. 1219) Thus the analytical gap between the existing data and the challenged opinions was simply too great to be reliable. *Propulsid Products Liability Litigation Black v. Johnson & Johnson, et al*, 261 F. Supp. 2d 603, 616 (E. D. La. 2003). Such analysis is absolutely the role of the gatekeeper, and it cannot be said the trial court's analysis was clearly erroneous.

III. EVEN PLAINTIFF'S TOXICOLOGY EXPERT CONCEDES THAT DR. SHUKAN'S METHODOLOGY WAS NOT APPLIED IN A RELIABLE FASHION TO THE FACTS OF THE CASE.

Pursuant to Miss. R. of Evid. 702, not only must the proffered opinion be based upon sufficient facts or data, but the witness must have also applied the principles and methods reliably to the facts of the case. Plaintiff's sole witness at the *Daubert* hearing, toxicologist Christopher Long, M.D., admitted that Dr. Shukan's conclusion that 100 mg. of Demerol was administered to Atravius Coleman at approximately 1:30 p.m. on February 23, 2002, was inconsistent with the known effects of Demerol and the

documented clinical course of Atravius Coleman. Significantly, even though he was called to support Dr. Shukan's conclusions, Dr. Long believed that Dr. Shukan was of the opinion that the Demerol in Atravius Coleman's system came from his mother during delivery. (T. 85) When confronted with Dr. Shukan's actual opinion that 100 mg. of Demerol was administered to Atravius at the time of the circumcision, Dr. Long could not reconcile this opinion with what is known to have occurred, i.e. the fact that Atravius Coleman lived approximately another 11 hours without the benefit of mechanical ventilation. The transcript of the hearing contains the following significant exchanges:

Q. In fact, if this baby had been given a 100 milligram dose at 1:30 in the afternoon, just how quick would he have died of respiratory depression?

A. Very quickly. Easily within a couple of hours.

Q. Or less?

A. Or less.

(T-90)

Q. . . . . 20 milligrams per kilogram. How long would it be before that baby stopped breathing?

A. It would be relatively quickly.

Q. Relatively quickly?

A. Yes.

BY THE COURT: Somebody tell me what "relatively quickly" would be.

BY THE WITNESS: Within 10 to 15 minutes. It would be very quick.

BY THE COURT: Ten or 15 minutes.

Q. Ten or 15 minutes. Have you done the calculation on this child?

A. No, sir.

Q. Well, would you agree that this baby, his weight varies. One time it's in the chart at 5 pounds 11 ounces, another time it's five pounds 13 ounces. But let's use the five pounds 11 ounces for just a second because that's the way my calculation is done. And we can do the 13 ounces if would like. But if we have a 100 milligram does and we convert that to kilograms, do you agree that it is 2.58 kilograms?

A. Yes.

Q. Okay. If you divide the 2.58 kilograms into the 100 milligram dose, do you realize that that is 38 milligrams per kilogram?

A. Yes.

Q. And that's a lethal dose?

A. Reasonably, yes, sir.

Q. And the effects of giving a dose of 100 milligrams to this infant would have meant that this infant would have stopped breathing how quickly? Roughly?

A. Within 10 or 15 minutes.

Q. Did that happen?

A. No, sir, it didn't. There were no signs or symptoms of toxicity.

Q. So Dr. Shukan's testimony that you've just watched is not scientifically based; is it? There's no way this baby could have survived for 12 hours after receiving a 100 milligram dose of Demerol, is it?

A. Well, that's not true.

Q. Well, I mean without support. Without ventilating the baby, without providing support?

A. The baby would require emergency assistance.

Q. The baby didn't get it, did it?

A. No, it didn't. Not - -

Q. - - So this baby, if it got this dose, would have been dead, you say, in 10 to 15 minutes.

A. On intravenous administration, yes, sir. I think that is very reasonable.

* * * *

Q. (continuing:) His calculations of a 100 milligram dose are not valid, are they?

* * * *

A. No, his calculations are valid. In light, **they are inconsistent with what was occurring in the child**.

Q. Well, what occurred in the child, Doctor, we know what happened because it is documented in the medical records. **So, therefore, Doctor, based upon scientific principles that you've applied here in the courtroom, would you agree with me this baby did not receive a 100 milligram dose of Demerol at 1:30 in the afternoon?**

A. **I don't believe that he did.**

(T. 93-95)

Thus, even Plaintiff's own expert, brought to *Daubert* hearing for the sole purpose of shoring up the proffered expert testimony clearly could not support the opinions, and unequivocally testified that Dr. Shukan's opinion did not comport with Atravius Coleman's known clinical course.

IV. THE CIRCUIT COURT'S EXCLUSION OF THE TESTIMONY OF DR. SHUKAN AND DR. HAYNE IS CONSISTENT WITH THE PRECEDENT OF THE MISSISSIPPI SUPREME COURT AND COURT OF APPEALS.

The Mississippi Supreme Court's holding in *Hill v. Mills,* 26 So. 3d 322 (Miss. 2010), is directly applicable to this case. The Plaintiffs in *Hill* filed a medical negligence action following the death of the Plaintiffs' unborn child. *Id.* at 325. In support of their claims, the Plaintiffs retained Dr. Fuselier to serve as an expert witness as to medical causation. *Id.* Dr. Fuselier was unable to locate any pertinent literature or materials to support his opinion in the case and did not produce any such documents in response to

his deposition notice which requested those items. *Id.* Following Dr. Fuselier's deposition testimony and the lack of the production of any scientific materials to support his opinions, the Defendant filed a motion to exclude the testimony under Rule 702. *Id.* at 326. As did the Defendants in the instant case, the defendant in *Hill* offered the testimony of an obstetrical expert, Dr. John Morrison, who testified that Dr. Fuselier's opinions were not accepted in the scientific community and produced peer reviewed literature directly contradicting one of his opinions.

In upholding the trial court's grant of the Defendant's motion to exclude, this Court reiterated that expert testimony must have a reliable, scientific basis beyond subjective or unsupported speculation. *Id.* at 329 (citing *Daubert,* 509 U.S. at 589-591). In its analysis, the Court was very deliberate in addressing the fact that in situations such as the instant case, where one party can demonstrate through peer reviewed literature the absence of support within the scientific community of an expert opinion, the party proffering the challenged opinion cannot remain silent. As stated by this Court:

> An expert whose opinions are under scrutiny may not ignore allegations of unreliability and nonacceptance within the scientific community, but rather must respond with some evidence that the opinions are, in fact, accepted within the scientific community.

Id.

In emphasizing the importance of testing the basis of an expert's opinions, this Court noted that the failure to do so would cause a return to "junk science" and the admission of testimony lacking acceptance and support within the scientific community. *Id.* The Court concluded its opinion as follows:

> We restate for emphasis that, when the reliability of an expert's opinion is attacked with credible evidence that the opinion is not accepted within the scientific community, the proponent of the opinion under attack should provide at least a minimal defense supporting the reliability of the opinion. The proponent of the expert cannot sit on the sidelines and assume the trial court will ignore the unrebutted evidence and find the expert's opinion reliable. Were we automatically to allow introduction of expert opinions which are based upon nothing more than personal experience in cases where those opinions are contradicted in the scientific literature, we would effectively render Rule 702 and *Daubert* a nullity.

Id. at 332-333 (citing, *Smith v. Clement,* 983 So. 2d 285, 290 (Miss. 2008)).

In this case, Drs. Shukan and Hayne based their opinions on the process of back extrapolation which necessarily required utilizing a reliable half-life of Demerol and establishing the reliability of the post-mortem Demerol level to determine the antemortem level of Demerol of Atravius Coleman. The Defendants challenged the basis of Dr. Shukan and Dr. Hayne's opinions with a number of experts who testified that the challenged opinions lacked support within the scientific community and further provided peer reviewed literature proving that Drs. Shukan and Hayne did not have a reliable basis for their opinions. As in *Hill*, Doctors Shukan and Hayne remained silent. Neither can Plaintiff rely upon the testimony of Dr. Long to make Dr. Shukan and Dr. Hayne's testimony reliable. Dr. Long himself was unable to produce any scientific literature or basis, other than his personal opinion, to support his contention that post-mortem redistribution does not occur when the patient has only been exposed to the drug for less than 24 hours. Further, making the same error as Doctors Shukan and Hayne, Dr. Long had not familiarized himself with the scientific literature establishing the half-life of Demerol in a neonate, and did not attempt to explain why one should base an opinion only on data at one extreme of a large range while arbitrarily disregarding all other values which do not fit a pre-conceived theory. Dr. Long's

testimony only confirmed that the unfounded opinions of Doctors Shukan and Hayne did not comport with the known facts of the clinical course of Atravius Coleman.

Application of Rule 702, and the case law interpreting it, support the trial court's exclusion of the testimony of Dr. Shukan and Dr. Hayne. As it cannot be said that the trial court committed abuse of discretion in excluding the demonstrably unreliable opinions of Dr. Shukan and Dr. Hayne, this Court should uphold the trial court's ruling.

V. PLAINTIFF DID NOT ARGUE THE ABILITY TO PROVE MEDICAL CAUSATION WITHOUT THE EXCLUDED TESTIMONY TO THE TRIAL COURT.

The law is well settled in Mississippi that appellate courts will not put trial courts in error for issues not first presented to the trial court for resolution, and that issues not presented in the trial court cannot be first argued on appeal. *Pittman v. Dykes Timber Co., Inc.,* 18 So. 3d 923 (Miss. Ct. App. 2009); Purvis *v. Barnes*, 791 So. 2d 199, 202 (Miss. 2001).

In the instant case, Plaintiff chose not to argue to the trial court that without the excluded testimony of Dr. Shukan and Dr. Hayne, issues of material fact existed such that summary judgment should not be entered for the Defendants. (R. 1220-21) Plaintiff cites no authority to this court for their contention that the trial court's grant of a summary judgment was erroneous regardless of whether the challenged opinions were excluded, and this Court should disregard those arguments here as that issue was not properly preserved for appeal.

CONCLUSION

Trial judges are given great discretion in their gatekeeping authority under *Daubert*. In this case, the trial court conducted a lengthy evidentiary hearing, meaningfully participated in the questioning of numerous witnesses, and authored a well reasoned thirteen page Opinion summarizing the issues and testimony presented to it. The trial court correctly noted its "limited and closely defined interest" in assessing the reliability of the challenged opinions of Plaintiff's experts, Dr. Shukan and Dr. Hayne. The trial court did not abuse its discretion in excluding the opinions of those experts relating to back extrapolation as those opinions were demonstrated to be the product of scientifically unsound methods and principles and Plaintiff failed to support the challenged opinions as required by the jurisprudence of Mississippi. Accordingly, the decision of the trial court excluding the opinions of Dr. Shukan and Dr. Hayne based upon back extrapolation should be upheld, and the entry of judgment for the Defendants should be affirmed.

Dated this the 10 day of September, 2010.

Respectfully submitted,

BOLIVAR MEDICAL CENTER

BY: _____
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CERTIFICATE OF SERVICE

I, Kimberly N. Howland, attorney for Appellee, Bolivar Medical Center, do hereby certify that I have this day mailed, by United States mail, postage prepaid, a true and correct copy of the above and foregoing document to the following:

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THIS, the 10TH day of September, 2010.

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