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CAUSE NO. 15C0849-202

STEVE MIZYED and NADIA WALRAVEN, Individually and as Next Friends and Guardians of KAI MIZYED, a Minor,	§	**IN THE DISTRICT COURT OF**
Plaintiffs,	§	
vs.	§	
	§	**BOWIE COUNTY, TEXAS**
JAMES ANTHONY SCALES, M.D.; COLLOM & CARNEY CLINIC ASSOCIATION; CHRISTUS HEALTH ARK-LA-TEX D/B/A CHRISTUS ST. MICHAEL HEALTH SYSTEM; and ARK-LA-TEX HEALTH NETWORK,	§	
Defendants	§	**202ND JUDICIAL DISTRICT**

BRIEF OF THE AMERICAN COLLEGE OF OBSTETRICS AND GYNECOLOGISTS AND THE AMERICAN MEDICAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' OBJECTIONS TO THE ADMISSIBILITY OF PLAINTIFFS' CAUSATION EXPERTS, AND MOTION TO EXCLUDE

Respectfully Submitted,

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I. STATEMENT OF INTEREST OF AMICI CURIAE

The American College of Obstetricians and Gynecologists ("ACOG") is a non-profit membership organization dedicated to the advancement of women's health. With more than 58,000 members, ACOG is the nation's leading professional association of physicians providing health care for women. ACOG's objectives are to foster and stimulate improvements in all aspects of health care of women; to establish and maintain the highest possible standards for education; to foster the highest standards of practice in its relationship to public welfare; to promote high ethical standards in practice; and to promote publications and encourage contributions to medical and scientific literature. ACOG's core values include access for all women to high quality safe health care, professionalism of its membership, and scholarship in medical science. ACOG works to provide evidence-based knowledge in women's health to its membership and the women they serve and to promote quality, safety, efficiency and stability for the delivery of women's health care services.

The issues presented in this case are of great importance to ACOG, its physician members, and the women they serve. The quality of evidence proffered and admitted as "medical science" in professional liability litigation can significantly influence ACOG's members' medical practices and the cost and availability of medical services. The issues to be resolved in this case will therefore have an immediate and lasting effect on women's health care in the State of Texas.

The American Medical Association ("AMA") is the largest professional association of physicians, residents and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents and medical students are represented in the AMA's policymaking process. AMA members practice in every medical specialty, including

obstetrics and gynecology. The objectives of the AMA are to promote the science and art of medicine and the betterment of public health.

The Amici Curiae and their members have an interest in ensuring that physicians can deliver high-quality care to their patients.

Counsel for the Amici Curiae have not been paid for the preparation of this Brief and do not represent any party in connection with this matter.

II. INTRODUCTION

CHRISTUS Health Ark-La-Tex d/b/a CHRISTUS St. Michael Health System and Ark-La-Tex Health Network ("Defendants") have objected to the admissibility of certain causation opinions rendered by Plaintiffs' experts, Dr. Martin Gubernick, Dr. Donald Null, and Dr. John Seals, and have moved to have those opinions excluded from evidence as unreliable under the requirements of the TEXAS RULES OF EVIDENCE and the *Daubert/Robinson* analysis.[1] While Dr. Null and Dr. Seals endorse the theory that the infant's brain injury in this case was caused by the force of uterine contractions essentially "squeezing" the fetus' head (sometimes called the "Cranial Compression Ischemic Encephalopathy" ("CCIE") theory), Dr. Gubernick freely admits that the CCIE theory is not grounded in medical science. Dr. Gubernick nonetheless opines that "mechanical forces" from too many contractions and too little recovery time between the contractions caused blood flow to the head to be restricted, but he simply cannot explain physiologically how that occurs. Whatever the theory, such opinions implicate a number of important issues. ACOG and the AMA urge that this Court disallow this theory, by whatever name, for the following reasons.

[1] *See* Defendants' Objections to the Admissibility of Opinion of Plaintiffs' Causation Experts, Motion to Exclude, and Motion for Summary Judgment (hereafter "Defs.' Objections").

First, the mechanism of injury proposed by Plaintiffs does not exist in clinical medicine. There have been no studies or tests showing that the type of injury experienced by the infant in this case can be caused by uterine contractions, as theorized by Plaintiffs. Further, there is no reliable literature showing that the hypothetical mechanism of injury ever has been reported or even observed outside of litigation.

Second, in practice, obstetricians are expected to carefully evaluate the risks and benefits of medical or surgical intervention during labor, and to act based on a foundation of medical knowledge derived from their own education and experience as well as good quality research evidence. Permitting Plaintiffs to introduce these untested theories of causation as medical science would create a situation in which physicians use one set of scientific principles in treating patients, but are judged in a courtroom by another.

Finally, obstetrical litigation already contributes significantly to the continuing and important problem of providing patients in Texas with adequate access to quality obstetrical care. Adding an entirely new, unproven, unaccepted, and unsupported liability theory with potentially broad application to any obstetric case involving delivery after a trial of labor would only exacerbate an already difficult and challenging situation.

As set forth below, Amici urge that this Court to sustain the objections of Defendants, and disallow Plaintiffs' unproven theory/theories of causation.

III. ARGUMENT AND AUTHORITIES

A. The Causation Opinions of Dr. Martin Gubernick, Dr. Donald Null, and Dr. John Seals Are Unreliable and Inadmissible Under Texas Law

1. *Outside the Courtroom, Physicians Rely Upon Sound Medical Science to Treat Patients*

A fundamental tenet of medicine is that every medical or surgical intervention has risks and benefits that must be weighed, with a clear understanding of each, before proceeding in any

clinical situation. In obstetrics, for example, physicians generally do not intervene in labor by giving medication to slow or stop contractions or proceeding to surgical delivery, without good cause for doing so. Such interventions carry their own risk, and must be evaluated in light of the clinical situation and good medical science supporting the need for intervention.

A physician may rely upon her own clinical experience, her education and training, or evidence of good quality as reported in relevant medical literature. Where, as with the "CCIE" theory or Dr. Gubernick's unexplained "mechanical forces" theory, injury to the fetus is not taught in medical school or residency programs and is unknown in clinical practice, the quantity and quality of research evidence supporting the theory takes on even greater importance.

In evaluating research evidence, many practitioners and scientific organizations use a method developed by the U.S. Preventive Services Task Force,[2] in which medical research studies are graded for quality, with the highest quality evidence given the greatest weight in practice.[3] According to the USPSTF method, evidence obtained from randomized controlled interventional trials is the most highly ranked form of evidence and provides the strongest, highest quality evidence.[4] Interventional studies, also called clinical trials (in which the investigator assigns subjects to exposed and non-exposed groups and compares the groups' outcomes), are ranked higher than observational studies (in which the investigator observes the

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[2] The U.S. Preventive Services Task Force ("USPSTF") is an independent, volunteer panel of national experts in prevention and evidence-based medicine. Since 1998, the Agency for Healthcare Research and Quality has been authorized by Congress to convene the Task Force and provide ongoing scientific, administrative and dissemination support. *See About the USPSTF*, U.S. PREVENTIVE SERVICES TASK FORCE, https://www.uspreventiveservicestaskforce.org/Page/Name/about-the-uspstf (last visited Feb. 14, 2018).

[3] *See Methods and Processes, Procedure Manual, Section 4. Evidence Report Development*, § 4.2 *Internal and External Validity Assessment of Individual Studies*, U.S. PREVENTIVE SERVICES TASK FORCE, https://www.uspreventiveservicestaskforce.org/Page/Name/section-4-evidence-review-development (last visited Feb. 14, 2018).

[4] *See id.*

natural course of events of exposure and outcome).[5] The type of evidence that is lowest ranked, but still acceptable, is opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.[6]

Case reports, which are detailed published reports documenting the clinical course of an individual patient, generally are not considered high quality evidence in validating a theory of medical causation. There are no controls or comparison groups in case reports, and case reports often lack information about their subjects that could affect the conclusions reasonably drawn from them. As one Georgia court has explained:

> [C]ase reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation.[7]

Indeed, a "fundamental principle of evidence-based medicine," among others, "is that the strength of medical evidence supporting a [theory of medical association] is hierarchical."[8] The top of the hierarchy-the best evidence—includes randomized clinical trials and epidemiologic studies, while the "bottom" includes "unsystematic clinical observations" or case reports.[9] Notably, the Supreme Court of Texas has cautioned courts to reject such unreliable evidence as legally sufficient proof of causation.[10]

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5 *See id.*

6 *See id.*

7 *Siharath v. Sandoz Pharms. Corp*., 131 F. Supp. 2d 1347, 1361 (N.D. Ga. 2001) (quoting *Casey v. Ohio Med. Prods*., 877 F. Supp. 1380, 1385 (N.D. Cal. 1995)).

8 FED. JUDICIAL CTR., *Reference Manual on Scientific Evidence* 723 (3d ed. 2011).

9 *Id*. at 723-24.

10 *See Merrell Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997) (quoting the FDA regulations in 21 C.F.R. § 314.126 (1996) in cautioning courts to reject as unreliable evidence consisting of "[i]solated case reports, random experience, and reports lacking the details which permit scientific evaluation").

As an example of the review and evaluation of medical literature that is familiar to many OB/GYN practitioners, ACOG develops evidence-based clinical practice guidelines to assist its members in treating patients. ACOG's guidelines are derived from the best available evidence of clinical efficacy.[11] Evidence-based clinical practice guidelines are intended to be used by physicians and other health care providers as a means of standardizing care and improving the quality of health care; therefore, ACOG considers both the quality and the quantity of the evidence when developing clinical practice guidelines and directly links its recommendations to the evidence.[12]

ACOG's process for developing evidence-based clinical practice guidelines begins with an extensive search of the medical literature to locate relevant articles published on the topic.[13] The studies are reviewed and evaluated for quality and graded according to the USPSTF method; only studies determined to provide overall evidence of "good quality" are considered in the development of ACOG's guidelines.[14] ACOG's guideline development process also involves extensive peer review of the proposed guidelines by various ACOG committees comprised of subject matter experts.[15]

As Defendants report within their Objections, ACOG, together with the American Academy of Pediatrics, convened the Task Force on Neonatal Encephalopathy to review and summarize current scientific and clinical knowledge about the mechanism and timing of fetal

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[11] See *Reading the Medical Literature*, AM. C. OF OBSTETRICIANS & GYNECOLOGISTS, http://www.acog.org/Resources-And-Publications/Department-Publications/Reading-the-Medical-Literature (last visited Feb. 14, 2018).

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] *Id.*

and neonatal brain injury, the causation issue presented.[16] The task force was composed of 16 physicians specializing in obstetrics, perinatal medicine, pediatrics, neurology, and maternal-fetal medicine, including liaison members of the American Academy of Pediatrics, the Council on Resident Education in Obstetrics and Gynecology, the Royal College of Obstetricians and Gynecologists, the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, the Society for Maternal-Fetal Medicine, the Society of Obstetricians and Gynecologists of Canada, and a scientist-liaison from the Centers for Disease Control and Prevention National Center on Birth Defects and Developmental Disabilities. [17] Along with 88 consultant physicians and Ph.D.-level scientists, the task force reviewed approximately 1,500 references to update the information contained in a 2003 report on neonatal encephalopathy and cerebral palsy.[18] The references were graded according to the levels of evidence that ACOG uses for evidence-based guidelines.[19]

The work of the task force culminated in a 236-page report, which was jointly published by ACOG and the American Academy of Pediatrics in 2014. The report is entitled *Neonatal Encephalopathy and Neurologic Outcome* (American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, 2nd ed. 2014) (the "Report"), and presents "the current state of scientific and clinical knowledge relating to neonatal

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[16] *See* Defs.' Objections 12-13 (citing AM. C. OF OBSTETRICIANS & GYNECOLOGISTS' TASK FORCE ON NEONATAL ENCEPHALOPATHY, *Neonatal Encephalopathy and Neurologic Outcome, Second Edition* (Mar. 2014) (attached as Apx. Tab. A)).

[17] *See id.*; AM. C. OF OBSTETRICIANS & GYNECOLOGISTS' TASK FORCE ON NEONATAL ENCEPHALOPATHY, *Neonatal Encephalopathy and Neurologic Outcome* xvii (2d ed. 2014).

[18] *See id.*

[19] *See id.* at ii.

encephalopathy and neurologic outcomes."[20] The Report was reviewed and endorsed or supported by 12 different organizations concerned with women's and children's health, including organizations of obstetricians and gynecologists from the United States, Great Britain, Canada, Australia, Japan and New Zealand.[21] The task force and associated consultants worked for two years to conduct an extensive review of medical literature and to summarize the best available primary-source scientific data and expertise of major contributors in the field relating to neonatal encephalopathy.[22] Notably, the mechanism of injury proposed by Plaintiffs here is not described anywhere in the task force's comprehensive Report.[23]

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[20] *See id.* at xvii. "Neonatal encephalopathy" is "a clinically defined syndrome of disturbed neurological function in the earliest days of life" of a term newborn. *See id.* at xxii.

[21] *See id.* at xv, xviii.

[22] *See id.* at xvii, xxii-xxvi.

[23] *See generally id.* (Neonatal encephalopathy can be caused by an event before, during or after labor and delivery.) The Report incudes a summary of multi-dimensional criteria which are consistent with neonatal encephalopathy that is caused by an intrapartum event. *See id.* at 208-09. These criteria include signs of global hypoxia:

> (1) Apgar score at 5 and 10 minutes of life. More specifically, "If the Apgar score at 5 minutes is greater than or equal to 7, it is unlikely that peripartum hypoxiaischemia played a major role in causing neonatal encephalopathy."
>
> (2) Fetal umbilical artery acidemia: "If the cord arterial gas pH levels are above 7.20, it is unlikely that intrapartum hypoxia played a role in causing neonatal encephalopathy."
>
> (3) Presence of multisystem organ failure consistent with hypoxic-ischemic encephalopathy.

See id. According to Defendants' Objection, the clinical evidence is that K.M. had none of the recognized signs of global ischemia. (Defs.' Objection 12-13).

2. *Plaintiffs' Theories of Causation – Whether Dr. Gubernick's Unexplained "Mechanical Forces" Theory or "CCIE" – Are Unknown in Practice, Not Reported in the Literature, and Not Verified by Adequate Studies or Texts*

Texas law provides that in a medical malpractice case, causation must be proven by expert testimony.[24] A medical malpractice plaintiff must present reliable expert testimony to prove that in reasonable medical probability his or her injuries were caused by the negligence of the defendant.[25]

The trial court is the gatekeeper ensuring that expert testimony is based on a reliable foundation and is relevant to the issues in the case.[26] Rule 702 of the TEXAS RULES OF EVIDENCE, which governs the admission of expert testimony, provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue.[27]

This rule requires that courts bring more rigorous scientific study into the expression of legal opinions offered in court by scientific and medical professionals and ensure that an expert employs "in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field."[28] Thus, courtroom science should mirror real mainstream science.

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[24] *See Jelinek v. Casas*, 328 S.W.3d 526, 532-33 (Tex. 2010); *Guevara v. Ferrer*, 247 S.W.3d 662, 665 (Tex. 2007).

[25] *See Jelinek*, 328 S.W.3d at 532–33; *THN Physicians Ass'n v. Tiscareno*, 495 S.W.3d 914, 922 (Tex. App.—El Paso 2016, no pet.).

[26] *See E.I. du Pont de Nemours & Co., Inc. v. Robinson*, 923 S.W.2d 549, 556 (Tex. 1995).

[27] TEX. R. EVID. 702.

[28] *See Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999).

Plaintiffs allege that K.M. suffered an intrapartum ischemic brain injury. Their theory is that this ischemic brain injury was caused by the "mechanical forces of labor" – i.e. contractions during labor and delivery.[29] Unfortunately, all of Plaintiffs' experts, including the de-designated Dr. Schifrin himself, agree that this theory (whether called CCIE, cranial compression, or other similar name or physiological description, including Dr. Gubernick's unexplained "mechanical forces") is unproven, untested, not found in peer reviewed literature, and is not accepted in the medical community. Such courtroom science as advanced by Plaintiffs here should be rejected.

a. The Mechanism of Injury Proposed by Plaintiffs is Not Observed in Practice or Supported by Medical Literature

Plaintiffs' retained neonatology expert, Dr. Null, endorses and opines the causation theory sometimes referred to as "cranial compression ischemic encephalopathy" or CCIE, the creation of Dr. Barry Schifrin, whom Plaintiffs have de-designated as a testifying expert in this case.[30] Dr. Schifrin postulates that "excessive" contractions increase the intracranial pressure of the fetus until it becomes higher than the intra-amniotic pressure and this affects blood going to the brain without affecting the rest of the organs and systems.[31] Thus, Dr. Schifrin's causation theory, which has been excluded as unreliable by other courts, is that this intracranial pressure results in a hypoxic ischemic injury or an ischemic injury to the brain.[32] And, while he testified that he is not qualified to give a causation opinion regarding how anything that occurred during

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[29] *See* Defs.' Objections 6.

[30] *See id.* at 8 (citing Schifrin Dep. 119:7-10; Null Dep. 31:19-22).

[31] *See id.* at 6 (citing Schifrin Dep. 126:11-17).

[32] The "mechanical" compressive forces Dr. Schifrin has linked to CCIE include the use of Pitocin, excessive uterine activity, malposition of the fetus, pushing prior to the mother's full cervical dilation, and fundal pressure. *See Smith v. Braswell*, 804 S.E.2d 709, 711-12 (Ga. Ct. App. 2017) (concluding that trial court did not abuse its discretion in excluding all Dr. Schifrin's causation opinions and, specifically, CCIE theory of injury based on *Daubert's* reliability factors).

labor and delivery caused injury to K.M.,[33] to the extent he attempts to offer opinions on causation, Dr. Seals endorses the CCIE theory.[34]

Dr. Gubernick, Plaintiffs' obstetrical expert, admits CCIE has been utterly discredited and he attempts to differentiate his causation theory from CCIE (although it sounds very similar).[35] He claims that the Pitocin administered to Ms. Walraven caused her contractions to be too frequent (referred to as tachysystole or hyperstimulation),[36] made them too strong, with resting time between the contractions that was too short, and with tonicity of the uterus that was too high.[37] Dr. Gubernick says that all of this went on too long and that there are unnamed "biological variability[ies]" that come into play as well.[38]

The most glaring absence of support for these theoretical mechanism of injury is that Plaintiffs are unable to point to a single reported instance of this kind of injury occurring in the way they propose in actual clinical practice (i.e., outside of litigation). Despite that women have experienced contractions in labor since the dawn of time and that the vast majority of births involve at least a trial of labor, the mechanism of injury proposed by Plaintiffs has never been observed in practice, nor studied and documented in reputable scientific journals. Indeed, it is undisputed among these experts that babies are designed to withstand the mechanical forces of labor (contractions) – otherwise, every baby born in a vaginal birth would be injured.[39]

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33 Defs.' Objections at 17 (citing Seals Dep. 83:14-84:12).

34 Defs.' Objections at 8 (citing Seals Dep. 14:14-22; 83:14-84:12).

35 *See id.* at 17 (citing Gubernick Dep. 86:25-87:10, 104:19-20, 107:3-13, 108:9-23, 173:9-24).

36 *See id.* at 6 (citing Gubernick Dep. 68:13-16).

37 *See id.* (citing Gubernick Dep. 99:11-100:17).

38 *See id.* (citing Gubernick Dep. 131:1-20).

39 *See id.* at 29 (citing Gubernick Dep. 104:3-9; Null Dep. 15:13-17, 63:20-64:9, 88:25-89:1; Seals Dep. 15:15-16:2).

Collectively, the experts' experience involves thousands of patients, including hundreds of cases of neonatal brain injury, making the lack of clinical experience with the proposed mechanism of injury startling. The opinions of Drs. Gubernick, Null and Seals were formed solely for litigation; none of these experts can describe any real application of their causation theories.[40] Dr. Null, who has been practicing as a neonatologist for about 40 years, has never seen the "compressive forces" theory he proposes outside of litigation.[41] He cannot recall any patient of his for whom the attending physicians diagnosed an injury due to severe compression of the skull during labor and delivery.[42] And, notably, none of K.M.'s providers have diagnosed him with CCIE, compressive forces of injury, or obstetrical trauma.[43]

The significance of this complete lack of clinical validation cannot be overstated. It is all very well to theorize that this type of injury could happen during labor, but without any verifiable evidence that such injury ever has happened in practice, such theorizing is nothing more than an interesting exercise.

b. Plaintiffs Have No Medical Literature to Support Their Causation Theories

Further, none of the experts are able to identify a single verifiable report in the literature describing the mechanism of injury they propose.[44]

Dr. Null cannot cite any literature or neonatology article supporting his CCIE/cranial compression causation theory,[45] and he knows of no studies done to test the CCIE/cranial

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40 *See id.* at 33 (citing Null Dep. 67:2-68:2).

41 *See id.* at 10 (citing Null Dep. at 67:2-68:2).

42 *See id.* (citing Null Dep. 97:24-98:8).

43 *See id.* at 34 (citing Null Dep. 154:11-24; Gubernick Dep. 91:12-19; Seals Dep. 87:10-17).

44 *See id.* at 26 (citing Gubernick Dep. 77:14-22, 170:17-172:13, 189:19-191:6; Null Dep. 64:21-25, 89:2-9, 103:13-18, 142:15-143:12; Seals Dep. 52:14-18, 66:1-6, 76:12-22).

compression theory.[46] Dr. Null is unaware of any data in the scientific community establishing that severe compression can cause injury to the fetus's brain.[47] He understands that the CCIE/cranial compression theory is not generally accepted in the relevant scientific community.[48] To his knowledge, this theory is not taught in any medical school or residency program,[49] and he is unaware of any neonatologists or pediatricians who have publicly espoused the theory of CCIE and/or severe compression forces during labor causing injury to the fetal brain.[50]

Dr. Gubernick could not identify any reliable peer-reviewed literature that supports his conclusory opinion.[51] As noted above, the Report presents the current medical science that global interruption of oxygen/hypoxia is the only medically recognized pathway for intrapartum neonatal brain injury. First, Dr. Gubernick cannot explain the physiological mechanism (the "how and why") by which the "mechanical forces of labor" can ever cause injury to the fetal brain absent evidence of global hypoxia (i.e., Apgar score at 5 minutes less than 7, cord arterial gas pH levels less than 7.2, and multisystem organ failure). Rather, he testified that "the physiologic mechanisms are still open to debate. . . . there's a bit of ambiguity as to the actual

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45 *See id.* at 9 (citing Null Dep. 29:3-9, 65:10-16, 66:13-15, 69:1-3, 85:25-86:3).

46 *See id.* at 10 (citing Null Dep. 64:21-25, 103:13-18); *see also* Null Dep. 142:15-143:12 (affirmatively acquiescing that there are no randomized controlled studies, cohort studies, case-controlled studies, or peer-reviewed studies that prove that uterine hyperstimulation can create sufficient intracranial pressure to cause hypoxic ischemic injury).

47 *See* Defs.' Objections 10 (citing Null Dep. 89:2-9).

48 *See id.* (citing Null Dep. 152:6-14).

49 *See id.* (citing Null Dep. 66:16-19).

50 *See id.* (citing Null Dep. 105:21-25).

51 *See id.* at 26 (citing Gubernick Dep. 119:4-120:5).

mechanism other than [hypoxic ischemic encephalopathy ("HIE")]."[52] Dr. Gubernick admitted repeatedly that he simply does not know how and why the mechanical forces of labor can cause focal brain ischemia without "HIE":

> [K.M.] suffered an ischemic injury, separate and apart from hypoxic ischemic encephalopathy, due to excessive uterine activity, due to the inappropriate use of Pitocin where the contractions came too frequently, where the resting time between the contractions was too short, and the tone -- the tonicity of the uterus itself from the inappropriate use of Pitocin was too high. So as a result of oxygen depravation a mechanical ischemic injury, whether that be due -- it could potentially be due to head compression, it could be due to other ischemic factors, time will tell, but there was a mechanical -- some form of mechanical ischemic injury which is well-known in the obstetrical literature due to the inappropriate use of Pitocin.
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> . . .
>
> I know Dr. Schifrin has a theory about the compression of the head being one of them. ***Could it be a time factor, that there's not enough resting time between the uterine contractions, could it be a tone factor, could it be an amplitude factor, could it be a combination of all of those factors plus head compression? I don't know.*** [53]
>
> . . .
>
> I'm going to say that the inappropriate use of Pitocin lead to contractions coming too frequently, too close together, with hypertonicity, ***and the secondary effect of that could have been head compression.*** That could be a secondary effect of what the Pitocin did.[54]

Further, it is clear that Dr. Gubernick opined that K.M.'s injury "is due to the compressive forces." He could not say whether the ischemic injury is due to pressure in the head, failure to get blood adequately to the placenta because there isn't enough resting time between the contractions, too strong contractions, or the tone of the uterus such that it is diminishing blood flow to the placenta which ultimately leads in a different ischemic pathway

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[52] *See id.* at 26 (citing Gubernick Dep. 189:19-190:11).

[53] Defs.' Objection at 19 (citing Gubernick Dep. 99:11-100:17 (emphasis added)).

[54] *Id.* (citing Gubernick Dep. 102:1-11 (emphasis added)).

than an anoxic injury. Dr. Gubernick testified he would not be explaining the physiology of that injury, but only that it happened because the health care providers inappropriately used Pitocin.[55] He believes Dr. Schifrin's opinions about cranial compression and ischemic injury have to be considered.[56] Thus, Dr. Gubernick's opinion is that K.M. had an intrapartum mechanical ischemic injury, but he cannot explain the physiology as to exactly how it happened, only that it could be either or a combination of diminished blood flow, inappropriate use of Pitocin, or head compression.[57]

The only study Dr. Gubernick cited to support his opinion is published by Dr. Schifrin about the "Fetal Reserve Index."[58] This study was done of 50 medicolegal cases in which Dr. Schifrin was a testifying expert.[59] Dr. Gubernick admitted that the article does not support his causation theory; instead, the article demonstrates that "electronic fetal monitoring in and of itself is a poor predictor of neonatal outcome."[60] Dr. Gubernick further admitted the article is not a valid scientific study and thus is not reliable scientific evidence of anything.[61]

Dr. Seals testified that to his knowledge, there is no peer-reviewed literature that supports the notion that external forces on the skull can cause an increase in intracranial pressure which results in a hypoxic ischemic injury or an ischemic injury to the brain.[62] Dr. Seals testified that

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55 *Id.* (citing Gubernick Dep. 104:11-106:13).

56 *Id.* (citing Gubernick Dep. 108:4-23).

57 *Id.* (citing Gubernick Dep. 110-7-13).

58 *See* Robert D. Eden, et al., *The "Fetal Reserve Index": Re-Engineering the Interpretation and Responses to Fetal Heart Rate Patterns*, FETAL DIAGN. THER. (2017).

59 *See* Eden, at 2.

60 *See id.* (citing Gubernick Dep. 171:10-13).

61 *See id.* (citing Gubernick Dep. 172:4-13).

62 *See id.* at 10 (citing Seals Dep. at 76:12-22, 52:14-18, 66:1-6).

the notion of CCIE is not generally accepted in the medical community.[63] Like Dr. Null, Dr. Seals is not aware of this mechanism of injury being taught in medical school or residencies.[64]

Thus, by their experts' own concessions, Plaintiffs' theory is no more than an unsupported and untested hypothesis.

3. *Plaintiffs' Theories Could Be, But Have Not Been, Tested*

Any suggestion that it would be unethical to test Plaintiffs' theory of fetal brain injury is disingenuous. At a minimum, a retrospective observational study could be undertaken, using appropriate case controls for comparison, to evaluate the association (if any) between the conditions of labor forming the basis of plaintiffs' theory (the frequency, amplitude, duration, and rest periods between contractions; fetal presentation; and duration of the stages of labor) and fetal ischemic brain injury.[65] This has not been done. However, existing data and studies related to neonatal brain injury were collected, reviewed and included in the ACOG Task Force on Neonatal Encephalopathy Report discussed above, and none of the vast body of studies reviewed even remotely supports plaintiffs' theory.

a. Plaintiffs' Proposed Mechanism of Injury Does Not Enjoy "Widespread Acceptance" in the Medical Community

The theories of causation proposed by Plaintiffs have not gained general acceptance in the field of obstetrics. To the contrary, as discussed above, the theories are virtually unknown to practicing obstetricians outside the legal arena.

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63 *See id.* (citing Seals Dep. 135:9-14).

64 *See id.* (citing Seals Dep. 87:18-23).

65 *See id.* at 26.

Theories of medical causation should be subjected to at least the same level of critical analysis applied in practice before they are accepted in the courtroom.[66] Until "good quality" evidence is found to support a medical theory or hypothesis, expert testimony espousing the theory should not be admitted as "scientific knowledge."[67] What "science treats as a useful but untested hypothesis the law should generally treat as inadmissible speculation."[68] Especially in professional liability litigation, it would be unfair and prejudicial to admit as "medical knowledge" a theory that has not been studied and found to have merit by physicians outside the courtroom.[69] The theory that compressive forces during labor caused ischemic injury, which lacks even minimal proof of its occurrence in clinical practice, should be given the same weight in the courtroom that it warrants in the actual practice of medicine - none.

4. *Allowing an Unsupported and Potentially Broad New Theory of Obstetrical Liability Will Negatively Impact Adequate Access to Obstetrical Care*

Adequate access to obstetrical services remains a significant problem nationwide, particularly in rural areas. Workforce projections of obstetrician-gynecologists in the United States report that over the next decade, demand for these services is projected to increase

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66 The Texas Supreme Court has stated:

> Our legal system requires that claimants prove their cases by a preponderance of the evidence. In keeping with this sound proposition at the heart of our jurisprudence, the law should not be hasty to impose liability when scientifically reliable evidence is unavailable. As Judge Posner has said, '[l]aw lags science; it does not lead it.'

See Havner, 953 S.W.2d at 728 (quoting *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir.1996)).

67 *See Robinson*, 923 S.W.2d at 557 (scientific evidence not grounded in methods and procedures of science is no more than subjective belief or unsupported speculation and, therefore, is not reliable and not admissible); *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993).

68 *Tamraz v. Lincoln Elec. Co.*, 620 F.3d 665, 677 (6th Cir. 2010).

69 *See Braswell*, 804 S.E.2d at 711 (excluding Dr. Schifrin's CCIE causation theory because theory has not been reliably tested, has not been subject to peer review and publication, is not generally accepted in the scientific community, and has not been clinically diagnosed in any other patients).

nationally at a modest 6%, but that several states, including Texas, will be vulnerable because of projected increases in the adult female population that would partially explain the increased overall demand for women's services.[70]

Obstetrical litigation is prevalent. According to the Medscape Malpractice Report 2017, of the top 10 specialties for lawsuits, obstetrical-gynecological and women's health specialties tied with surgery for the most filed.[71] The most recent study conducted by ACOG, 73.6% of all obstetricians and gynecologists had at least one lawsuit filed against them during their career, with 63.5% of those claims relating to obstetrical care.[72] The most common obstetrical lawsuit involves an infant born with a form of cerebral palsy or other neurological impairment. According to ACOG's most recent survey, of all lawsuits relating to obstetrical care, the most common subject matter (27.4% of all cases) is a neurologically-impaired infant.[73] The incidence of neonatal encephalopathy, the clinical manifestation of disordered neonatal brain function, is approximately 3 out of every 1000 live births; this equates to approximately 12,000 new cases per year in the United States alone.[74] A reasonably busy obstetrician, therefore, will likely encounter multiple such cases during a career.

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[70] *See The Obstetrician-Gynecologist Workforce in the United States*: *Facts, Figures, and Implications, 2017*, AM. C. OF OBSTETRICIANS & GYNECOLOGISTS, https://www.acog.org/Clinical-Guidance-and-Publications/The-Ob-Gyn-Workforce/The-Obstetrician-Gynecologist-Workforce-in-the-United-States (last visited Feb. 15, 2018).

[71] Sandra Levy & Leslie Kane, *Medscape Malpractice Report 2017*, MEDSCAPE (Nov. 15, 2017), https://www.medscape.com/slideshow/2017-malpractice-report-6009206 (last visited Feb. 15, 2018).

[72] *See* Andrea M. Carpentieri et al., *Overview of the 2015 American Congress of Obstetricians and Gynecologists' Survey on Professional Liability*, AM. C. OF OBSTETRICIANS & GYNECOLOGISTS, at 2-4, https://www.acog.org/About-ACOG/ACOG-Departments/Professional-Liability/2015-Survey-Results (last visited Feb. 15, 2018).

[73] *See id.*

[74] *See* AM. C. OF OBSTETRICIANS & GYNECOLOGISTS' TASK FORCE ON NEONATAL ENCEPHALOPATHY, NEONATAL ENCEPHALOPATHY AND NEUROLOGIC OUTCOME 6 (2d ed. 2014).

There are many risk factors for neonatal encephalopathy, and the causal pathway can involve multiple risk factors beginning before the start of the pregnancy.[75] Given the current state of medicine, in most cases of neonatal encephalopathy, clinicians cannot determine whether an acute hypoxic-ischemic event during the intrapartum period was the true cause.[76]

The detrimental effects of obstetrical litigation, including cases involving neurological injury, have been studied frequently. Obstetricians pay among the highest malpractice premiums of all medical specialties, on average, 10.6% of gross revenues (not take-home pay). Almost half (49.7%) report having made changes to their practice as the result of malpractice liability fears, including decreasing the number of high-risk obstetrical patients, decreasing the total number of deliveries, increasing the number of Cesarean deliveries ("C-sections"), and halting the practice of obstetrics altogether. Nearly 40% reported having made similar changes as a result of the cost or unavailability of adequate malpractice insurance coverage.[77]

All of this underscores the important need to prevent unwarranted expansions of obstetrical liability theories. ACOG, the American Medical Association, and many other organizations are striving to address the challenges of obstetrical care access; that task only becomes more difficult and intractable if unproven, speculative causation theories permeate and expand obstetrical litigation.

The Plaintiff's "mechanical forces" or "compressive forces" theories, whether called "CCIE" or some other title, is particularly worrisome, given its potential applicability to almost any birth in which a trial of vaginal delivery is made. Its premise is that compression of the

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75 *See id.* at 4-12.

76 *See id.* at 207.

77 *See* Carpentieri *supra* note 60.

fetus' head during labor can be severe enough to cause ischemic brain damage. All vaginal deliveries, however, naturally feature some degree of cranial compression as the fetus descends through the birth canal. In addition, the proponents of the theory propose that uterine contractions alone may cause sufficient cranial compression to result in ischemic injury, even if the baby is delivered by C-section before ever descending into the birth canal. This creates the opportunity for almost any case involving a neurologically-impaired infant born after trial of labor, whether vaginally or by C-section, to assert the theory. Moreover, with no science behind the theory, there is no accepted method for defending against it by, for example, measuring the degree of compression, showing that it was within normal range, or proving what effect (or lack thereof) certain degrees of compression have.

Adoption of the Plaintiff's causation theories have potential ramifications far beyond the results of individual lawsuits. The criteria for admitting scientific testimony into the courtroom has a profound impact, not only on the outcome of this litigation, but on the practice of medicine and patient health and welfare. The American Medical Association ("AMA") Code of Medical Ethics emphasizes that "[i]nformed consent to medical treatment is fundamental in both ethics and law."[78] Reliance on the best available evidence is essential to medical decision making and patient autonomy. When this evidence is clouded by inaccurate and unfounded scientific opinions legitimized by the courts, physicians have an uphill battle helping their patients make the best informed decisions. Admission of the Plaintiffs' causation theories here imbues the medical decision-making process with court-approved, unsound scientific testimony. This infringes on a patient's basic right to receive essential, relevant information from their physicians and their physicians' obligation to "provide guidance about what they consider the optimal course

[78] AMA, AMA CODE OF MED. ETHICS, Op. 2.1.1 (2016), https://www.ama-assn.org/delivering-care/informed-consent (last visited Feb. 19, 2018).

of action . . . based on the physician's objective professional judgment."[79] Unscientific determinations in the courtroom further complicate the already difficult decision-making processes of health care providers and their patients. Medical decisions by both patients and physicians involve a variety of factors that must be weighed—this already complex process will be further clouded if physicians must contend with unproven theories legitimized by the courts. Once an expert opinion is rubber stamped as legitimate, it can be difficult for physicians to counteract it outside the courtroom, posing a real danger to patients who need treatment.

Given the current challenges in ensuring adequate access to obstetrical care, the introduction of Plaintiffs' unsupported liability theory of potentially near-universal application obviously would be counterproductive.

IV. CONCLUSION

The American College of Obstetricians and Gynecologists and the American Medical Association respectfully request that the Court consider this *Amici Curiae* brief and exclude the unsupported theories of medical causation offered by Plaintiffs' expert witnesses, Martin Gubernick, M.D., Donald Null, M.D., and John Seals, M.D. These theories lack scientific validity in the medical field of obstetrics and lack the indicia of reliability required for its admission in evidence in this legal proceeding.

[79] *Id*. at 1.1.3; *see also id.* at 1.1.4.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the above and foregoing Brief of Amici Curiae was served on the 20th day of February 2018, on the following counsel of record:

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CAUSE NO. 15C0849-202

STEVE MIZYED and NADIA WALRAVEN, Individually and as Next Friends and Guardians of KAI MIZYED, a Minor,	**§**	**IN THE DISTRICT COURT OF**
Plaintiffs,	**§**	
vs.	**§**	
	§	**BOWIE COUNTY, TEXAS**
JAMES ANTHONY SCALES, M.D.; COLLOM & CARNEY CLINIC ASSOCIATION; CHRISTUS HEALTH ARK-LA-TEX D/B/A CHRISTUS ST. MICHAEL HEALTH SYSTEM; and ARK-LA-TEX HEALTH NETWORK,	**§**	
Defendants	**§**	**202ND JUDICIAL DISTRICT**

APPENDIX TO BRIEF OF THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS AND THE AMERICAN MEDICAL ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF DEFENDANTS' OBJECTIONS TO THE ADMISSIBILITYOF PLAINTIFFS' CAUSATION EXPERTS, AND MOTION TO EXCLUDE

In compliance with rule 11 of the TEXAS RULES OF APPELLATE PROCEDURE, Amici Curie The American College of Obstetricians and Gynecologists and the American Medical Association submit this Appendix to their Brief of Amici Curiae containing the following item:

Tab A: AM. C. OF OBSTETRICIANS & GYNECOLOGISTS' TASK FORCE ON NEONATAL ENCEPHALOPATHY, *Neonatal Encephalopathy and Neurologic Outcome, Second Edition* (Mar. 2014)