STATE OF NEW JERSEY,	:	SUPERIOR COURT OF NEW JERSEY, LAW DIVISION, CRIMINAL PART
Plaintiff,	:	COUNTY OF MIDDLESEX
v.	:	
DARRYL NIEVES,	:	Indictment No. 17-06-0785-I
Defendant.	:	

PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW

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PRELIMINARY STATEMENT

The primary question in this matter is whether the State has proven the general acceptance of shaking-only Shaken Baby Syndrome, or Abusive Head Trauma ("SBS/AHT"). Central to that question is whether reliable scientific evidence exists that a person can shake a child with sufficient force to cause a "triad" of symptoms -- bleeding in the brain, bleeding in the eyes, and neurological impairment -- without also causing neck injuries or bruising. The second, related question is whether the State's expert rendered a reliable SBS/AHT diagnosis, based on her own standards, by considering and ruling out all other possible causes for the "triad" in this case. The State has failed to satisfy its burden in relation to both issues.

Initially, the State's proofs have shown that shaking-only SBS/AHT, rather than being a reliable diagnosis, is a relatively modern theory, based on an assumption that has never been proven. It is undisputed that the original hypothesis was based on a guess: that shaking can cause force equivalent to a 30-mile-per-hour car crash and thus, like a car crash, produce bleeding in the brain. It is also undisputed, as the State's sole expert testified, that no study has validated this theory in the forty-plus years since it was developed. To the contrary, the available studies, including those presented by the State, have shown that shaking can cause injury to a child's neck, but

cannot produce adequate force to cause the "triad." In other words, the best available data, including that presented by the State, shows that shaking-only SBS/AHT remains a hypothesis, rather than a verified scientific principle.

Equally troubling are the State's proofs regarding the diagnosis in this particular matter. As the State's expert testified, there is no diagnostic or confirmatory test for shaking-only SBS/AHT. Rather, abuse by shaking is assumed when the "triad" is detected, and is only ruled out if some other alternative explanation for those symptoms is found. A reliable SBS/AHT diagnosis can therefore only be reached if all possible explanations are considered and fairly ruled out. In this case, however, the State's expert did not mention a recognized alternative explanation in her diagnostic report and did not claim to have taken any steps to consider the diagnosis until three-and-a-half years later, during cross-examination. These omissions and delayed details, on their own, prevent the State from clearly showing that its expert followed her own diagnostic framework and that her opinion is reliable.

Accordingly, the State has failed to prove the reliability of its proposed expert testimony, despite seeking to use that testimony to incarcerate the defendant and keep him from his child. This Court must therefore find that the State has not met its burden and exclude the expert testimony from trial.

PROCEDURAL HISTORY AND FACTUAL BACKGROUND

The case stems from an emergency room visit for Darryl Nieves's then-11-month-old son, D.J.[1] During that visit, doctors found three symptoms: subdural hemorrhages, retinal hemorrhages, and neurological issues. Based on that "triad" of symptoms, and the alleged exclusion of other possible causes, Dr. Gladibel Medina diagnosed D.J. with SBS/AHT. The circumstances that led to that diagnosis, however, started when D.J. was born.

D.J.'s mother, Lucy Pham, gave birth through emergency caesarian section on March 9, 2016, when only 25 weeks pregnant. Baby D.J. experienced a plethora of medical issues due to his extreme prematurity, including with his respiratory system and a heart condition that required multiple surgeries. Ultimately, D.J. remained in hospital care for the first seven months of his life, until October 2016. In the months following his release, D.J. was treated with cardiac medication and an oxygen tank, among other things. Nieves and Pham also had a nurse visit every week and often brought D.J. to the pediatrician's office.

On February 3, 2017, when he was 11 months old, D.J. went "limp" and "passed out" during a diaper change. Nieves performed "mini-CPR" and D.J. regained consciousness and was alert by the time an ambulance arrived. A second episode occurred on February

[1] This pseudonym is used to protect the privacy of the child.

8. Again, D.J. "passed out" during a diaper change. Again, the symptoms resolved after Nieves supplied oxygen.

A third episode occurred on February 10 when D.J. again became unresponsive and limp. Nieves and Pham called 911 and an ambulance transported D.J. to St. Peter's Hospital. D.J.'s "seizure-like activity" ceased once he was given seizure medication.

Subsequent testing found subdural hemorrhages and retinal hemorrhages -- two of the three "triad" symptoms used to diagnose SBS/AHT. D.J.'s neurological impairment -- the three episodes of limpness and unconsciousness -- was considered the third symptom. Nieves and Pham denied any accidental or intentional trauma caused to D.J. Based on the presence of the symptoms, the lack of other injuries, and the purported exclusion of all other possible explanations, Dr. Medina diagnosed D.J. with AHT.

Nieves was charged and arrested on February 17, 2017. On June 30, the Middlesex County Grand Jury charged Nieves in Indictment Number 17-06-785-I with second-degree aggravated assault, N.J.S.A 2C:12-1b(1), and second-degree endangering the welfare of a child, N.J.S.A. 2C:24-4a(2). While released pre-trial, Nieves has not been allowed to have contact with D.J. or Pham's other child in the over 3.5 years since his arrest.

On July 2, 2018, Nieves filed a motion for a Frye[2] hearing on the reliability of shaking-only SBS/AHT in and Dr. Medina's diagnosis in particular. On November 2, this Court granted the motion. On July 11, 2019, following multiple discovery issues and the defense's retention of three expert witness, the State filed a motion for reconsideration. On September 11, the Court granted the State's motion and reversed its prior order.

On October 1, Nieves filed a notice for leave to appeal with the Appellate Division. On October 30, the Appellate Division granted leave to appeal and summarily remanded the matter for this Court to "conduct a hearing pursuant to Rule 104 to determine the admissibility of testimony from the State's experts on the issue 'Shaken Baby Syndrome/Abusive Head Trauma.'" The State did not appeal that decision.

A Frye hearing was held before this Court over five days between September 24 and October 15, 2020. During the hearing, the State presented the testimony of one witness -- Dr. Medina, a child abuse pediatrician -- while Nieves presented the testimony of three witnesses -- a pediatric neurologist, a radiologist, and a biomechanist. Following the hearing, this Court ordered that the parties file briefs on the reliability of shaking-only SBS/AHT and Dr. Medina's diagnosis by November 5.

[2] Frye v. United States, 293 F. 1013 (D.C. Cir. 1923).

STATEMENT OF SCIENCE

The two questions to be addressed in this case are: (1) whether shaking-only SBS/AHT is a reliable and generally accepted diagnosis; and (2) whether Dr. Medina rendered a reliable opinion when she diagnosed D.J. with SBS/AHT. Resolution of those issues involves application of N.J.R.E. 702, which governs the admission of expert testimony, and established principles of science, including the scientific method. This Statement of Science is intended to offer a brief explanation of those topics and how they intersect.

I. N.J.R.E. 702 and General Acceptance

Our Rules of Evidence allow for the presentation of expert opinions in limited circumstances. N.J.R.E. 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence 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.

In order for evidence to be admissible under N.J.R.E. 702, three requirements must be met:

> (1) the intended testimony must concern a subject matter that is beyond the ken of the average juror;
>
> (2) the field testified to must be at a state of the art such that an expert's testimony could be sufficiently reliable; and

> (3) the witness must have sufficient expertise to offer the intended testimony.

State v. Kelly, 97 N.J. 178, 208 (1984); see also State v. J.R., 227 N.J. 393, 409 (2017) (quoting Kelly, 97 N.J. at 210) ("[T]he expert must utilize a technique or analysis with 'a sufficient scientific basis to produce uniform and reasonably reliable results so as to contribute materially to the ascertainment of the truth.'"); State v. Moore, 188 N.J. 182, 206 (2006) (quoting Rubanick v. Witco Chem. Corp., 125 N.J. 421, 449 (1991)) (expert testimony must be "based on a sound, adequately-founded scientific methodology involving data and information of the type reasonably relied on by experts in the scientific field"); Landrigan v. Celotex Corp., 127 N.J. 404, 417 (1992) (expert must "demonstrate that both the factual bases and the methodology are scientifically reliable").

In criminal cases, New Jersey continues to apply the reliability standard announced in Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923): that the theory or technique "must be sufficiently established to have gained general acceptance in the particular field in which it belongs."[3] State v. Harvey, 151 N.J. 117, 169 (1997). This requires that the proponent "clearly establish" that the expert testimony is generally accepted in

[3] In 2018, the Supreme Court adopted a new standard for civil cases only. In re Accutane Litigation, 234 N.J. 340, 399 (2018); see also State v. J.L.G., 234 N.J. 265, 280 (2018).

the relevant scientific community. Id. at 170. The "clearly established" standard specifically applies in criminal cases because "it is important to recognize that a high degree of reliability is necessary where the freedom, or even the life, of an individual is at stake." Biunno, Weissbard & Zegas, Current N.J. Rules of Evidence, cmt. 3 on N.J.R.E. 702 (2019).

"Proof of general acceptance within a scientific community can be elusive" and "involves more than simply counting how many scientists accept the reliability of the proffered technology." Harvey, 151 N.J. at 171. "General acceptance[,]" moreover, "is not an end in itself." State v. Doriguzzi, 334 N.J. Super. 530, 546 (App. Div. 2000). Rather, "[i]t is reliability that must be assured" above all else. In re R.S., 173 N.J. 134, 136 (2002). General acceptance is merely an indication "used to ascertain whether a sufficient level of reliability has been achieved to allow consideration of the scientific test by the factfinder." Doriguzzi, 334 N.J. Super. at 546. Consistent with these principles, our Supreme Court has recognized that "[p]roving general acceptance 'entails the strict application of the scientific method, which requires an extraordinarily high level of proof based on prolonged, controlled, consistent, and validated experience.'" Harvey, 151 N.J. at 171 (quoting Rubanick, 125 N.J. at 436). In this respect, our courts are aligned with scientists themselves, both in terms of goals -- to

differentiate tested scientific principles from unproven theories and pseudoscience -- and methods. Indeed, "the essence of science[,]" like the essence of admitting expert testimony, "is the scientific method." National Research Council of the National Academy of Science, Reference Manual of Scientific Evidence 39 (3d ed. 2011) (hereafter "Reference Manual").[4]

II. The Scientific Method

The scientific method is defined as a "method of procedure that has characterized natural science since the 17th century, consisting in systemic observation, measurement, and experiment, and the formulation, testing, and modification of hypotheses." The New Oxford American Dictionary 1526 (2001). The method requires the scientist to: (1) observe some aspect of the universe; (2) form a hypothesis that is consistent with that observation; (3) use the hypothesis to make predictions; (4) test those predictions by experiments or further observations, and (5) if "the testing fails to confirm your hypothesis, then you modify your hypothesis and you try again." (3T54-17 to 55-2; 4T59-18 to 61-8); Reference Manual at 40.[5] Steps four and five

[4] Available at https://www.fjc.gov/content/reference-manual-scientific-evidence-third-edition-1.

[5] 1T = Transcript of Frye hearing - September 24, 2020
2T = Transcript of Frye hearing - September 29, 2020
3T = Transcript of Frye hearing - September 30, 2020
4T = Transcript of hearing - October 13, 2020
5T = Transcript of hearing - October 15, 2020

are repeated until there are no discrepancies between the theory and the observed results. See generally National Research Council of the National Academy of Science, Strengthening Forensic Science in the United States: A Path Forward, 112-13 (2009) (hereafter "Strengthening Forensic Science").[6]

An underlying assumption of the scientific method is "that events occur in consistent patterns that can be understood through careful comparison and systematic study." Id. at 112. Because of this, it is critical that "data are accumulated methodically, strengths and weaknesses of information are assessed, and knowledge about causal relationships is inferred." Ibid. Scientists must also be aware of the limitations of knowledge, such as their own inferences and underlying assumptions, and must put practices in place to detect bias and minimize its effects on their conclusions. Ibid.

Once developed, hypotheses are tested, "measured against the data, and are either supported or refuted." Ibid. "Typically, experiments or observations must be conducted over a broad range of conditions before the roles of specific factors, patterns, or variables can be understood." Ibid. Scientists must "continually observe, test, and modify the body of knowledge." Ibid. "Rather than claiming absolute truth, science approaches

[6] Available at https://www.ncjrs.gov/pdffiles1/nij/grants/228091.pdf.

truth either through breakthrough discoveries or incrementally, by testing theories repeatedly." Ibid. "Ultimately, the goal is to construct explanations ('theories') of phenomena that are consistent with broad scientific principles," which can then be reviewed and tested by other scientists. Id. at 112-14.

As the National Academy of Science explains, these types of reviews are what "push the scientist to explain his or her work clearly and which raise questions that might not have been considered." Id. at 112. The review of peers "might extend to independent reproduction of the results or experiments designed to test the theory under different conditions." Ibid. "Acceptance of the work comes as results and theories continue to hold, even under the scrutiny of peers, in an environment that encourages healthy skepticism." Ibid.

III. Recognizing and Minimizing Bias and Error

As discussed, scientists must be aware of both their own underlying assumptions and biases, put in place practices to detect and to reduce bias and errors, and ensure that they interpret their findings "within the constraints of what the science will allow" and avoid "overstatement (going beyond the facts)." Id. at 112-13. One common type of bias is confirmation bias, or circular reasoning, which is a phenomenon where an individual seeks to prove a hypothesis by interpreting evidence in ways that are partial to existing beliefs or expectations.

Raymond S. Nickerson, Confirmation Bias: A Ubiquitous Phenomenon in Many Guises, 2 Rev. of General Psychol. 175, 175 (1998). In many senses, confirmation bias can be equated to "building a case to justify a conclusion already drawn[,]" ibid., or working backwards so that "the idea that you started with becomes the conclusion." (2T133-23 to 134-4) Confirmation bias may lead one to "selectively gather[], or give[] undue weight to, evidence that supports one's position while neglecting to gather, or discounting, evidence that would tell against it." Nickerson, 2 Rev. of General Psychol. at 175. Accordingly, "rather than concluding based on other facts" and being open to criticism and new ideas, "you're concluding based on an idea that you had to begin with[,]" regardless of whether other evidence supports or undermines your theory. (2T133-23 to 134-4; 3T96-9 to 19)

A related concept also arises based on how the relevant scientific community is defined. As the Supreme Judicial Court of Massachusetts has cautioned, a judge "must not define the 'relevant scientific community' so narrowly that the expert's opinion will inevitably be considered generally accepted." Canavan's Case, 733 N.E.2d 1042, 1050 n.6 (Mass. 2000). "If the community is defined to include only those experts who subscribe to the same beliefs as the testifying expert, the opinion will always be admissible." Ibid. A relevant scientific community must therefore "be defined broadly enough to include a

sufficiently broad sample of scientists so that the possibility of disagreement exists." Ibid. Similar concerns have been expressed by other courts and commentators. See, e.g., Paul C. Giannelli, The Admissibility of Novel Scientific Evidence: Frye v. United States, a Half-Century Later, 80 Colum. L. Rev. 1197, 1209-10 (1980) ("If the 'specialized field' becomes too narrow, the consensus judgement mandated by Frye becomes illusory; the judgement of the scientific community becomes, in reality, the opinion of a few experts.").

Additional caution has also been expressed, including by our Supreme Court, when general acceptance is based on experts whose careers, livelihoods, or reputations depend upon a theory's acceptance. See, e.g., Windmere, Inc. v. Int'l Ins. Co., 105 N.J. 373, 380 (1987) (quoting People v. Kelly, 549 P.2d 1240, 1249 (Cal. 1976)) (noting risk of "bias" when an expert has "virtually built his career on the reliability of the technique"); People v. Young, 391 N.W.2d 270, 276 n.24 (Mich. 1986) ("Scientific community approval is absent where those who have developed and whose reputation and livelihood depends on use of the new technique alone certify, in effect self-certify, the validity of the technique."). Simply put, an expert may be less likely to accept flaws in a theory that she has had "a long association with" or has a "vested career interest" in. In re Jordan R., 140 Cal. Rptr. 3d 222, 234 (Cal. App. 2012).

PROPOSED FINDINGS OF FACT

The State had the burden to clearly establish that shaking-only SBS/AHT is scientifically reliable and generally accepted within the relevant scientific communities. In addition, the State also had the burden of demonstrating that Dr. Medina rendered a reliable opinion when she diagnosed D.J. with SBS/AHT.

To meet its burden, the State presented the testimony of Dr. Medina, the director of the Dorothy B. Hersh Regional Child Protection Center at St. Peter's University Hospital. (1T8-9 to 18, 11-1 to 25) Dr. Medina has practiced medicine for 25 years, is certified in general pediatrics and child abuse pediatrics, and was qualified as an expert in the fields of pediatrics and child abuse pediatrics. (1T8-13 to 16-5, 25-17 to 26-16) Dr. Medina does not have any experience in optometry, neurology, radiology, or biomechanics, and has not published any research or articles on SBS/AHT. (1T22-23 to 24-12)

The defense presented three expert witnesses, covering the fields of neurology, radiology, and biomechanics.

Dr. Joseph Scheller testified as an expert in pediatric neurology and neuroimaging. (2T110-24 to 111-21) Dr. Scheller is a neurologist who has worked in pediatric neurology for 33 years, including at several hospitals. (2T77-7 to 9, 78-10 to 81-15) Dr. Scheller is board certified in pediatrics and

neurology, with a specialty in pediatric neurology, and has a certification in neuroimaging. (2T81-7 to 84-3, 86-1 to 87-5, 108-2 to 110-8) Dr. Scheller conducts retinal examinations and diagnoses retinal hemorrhages as part of his normal practice (2T87-11 to 89-6, 105-18 to 106-14), and has written peer-reviewed articles on topics including retinal hemorrhages, imaging, and SBS/AHT. (2T89-15 to 90-12)

Dr. Julie Mack testified as an expert in radiology and pediatric radiology. (3T24-16 to 20) Dr. Mack graduated from Harvard Medical School in 1990, is board certified by the American Board of Radiologists, and has an additional certification in pediatric radiology. (3T10-23 to 13-11) Dr. Mack has worked as a radiologist at Penn State Hershey Medical Center since 2006 and currently serves as the Division Director of Breast Imaging. (3T13-12 to 14-12) Dr. Mack maintains an interest in pediatric radiology and has published, consulted, and testified on that topic. (3T14-13 to 17-15, 19-12 to 23-20)

Lastly, Dr. Chris Van Ee testified as an expert in biomechanics. (4T26-5 to 8) Dr. Van Ee holds a Ph.D. in biomedical engineering from Duke University and currently works in impact biomechanics and mechanical engineering at a consulting firm in Michigan. (4T5-24 to 6-15, 12-9 to 13-9) Dr. Van Ee's experience involves impact biomechanics, which is "the study of the human body and how it responds to forces or

accelerations[,]" including the injuries that may be caused. (4T7-2 to 8-19) Dr. Van Ee is also an adjunct professor at Wayne State University, has testified as an expert in roughly 70 to 80 cases, and has published and reviewed multiple peer-reviewed articles, including on the production of subdural hematomas and retinal hemorrhages through impact. (4T11-14 to 12-8, 14-5 to 15-20, 18-14 to 19-1)

Based on this testimony, the evidence presented, and the relevant scientific principles, Nieves respectfully proposes the following findings of fact.

POINT I

THE STATE HAS FAILED TO CLEARLY ESTABLISH THAT SHAKING-ONLY SBS/AHT IS SCIENTIFICALLY RELIABLE THROUGH VALID SCIENTIFIC EVIDENCE.

The State bore the responsibility of clearly establishing the general acceptance and reliability of shaking-only SBS/AHT. To meet this burden, the State had to do more than establish that children can be injured through head trauma and that shaking can be harmful. Instead, the State was required to demonstrate that humans can shake infants with sufficient force to cause a triad of symptoms -- bleeding in the brain, bleeding in the eyes, and neurological impairment -- without also causing neck trauma or other injuries.

As discussed below, the State failed to meet this burden because the existing biomechanical research has indisputably

failed to validate this theory, and has instead indicated that shaking cannot create sufficient force to cause the "triad," particularly without causing neck injuries. Likewise, research has also failed to validate the medical theories -- such as the vitreoretinal traction theory -- that have been proposed to explain how shaking can cause the "triad." Given this lack of scientific validation, the State has failed to demonstrate that shaking-only SBS/AHT is more than an unproven hypothesis, such that it cannot be deemed generally accepted or reliable.

A. SHAKING-ONLY SBS/AHT IS A MODERN DIAGNOSIS THAT IS ROOTED IN BIOMECHANICAL PRINCIPLES BUT WHICH HAS NEVER BEEN VALIDATED AS A BIOMECHANICAL CONCEPT.

1. Shaking-Only SBS/AHT Must Be Viewed Separately from SBS/AHT in General Because that Term Covers a Wide Variety of Mechanisms of Abuse, Most of Which Are Well Accepted and Not in Dispute in this Case.

Several witnesses, including Dr. Medina, testified about the general history of SBS/AHT. While these histories overlapped, one persistent divergence was how to define SBS/AHT, and how long that diagnosis has been recognized. The source of this divergence is simple: the term "abusive head trauma" has come to encompass a wide variety of abuse, with shaking being just one proposed mechanism. Indeed, in 2009, the American Academy of Pediatrics started using the term Abusive Head Trauma, rather than Shaken Baby Syndrome, so as to "broaden[] the terminology to include all mechanism of injury, not just

shaking alone . . . .” (1T31-17 to 24) Recognizing shaking-only SBS/AHT as a distinct diagnosis is essential to a fair resolution of this case because shaking-only SBS/AHT is on a very different footing than other forms of AHT.

No one denies that children may be harmed through head trauma, as has long been recognized. (1T30-19 to 32-21) No one disputes, for example, that a child may be abused through “inflicted injury to the head,” shaking with impact, or crushing injuries. (1T26-18 to 25, 31-17 to 32-14; 3T103-22 to 104-22) Likewise, this case does not involve a challenge to diagnosing abuse when children display symptoms such as “bruises and contusions,” spinal cord injuries, internal organ injuries, or bone fractures. (1T27-8 to 24) Simply put, these forms of injury are based on accepted medical evidence and are not at issue. Rather, the only diagnosis in dispute is when shaking-only SBS/AHT is alleged and the child does not display neck damage or external injuries.

One must be careful to not conflate head trauma in general, which is not in dispute, with SBS/AHT caused by shaking. Because there is a wide spectrum of injuries associated with abusive head trauma, there is a risk of imputing the general acceptance of head trauma with shaking-only SBS/AHT. Indeed, this line was often blurred at the Frye hearing, such as when Dr. Medina stated that SBS/AHT has been recognized for 160 years, and when

the State questioned witnesses about the acceptance of AHT without specifying whether it related to shaking-only SBS/AHT. (1T30-19 to 32-21, 34-12 to 15; 3T103-22 to 24; 5T3-18 to 20)

To properly understand SBS/AHT, these issues, while interrelated, must be considered separately. Specifically, as discussed below, shaking-only SBS/AHT must be viewed as an independent theory based on biomechanics, the general acceptance and reliability for which must stand or fall independent of abuse by head trauma in general.

2. Shaking-Only SBS/AHT Was Based on the Theory that Abuse Should Be Assumed When Children Suffer Subdural Hematomas, Biomechanical Research Showing that Subdural Hematomas Can Be Caused by Car Accidents, and the Hypothesis that Shaking Can Create Similar Forces as Car Accidents.

The theory of shaking-only SBS/AHT stems from the understandable desire of doctors to diagnosis observed but unexplained symptoms in children. In 1971, Dr. A.N. Guthkelch, an English neurosurgeon, authored an article about unexplained subdural hematomas -- or blood between the brain and the skull -- in children who did not display "any external signs of trauma." (1T31-2 to 6; 2T118-9 to 119-9); see also A.N. Guthkelch, Infantile Subdural Haematoma and its Relationship to Whiplash Injuries, 2 British Med. J. 430, 430-31 (1971). Faced with an absence of other explanations, Dr. Guthkelch hypothesized that the children may have experienced "physical abuse" by shaking. (1T31-2 to 6; 2T118-9 to 119-9) Prior to this

point, shaking was not viewed as a valid mechanism of abuse. (2T119-7 to 9, 121-4 to 6)

In posing this hypothesis, Dr. Guthkelch relied on two distinct areas of research. First, Dr. Guthkelch cited research regarding suspected child abuse, Guthkelch, 2 British Med. J. 430, including from Dr. C. Henry Kempe, who coined the term "battered-child syndrome" to describe physical abuse that often went unrecognized by treating physicians. C. Henry Kempe, M.D., et al., The Battered-Child Syndrome, 181 J.A.M.A. 17, 17 (1962). In an effort to address such undetected abuse, Dr. Kempe and his co-authors suggested that the "battered-child syndrome" "should be considered in any child exhibiting evidence of possible trauma or neglect," including subdural hematomas. Id. at 29.

The second major area of research relied on by Dr. Guthkelch was the study of biomechanics. Biomechanics, and impact biomechanics in particular, looks "at the human body as from a mechanical perspective trying to understand what are the forces or accelerations that give rise to injury." (4T26-12 to 20) Impact biomechanics, for example, has been used to understand and address the injuries that will arise from the acceleration and impacts associated with events like car accidents, helmet-to-helmet tackles, and military combat. (4T7-9 to 16, 11-19 to 12-8, 102-15 to 103-10) It has also been used

forensically to determine whether a specific event can account for observed trauma or injuries. (4T8-14 to 19, 26-20 to 27-1)

As explained by Dr. Van Ee, it was biomechanists in the 1940s who first hypothesized that angular acceleration can cause "subdural hematoma, intracranial hemorrhage, [and] hemorrhage inside of the skull around the brain." (4T27-2 to 12) As opposed to linear acceleration, which looks at how quickly something starts or stops alone a line, angular acceleration considers something being spun and the resulting force from it being stopped. (4T27-13 to 25) "If the stop occurs fast, there's greater angular acceleration. If it occurs slowly, . . . that's low angular acceleration." (4T27-25 to 28-5) High angular acceleration, as Dr. Van Ee explain, can create separation between the stopped component -- like a skull -- and other components -- like a brain. (4T28-6 to 22) Accordingly, angular acceleration can cause concussion, "subdural bleeding, and in some cases diffuse axonal injuries or . . . breaking or stretching of the nerves in the brain." (4T28-23 to 29-16)

These theories about angular acceleration were incorporated into SBS/AHT through Dr. Guthkelch's reliance upon a 1969 study by Dr. Ayyub Ommaya, which itself grew out of the earlier research on angular acceleration. (4T29-17 to 30-2) In that study, 50 rhesus monkeys were subjected to whiplash in simulated car accidents, without experiencing impact to the head. Ayub K.

Ommaya, Whiplash Injury and Brain Damage, 204 J.A.M.A. 285, 285-86 (1968). Following the accidents, which occurred at roughly 30 miles per hour, 19 of the 50 monkeys were observed to have been concussed and 15 of those 19 were found to have small subdural hemorrhages. Id. at 286; (2T122-8 to 21) As described by Dr. Guthkelch, this study showed that subdural hematomas can be caused by a "sustained whiplash injury to the neck as a result of an automobile accident" without injury to the "head itself." Guthkelch, 2 British Med. J. at 430.

Based on this research, Dr. Guthkelch then "submitted" as a hypothesis that subdural hematomas could also be caused by shaking a child. Ibid. Specifically, and despite not citing any evidence for support, Dr. Guthkelch speculated that shaking could cause the same amount of force and injuries as a 30 mile-per-hour car crash because "[i]t seems clear that the relatively large head and puny neck muscles of the infant must render it particularly vulnerable to whiplash injury . . . ." Ibid. Dr. Guthkelch, in other words, brought the principles of biomechanics into the arena of child abuse research by presenting shaking as a new, unsupported, theory of abuse, which could be an "assumed" cause of "all cases of infantile subdural haematoma . . . unless proved otherwise . . . ." Id. at 431.

3. Despite Its Theoretical Basis, Shaking-Only SBS/AHT Was Subsequently Popularized and Adapted into a Diagnosis in

Which Abuse Is Presumed if Children Display a "Triad" of Symptoms.

Despite its theoretical nature, Dr. Guthkelch's shaking hypothesis soon gained traction with other doctors seeking to address unexplained injuries in children. By 1974, Dr. John Caffey adopted and popularized Dr. Guthkelch's theory under the name "shaken baby syndrome." (1T31-7 to 16, 129-2 to 4; 2T120-14 to 121-1) Like Dr. Guthkelch, Dr. Caffey "suspected" that the children he observed were shaken "because they had a number of injuries," including subdural hematomas, without evidence of impact. (2T122-22 to 123-11) Dr. Caffey built upon Dr. Guthkelch's hypothesis by proposing that retinal hemorrhages -- bleeding in the eyes -- is also indicative of abuse by shaking. John Caffey, On the Theory and Practice of Shaking Infants, 124 Amer. J. of Diseases and Children 161, 167 (1972).

In addition, Dr. Caffey reinforced the view that shaking abuse is widespread, and should be presumed. Despite acknowledging that the incidence of shaking "is unknown and cannot be even estimated satisfactorily[,]" Dr. Caffey asserted that "[w]hiplash-shaking appears to be practiced widely in all levels of society" and that "aggressive study" was needed to protect children. Id. at 169. To that end, Dr. Caffey predicted that "a new pediatric subspecialist will soon emerge, a pediatric traumatologist, who will head trauma teams in the

larger medical clinics and attack the problem of traumatic diseases" in children. Ibid.

Dr. Caffey's writings proved to be both influential and prescient. Since the publication of his article, child abuse has become a diagnosis rendered by roughly 350 pediatric subspecialists known as child abuse pediatricians (CAPs). (1T30-1 to 15; 2T112-10 to 15) If abuse is suspected, hospitals or doctors will generally contact a CAP, like Dr. Medina, to "put a picture together" and render an opinion as to whether or not the child was abused. (1T30-1 to 15)

As Dr. Medina explained, there is no test or "specific diagnostic criteria" to determine whether abuse occurred or to even "define what abusive head trauma is." (1T113-14 to 20, 158-2 to 6) Consistent with its ill-defined nature, doctors will consider a list of possible symptoms, rather than "one specific symptom or finding," to diagnose AHT. (2T113-15 to 114-4) Dr. Medina, for example, testified that she considers ten factors: preexisting conditions, subdural hematomas, retinal hemorrhages, brain malfunction (seizures), lethargy, scalp fracture, scalp swelling, neck injury, limb fracture, rib fracture, external body injury, and internal body injury. (1T155-12 to 156-23)

While testifying that no factor is dispositive, Dr. Medina made clear that she is more likely to diagnose AHT when more factors are present (1T156-24 to 157-22, 158-25 to 159-1, 160-2

to 5), and that some factors, commonly known as the "triad," are considered more significant for shaking-only SBS/AHT. (1T158-12 to 17) Consistent with Drs. Guthkelch's and Caffey's writings, the "triad" consists of "[s]ubdural hemorrhages, severe retinal hemorrhages and any neurological presentation, known as encephalopathy." (1T53-7 to 12) In addition, children diagnosed with SBS/AHT also generally lack external injuries or other signs of traumas. (1T158-12 to 17)

These findings, like Drs. Guthkelch and Caffey suggested, operate as presumptive evidence of abuse. Despite suggesting that the "triad" merely flags "a concern for abusive head trauma," Dr. Medina testified that "those findings, when multiple exist in a single patient, are more specific . . . for inflicted injury" than accidental trauma, and are "confident within medical certainty" for abuse, despite the absence of other symptoms. (1T52-9 to 53-4, 161-4 to 12) Dr. Medina also made similar comments about the individual components of the triad, particularly concerning retinal hemorrhages and subdural hematomas. (1T55-5 to 8, 55-25 to 56-9, 158-12 to 17) The importance of the triad, and its ability to establish abuse, is also demonstrated by the ways in which abuse is suspected and investigated.

Concern for abuse is most often raised by a pediatrician or emergency room doctor. (1T28-12 to 16, 29-1 to 7) Signs of

potential abuse vary and may include "external bruises or physical injuries." (1T27-25 to 28-25) However, for children without external injuries, like those suspected of having been shaken, the most likely triggering symptom is encephalopathy, or neurological impairment, such as apnea, seizures, or any other "altered mental status." (1T27-25 to 28-11, 53-7 to 12) In other words, a child abuse investigation will often begin based on a finding of one of the three triad factors.

Once neurological impairment is detected, the child's brain will be examined, such as with a CAT scan or MRI, to determine whether the impairment is "the outward presentation or demonstration of something that has gone wrong intracranially." (1T72-4 to 9; 2T84-17 to 85-25; 3T68-17 to 69-11) It is at this stage that the second prong of the triad -- subdural hematomas or hemorrhages -- may be found. A subdural hematoma is "bleeding under the dural membrane," which is the outermost of the three membranes that surround the brain. (1T46-19 to 48-11, 53-13 to 19) The other two membranes are the pia, which tightly adheres to the brain, and the arachnoid, which is between the pia and dura. (1T46-19 to 24) Ordinarily, the arachnoid is separated from the pia by a roughly four-millimeter fluid-filled space. (4T47-7 to 48-11) In contrast, there is normally no space between the dura and the arachnoid absent subdural hematoma, meaning a collection of blood or fluid. (1T53-13 to 54-4)

If a hematoma is found, doctors will seek to detect the third triad symptom -- retinal hemorrhages. (1T55-9 to 15, 115-22 to 116-21; 3T64-1 to 10) A retinal hemorrhage "is one or more drops of blood" in the eyes (1T57-6 to 57-12; 2T124-19 to 125-5, 173-13 to 23) Severe retinal hemorrhages, which are believed to be the most often associated with SBS/AHT, are multi-layered, meaning blood is found on at least two retinal layers, and are "too numerous to count," meaning there are over 20 drops of blood. (1T55-15 to 56-4, 58-7 to 20; 2T175-11 to 177-14)

If some combination of these three symptoms are observed, a child abuse pediatrician will generally get involved to determine if abuse may have occurred. (1T30-10 to 15) In conducting that analysis, the CAP will engage in a differential diagnosis aimed at ruling out any other possible explanation for the symptoms. The CAP will, in other words, presume that the triad is indicative of abuse, and will diagnose the child with SBS/AHT, unless some other finding rebuts that presumption.

As part of this review, the CAP must conduct "a comprehensive evaluation" of the child's medical history, including "what brought the child to the hospital and what has been the child's demeanor, behavior immediately prior to the presentation and prior to that . . . ." (1T29-8 to 16) The evaluation must also include a "physical exam" of the child and subsequent "consultation with multiple subspecialties . . . to

conduct a comprehensive evaluation of other possible" explanations for the symptoms. (1T29-17 to 30-3) The child abuse pediatrician will then review the child's history, "the physical findings, the laboratory tests, [and] the imaging studies" to determine whether an alternate explanation exists. (1T30-1 to 9)

The CAP must, for example, consider the "many" alternate causes of subdural hematoma, including coagulation abnormalities, benign expansion of the subarachnoid space (BESS), meningitis, and non-abusive trauma, such as child birth. (1T54-1 to 22, 113-25 to 115-4) Likewise, the CAP must consider whether the retinal hemorrhages could have other sources, such as aneurisms, strokes, vomiting, coughing, "[o]r anything that causes too much pressure inside the brain . . . ." (1T115-4 to 21; 2T175-3 to 8) Absent an alternate finding of causation, abuse will be diagnosed. Or, as Dr. Medina explained, the triad creates "a probability" of abuse which "in the absence of pathology" to otherwise explain the symptoms "is what gives the final diagnosis." (2T54-12 to 55-12)

4. While Diagnosed by Medical Doctors, the Foundation and Reliability of SBS/AHT Depends on Biomechanics.

While SBS/AHT has evolved over the past four decades, the diagnosis, as it did in the 1970s, continues to rest primarily upon biomechanical principles. Although CAPs are medical doctors and consult various other doctors, their differential diagnosis

cannot lead to a finding of SBS/AHT without first proving the basic premise that humans can shake a child with sufficient force to cause brain and eye bleeding. In other words, one cannot conclude that shaking caused the triad by ruling out other possible explanations without first knowing that shaking is capable of causing the triad in the first place. Biomechanics thus lie at the heart of the diagnosis, biomechanists are part of the relevant scientific community, and the diagnosis cannot be reliably reached without shaking-only SBS/AHT being demonstrated as biomechanically possible.

"As used in the medical community, a differential diagnosis is a medical construct for determining 'which one of two or more diseases or conditions a patient is suffering from, by systematically comparing and contrasting their symptoms.'" Creanga v. Jardal, 185 N.J. 345, 355 (2005) (quoting Dorland's Illustrated Medical Dictionary 377 (23d ed. 1957)). "The first step in properly conducting a differential diagnosis is for the expert to 'rule[] in' all plausible causes for the patient's condition by compiling 'a comprehensive list of hypotheses that might explain the set of salient clinical findings under consideration.'" Id. at 356 (alteration in original) (quoting Clausen v. M/V New Carissa, 339 F.3d 1049, 1057 (9th Cir. 2003)). In other words, the expert must first determine "which of the competing causes are generally capable of causing the

patient's symptoms or mortality.'" Ibid. (quoting Clausen, 339 F.3d at 1057-58); see also Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1413 (D. Or. 1996) (stating differential diagnosis requires evidence that "general causation has been proven for the list of possible causes it eliminates").

"A differential diagnosis that 'rules in a potential cause that is not so capable'" of causing the patient's symptoms "has not been properly conducted" and should not be admitted at trial. Creanga, 185 N.J. at 356 (quoting Clausen, 339 F.3d at 1058). This is because ruling out other potential causes means little unless "the final, suspected 'cause' remaining after [the] process of elimination [is] actually . . . capable of causing the injury[,]" as demonstrated through "scientifically valid methodology." Hall, 947 F. Supp. at 1413 (quoting Cavallo v. Star Enterprise, 892 F. Supp. 756, 771 (E.D. Va. 1995)). Simply put, an expert cannot establish that "A" caused "B" by ruling out "X," "Y," and "Z," without first establishing that "A" is capable of being the cause. See Ruggiero v. Warner-Lambert Co., 424 F.3d 249, 254-55 (2d Cir. 2005) (excluded expert testimony that "may have used a differential diagnosis to rule out competing causes . . . without establishing that" the claimed cause was "among" the possible causes).

To find otherwise would allow someone to use a differential diagnosis to "prove" any hypothesis, no matter how flawed. One

cannot, for example, testify that the triad is caused by having black hair just because a doctor can rule out accidental injury and what she believes are all other possible causes. Rather, the differential diagnosis can only be of value if the clinician is choosing between valid, recognized explanations, rather than unproven theories or hunches. Accordingly, while various medical fields are relevant to the exclusion of other possible causes of "the triad," the core of the SBS/AHT diagnosis remains the biomechanical possibility of shaking causing those symptoms.

As noted, Dr. Ommaya's biomechanical study on the "levels of rotational acceleration" from whiplash, Ommaya, 204 J.A.M.A. at 285, served as the basis for the original shaking theory, Guthkelch, 2 British Med. J. at 430, and is the foundation upon which SBS/AHT studies have been built. (1T34-15 to 21) As Dr. Medina explain, "what we know about shaking, and the established thresholds for intracranial injury comes from that study, which then everything else in biomechanics is based on those injury thresholds." (1T34-21 to 25, 35-18 to 20) Indeed, Dr. Medina testified that this is one of the "basic studies" CAPs are taught because it "triggers all the biomechanical studies as the minimum amount of force needed." (1T36-11 to 18) As Dr. Medina further explained, the Ommaya study showed that shaking can "cause injury to primates" (1T35-1 to 4), and that the resultant injury thresholds -- meaning the "forces required to generate"

injuries -- were then "scaled to adult humans, and from there attempted to be scaled to infants" to show that shaking could cause subdural hematomas in children. (1T36-4 to 10) Biomechanics, as discussed below, has also been consistently used "to test the hypothesis" of SBS/AHT. (4T31-24 to 32-6)

Biomechanics is thus central to SBS/AHT, as further evidenced by other portions of Dr. Medina's testimony. As Dr. Medina testified, "[w]e know that children can sustain intracranial injuries by care givers" based on "the concept of whiplash injury or a shaking injury, back and forth movement, at least once violently . . . ." (1T34-12 to 17) Dr. Medina also testified that shaking can cause damage through "the movement of the brain inside the skull" and the resulting "acceleration" and "deceleration," "hyperflexion, hyperextension" and angular rotational forces. (1T168-8 to 25, 170-17 to 21; 2T53-15 to 54-7) In addition, Dr. Medina explained that shaking can cause the same injuries as a car accident because "shaking is worse" than a car accident and that both involve "a back and forth movement in the anterior-posterior direction" with "hyperflexion and hyperextension of the neck." (1T124-16 to 25)

Thus, the history of shaking-only SBS/AHT, the present diagnostic framework, and Dr. Medina's own testimony demonstrate the centrality of biomechanics to that diagnosis. Without generally accepted and reliable evidence that shaking can cause

the triad, a diagnosis cannot be made by excluding other causes. Without such evidence, capable of satisfying the scientific method, in other words, testimony regarding shaking-only SBS/AHT is not sufficiently reliable and cannot be admitted at trial.

5. Shaking-Only SBS/AHT Is Not Reliable Because Even Its Proponents Recognize That It Was Based Upon an Unsound Biomechanical Basis and Has Never Been Validated.

Although a primarily biomechanical theory, shaking-only SBS/AHT has never been supported, let alone verified, by biochemical studies or research. To the contrary, even Dr. Medina recognized that the Ommaya study provided a questionable basis for the initial theory, that no subsequent study has demonstrated its validity, and that there is a debate, or controversy, over whether shaking can cause the triad. The absence of proof, rather than rendering biomechanics irrelevant, as Dr. Medina suggested, demonstrates the still-theoretical nature of shaking-only SBS/AHT.

i. Shaking-only SBS/AHT was premised upon an unproven assumption concerning biomechanics.

As noted, Dr. Guthkelch first postulated that shaking can cause subdural hematomas based on Dr. Ommaya's finding that such injuries could be caused by whiplash in car accidents. Guthkelch, 2 British Med. J. at 430. Dr. Guthkelch did not, however, offer a basis for believing that shaking could cause the same force and injuries as a 30 mile-per-hour car crash.

Moreover, Dr. Ommaya's study involved rhesus monkeys, which have different anatomical structures than humans (1T126-3 to 17), and suffered different injuries than those considered consistent with shaking-only SBS/AHT. For example, the study found that the monkeys suffered neck injuries, which are not present for shaking-only cases, and did not have reported retinal hemorrhages, one of the triad symptoms. (1T35-11 to 18, 126-20 to 127-23, 167-1 to 168-7; 2T122-5 to 18; 4T84-3 to 85-20)

Thus, shaking-only SBS/AHT, despite being defined by biomechanics, was initially premised upon an unproven theory, rather than a validated biomechanical basis. Indeed, Dr. Ommaya opined roughly 30 years later, in 2002, that Drs. Guthkelch and Caffey may have relied on his study without "realizing that the energy level of acceleration in our work related to speeds at motor vehicle crashes at 30 mph" and thus involved forces "not seen in even the most violent shaking" without impact. A.K. Ommaya, et al., Biomechanics and Neuropathology of Adult and Paediatric Head Injury, 16 Brit. J. of Neurosurg. 220, 221-22 (2002); (4T34-25 to 35-25) In other words, doctors like Guthkelch and Caffey, while understandably trying to address unexplained injuries in children, were "drawing conclusions based on an assumption" about shaking without knowing whether "that assumption was true." (2T123-23 to 124-3) While such theorizing is appropriate when forming an initial hypothesis, it

is not the type of scientific evidence upon which validation, reliability, and general acceptance can be based.

ii. It is undisputed that subsequent studies have failed to validate the biomechanical hypothesis that shaking can cause the triad and that it can cause the triad without also causing neck injuries.

Even more troubling, subsequent studies have failed to validate the shaking-only SBS/AHT hypothesis. As Dr. Medina explained, other scientists and biomechanics have used the injury thresholds from the Ommaya study "to determine whether vigorous shaking of an infant can reach those thresholds to then produce intracranial trauma." (1T35-20 to 36-3) This has been done through "different animal models" and studies of "anthropomorphic dolls," similar to crash test dummies, to see "if the values generated" by shaking "reach those established by the Ommaya study to cause injury." (1T36-19 to 37-9) Despite repeated testing, every expert, including Dr. Medina, recognized that no biomechanical study has been able to demonstrate that shaking can create the type of forces thought to cause injury. In other words, no testing has been able to validate the hypothesis underlying shaking-only SBS/AHT.

One of the first studies "[t]o test the hypothesis" was conducted by Dr. Ann-Christine Duhaime in 1987. Ann-Christine Duhaime, et al., The Shaken Baby Syndrome: A Clinical Pathological, and Biomechanical Study, 66 J. Neurosurg. 409, 411

(1987). Dr. Duhaime had football players "shake a test device that represented a one-month-old child" "to see if shaking alone could reach the thresholds established by the Ommaya study." (1T37-15 to 21; 4T88-14 to 89-5) "[T]he accelerations that they measured[,]" however, "were very low and below the level of where they thought injury would take place for a child" until the test device were also impacted. (1T37-22 to 24; 4T88-14 to 89-5) Thus, Dr. Duhaime concluded that "impact needed to take place" (1T37-24 to 38-3, 121-25 to 122-16; 2T127-10 to 23), and "that shaking alone does not produce the shaken baby syndrome." Duhaime, 66 J. Neurosurg. at 409.

These results were then later "confirmed," as testified to by Dr. Medina, when Dr. Michael T. Prange conducted a shaking study with more advanced surrogate models in 2003. (1T38-4 to 9); Michael T. Prange, et al., Anthropomorphic Simulations of Falls, Shakes, and Inflicted Impacts in Infants, 99 J. Neurosurg. 143 (2003). As explained by Dr. Medina, Dr. Prange "found that vigorous shaking produced forces similar to those involved in small falls, like short-distance falls" and not like the falls from "higher distances . . . required to reach those thresholds that would do intracranial injury." (1T38-9 to 14) Likewise, Dr. Duhaime reached the same results, and found that shaking could not create adequate force, when she used more advanced models in 2010. (1T123-17 to 24) In other words, as Dr. Medina conceded,

"according to Duhaime and Prange, you couldn't reach the minimum established threshold with shaking alone." (1T38-15 to 17)

These findings are also consistent with even the most favorable studies cited by Dr. Medina, which she claimed showed that shaking could "surpass[] the injury thresholds produced by the original Ommaya study." (1T38-18 to 39-4) As Dr. Medina conceded, that level of force was only produced by "changing the pattern of shaking" and style of model to "allow[] for chin-to-chest impact and occiput-to-back impact" of the model's head. (1T38-18 to 39-4); Carole A. Jenny, et al., Biomechanical Response of the Infant Head to Shaking: An Experimental Investigation, 34 J. of Neurotrama 1 (2017); C.Z. Cory & M.D. Jones, Can Shaking Cause Fatal Brain Injury? A Biomechanical Assessment of the Duhaime Shaken Baby Syndrome Model, 318 Med. Sci. Law 317 (2003). Thus, rather than demonstrating the viability of shaking-only SBS/AHT, these studies found that shaking could only produce the necessary force for intracranial injury if accompanied by impact. (4T90-23 to 92-6) Moreover, and contrary to Dr. Medina's interpretation, Dr. Van Ee testified that even with that impact, the researchers were only able to produce the force needed for concussion, and not for "subdural or diffuse axonal injury." (4T91-25 to 92-4); see Cory, 318 Med. Sci. Law at 317 (stating that shaking with impact got "closer

to" but did not exceed "the internal head injury, subdural haematoma, tolerance limits").

A similar lack of support has also come from the studies involving animals, including two studies from 2009 and 2012 in which lambs were shaken. J.W. Finnie, et al., Neuropathological Changes in a Lamb Model of Non-Accidental Head Injury (The Shaken Baby Syndrome), 19 J. of Clinical Neuroscience 1159 (2012); John W. Finnie, et al., Diffuse neuronal perikaryal amyloid precursor protein immunoreactivity in an ovine model of non-accidental head injury (the shaken baby syndrome), 17 J. of Clinical Neuroscience 237 (2009). (1T128-24 to 128-6; 2T180-16 to 183-24) In contrast to what would be expected in a shaking-only SBS/AHT case, every lamb experienced spinal injuries. (1T128-7 to 8) In additional, only two of the lambs had retinal hemorrhages. (1T128-9 to 11; 2T184-25 to 186-11)

Accordingly, the State's proofs failed to show that shaking-only SBS/AHT has been validated and is biomechanically possible. Dr. Van Ee, the only biomechanist to testify, also cast additional doubt on the validity of shaking-only SBS/AHT.

Dr. Van Ee testified about the long line of research showing that angular acceleration can cause symptoms such as subdural hematomas and intracranial hemorrhages. (4T27-2 to 29-24) Dr. Van Ee also testified, however, that injury is more likely to arise with impact and that, without impact, "the

threshold for injury seems higher than if you have contact with it." (4T30-23 to 31-4) Moreover, Dr. Van Ee testified, like Dr. Medina, that no study has shown that shaking can cause subdural hematomas and retinal hemorrhages. (4T52-25 to 54-13)

In explaining that outcome, Dr. Van Ee testified, in line with Dr. Ommaya's later conclusions, that the "levels of force" from the original Ommaya study "are far beyond what a person can generate in shaking." (4T36-1 to 20) Specifically, although both involve whiplash, Dr. Van Ee testified that shaking is more comparable to being "rear-ended at five miles per hour," which typically would not result in "anything like" a subdural hematoma, than a 30-mile-per-hour crash. (4T36-20 to 37-14)

Similarly, Dr. Van Ee also compared the force found in shaking to other traumatic events, like falls. As Dr. Van Ee explained, the purpose of comparing shaking and other events was two-fold. First, the purpose was to determine whether shaking can cause the triad, both by seeing whether shaking creates the levels of force found in events that can cause the triad and by determining if events with similar or higher levels of acceleration than shaking can cause the triad. Second, this comparison was also used to see if the triad can be caused without the level of acceleration that would produce neck injuries, which are not associated with shaking-only SBS/AHT.

Turning to the first issue, Dr. Van Ee testified that past studies have shown that "the angular accelerations that are created in shaking . . . are less than what we see in even a one-foot fall" onto a carpet, which is normally not associated "with a subdural hemorrhage or a massive traumatic head injury." (4T38-21 to 39-6) Likewise, Dr. Van Ee testified that research, including the 2003 Prange study and an earlier study from Dr. Jenny, showed that shaking produced less force than a five-foot fall onto foam, and that even shaking combined with a slam onto a mattress created less force than a one-foot fall onto carpet. (4T41-10 to 47-2, 48-14 to 49-4) Dr. Van Ee also emphasized that these studies used relatively small models -- representing a 1.5-month old, and a five-pound baby, respectively -- and that even "less overall head acceleration" would be expected with children who weigh over 10 pounds, and thus harder to shake. (4T47-6 to 48-14) Accordingly, in most children, the force produced by shaking would likely fall even further below the threshold for injury.

Dr. Van Ee also made this point based on his own research comparing shaking with accelerations from different falls, football injuries that led to concussions, and car accidents with and without impact. (4T49-5 to 51-2) The premise of this study, as Dr. Van Ee explained, was that if shaking causes injury due to acceleration, then the triad should also be caused

by acts that create more acceleration than shaking does. (4T51-3 to 9) This, however, turned out not to be the case, including in cases of car accidents without impact and one-foot falls onto linoleum. (4T51-9 to 17) Accordingly, this research confirmed the earlier biomechanical findings, which failed to show that shaking can create the triad. (4T54-14 to 55-2)

At the same time, however, this research also showed that shaking can reach the threshold to cause neck injury in children. (4T39-19 to 24) As Dr. Van Ee testified, children are particularly prone to such injuries because of their weak necks and their proportionally large heads, as demonstrated in studies of car seats. (4T32-7 to 34-14) As a result, "the first place to look for injury, from a biomechanics standpoint, would be the neck." (4T38-14 to 17) Therefore, although "we don't know if you can get [to the injury threshold] with shaking for the head," we do "know you can get there for the neck[,]" which demonstrates that shaking cannot cause the triad without also causing neck injuries, as SBS/AHT presupposes. (4T39-19 to 24)

iii. The Lack of Biomechanical Validation Demonstrates that Shaking-Only SBS/AHT Is Not Generally Accepted and Reliable.

Based on the above, the State failed to clearly demonstrate that shaking-only SBS/AHT is biomechanically possible, and thus generally accepted and reliable. Indeed, even Dr. Medina acknowledged as much, including by conceding that we "can't

really come to a consensus" as to whether shaking can cause the triad. (1T39-5 to 15, 166-13 to 168-7) As Dr. Medina explained, the lack of corroborative biomechanical findings, and research showing that shaking cannot create enough force to cause the triad, has led to SBS/AHT being "challenged in terms of the mechanism of shaking" and "controversy" as to whether shaking "can cause the forces needed to generate intracranial injury in infants" ever since Dr. Duhaime's 1987 study. (1T34-7 to 11, 35-1 to 5, 129-5 to 24, 132-14 to 18)

This lack of biomechanical support, and the controversy over the shaking theory, on its own, demonstrates a lack of scientific reliability. The essence of science is the scientific method, which requires that scientists form a testable hypothesis, precisely define operative terms and concepts, devise a methodology to test the hypothesis, systematically apply the methodology and collect the data, and then modify the hypothesis in light of the results. See, e.g., Reference Manual at 39; Strengthening Forensic Science at 112-13. A hypothesis will be accepted only if it is holds up "under the scrutiny of peers, in an environment that encourages healthy skepticism." Strengthening Forensic Science at 112. The scientific method therefore puts the onus of proving reliability on proponents of a theory. It does not require, and scientifically could not

require, that a theory be accepted unless other scientists actively prove its impossibility. (4T39-7 to 18)

Here, the hypothesis that shaking can cause the triad without neck injuries has been tested repeatedly, without ever being validated. Accordingly, the lack of scientific validation must, contrary to any claims by the State, inure against the reliability and admission of shaking-only SBS/AHT, such that it cannot be generally accepted or deemed reliable. To conclude otherwise would run counter to the most basic scientific principles.

Finding shaking-only SBS/AHT reliable, despite its lack of biomechanical support, would also run contrary to the established significance of biomechanics and its importance to SBS/AHT. Biomechanics is a clearly accepted science that undergirds countless facets of everyday life, from the use of seatbelts to the helmets used in football games. (4T29-17 to 31-4, 103-6 to 24) Biomechanics, moreover, rather than resting on unproven "assumptions," is based on significant research involving computer models, infant cadaver studies, and research involving live subjects, such as animals, boxers, and videotaped incidents of shaking and other abuse. (1T40-4 to 6; 4T29-4 to 16, 40-16 to 41-2, 106-17 to 108-12, 110-14 to 121-6)

Biomechanics also cannot be discarded, and biomechanists cannot be excluded from the relevant scientific community,

because biomechanics serves as the basis of shaking-only SBS/AHT and has been repeatedly used to test SBS/AHT. Indeed, even Dr. Medina cited to biomechanical studies when she believed, albeit wrongly, that they were more supportive of her position. See (1T38-18 to 39-4) (inaccurately citing Cory and Jenny studies to claim "discrepancy as to what causes the minimum established threshold" for injury). Therefore, and as discussed in more detail in Point I.D, shaking-only SBS/AHT is as much, if not more so, a biomechanical concept as it is a medical concept. The validity and general acceptance of shaking-only SBS/AHT in the field of biomechanics is thus core to its overall reliability, and the lack of evidence on that point, as conceded by Dr. Medina, demonstrates its lack of general acceptance.

In addition, and contrary to Dr. Medina's claims that biomechanics has "not proved any premise" regarding SBS/AHT (1T39-5 to 15, 166-13 to 168), the hearing showed that biomechanics tended to actively disprove the shaking-only theory. (1T39-5 to 15, 166-13 to 168-7) As discussed, and contrary to Dr. Medina's testimony that "no one really knows the injury thresholds that are required to cause injury in terms of biomechanics" (1T39-5 to 40-12, 41-14 to 42-25, 166-13 to 168-7), Dr. Van Ee, an actual biomechanist, stated that there are quantifiable ranges of force in which injuries happen and that they showed that shaking cannot cause the triad, but can cause

neck injuries. (4T106-4 to 11) Accordingly, the research not only fails to support the SBS/AHT theory, but also tends to disprove it by showing that "injurious angular acceleration/deceleration" is unlikely to result "in direct damage to bridging veins and diffuse axonal injury" without simultaneously injuring the neck or torso. (4T38-3 to 9)

iv. SBS/AHT Is Not Generally Accepted and Reliable.

Based on the above, the State has failed to show that shaking-only SBS/AHT is generally accepted and reliable as a biomechanical principle. Simply put, while shaking cannot be categorically excluded as a cause of the triad, just as science cannot prove any other negative, it is undisputed that the current research fails to validate the theory. (4T62-3 to 23, 108-24 to 109-24) As Dr. Van Ee explained, shaking-only SBS/AHT is a hypothesis "[t]hat's been tested by multiple people using different methods, and every time it's come back is that it doesn't look like it fits." (4T92-13 to 20, 95-19 to 96-20) Although this is "not the end of the story" and future tests may provide a contrary result, "the data that we have suggests that there's good reason to question that the rotational accelerations are sufficient to rip bridging veins" and that reaching that threshold would not also cause neck injuries. (4T39-7 to 18, 92-18 to 25, 96-21 to 97-5)

While unsatisfying, the truth is that "[s]ometimes there's things we just don't know" (4T93-1 to 20), and scientists must be willing to accept that fact, and the limitations on their existing knowledge, if science is to remain reliable. See Strengthening Forensic Science at 112. Confirmation bias and articles of faith cannot substitute for the strictures of the scientific method. Because the State offered no expert or evidence to show that the scientific method has been satisfied for shaking-only SBS/AHT, that diagnosis cannot be deemed scientifically reliable and cannot form the basis of a properly performed differential diagnosis.

6. Shaking-Only SBS/AHT Is Additionally Unreliable Because It Relies on Other Unproven Hypotheses.

The lack of biomechanical evidence to support the shaking-only SBS/AHT theory, on its own, renders that diagnosis scientifically unreliable. However, Dr. Medina's testimony also demonstrated that shaking-only SBS/AHT is additionally based upon other unproven hypotheses concerning the potential causes of subdural hematomas and retinal hemorrhages. Because the State failed to demonstrate that these theories are reliable, and even acknowledged that two theories have not been validated, it has further failed to prove the reliability and general acceptance of shaking-only SBS/AHT.

i. The State Failed to Clearly Prove that Shaking Can Cause Bridging Veins to Rupture in Healthy Children.

Despite its lack of biomechanical validity, Dr. Medina maintained that severe "shaking continues to be accepted as a mechanism" for subdural hematomas based on the premise that shaking can lead to the tearing or rupturing of bridging veins -- large veins that bring blood from the brain back to the heart. (1T41-2 to 7, 120-7 to 16, 169-1 to 170-7) As Dr. Medina explained, this theory is based on "the assumption" that bridging veins can rupture just as they do for children with benign enlargement of the subarachnoid space (BESS). (1T169-10 to 15) Dr. Medina did not, however, explain the basis for this "assumption" and conceded that no studies validated this theory. (1T169-9 to 25) Accordingly, the State failed to demonstrate that this theory is clearly reliable, thus further demonstrating the inadmissibility of shaking-only SBS/AHT.

BESS is an "anatomic variation" that can cause fluid buildup of "a few millimeters" in the space between the pia and the arachnoid. (1T47-17 to 22' 3T34-8 to 19) According to Dr. Medina, children with BESS can be "at increased risk for subdural trauma" because the fluid puts increased pressure on the bridging veins that "traverse the surface of the brain," thus causing them to tear with minimal or even no movement. (1T45-3 to 10, 47-25 to 48-19) This tearing, in turn, can cause subdural hematomas, although they are usually benign. (1T48-21 to 51-22, 54-23 to 55-4)

Extrapolating from these facts, Dr. Medina testified that trauma from BESS "allows us to understand that infant brains can be injured easier by forces that cause movement of the brain within the intracranial cavity" even when the child does not have BESS. (1T48-12 to 19) Specifically, Dr. Medina testified that "the medical diagnosis of BESS validates that stretching of the bridging veins and [that] tension can cause them to rupture" "[i]n any other context." (1T51-3 to 5) Dr. Medina further opined that, based on BESS, "[i]n a shaking situation, the intracranial movement, by the same mechanism of stretching and tension, can also break" and that shaking-only SBS/AHT has "been proven by the condition of BESS in the literature." (1T51-5 to 12, 120-20 to 121-24; 2T53-15 to 54-11)

Dr. Medina did not, however, explain why these conclusions could be made about children without BESS, particularly when BESS can result in subdural hematomas without any force. (1T121-2 to 24) As Dr. Mack explained, bridging veins carry a significant amount of blood, and are thus large, strong, and can stretch without breaking easily. (3T31-6 to 32-2) There is therefore no reason to assume, as Dr. Medina did, that these veins will tear easily when a child does not have BESS.

Indeed, Dr. Medina conceded that "[n]o study shows that there is a tear in a bridging vein" from shaking or that her theory had been validated. (1T169-9 to 25) Dr. Mack likewise testified

that "there's no good evidence" to prove "the hypothesis" that "shaking can cause bridging vein rupture" and that the animal studies involving shaking "did not document bridging vein rupture." (3T113-5 to 115-6) Moreover, Dr. Mack also disputed the notion that bridging vein rupture can ever be benign, and that children with BESS experience bridging vein ruptures, because the resulting blood loss would be "a surgical emergency" inconsistent with what is seen in BESS. (3T32-3 to 34-7) Instead, Dr. Mack testified that BESS subdural hematomas are due to leakage from small veins in the dura, which would account for the smaller amount of blood while also further weakening Dr. Medina's bridging-vein hypothesis. (3T47-3 to 48-3)

Thus, at bottom, the State failed to prove the general acceptance and reliability of the bridging-vein-rupture theory because Dr. Medina admitted that it is based on unexplained assumptions regarding BESS, because it is undisputed that no studies have confirmed it, and because it may be based on a mistaken understanding of BESS and how subdural hematomas are formed. Or, stated differently, the State's proffered evidence to support one of the three prongs of the triad -- subdural hematomas -- was based upon an unproven hypothesis, or "assumption," rather than scientific evidence.

ii. The State Failed to Clearly Establish the Reliability of Its Medical Theories Concerning the Mechanism for Retinal Hemorrhages.

Dr. Medina testified that severe retinal hemorrhages are caused, and highly related to, abuse by shaking. Beyond being biomechanically unsupported, Dr. Medina could not offer any medical or scientific evidence to support this theory. The studies that Dr. Medina did cite, moreover, involved cases of "confessed" abuse that only provided limited anecdotal support, and were incapable of providing a reliable and generally accepted theory for how severe retinal hemorrhages can occur. Accordingly, the State further failed to validate the reliability of shaking-only SBS/AHT.

Dr. Medina testified that "the vitreoretinal traction theory" is "what is felt to be the cause" of the severe retinal hemorrhages thought to be associated with shaking-only SBS/AHT. (2T62-14 to 20) Under this theory, shaking causes the vitreous, "a jelly-like substance within the eye," to "pull against the retina causing rupture of the retinal veins" that line the walls of the eye. (1T57-13 to 58-6, 67-22 to 68-6; 2T62-14 to 20, 178-20 to 179-13) Dr. Medina did not, however, identify any scientific evidence to support this theory and conceded that there is no test to determine what causes a retinal hemorrhage. (2T58-4 to 59-16)

Moreover, as the above quotes demonstrate, the vitreoretinal traction theory is only a theory about what is "felt" to cause retinal hemorrhages, rather than a validated

principle of science. Indeed, the hypothesis has not been proven in animal studies, mechanical models, or in videos of children who have been shaken. (2T179-14 to 18, 180-10 to 15) Moreover, Dr. Scheller testified that this theory is anatomically impossible because "the eye moves together with the head[,]" such that it vitreous cannot obtain independent movement (2T179-18 to 180-9), while Dr. Mack testified that the idea of different retinal hemorrhage patterns is controversial and not generally accepted. (3T122-2 to 123-5) Accordingly, the State failed to show that the vitreoretinal traction theory is supported in science, let alone generally accepted and sufficiently reliable to be admitted at trial.

Recognizing this deficiency, Dr. Medina opined that her theory, and the belief that shaking causes severe retinal hemorrhages, was "confirmed" by studies which found high rates of such hemorrhages in cases of "confessed" shaking. (1T43-20 to 44-24, 58-22 to 59-4, 68-23 to 71-9, 116-22 to 117-12; 2T59-21 to 62-13) Those studies, however, did not explain how retinal hemorrhages can occur and did not validate the vitreoretinal traction theory. Matthieu Vinchon, et al., Confessed Abuse Versus Witnessed Accidents in Infants: Comparison of Clinical, Radiological, and Ophthalmological Data in Corroborated Cases, 26 Childs Nervous System 637, 642 (2010); Catherine Adamsbaum, et al., Abusive Head Trauma: Judicial Admission Highlight

Violent and Repetitive Shaking, 126 Pediatrics 546 (2010). Instead, they merely provided anecdotal evidence of a correlation, rather than validated evidence of causation.

These studies, moreover, suffered from several issues that further undermined their use, some of which were recognized by Dr. Medina. Initially, as Dr. Medina acknowledged, the confession cases involved instances in which abuse was already suspected, with the confessions occurring only after the retinal hemorrhages were found and the individual was criminally investigated for abuse. (1T60-20 to 64-6, 67-22 to 70-12, 117-13 to 118-4) Thus, the confessions were not derived from the type of on open-ended questioning normally used to get medical treatment, and instead came from the pressure of an interrogation in which abuse was already presumed and criminal charges may have already been brought. (2T132-17 to 133-13)

In that respect, the studies created a risk of confirmation bias or circular reasoning. (2T133-14 to 134-4) As Drs. Mack and Scheller testified, these types of studies -- in which abuse is already suspected, an individual is pressured to confess, and all statements are viewed as possible confirmation of abuse -- exclude cases where shaking occurred without retinal hemorrhages and do not consider whether the hemorrhages could have had other causes. (2T135-16 to 137-5; 3T60-7 to 61-1)

It is also difficult to assess the limitations of these studies, as Dr. Van Ee testified, because of the nature of the studies and confessions themselves. (4T97-6 to 22) For example, the studies have not adequately described the confessions and their surrounding circumstances and have not attempted to quantify their reliability, even though the individual may not have actually confessed to violent shaking, initially denied the allegations, and only gave a statement under significant pressure. (4T78-18 to 81-13, 97-23 to 100-5) The Vinchon study, for example, noted that the authors had "limited data regarding details of the confession" and did not describe them. Vinchon, 26 Childs Nervous System at 642. Similarly, the Adamsbaum study conceded that confessions are unscientific and of questionable reliability, and only provided excerpts of the confessions that often did not describe the shaking, let alone demonstrate that it was violent. Adamsbaum, 126 Pediatrics at 551, 553.

Accordingly, while not totally lacking in value, these studies cannot validate shaking-only SBS/AHT for at least two reasons. First, they do not even attempt to explain how shaking can cause the symptoms of SBS/AHT and thus, even if entirely reliable, cannot compensate for the lack of biomechanical and medical evidence on that point. Second, the studies <u>are not entirely reliable</u> and instead suffer from a lack of transparency, the unreliable nature of confessions, and the ways

in which vague statements about "shaking" can be subjectively interpreted when abuse is already assumed. Indeed, it is for these reasons that Dr. Scheller testified that he does not consider confessions medical evidence (2T133-14 to 22), and even the Adamsbaum study noted their unscientific nature.

Moreover, whatever anecdotal value can be derived from the confession studies is further diminished by the instances in which shaking has been documented through video recordings. As Dr. Medina testified, the only study to have relied upon documented cases of shaking -- through nannycam recordings -- did not reveal retinal hemorrhages in any of the shaken children. (1T118-9 to 119-9) Likewise, Drs. Scheller and Van Ee also testified that there are "no reports of witnessed cases where we've seen subdural hematomas or retinal hemorrhages," including in about 20 cases of recording shaking. (2T130-12 to 15, 131-13 to 132-7 to 8; 4T55-3 to 11, 121-17 to 122-4) It is undisputed that there have been no "objectively confirmed cases of shaking that resulted in the triad[.]" (2T132-9 to 16)

This fact further calls into question the value of studies that have relied on vague "confessions" from accused individuals rather than definitive cases of violent shaking, as well as the very premise of shaking-only SBS/AHT. Indeed, when confronted with the cases of shaking that have not produced the "triad," Dr. Medina simply noted that retinal hemorrhages are only

present in about 85 percent of cases and that "[n]ot every shaking event leads to severe retinal hemorrhages." (1T119-22 to 23 (1T119-10 to 16) In other words, instead of questioning her hypothesis after "the one study . . . where there's actual physical proof of shaking" showed that "not one child had severe retinal hemorrhages" (1T119-24 to 120-7), Dr. Medina instead absurdly speculated that every recorded instance of shaking fall within the 15 percent of cases that do not result in retinal hemorrhages. This type of thinking, in which a hypothesis is accepted as fact and all contrary evidence is disregarded, runs counter to basic scientific principles and further evinces the State's failure to prove the reliability of the shaking-only SBS/AHT theory.

B. THE STATE HAS FAILED TO CLEARLY ESTABLISH THAT SHAKING-ONLY SBS/AHT IS GENERALLY ACCEPTED IN THE RELEVANT SCIENTIFIC COMMUNITY.

1. The Relevant Scientific Community for Determining the Acceptance and Scientific Reliability of Shaking-Only SBS/AHT Includes Impact Biomechanists.

Shaking-only SBS/AHT includes multiple areas and disciplines of science. An SBS/AHT diagnosis relies on findings made by radiologists, neurologists, geneticists, and pediatricians, among others. Shaking-only SBS/AHT is also based on a biomechanical theory and which cannot be diagnosed absent the foundational assumption that shaking can create sufficient

force to create the triad. The scientific communities for which SBS/AHT must be assessed are thus also varied.

The most relevant scientific community, moreover, may also depend on the particular facet of the SBS/AHT diagnosis at issue. A hematologist, for example, could be best suited to determine whether a blood disease can cause retinal hemorrhages, but would be out of her depth in making similar findings regarding a metabolic disorder. In other words, while each subspecialty has a role to play in putting the diagnosis together, some may be more relevant than others in judging the reliability of a specific situation or SBS/AHT component.

Biomechanists are among the relevant scientific communities for judging the reliability of SBS/AHT. Shaking-only SBS/AHT was theorized based on Dr. Ommaya's biomechanical study, makes claims regarding the effect of acceleration and other biomechanical principles, has been repeatedly tested by biomechanical studies, and cites biomechanical studies deemed favorable to its validity. As discussed above, without its biomechanic underpinnings, the differential diagnosis process could only rule out possible causes without demonstrating that the observed injuries could have been caused by shaking. Biomechanics therefore plays as big of a role in shaking-only SBS/AHT as any other field and biomechanists are in the best

position to advise the Court about the reliability of the biomechanic principles underlying shaking-only SBS/AHT.

2. Shaking-Only SBS/AHT Is Not Generally Accepted and Considered Reliable Among the Relevant Scientific Community.

The State did not offer any witness qualified in the area of biomechanics. The State's only witness, Dr. Medina, has no training or experience in that field and could not provide more than a rudimentary explanation of what biomechanics is. Dr. Medina is also a clinician, not a scientist. While she treats patients, Dr. Medina has not maintained or analyzed data from her assessments, and did not conduct any research or publish any peer-reviewed articles on the topic.

Moreover, Dr. Medina did not claim that shaking-only SBS/AHT has been biomechanically validated or that it is generally accepted and considered reliable among biomechanists. Instead, she explicitly and repeatedly conceded that no biomechanical study has proven the shaking-only theory SBS/AHT, particularly where shaking is not accompanied by impact force. Thus, the State, which had the burden of proof and persuasion, offered no evidence of general acceptance of shaking-only SBS/AHT within the relevant scientific community.

Further, even if Dr. Medina's testimony minimally satisfied the State's burden of production, it still wholly failed to satisfy the State's burden of persuasion. Dr. Van Ee was the

only member of the relevant scientific community to testify and found the support for shaking-only SBS/AHT sorely lacking. Like Drs. Medina, Scheller, and Mack, Dr. Van Ee noted that no study has validated the shaking-only theory and that even studies involving some impact -- like those of Drs. Cory and Jenny -- did not meet the minimum threshold thought necessary for intracranial injuries. In addition, shaking-only SBS/AHT has not found support in the available animal studies and has not been corroborated by recorded instances of shaking.

In addition, Dr. Van Ee testified about the current research showing that shaking, while not be able to produce the triad, can cause neck injuries. Based on this data, current research shows that shaking cannot produce the result hypothesized by proponents of shaking-only SBS/AHT -- subdural hematomas and severe retinal hemorrhages -- but can produce a result that should be absent from the diagnosis -- neck injuries. In other words, while additional research can and should occur, the field of biomechanics both fails to support, and actively undermines, the shaking-only theory of SBS/AHT.

The State therefore failed to clearly establish general acceptance of shaking-only SBS/AHT as reliable in the relevant scientific community.

3. Even If the Relevant Community Only Includes Medical Doctors, Shaking-Only SBS/AHT Is Not Generally Accepted and Reliable.

As discussed in the preceding sections, the State failed to clearly establish that shaking-only SBS/AHT is biomechanically possible, let alone deemed reliable and generally accepted within the field of biomechanics. In addition, the State also failed to demonstrate that there is a generally recognized and reliable medical explanation for how shaking can cause the "triad." The State did not, for example, offer the testimony of any radiologists, neurologists, ophthalmologists, or other specialists to detail such a mechanism. Instead, the State solely relied upon the testimony of Dr. Medina -- who is not trained to review medical images and generally relies upon examinations performed by other doctors.

Dr. Medina, moreover, only offered mechanisms of injury that she herself recognized were theoretical and unproven, including the vitreoretinal traction theory. As Dr. Medina conceded, no scientific studies have validated these hypotheses. Moreover, as Drs. Scheller, Mack, and Van Ee testified, these proposed explanations may not be anatomically possible, have been contradicted by animal studies, and have been undermined by instances of recorded shaking. Thus, even if biomechanics is removed from the equation, the State has failed to even demonstrate that there is a reliable and generally accepted medical explanation for shaking-only SBS/AHT.

4. At a Minimum, There Is a Genuine Dispute, and Therefore No General Acceptance Exists.

The testimony and reports of Drs. Medina, Scheller, Mack, and Van Ee, along with the other evidence submitted to this Court, have made it abundantly clear that, at the very least, there is a dispute in the scientific community as to whether shaking can create the triad without causing neck injury. Dr. Medina conceded, and every other expert agreed, that no study has shown that this theory is biomechanically possible and that there is at least "debate" and "criticism" as to its validity. Dr. Medina, for example, agreed to the following on cross-examination:

> [DEFENSE COUNSEL:] And it's fair to say that since Duhaime's study in 1987 there is debate about whether shaking alone can reach that threshold for injuries.
>
> [DR. MEDINA:] Yes, ma'am.
>
> [DEFENSE COUNSEL:] And by injuries, I mean the injuries that child abuse pediatricians like yourself look for to make this diagnosis.
>
> [DR. MEDINA:] That we look for in corroboration with ophthalmologists. Yeah.
>
> [DEFENSE COUNSEL:] Right.
>
> [DR. MEDINA:] Yes.
>
> [DEFENSE COUNSEL:] So what I'm saying is, the -- since 1987 there has been debate about whether just shaking alone can reach the force that would cause the injuries, including retinal hemorrhages, including subdural

> hematomas, that a child abuse pediatrician looks for to diagnose abusive head trauma.
>
> [DR. MEDINA:] Yes, ma'am.
>
> [DEFENSE COUNSEL:] Or child abuse.
>
> [DR. MEDINA] Yes, ma'am.
>
> [(1T129-5 to 24)]

One need not go any further than Dr. Medina's own testimony to establish a lack of scientific consensus. Even before the defense put on its witnesses, the State had failed to clearly establish shaking-only SBS/AHT as generally accepted as reliable in the scientific community. The testimony of Drs. Scheller, Mack, and Van Ee only further demonstrated this fact.

POINT II

THE STATE HAS FAILED TO CLEARLY ESTABLISH THAT DR. MEDINA OFFERED A RELIABLE OPINION.

In addition to proving the reliability of shaking-only SBS/AHT, the State also bore the responsibility of clearly establishing that Dr. Medina offered a reliable opinion when she diagnosed D.J. Central to that issue is whether Dr. Medina adequately followed the differential diagnosis outlined in Point I.A.3. Specifically, as, Dr. Medina testified, there is no confirmatory test for SBS/AHT, meaning it can only be diagnosed by ruling out every other possible explanation. (1T72-10 to 73-10, 113-14 to 20) Doctors must "take into account the medical history of the child, the history provided by the care

givers[,]" "the actual abnormalities that you see[,]" and the medical evaluations, which involve "the subspecialties evaluation to ensure that there is no" possible alternative cause. (1T72-18 to 73-16) It is only if this process is followed, and no other possible causes can be identified, that a SBS/AHT diagnosis can be deemed acceptable and "reliable." (1T72-18 to 74-9)

As discussed below, the State failed to show that this process was followed, and to satisfy its burden of proof, because the record does not clearly establish that Dr. Medina excluded all possible causes for D.J.'s symptoms.

A. D.J. HAS A COMPLEX MEDICAL HISTORY WHICH DR. MEDINA TESTIFIED SHE FULLY CONSIDERED IN DIAGNOSING SBS/AHT. DRS. MACK AND SCHELLER, HOWEVER, SEPARATELY CONCLUDED THAT D.J.'S SYMPTOMS WERE LIKELY CAUSED BY A DIFFERENT CONDITION, BESS, WHICH THE STATE FAILED TO SHOW WAS ADEQUATELY CONSIDERED BY DR. MEDINA.

1. D.J. Has a Complex Medical History that Includes Being Born Extremely Premature, Having Multiples Surgeries, and Being Hospitalized for the First Seven Months of His Life.

The first year of D.J.'s life was marked by "a very complicated birth history," multiple medical emergencies, and months of hospitalizations. (1T87-13 to 14) D.J. "was born extreme premature," after only 25 weeks of pregnancy, in March 2016. (1T87-14, 91-5 to 18, 100-19 to 24, 152-9 to 152-17) D.J. weighed a little over a pound at birth. (1T100-25 to 101-7)

Such extreme prematurity can cause many medical problems, including neurological issues. (1T87-14 to 15, 150-7 to 18, 152-

18 to 153-10) Prematurity can predispose children to vomiting and breathing problems, delayed reactions to coughing and gagging, diabetes, and delays in developmental milestones. (1T150-19 to 151-9, 154-3 to 155-8) Premature babies, and especially male premature babies, are also especially prone to subdural hematomas from the birth process. (1T153-11 to 24)

In this case, D.J. was hospitalized for the first seven-and-a-half months of his life. (1T87-16 to 17, 152-9 to 13) D.J. was primarily hospitalized at St. Peter's University Hospital, where he was born, but was also sent to the Children's Hospital of Philadelphia (CHOP) for multiple surgeries. (1T91-19 to 92-10) Specifically, D.J. had "cardiac issues," including "some openings in his heart" that were "surgically repaired" at CHOP in May and July 2016. (1T87-21 to 88-1, 91-21 to 92-10) Following those surgeries, D.J. was returned to St. Peter's until his discharge in October 2016. (1T88-1 to 12)

2. D.J. Suffered Three "Seizure" Incidents in February 2017, for Which His Parents Sought Immediate Medical Treatment.

Nieves and D.J.'s mother, Lucy Pham, reported three "seizure" episodes while Nieves was caring for D.J. between February 3 and 10, 2017, less than four months after his discharge from St. Peter's. (1T85-9 to 13)

On February 3, D.J. became "unresponsive" during a diaper change. (1T85-14 to 16, 140-17 to 23, 141-20 to 23) Nieves,

D.J.'s primary caretaker, performed "mini-CPR" by blowing into D.J.'s mouth, contacted Pham, and then called an ambulance. (1T85-16 to 18, 140-24 to 141-3; 2T21-5 to 8) By the time the ambulance arrived, D.J. "was better" and relatively alert. (1T85-16 to 18, 141-4 to 6) As a result, the ambulance workers advised Nieves and Pham that they could take D.J. to their pediatrician rather than the emergency room. (1T141-4 to 6) Based on this advice, Nieves and Pham "immediately" took D.J. to his pediatrician, who believed D.J. was experiencing acid reflux. (1T85-18 to 22, 141-11 to 19) Following this visit, Nieves and Pham implemented reflux precautions and reported D.J.'s condition to the pediatrician. (1T85-23 to 86-4)

On February 8, D.J. again "went limp" while Nieves was putting him in bed. (1T141-24 to 142-4) Nieves applied oxygen, which appeared to resolve the issue. (1T86-5 to 8, 142-5 to 9)

Lastly, on February 10, D.J. had "seizure-like activity" including "stiffening" and "limpness" when Nieves went to pick him up for a diaper change. (1T81-18 to 82-5, 86-9 to 15, 142-10 to 143-1) Nieves immediately brought D.J. to Pham. (1T143-2 to 4) Nieves and Pham then called 911, took a video of D.J.'s condition, and brought D.J. to St. Peter's in an ambulance. (1T82-5 to 8, 101-8 to 21, 143-2 to 11)

3. Doctors Detected the "Triad," and Suspected Possible Abuse, During D.J.'s Hospitalization.

Although not involved until days later, Dr. Medina testified that D.J.'s treatment began with EEG scans to detect seizure activity. (1T102-13 to 16) Dr. Medina testified that no seizure activity was observed and that no "clinical indications of seizures" were detected. (1T84-13 to 19, 102-13 to 16) Dr. Medina also testified on direct examination that D.J. did not display any irritability, vomiting, or unusual behavior during that time. (1T95-23 to 96-10) However, on cross-examination, Dr. Medina noted that D.J. had some "seizure-like activity" and vomited while in the emergency room. (1T102-24 to 103-5) Dr. Medina's report also shows that D.J. was given four milligrams of rectal diazepam, an anti-seizure medication, and that his "seizure-like activity" stopped afterward.

D.J. was then examined by a neuroradiologist who diagnosed him with "subdural bleeds" and "some areas of atrophy" or "volume loss" on his brain. (1T84-7 to 9, 84-24 to 85-1, 102-17 to 20) According to Dr. Medina, this finding, combined with D.J.'s seizure-like incidents, "raised concern" for abuse "because seizures are usually not associated with or not a cause for subdural hemorrhages, even though subdural hemorrhages can give you seizures." (1T82-13 to 23) Accordingly, doctors began looking for other abnormalities, which led to D.J. undergoing an "ophthalmological exam that revealed severe multi-layered retinal hemorrhages on both eyes." (1T82-24 to 83-2, 84-9 to 12)

In addition, doctors conducted a skeletal survey of D.J. on February 14. (1T162-17 to 163-3) That survey found no evidence of acute or healing fractures, as did a second exam on February 24. (1T163-4 to 164-12) D.J. also had no neck or spinal injuries. (1T164-13 to 165-12)

Dr. Medina testified that the hospital contacted the Division of Child Protection and Permanency (DCP&P) and that the hospital and DCP&P contacted her on February 15, five days after D.J.'s hospitalization. (1T80-24 to 82-19 to 83-9, 102-21 to 23, 105-21 to 106-11) As Dr. Medina explained, her job is to determine the cause of findings made by other doctors after there is concern for abuse. (1T106-19 to 109-2, 112-8 to 113-3)

4. Dr. Medina Ordered Additional Evaluations of D.J., Which Resulted in an 18-Page Report Issued on April 26, 2017.

Dr. Medina testified, consistent with her 18-page report, that she ordered an "initial" medical evaluation on February 15 and 16, which included "a comprehensive metabolic evaluation" from a geneticist and a "full hematological consultation" to look for metabolic or coagulation issues that "could be associated with subdural bleeding and retinal hemorrhages." (1T83-14 to 25)

On February 17, Dr. Medina spoke with Nieves and Pham at D.J.'s bedside, about a week after his hospitalization. (1T97-8 to 10, 136-5 to 17) Nieves and Pham provided consistent accounts

of D.J.'s medical history, including the three seizure events. (1T83-13 to 16, 97-11 to 14) Their statements were also consistent with the information they had previously given to DCP&P. (1T143-12 to 21) Dr. Medina further testified that Pham said that she had no concerns about Nieves harming D.J. when she was interviewed separately, and that Nieves also said he would never hurt D.J. (1T143-22 to 144-7) Dr. Medina's report also shows that D.J. was being visited weekly by a nurse, that he had regular doctor visits, and that he had follow-ups with various doctors after his initial hospitalization.

Dr. Medina testified on direct-examination that Nieves and Pham denied any history of accidental trauma. (1T83-13 to 16, 97-11 to 14, 137-2 to 139-17) On cross-examination, however, Dr. Medina testified that D.J.'s half-brother had been jumping in the crib with D.J. about a month earlier. (2T19-17 to 20-22) Dr. Medina testified that she ruled this out as a potential cause based on the acuteness of the retinal hemorrhages and D.J.'s altered mental state. (2T41-9 to 19)

In addition to speaking with Pham and Nieves, Dr. Medina conducted a "cursory" external examination of D.J. (1T144-11 to 23; 2T31-3 to 7) Dr. Medina reported that D.J. was undersized and "developmentally delayed, as expected for a preemie," but that he appeared comfortable and smiled. (1T81-14 to 25, 96-17 to 97-7, 145-23 to 146-1; 2T13-21 to 14-3, 42-20 to 43-11) She

also testified that his soft spot was flat and that he had no bruises or grip marks. (1T145-10 to 16, 170-22 to 171-19) Dr. Medina did not independently assess details such as D.J.'s weight and head circumference, and did not look at his eyes. Dr. Medina also did not recommend a course of treatment. (1T144-24 to 145-9; 2T31-8 to 32-21) Dr. Medina's report shows that D.J. weighed eight kilograms, or 17.6 pounds.

Dr. Medina's report shows, and she testified, that the following additional information was received after February 16. On February 24, a second skeletal survey showed that D.J. had no acute or healing fractures. On February 23 and 24, a video EEG found no evidence of seizure activity. In April, the geneticist concluded that D.J. did not suffer from any relevant metabolic conditions, and D.J. had an ophthalmological follow up, which did not detect any new hemorrhages. (1T84-1 to 87-3, 97-15 to 98-3, 163-4 to 164-12; 2T14-9 to 15-12)

Based on this review, Dr. Medina diagnosed D.J. with AHT in April 2017. (1T98-10 to 14) Dr. Medina explained that she made this diagnosis because D.J. "presented to the hospital with altered mental status, subdural hemorrhages, and retinal hemorrhages in the pattern that is severe and usually associated with very specific circumstances . . . ." (1T98-14 to 21) Although severe hemorrhages could have other causes, Dr. Medina concluded that those other conditions, such a "hyperacute

increase in intracranial pressure or an aneurysm," were not present. (1T98-14 to 21) Likewise, although the subdural bleeding "could have [been] because of other underlying conditions," Dr. Medina found that its presence, "along with retinal hemorrhages and his sudden altered mental status during diaper changes only and irritability over that two-week period, [was] more specific for an inflicted injury, such as abusive head trauma through shaking." (1T98-22 to 99-3)

Dr. Medina also clarified that she diagnosed D.J. with AHT based on a shaking event "with or without impact," meaning he either could have been shaken alone or shaken and hit against something. (2T8-18 to 90-20, 31-25 to 32-5) Dr. Medina testified that she made this diagnosis even though D.J. had no bruises or broken bones and "[t]here was nothing to indicate that DJ was hit against anything" because the impact could have been against a soft surface. (2T9-21 to 10-9, 52-25 to 53-14)

5. Drs. Mack and Scheller Independently Concluded that D.J.'s Symptoms Were More Likely Attributable to BESS, or a Subdural Hygroma, than Abuse by Shaking.

As detailed in their reports and testimony, both Drs. Mack and Scheller independently found that D.J. likely suffered from BESS, or a subdural hygroma, rather than abuse. These opinions were not offered at the hearing to resolve the actual cause of D.J.'s symptoms as a factual matter. Instead, these diagnoses were detailed because they demonstrate an alternative

explanation that needed to be excluded before Dr. Medina could diagnose D.J. with shaking-only SBS/AHT, and thus went to the core of her differential diagnosis.

i. BESS Is a Diagnosis That Can Mimic the SBS/AHT Triad.

As discussed in Point I.A.6.i, BESS is an anatomical condition in which fluid collects in the skull and causes "a few millimeters" of growth in the subarachnoid or subdural spaces. (1T47-17 to 22; 3T40-2 to 41-14) BESS may be diagnosed when the space expands from around four millimeters, which is considered normal, "to 7 millimeters" or higher. (1T47-17 to 22) As Dr. Mack testified, BESS is a "poorly understood" condition that encompasses multiple other terms, including subdural hygromas and benign external hydrocephalus. (3T41-3 to 9, 49-13 to 19, 90-2 to 12, 90-23 to 25) As Dr. Mack testified, "[w]e don't understand why some kids get it and others don't[,]" why it occurs, and why it "usually resolves by a year or so of age[,]" but that it is "more common in certain subgroups of infants" including males and premature infants." (3T41-15 to 42-3)

BESS symptoms also vary and may never arise. (3T42-6 to 13) BESS may, for example, be associated with larger heads. (1T41-15 to 25) BESS may also require intervention, such as by draining liquid from the skull, but often will not. (3T42-3 to 6)

BESS has significance in the SBS/AHT context because, as already discussed, it can predispose children to "subdural bleeding" or hemorrhaging in the subarachnoid space. (1T48-21 to 49-2, 50-11 to 52-8) Such collections can occur with little or no trauma, either from the bridging veins, as Dr. Medina opined, or from the dura, as Dr. Mack testified. (3T17-16 to 19-2, 30-18 to 20, 43-15 to 51-11) Moreover, while normally benign, BESS can cause an altered mental state and other outward symptoms. (1T49-1 to 22) For example, BESS can "present with seizures" that can be caused by the collection of fluid. (3T42-6 to 7, 44-1 to 11) In addition, BESS can create symptoms related to increased pressure in the brain, including changes in the eyes and severe retinal hemorrhages. (3T42-14 to 43-6, 91-20 to 93-7, 123-6 to 124-2) Thus, BESS can be an alternative explanation for symptoms that would otherwise be deemed indicative of abuse.

ii. Dr. Mack Opined that D.J. Displayed Evidence of BESS and that BESS Could Better Explain D.J.'s Symptoms than a Diagnosis of Abuse by Shaking.

Dr. Mack concluded that D.J. likely suffered from BESS based on her review of his various ultrasounds and scans. (3T69-12 to 70-25) As Dr. Mack explained, while it is normal to have fluid in the subarachnoid space, "the distance between the thickness of that space, or the depth of the space between the brain and the dura is usually" around four or five millimeters.

(3T75-15 to 76-2) This definition of normality was consistent with Dr. Medina's testimony. (1T47-17 to 22)

In D.J.'s case, Dr. Mack began with neurosonograms from March, April, and June 2016, which were taken due to D.J.'s prematurity. (3T78-11 to 21, 81-4 to 9) The March 22 scan recorded a distance between the brain and dura of 2.5 millimeters, which is "well within that range of what we consider average of normal." (3T78-22 to 79-5, 110-23 to 111-13) By April, the space had expanded to 4 millimeters, which Dr. Mack testified is "enlarged a little" but still "kind of average." (3T79-7 to 14) By June, however, the space had continued "increasing" and was almost 7 millimeters, and thus "approaching what some would call abnormal" but which might not raise serious red flags in light of D.J.'s severe prematurity. (3T79-14 to 17, 111-14 to 112-12)

A similar trend was also demonstrated by a neurosonogram from July 22, after D.J. had surgery at CHOP. (3T71-1 to 4, 73-14 to 74-22) In that ultrasound, the technologist measured the pace between D.J.'s brain and the dura and found a distance of 11 millimeters on one side, 9 millimeters on the other side, and 7 millimeters between the two hemispheres. (3T75-1 to 10) These measurements, as Dr. Mack explained, demonstrated "expansion of the spaces around the brain, subarachnoid space" to an abnormal

degree, which could indicate "a benign expansion of the subarachnoid space." (3T75-10 to 77-9)

Dr. Mack also testified that the scans demonstrated a slow, "progressive increase" in size, rather than "a sudden increase over time," and that the condition existed before D.J. experienced his seizure episodes. (3T80-14 to 81-9, 124-12 to 25, 129-10 to 130-10) Thus, the scans showed that the space was "expanding slowly over time," which is "not uncommon in premature infants." (3T81-14 to 21) In other words, the expansion was not totally atypical, and would normally not be treated, despite being above average. (3T77-9 to 78-10)

Dr. Mack testified that benign enlargement was also consistent with D.J.'s MRI from February 2017. (3T81-22 to 82-19) In addition to displaying a "a subarachnoid space that measures nine millimeters" (3T89-6 to 90-2), Dr. Mack noted that the fluid in the subarachnoid space, as evidenced by its color and density, was something other than blood, and thus not consistent the type of major bleeding one would expect from the type of bridging vein rupture proposed by Dr. Medina. (3T81-22 to 85-6) Rather, it was more likely that the fluid was "benign extra axial collections" from the dura, which could have given rise to a small amount of blood. (3T88-19 to 89-5)

Thus, Dr. Mack testified that D.J.'s scans showed an expanding subarachnoid space of up to 10 millimeters, that the

expansion was mostly from fluid, and that there was no evidence of swelling, brain injury, or bridging vein rupture. (3T88-2 to 18, 90-21 to 22) Accordingly, the symptoms were more consistent with BESS than abuse. (3T90-2 to 12, 90-23 to 25) Indeed, that diagnosis was not only consistent with the scans, but could also mimic or cause subdural hematomas, cause seizures, and result in severe retinal hemorrhages. (3T90-12 to 19, 91-1 to 92-7, 117-3 to 14, 123-6 to 124-2)

iii. Dr. Scheller Similarly, but Independently Concluded that D.J. Displayed Evidence of a Subdural Hygroma, or BESS, that Could Explain His Symptoms.

Dr. Scheller independently reached a conclusion similar to Dr. Mack's. Dr. Scheller, who is qualified to review imaging scans, testified that D.J.'s MRI from February 13, 2017 showed "a large fluid collection between D.J.'s brain and the inside of the skull" but only a "small sliver of a blood clot within that fluid." (2T147-22 to 148-13) Specifically, like Dr. Mack, Dr. Scheller testified that the MRI showed an abnormal substance -- or hygroma -- between the dura and the arachnoid, with "a tiny sliver of recent blood clotting" about an inch below the left top of D.J.'s head. (2T159-25 to 166-14) Due to the lack of evidence of trauma, Dr. Scheller opined that the "small fresh blood clot is a complication of something that has been sitting there for a period of time" -- like a hygroma. (2T145-13 to 146-7, 165-14 to 166-16)

Dr. Scheller, like Dr. Mack, also testified that hygromas can form without a clear explanation, by minor trauma, or, as in the case of D.J., due to prematurity. (2T167-3 to 169-5) He also testified that hygromas can have no symptoms, but can cause a large head, poor feeding, or delays in development. (2T166-17 to 167-2, 169-6 to 12) And, while less common, they can also "cause seizures." (2T169-11, 172-6 to 175-10)

To that end, Dr. Scheller testified that D.J.'s seizure activity could have been caused by the hygroma and the resultant intracranial pressure. (2T171-22 to 172-5) Likewise, Dr. Scheller also testified that the hygroma could have caused D.J.'s retinal hemorrhages. As Dr. Scheller explained, "[w]hen something bad happens to the brain that affects the adjacent blood flow in the eye, there can be a backup of blood flow and that can cause a" hemorrhage in the retinal veins, which are particularly weak, no different than how stepping on a garden hose can cause a leak on the weakest part of the hose. (2T173-24 to 175-10, 177-15 to 19, 190-4 to 18)

Accordingly, Dr. Scheller testified that there "was no evidence at all that . . . D.J. was a victim of abuse." (2T144-17 to 145-2) As Dr. Scheller explained, D.J. had no signs of abuse -- including neck injuries or bruising. (2T191-17 to 25, 199-6 to 15) In addition, like Dr. Mack, Dr. Scheller testified that D.J.'s small blood clot was inconsistent with the type of

"large blood clot" that would develop if, as Dr. Medina opined, one of D.J.'s bridging veins had ruptured. (2T169-17 to 171-21) As a result, Dr. Scheller testified that D.J.'s symptoms were more likely caused by a hygroma, or BESS, and that Dr. Medina could not make an SBS/AHT diagnosis without first addressing this alternative explanation. (2T199-19 to 200-7)

6. Dr. Medina Did Not Mention Consulting with Radiologists About D.J.'s Prior Scans or Ruling Out BESS as a Potential Diagnosis Until Questioned on Cross-Examination.

As Dr. Medina acknowledged, her diagnostic reports need to be comprehensive because they are used by the State to determine whether parents and their children will be separated and whether a parent will be criminally prosecuted. (2T24-25 to 25-14) Moreover, the report is essential because SBS/AHT lacks a diagnostic or confirmatory test, as Dr. Medina acknowledged, and solely depends on ruling out every other possible cause through a differential diagnosis. (1T72-10 to 73-10, 113-14 to 20) Nonetheless, and despite recognizing that BESS can mimic the "triad," Dr. Medina's report includes no indication that she excluded it before diagnosing D.J. with SBS/AHT.

Indeed, Dr. Medina did not even mention BESS in her report, including among the excluded diagnoses. (2T28-2 to 30-16) Dr. Medina also did not report that she directly spoke with a radiologist, had a radiologist comprehensively review all of D.J.'s prior scans, or sought a radiologist's assistance to

assess D.J. for BESS. (2T28-2 to 30-22) In other words, Dr. Medina's report, despite being 18 pages long, and taking two months to write, provides no evidence that BESS was ever considered or reliably excluded as a possible cause.

Dr. Medina also did not claim to take such steps during her direct examination. Dr. Medina did not, for example, testify that she consulted with any subspecialists, spoke directly with a radiologist, or had a radiologist review all of D.J.'s scans. Likewise, Dr. Medina did not say that she took any steps to eliminate BESS as a possible cause and did not even mention the diagnosis other than to cite as a reason to believe that shaking can cause bridging vein ruptures and to briefly mention its ability to mimic SBS/AHT symptoms. (1T48-12 to 52-8)

Instead, Dr. Medina did not mention these alleged steps until her cross-examination and re-direct examination, over three-and-a-half years after writing her report. For example, Dr. Medina did not claim to have individually consulted with any subspecialists until cross-examination. (2T16-13 to 19-16) Likewise, it was not until cross that Dr. Medina stated, for the first time, that she consulted with a radiologist to review all of D.J.'s imaging, despite its "crucial" importance to her diagnosis. (2T23-11 to 28-1)

Further, it was not until re-direct that Dr. Medina testified that it is her "practice" to have radiologists review

prior films and that four radiologists reviewed D.J.'s neurosonograms and MRI. (2T35-20 to 37-4, 39-20 to 23) In explaining this omission from her report, Dr. Medina simply explained that her 18-page report was a "summary" that did not include everything that did. (2T24-4 to 24, 33-1 to 7) In other words, Dr. Medina testified that she did not consider these steps -- including the exclusion of an alternative explanation adopted by two other doctors -- to be significant enough to include in her report. (2T24-4 to 24, 33-1 to 7) This testimony, rather than providing reassuring clarity, casts further doubt on the thoroughness of Dr. Medina's analysis.

Such doubt also arose because Dr. Medina's testimony failed to provide a clear timeline of when these consultations occurred and what they involved. The radiologists that Dr. Medina named, for example, were the same radiologists who conducted the original scans, thus raising the question of whether Dr. Medina was simply referring to their initial reviews, rather than subsequent comprehensive reviews of the type performed by Dr. Mack. (2T39-20 to 41-8) Dr. Medina also did not specify when the reviews occurred or what the exact results were. Her report, moreover, which references each of the named radiologists, does not indicate that they reviewed more than a single scan. In other words, Dr. Medina failed to explain the timing and substance of these reviews, or what the doctors did.

Accordingly, the record suggests that Dr. Medina did not consult with radiologists to exclude a diagnosis of BESS, or at least did not did not do so in a sufficiently reliable and documented manner.

B. THE STATE HAS FAILED TO CLEARLY SHOW THAT DR. MEDINA RENDERED A RELIABLE DIAGNOSIS.

Under Dr. Medina's own standards, an SBS/AHT diagnosis cannot be reliably reach without first ruling out every possible other explanation for the "triad." This process must be thorough and exacting because an SBS/AHT diagnosis cannot be confirmed through diagnostic testing and will create lasting implications, including the loss of one's child and/or freedom, and the child's separation from a parent. To that end, the review process must be clearly documented for future proceedings, which, as in this case, can occur years after the diagnosis.

Here, however, Dr. Medina's report failed to show that she considered BESS or took any steps to rule it out as a diagnosis. Those omissions demonstrate that Dr. Medina did not consider BESS as a possible diagnosis before diagnosing SBS/AHT. Simply put, Dr. Medina, due to her important responsibilities and the significance of her report, reasonably would have and should have mentioned these steps if they were taken. That they were not mentioned, and were still omitted by the time the State finished its direct examination and Drs. Mack's and Scheller's

alternate theories had been memorialized, demonstrates that Dr. Medina's diagnosis is not clearly and sufficiently reliable.

Dr. Medina's subsequent explanations on cross-examination and re-direct, moreover, cannot compensate for these omissions. Dr. Medina's claim to have omitted important details from her 18-page report, for example, tends to undermine, rather than support, the thoroughness of her diagnosis. (2T24-4 to 24, 33-1 to 7) That the omitted information would be as significant as consulting with subspecialists and ruling out a possible alternative cause, as Dr. Medina claimed at the hearing, bespeaks a lack of thoroughness that cannot be overcome by testimony over three-and-a-half years later.

Accordingly, the State has not established the reliability of Dr. Medina's diagnosis because it has not clearly shown that she excluded all possible alternative explanations, including BESS, before diagnosing D.J. with SBS/AHT.

PROPOSED CONCLUSIONS OF LAW

The State had the burden of clearly establishing that shaking-only SBS/AHT is scientifically reliable and generally accepted within the relevant scientific communities. In addition, the State also had the burden of demonstrating that Dr. Medina rendered a reliable opinion when she diagnosed D.J. with shaking-only SBS/AHT. For the following reasons, and as discussed above, the State failed to meet its burden on both issues, such that testimony about shaking-only SBS/AHT should be excluded from trial both as a general principle and as applied in this case.

POINT I

THE STATE HAS FAILED TO MEET ITS BURDEN TO CLEARLY DEMONSTRATE THAT SHAKING-ONLY SBS/AHT IS RELIABLE AND GENERALLY ACCEPTED.

As discussed, expert testimony can only be admitted if the proponent of the evidence demonstrates that certain conditions have been met. Among those conditions is that the witness be properly qualified and that her testimony "will assist the trier of fact to understand the evidence or to determine a fact in issue . . . ." N.J.R.E. 702. As part of that analysis, the testimony must concern a topic that is "at a state of the art such that an expert's testimony could be sufficiently reliable . . . ." State v. Kelly, 97 N.J. 178, 208 (1984). The opinion must, in other words, rest upon "a sound, adequately-founded

scientific methodology." State v. Moore, 188 N.J. 182, 206 (2006) (quoting Rubanick v. Witco Chem. Corp., 125 N.J. 421, 449 (1991)). In New Jersey, this requires the proponent to clearly demonstrate that the theory has been "sufficiently established to have gained general acceptance in the particular field in which it belongs." Frye v. United States, 293 F. 1013, 1014 (D.C. Cir. 1923); State v. Harvey, 151 N.J. 117, 169-70 (1997).

There are three ways proponents can prove the reliability and general acceptance of scientific evidence: (1) testimony of knowledgeable experts; (2) authoritative scientific literature; and (3) persuasive judicial decisions which acknowledge such general acceptance. State v. Henderson, 208 N.J. 208, 247-48 (2011). Regardless of the type of evidence offered, the definition of the relevant scientific community is critical. As discussed in the Statement of Science, courts must avoid defining the community so narrowly that it excludes relevant fields or only focuses upon a narrow subset of scientists. Windmere, Inc. v. Int'l Ins. Co., 105 N.J. 373, 380 (1987); Canavan's Case, 733 N.E.2d 1042, 1050 n.6 (Mass. 2000).

Similarly, while the proponent need not demonstrate unanimous acceptance, State v. Tate, 102 N.J. 64, 83 (1986), a "moderate" degree of acceptance is insufficient. Tonsberg v. VIP Coach Lines, Inc., 216 N.J. Super. 522, 527 (App. Div. 1987). It is axiomatic that the existence of a genuine controversy within

the scientific community means that there is no general acceptance. See, e.g., Clemons v. State, 896 A.2d 1059, 1078 (Md. 2006) ("Although scientific unanimity is not required . . . it is clear that a genuine controversy exists within the relevant scientific community about the reliability and validity of [the evidence]."); State v. Gore, 21 P.3d 262, 271 (Wash. 2001) ("If there is a significant dispute among qualified scientists in the relevant scientific community, then the evidence may not be admitted."). To put it differently, "if the bottom line is general disagreement rather than general acceptance," the standard is not satisfied and the testimony cannot be admitted. State v. Spann, 130 N.J. 484, 510 (1993). It also is not enough for the State's expert to only demonstrate general acceptance of a particular component of the theory it seeks to validate. State v. Boyington, 153 N.J. Super. 252, 254-55 (App. Div. 1977). Instead, the State must validate every component necessary to the validity of the proposed testimony. See State v. J.L.G., 234 N.J. 265, 308 (2018) (finding State failed to prove reliability of all but one element of CSAAS).

There is no question that the "requirement of reliability applies to all scientific fields," Biunno, Weissbard & Zegas, Current N.J. Rules of Evidence, cmt. 3 on N.J.R.E. 702 (2019), even if testimony on that subject has previously been admitted

at trials. See J.L.G., 234 N.J. at 271-72 (excluding testimony deemed reliable 25 years earlier).

"Trial judges, as gatekeepers, decide [the] threshold question" of "whether expert testimony is sufficiently reliable before it can be presented to a jury." Id. at 305, 307-08; see also N.J.R.E. 104(a)(1) ("The court shall decide any preliminary question about whether a witness is qualified . . . or evidence is admissible."). "The court's function is to distinguish scientifically sound reasoning from that of the self-validating expert, who uses scientific terminology to present unsubstantiated personal beliefs." Landrigan v. Celotex Corp., 127 N.J. 404, 414 (1992). The court must make this determination both because the jury is ill-equipped to determine scientific reliability and because jurors may be improperly swayed by expert testimony. See Ryan v. KDI Sylvan Pools, 121 N.J. 276, 285 (1990) ("[W]hen unreliable testimony is labeled 'expert,' juries might not accurately assess its weight.").

This gatekeeping role can be difficult and "requires care" from the court. In re Accutane Litigation, 234 N.J. 340, 389 (2018). "Properly exercised, the gatekeeping function prevents the jury's exposure to unsound science through the compelling voice of an expert." Ibid. In other words, the court's leadership, careful consideration, and gatekeeping responsibility is needed to shield the jury from confusing or

unreliable evidence, and to ensure the defendant's "due process rights." State v. Ghigliotty, 463 N.J. Super. 355, 384 (App. Div. 2020); see also State v. Michaels, 136 N.J. 299, 316 (1994) ("If crucial inculpatory evidence is alleged to have been derived from unreliable sources due process interests are at risk."); State v. Cavallo, 88 N.J. 508, 520 (1982) (emphasizing danger of "prejudice, confusion and diversion of attention" when expert testimony "is not sufficiently reliable").

Based on these principles, and the Proposed Findings of Fact, this Court should conclude that the State has failed to establish the general acceptance and reliability of shaking-only SBS/AHT and thus exclude that testimony from trial.

A. THE STATE DID NOT CLEARLY ESTABLISH THAT SHAKING-ONLY SBS/AHT IS GENERALLY ACCEPTED IN THE SCIENTIFIC COMMUNITY THROUGH EXPERT OPINION OR AUTHORITATIVE SCIENTIC LITERATURE.

The original theory of shaking-only SBS/AHT was based on speculation rather than science. No scientific basis was cited to apply the results of Dr. Ommaya's primate study to the idea of abuse by shaking. Drs. Guthkelch and Caffey, for example, did not explain how shaking could create force similar to that experienced by primates that were subjected to 30-mile-per-hour car crashes. Instead, they guessed, as a hypothesis, that equivalent force and injuries could be produced by shaking.

This theory has been tested repeatedly in the subsequent decades, including by Drs. Duhaime and Prange. Such testing, as

previously discussed, is essential if a hypothesis is to be validated and ultimately accepted. But, as Dr. Medina conceded, no study has shown that shaking can reach the injury thresholds from the Ommaya study. Rather, they have consistently shown that shaking cannot produce equivalent force, even when coupled with minor impact, as seen in the studies conducted by Drs. Cory and Jenny. Similar results have also been reached in animal studies.

Research has also shown that events that produce more force than shaking do not cause the triad, thus further suggesting that shaking cannot cause those symptoms. Additional studies, including form Dr. Van Ee, have also shown that shaking can produce neck injuries without reaching the injury threshold for brain injury. Thus, this research challenges, if not disproves, two key principles of SBS/AHT: (1) that shaking can cause the triad; and (2) that shaking can cause the triad without neck injuries.

This research, and the absence of proof for the shaking-only theory, is not in dispute. To the contrary, the State established this through its own experts and cited authorities. The defense experts, including biomechanist Dr. Van Ee, just further demonstrated the theory's absence of scientific reliability.

Accordingly, and despite bearing the burden of proof and persuasion, the State failed to offer any evidence showing that

the shaking-only theory of SBS/AHT is biomechanically possible. Thus, the State has not demonstrated, either through expert opinion or authoritative scientific literate that shaking-only SBS/AHT is anything more than an unproven hypothesis. That level of proof falls far short of what Frye requires and warrants exclusion of the State's proffered testimony.

Exclusion is also required when one looks beyond the issue of biomechanics because the State offered similarly minimal evidence to support its medical theories of SBS/AHT. As with shaking-only SBS/AHT's biomechanical underpinnings, the State offered no scientific authority to supports its theory that shaking-only SBS/AHT is possible based on observations found in children with BESS and based on the vitreoretinal traction theory. Rather, Dr. Medina conceded that no scientific studies supported her views, cited to two studies that relied on non-scientific "confessions," and conceded that her theories were contradicted by the instances of shaking that have been recorded and where the "triad" was not found.

Thus, even before the defense put on its witnesses, the State had failed to clearly establish shaking-only SBS/AHT as generally accepted and reliable in the scientific community. Moreover, and even though it is not the defendant's burden, Drs. Scheller, Mack, and Van Ee further demonstrated that the shaking-only theory is not reliable. Therefore, there is no

question that shaking-only SBS/AHT fails the Frye test and cannot be admitted at trial.

B. THE STATE CANNOT CLEARLY ESTABLISH THAT SHAKING-ONLY SBS/AHT IS RELIABLE AND GENERALLY ACCEPTED IN THE SCIENTIFIC COMMUNITY THROUGH CITATION TO CASE LAW.

1. New Jersey Case Law Does Not Establish the General Acceptance of Shaking-Only SBS/AHT.

There is minimal case law in New Jersey addressing the reliability of SBS/AHT and nothing that favors admitting the challenged testimony in this case. While SBS/AHT has been cited in several cases, it has only been addressed in a single published opinion and in one prior Frye hearing.[7] As discussed below, the published opinion should be afforded no weight because it suffers from numerous deficiencies, while the prior Frye hearing, while resulting in an unpublished opinion, led to the exclusion of shaking-only SBS/AHT testimony.

The only published opinion to address the validity of SBS/AHT in New Jersey is State v. Compton, 304 N.J. Super. 477 (App. Div. 1997). That case, however, involved a plain-error challenge on appeal, meaning there was no Frye hearing to assess the reliability of SBS/AHT. Id. at 483-84. Moreover, no defense experts testified at trial and the opinion was issued in 1997, meaning it predates the significant scientific research that has

[7] Other cases, like State v. Galloway, 133 N.J. 631 (1993) and State v. P.Z., 152 N.J. 86 (1997), have referenced SBS/AHT without addressing its reliability or general acceptance.

occurred in the past 23 years. Ibid. Compton is therefore not based on a thorough review of the relevant issues and is now badly out of date such that it carries only nominal value.

Indeed, the Supreme Court has made it clear that where evidence establishes that the scientific community does not view "knowledge" previously accepted by our courts to be reliable, courts have an affirmative obligation to reconsider its admissibility, regardless of whether it was previously accepted. See State v. J.L.G., 234 N.J. 265, 271-72 (2018) (reevaluating and excluding CSAAS testimony deemed reliable 25 years earlier); State v. Henderson, 208 N.J. 208, 217-18 (2011) (revising identification standards based on new research); State v. Moore, 188 N.J. 182, 207-08 (2006) (amending 25-year-old rules governing hypnotically refreshed testimony because Court "had become convinced that the scientific evidence . . . counsels another course"). That is, as discussed above, the case in this situation where Compton was decided before the publication of almost every modern biomechanical study addressing SBS/AHT. Moreover, the Appellate Division -- the same court that issued Compton -- ordered that SBS/AHT be considered anew by this Court, thus further demonstrating that Compton does not control.

Other than the prior litigation in this matter, the most pertinent post-Compton development in New Jersey came from the Honorable Sohail Mohammed, J.S.C.,'s opinion in State v. Jacoby,

No. 15-11-917-I (Law Div. Aug. 17, 2018).[8] Although his opinion is not binding, Judge Mohammed is, along with this Court, the only judge in New Jersey to hold a Frye hearing on SBS/AHT. The questions Judge Mohammed was asked to resolve, moreover, are very similar to those present here, such that his opinion can provide some guidance to this Court.

The charges against Jacoby, like the charges in this case, arose from a hospital visit for Jacoby's 11-month-old son, P.J., who became unresponsive. Id. at ___ (slip op. at 2). At the hospital, P.J. was found to have a subdural hematoma and severe retinal hemorrhages, without any signs of bruising or trauma. Id. at ___ (slip op. at 3-4). Based on these findings, abuse was suspected, DCP&P was contacted, and the police interrogated Jacoby. Id. at ___ (slip op. at 4-5). During the interrogation, Jacoby said that he was trying to calm P.J. by rocking him when he felt the weight of P.J.'s head lift off the crook of his harm and then come back against him arm. Id. at ___ (slip op at 5). Jacoby also told the police that he said "God, I hope this is not my fault" when J.P. was being airlifted to the hospital. Id.

[8] The only other recent opinion, as the Court is aware, came from the denial of a Frye hearing in State v. Cifelli, No. 17-11-1303-I (Law Div. April 4, 2019). Because a Frye hearing was ordered in this case, Cifelli does not have particular relevance and will not be discussed further.

at ___ (slip op. at 5-6). The police deemed these statements to be a confession and arrested Jacoby. Id. at ___ (slip op. at 6)

In addition, based on the "triad" and a consideration of other possible causes, a child abuse pediatrician diagnosed P.J. with SBS/AHT. Id. at ___ (slip op. at 5) The CAP also categorized Jacoby's statement as a confession even though she did not believe anything that he admitted could cause P.J.'s symptoms. Ibid. Based on these findings, Jacoby was charged with second-degree aggravated assault and second-degree endangerment, along with fourth-degree cruelty. Id. at ___ (slip op. at 2).

A combined Frye hearing and bench trial was subsequently held, during which Judge Mohammed heard testimony from three expert witnesses, including Dr. Scheller. Id. at ___ (slip op. at 7) Following the hearing, Judge Mohammed made several findings before ruling in Jacoby's favor.

First, Judge Mohammed noted that the validity of shaking-only SBS/AHT is distinct from abuse in general. Id. at ___ (slip op. at 7). Judge Mohammed then traced the history of SBS/AHT, including the more recent medical and judicial scrutiny it has received. Id. at ___ (slip op. at 7-9). Based on this review and the testimony of the experts, Judge Mohammed determined that the SBS/AHT testimony was not sufficiently reliable, not generally accepted, and thus inadmissible.

In doing so, Judge Mohammed found that "there is no sufficiently reliable evidence and no general consensus in the scientific and medical community as to both the age and causation of subdural hematomas[,]" particularly given their numerous causes, including BESS. Id. at ___ (slip op. at 12). Judge Mohammed similarly found a lack of scientific support for testimony regarding the causes of retinal hemorrhages and the vitreoretinal traction theory. Id. at ___ (slip op. at 12-13). Finally, Judge Mohammed found that there is "no sufficiently reliable evidence and no general consensus in the scientific and medical community that shaking alone causes subdural hematomas and retinal hemorrhages to satisfy the Frye standard" or for the "presumption of abusive head trauma" that is triggered based on those findings. Id. at ___ (slip op. at 13-14)

Thus, Judge Mohammed found a lack of support for multiple theories underlying shaking-only SBS/AHT, such that it could not be admitted at trial. Id. at ___ (slip op. at 14). Moreover, the court also found that the State mischaracterized Jacoby's statement as a "confession," and, in doing so, "prematurely closed P.J.'s case" such that he may have been denied needed treatment. Id. at ___ (slip op. at 15-16). Judge Mohammad then acquitted Jacoby of the charges. Id. at ___ (slip op. at 16-18).

At minimum, this decision demonstrates that our courts have not recognized shaking-only SBS/AHT as a reliable and generally

accepted theory. In addition, Judge Mohammed's opinion provides a persuasive, albeit non-binding, analysis addressing many of the same topics facing this Court, including the general acceptance of the shaking-only theory, the vitreoretinal traction theory, and theories regarding the causation of subdural hematomas. Lastly, the opinion provides an example of how the SBS/AHT differential diagnosis, if not properly moored in science, can lead doctors and investigators to focus on abuse and view all evidence -- including "confessions" -- through that lens, to the detriment of the child, the parent, and the justice system as a whole. In short, the opinion provides additional grounds for caution in assessing the State's proffered testimony and another real-life example of why a firm scientific basis is needed before SBS/AHT can be diagnosed.

2. Although Other Courts Allow SBS/AHT Testimony, These Cases Have Not Involved Frye Hearings or the Specific Issues in this Case, and Still Other Courts Have Expressed Concerns about the Shaking-Only Hypothesis.

Defendant has been unable to find any cases in which a court held a Frye hearing on the issue in this case -- the feasibility of shaking-only SBS/AHT -- and found general acceptance for the theory that shaking creates sufficient force to cause the "triad," but without also causing neck injuries. Rather, the courts that have addressed the issue have either allowed SBS/AHT testimony without a hearing based on principles

not applicable in New Jersey, or after conducting a hearing that did not touch on these topics and which, in some cases, was also patently deficient. See Futrell v. Commonwealth, 471 S.W.3d 258, 283-85 (Ky. 2015) (testimony admitted without addressing causation and based on testimony of single state witness); State v. Leibhart, 662 N.W.2d 618, 628 (Neb. 2003) (same); Sissoko v. State, 182 A.3d 875, 902-03 (Md. Ct. Sp. App. 2018); (addressing differential diagnosis without addressing causation); Wolfe v. State, 509 S.W.3d 325, 340-41 (Tex. Crim. App. 2017) (same).

At the same time, multiple courts, although not resolving the issue, have recognized that the shaking-only theory may be "more an article of faith than a proposition of science." Prete v. Thompson, 10 F. Supp. 3d 907, 957 n.10(N.D. Ill. 2014); see also Commonwealth v. Millien, 50 N.E.3d 808, 820-21 (Mass. 2016) (noting "numerous scientific studies support[] the view that shaking alone cannot produce" the "triad"); People v. Bailey, 999 N.Y.S.2d 713, 718 (N.Y. Cty. Ct. 2014) (crediting testimony that "shaking a child hard enough to cause brain injury also would cause neck injury"), aff'd, 41 N.Y.S.3d 625 (N.Y. App. Div. 2016); State v. Patterson, 904 N.W.2d 43, 53 (S.D. 2017) (recognizing questionable "viability of the triad theory"); State v. Edmunds, 746 N.W.2d 590, 595-96 (Wis. Ct. App. 2008) ("[A] significant and legitimate debate in the medical community has developed in the past ten years

over whether infants can be fatally injured through shaking alone . . . ."); see also Cavazos v. Smith, 565 U.S. 1, 13 (2011) (Ginsburg, J., dissenting)(quoting Edmunds, 746 N.W.2d at 596) ("Doubt has increased in the medical community 'over whether infants can be fatally injured through shaking alone.'"). Thus, out-of-state case law provides little guidance other than further demonstrating that there is, at best, an active debate about the shaking-only hypothesis.

In any event, our courts have cautioned against relying too heavily upon out-of-state case law. As the Appellate Division has observed, "[r]eliance upon other courts' opinions can be problematic" and "is a hollow ritual" "[u]nless the question of general acceptance has been thoroughly and thoughtfully litigated in the previous cases . . . ." State v. Doriguzzi, 334 N.J. Super. 530, 545 (App. Div. 2000) (quoting People v. Kirk, 681 N.E.2d 1073, 1078 (Ill. App. 1997)). That is to say, if another jurisdiction determines that a theory is "generally accepted," but that determination is based upon little or no scientific evidence, or is otherwise flawed, it is of minimal use to our courts. Otherwise, "judicial notice could become a yellow brick road for judicial acceptance of bogus or at least unvalidated scientific theories or techniques." Ibid.

In other words, our courts have made clear that the proponent of the testimony must establish its general acceptance

within the scientific community, not the legal community. Indeed, the Supreme Court recently found the vast majority of Child Sexual Abuse and Accommodation Syndrome unreliable, and thus inadmissible, despite that diagnosis being accepted in 40 other states and the District of Columbia. State v. J.L.G., 234 N.J. 265, 288 (2018). This is because the focus must be on "whether a sufficient level of reliability has been achieved to allow consideration of the scientific test by the factfinder[,]" and not simply "counting up how many cases go in a certain direction." Doriguzzi, 334 N.J. Super. at 546.

Thus, courts have held very few adversarial hearings on SBS/AHT, no court appears to have resolved the issues here, but a growing number of courts have questioned the shaking-only theory. Accordingly, the out-of-state case law cannot support a finding of general acceptance and the question of whether the State has met that burden should primarily turn on the record developed in this case. Simply put, this Court is specifically, if not uniquely, situated to resolve these long-standing and significant issues in a thoughtful, fair, and reliable manner based on the record developed at the five-day-long Frye hearing.

C. BECAUSE THE STATE HAS NOT ESTABLISHED THAT SHAKING-ONLY SBS/AHT IS RELIABLE AND GENERALLY ACCEPTED IN THE SCIENTIFIC COMMUNITY, TESTIMONY ON THAT SUBJECT MUST BE EXCLUDED.

As discussed, the State has conceded that shaking-only SBS/AHT was based on an unscientific assumption about

biomechanics that has not be proven valid in the subsequent 40-plus years. The State further acknowledged that the medical theories used to explain shaking-only SBS/AHT -- including the vitreoretinal traction theory -- are similarly lacking in scientific validation and remain hypotheses. The State offered no expert opinions or authoritative literature to compensate for this lack of established reliability, and it cannot bridge that scientific gap by citing to judicial opinions, particularly as they do not permit a finding of general acceptance on the issues in this case. Accordingly, it is respectfully requested that this Court find that the State has failed to clearly establish the reliability and general acceptance of shaking-only SBS/AHT, such that testimony on that subject must be excluded under N.J.R.E. 702.

POINT II

THE STATE HAS FAILED TO CLEARLY DEMONSTRATE THAT DR. MEDINA RENDERED A RELIABLE DIAGNOSIS.

A proponent of expert testimony must not only show that the field of study or method is reliable, but also that the expert clearly applied the theory or method in a reliable manner. State v. Mervilus, 418 N.J. Super. 138, 139 (App. Div. 2011); see also State v. J.Q., 130 N.J. 554, 583 (1993) (stating courts must "assess the qualifications of the witness as well as the research basis for the expert proposition to be stated").

Without such reliability, the testimony cannot "assist the trier of fact to understand the evidence or to determine a fact in issue," as N.J.R.E. 702 requires. Instead, an unreliable opinion, like testimony on an unreliable subject, only has the capacity to mislead and confuse the jury, and must be excluded. State v. Michaels, 136 N.J. 299, 316 (1994).

In this case, the State failed to clearly show that Dr. Medina offered a reliable opinion, based on her own standards. As Dr. Medina testified, an SBS/AHT diagnosis is only reliable if every other possible alternative cause is first excluded. (1T72-10 to 74-9) Thus, a differential diagnosis that "fails to consider a plausible hypothesis that would explain the condition has not been properly conducted" and is not reliable. Creanga v. Jardal, 185 N.J. 345, 356 (2005) (quoting Clausen v. M/V New Carissa, 339 F.3d 1049, 1058 (9th Cir. 2003).

Dr. Medina documented her differential diagnosis in an 18-page report that was subsequently used by the State to accuse Nieves of abuse, charge him multiple crimes, and separate him from his young child. Nowhere in that report does it say that Dr. Medina considered whether D.J.'s symptoms could have been caused by a benign enlargement of the subarachnoid space (BESS), despite BESS being able to mimic SBS/AHT symptoms, premature children being predisposed to BESS, and D.J.'s scans showing clear evidence of BESS, as Drs. Mack and Scheller testified.

Instead, Dr. Medina did not make any mention of considering that diagnosis, despite the level of detail given to other possible causes in her report, until her cross-examination, years after she made her diagnosis.

This suggests that Dr. Medina did not consider BESS before diagnosing D.J. with SBS/AHT and only claimed to have done so when confronted with this failure on cross-examination. At best, she considered the diagnosis but completely failed to document that fact, including the steps she took to have radiologists review each of D.J.'s prior scans for possible enlargement. No matter which of these scenarios occurred, the State failed to clearly demonstrate the reliability of Dr. Medina's diagnosis.

A failure to consider BESS, as the report suggests, would clearly render Dr. Medina's diagnosis unreliable. A failure to document the consideration of a recognized and possibly applicable diagnosis, including the other doctors and procedures involved, however, is just as troubling. As noted, because there is no confirmatory test for SBS/AHT, the differential diagnosis relies on thoroughness and a guarantee that all reasonable alternative explanations have been considered and excluded. A doctor's failure to document the exclusion of a possible cause, which two other doctors have diagnosed, thus bespeaks a serious lack of care that defeats any claim that the diagnosis was clearly reliable, and which cannot be cured by post-hoc

explanations offered only when the doctor is pressed on cross-examination years later.

Accordingly, this Court should find that the State has failed to clearly establish the reliability of Dr. Medina's diagnosis and exclude her testimony.

CONCLUSION

The State has failed to meet its burden to clearly establish that shaking-only SBS/AHT meets the reliability standard of N.J.R.E. 702 and that Dr. Medina offered a reliable opinion in this case. Nieves therefore respectfully requests that the Court adopt the findings of fact and conclusions of law proposed herein and find the challenged testimony inadmissible.

Respectfully submitted,

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