

Daubert hearing regarding Shaken Baby Syndrome

Lewis D. Nicholls, Circuit Judge

Abstract

Circuit Judge, Lewis D. Nicholls, renders a response to Commonwealth of Kentucky Greenup Circuit Court Case No. 04-CR-205, Commonwealth of Kentucky Plaintiff vs. Order and Opinion re: Daubert Hearing (Christopher A. Davis, Defendant) concerning the issue of Shaken Baby Syndrome (SBS). Dr. Ronald H. Uscinski testified and opined that based upon the research conducted and reported so far, impact is necessary to generate adequate force to cause the injuries previously mentioned. Dr. Uscinski also pointed out that the impact curve created by Ommaya was only a projection of at what threshold the scientists believed humans would sustain injuries—it failed to take into account the different structure of human babies as compared to adult monkeys, and what impact this difference would make. Betty S. Spivack, M.D. also testified as a forensic pediatrician with the Office of the Chief Medical Examiner located in Louisville, Kentucky. She indicated that physicians will diagnosis SBS when they observe a subdural hematoma bilateral (both sides of the brain) coupled with a retinal hemorrhage observed in both eyes. However, this diagnosis is based on inconclusive research conducted in the scientific research community.

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Keywords: Shaken Baby Syndrome (SBS), subdural hematoma, retinal hemorrhaging, whiplash injuries

On September 19, 2005, the Defendant, by and through counsel, filed a motion for a Daubert hearing pursuant to KRE 104 and *Daubert vs. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). In his motion the Defendant moved the Court to determine:

1. The admissibility of proposed medical and scientific evidence that manual shaking can cause subdural hematomas and retinal hemorrhaging in infants.
2. Whether shaken baby syndrome meets the Daubert criteria for admissibility as a scientific theory to explain the injuries to the victim in this case.
3. The admissibility of proposed medical and scientific evidence that subdural hematomas and retinal hemorrhaging in infants can only be caused by manual shaking.
4. The admissibility of proposed medical and scientific evidence that the symptoms of subdural hematomas and retinal hemorrhaging would necessarily be immediately apparent.
5. The admissibility of proposed expert medical and scientific opinions that the injuries of the victim are consistent with shaken baby syndrome.

A Greenup Grand Jury indicted the Defendant of first-degree criminal abuse by violently shaking a child with the initials of A.D. The Defendant alleges that the child's medical records indicate that the only significant injury for the victim was a subdural hematoma and retinal hemorrhaging and there was no significant bruising, fractures, or evidence of impact. The Commonwealth's case is based upon the theory of shaken baby syndrome, hereinafter referred to as SBS. SBS is the theory that a caregiver can cause a subdural hematoma and retinal hemorrhaging by violently shaking a child without the child's head impacting with another surface. This theory explains why a baby can have the classic symptom of a subdural hematoma and a retinal hemorrhage usually in both eyes. But, the Defendant challenges whether there exists any basis in fact for the theory, and in particular where the consequences can cause a person

to be sentenced to the state prison system from five (5) to ten (10) years.

The Court conducted the hearing on Wednesday, March 29, 2006. The Hon. Clifford Duval, Hon. Maridelle Malone, and Hon. Mel Leonhart were present representing the Commonwealth. The Hon. Sam Weaver and Hon. Amy Craft were present representing the Defendant.

Finding of Fact

The Defendant called as its first and only witness Dr. Ronald H. Uscinski, M.D., FACS. Dr. Uscinski earned his B.S. at Fordham University in New York, New York in 1964. He earned his M.D. from Georgetown University in Washington, D.C. in 1968. He performed his internship at Bronx Municipal Hospital Center, Albert Einstein University College of Medicine, in New York from 1968 to 1969. He performed his residency in neurological surgery, Georgetown University and affiliated Hospital from 1971 to 1975.

Dr. Uscinski's experience included serving as a Medical Officer in the U.S. Navy at Parris Island, South Carolina, and aboard the U.S.S. Thomas A. Edison (SSNB 61 0-B) Atlantic Submarine Force, from 1969 to 1971.

Dr. Uscinski served as a Senior Surgeon, in the U.S. Public Health Service, Surgical Neurology Branch, National Institute of Neurological and Communicative Disorders and Stroke, (NIH) in Bethesda, Maryland from 1975 to 1976. He served as an instructor in neurosurgery at NIH from 1976 to 1977, and as an instructor in neurosurgery at Medical University of South Carolina, Charleston, South Carolina from 1977 to 1980. In 1978 he became board certified with the American Board of Neurological Surgery. From 1980 to 2000 he served as a Clinical Assistant Professor in the Dept. of Surgery (neurosurgery), at Georgetown University School of Medicine in Washington, D.C. From 2000 to the present he is still a Clinical Associate Professor at Georgetown.

In 2004 he was appointed as an Adjunct Research Fellow at the Potomac Institute for Policy Studies, in Arlington, Va.

Dr. Uscinski has published several papers including *The Shaken Baby Syndrome*, Uscinski R. *Journal of American Physicians & Surgeons*: Volume 9, #3; 76-77,2004; and *The Shaken Baby Syndrome: An Odyssey*. Uscinski RH. *Neurologia medicochirurgica* (Tokyo) 46, 57-6 1,2006.

Dr. Uscinski has made numerous presentations on the subject of shaken baby syndrome including locations at Washington, D.C., London, England, and Nara, Japan. See Dr. Uscinski Curriculum Vitae, Defendant's Exhibit # 1.

Dr. Uscinski testified that as a practicing neurosurgeon he became interested in the subject of SBS because it directly affected his medical practice. As a result of his interest, he began to survey the different medical publications that existed on the subject of SBS. His study of the subject combined with his clinical practice led him to the conclusion that based upon his training, education, and experience, and within a reasonable degree of medical probability, there is insufficient proof in the medical community that human beings can generate the required rotational acceleration by manual shaking necessary to cause an injury to a small child or infant resulting in a subdural hematoma and/or retinal bleeding unless there is an impact of the head with another surface. Dr. Uscinski opined that based upon the research conducted and reported so far, impact is necessary to generate adequate force to cause the injuries previously mentioned.

Dr. Uscinski began his testimony by stating that a subdural hematoma is a pooling of blood in the subdural space of the human brain that results from the tearing of blood vessels. The brain has three membranes that enclose it. They are the outer layer, the dura, the middle layer, arachnoid, and a thin inner layer, the pia. The subdural is the space between the dura and the arachnoid layers. Hematomas can be either acute or chronic. Dr. Uscinski explained that a blow to the head causes an acute hematoma with symptoms that manifest themselves immediately after the injury. A chronic hematoma shows up weeks or months after an initial injury that often times seem to be insignificant. There are no immediate symptoms, and retinal hemorrhaging, bleeding behind the eye, is a marker of the chronic hematoma.

Dr. Uscinski testified that in 1974 Dr. John Caffey, an M.D. from Pittsburgh, Penn., released a paper in the professional magazine *Pediatrics* in which he suggested that manual whiplash shaking of infants is a common primary type of trauma in the so called battered infant syndrome. It appears to be the major cause in these infants who suffer from subdural hematomas and intraocular bleeding. Dr. Caffey admitted that this opinion was based on, "**both direct and circumstantial**" evidence. See *Pediatrics*, *The Whiplash Shaken Infant Syndrome: Manual Shaking by the Extremities With Whiplash-Induced Intracranial and Intraocular Bleedings, Linked With Residual Permanent Brain Damage and Mental Retardation*, Vol. 54 No. 4, October 1974. Dr. Caffey went on to state in the article that, "Current evidence, though **manifestly incomplete and largely circumstantial**, warrants a nationwide educational campaign on the potential pathogenicity of habitual, manual casual whiplash shaking of infants, and on all other habits, practices and procedures in which the heads of infants are habitually jerked and jolted (whiplashed)." Caffey, *supra*.

Dr. Caffey's suggestion that a nationwide educational campaign be initiated took root, and the Nation went into a frenzy cautioning mothers, fathers, and caregivers to never shake your child. Although this was good advice, Dr. Caffey pointed out that his suggestion, although sound, was not based on any type of scientific study.

Dr. Uscinski testified that Ayub K. Ommaya, FRCS did experimentation with rhesus monkeys in 1968. This study concluded that:

"Experimental whiplash injury in rhesus monkeys has demonstrated that experimental cerebral concussion, as well as gross hemorrhages and contusions over the surface of the brain and upper cervical cord, can be produced by rotational displacement of the head on the neck alone, without significant direct head impact, these experimental observations have been studied in the light of published reports of cerebral concussion and other evidence for central nervous system involvement after whiplash injury in man." *The Journal of the American Medical Association*, Vol. 204, No. 4, page 75 (285), April 22, 1968. (Defendant's Exhibit #8)

Dr. Uscinski pointed out that the Ommaya experiment study produced injury to 19 out of 50 monkeys by seating them in a chair that accelerated whipping the monkey's head back and forth. However, the experiment was performed on monkeys instead of humans because they ended up killing the monkeys to examine their brains for injury. The purpose of this research was to study whiplash on humans in automobile accidents. It was suppose to illustrate that injuries could occur to primates through sheer acceleration forces without any impact to the monkey's head.

Researchers in the Ommaya study produced an impact curve that predicted at what level of acceleration the monkeys would start to experience brain injuries from the sheer acceleration forces without any impact on the head. The researchers prepared an impact curve and from it were able to tell at what level of acceleration they observed brain injury to the monkeys. They called this level the threshold of injury. Dr. Uscinski pointed out that there were two flaws with the way later researchers interpreted the study. First, researchers must not assume that by extending out the impact curve they could accurately predict what threshold level of injury was necessary to produce injury to infant human brains. They could tell at what threshold they started to observe injuries to the monkeys; however, these results could not be extended out to predict injuries to humans because humans, although similar in structure, are still different with larger heads in proportion to their bodies. Researchers needed to conduct further research to make this determination. Second, the researchers failed to take into account that in some cases the monkeys hit their heads on the back of the "monkey seat" during the acceleration process. Dr. Uscinski also pointed out whipping a head back due to acceleration forces one time in an acceleration chair is a different kind of motion than shaking a child repeatedly by holding onto the child's torso.

Next, Dr. Uscinski testified that Dr. A. N. Guthkelch conducted a study in 1971 published in the *British Medical Jour-*

nal. Dr. Guthkelch commented that, “One cannot say how commonly assault in the form of violent shaking rather than of direct blows on the head is the cause of subdural haematoma in infants who are maltreated by their parents. Possibly it will be found that the frequency of this mechanism varies between different nations according to their ideas of what is permissible, or at least excusable, in the treatment of children.” *British Medical Journal*, Infantile Subdural Haematoma and its Relationship to Whiplash Injuries, 1971,2,430-43 1. (Defendant's Exhibit # 13) Dr. Guthkelch concluded in his summary, “Subdural haematoma is one of the commonest features of the battered child syndrome, yet by no means all the patients so affected have external marks of injury on the head. This **suggests** that, in some cases, repeated acceleration/ deceleration rather than direct violence is the cause of the hemorrhage, the infant having been shaken rather than struck by its parent. Such an **hypothesis** might also explain the remarkable frequency of the finding of subdural hemorrhage in battered children as compared with its incidence in head injuries of other origin, and the fact that it is so often bilateral.” See Guthkelch, *supra*. (Bold type in this quotation is placed there by Judge Nicholls to suggest emphasis.)

Dr. Uscinski pointed out Guthkelch's work was based on several case studies and not a scientific examination using controlled experiments. In fact Dr. Guthkelch did not do any experiments himself, he merely commented on, and suggested a possible explanation for the case studies he cited. Furthermore, Dr. Uscinski pointed out that most of Dr. Guthkelch's hypothesis was based on the flawed work of Dr. Ommaya. Dr. Guthkelch's use of words such as “hypothesis” and “suggests” is a cogent clue that these are his ideas to explain symptoms usually seen in a patient, rather than a solid verifiable scientific study.

Dr. Uscinski then testified that a 1987 study at the University of Pennsylvania produced some surprising results. Dr. Ann-Christine Duhaime, M.D., Thomas A. Gennarelli, M.D., and others conducted a biomechanical study to test the hypothesis that infants were particularly susceptible to injury from shaking due to a relatively large head and weak neck. The researchers used models of 1-month-old human babies and had college football players shake the models. The researchers measured the forces on the models and recorded them. The research team reached the conclusion that, “the shaken baby syndrome, at least in its most severe acute form, is not usually caused by shaking alone. Although shaking may, in fact, be a part of the process, it is more likely that such infants suffer blunt impact.” *J. Neurosurg*, The shaken baby syndrome: A clinical, pathological, and biomechanical study, Vol. 66, page 409-415, March 1987. (Defendant's Exhibit # 10) The conclusion they reported in the abstract stated, “severe head injuries commonly diagnosed as shaking injuries required impact to occur and that shaking alone in an otherwise normal baby is unlikely to cause the shaken baby syndrome.” Duhaime, *supra*. The Duhaime study also demonstrated that a baby would most likely receive a neck injury before it would receive a head injury simply because human shaking by a human cannot generate the forces necessary to cause injury to the brain. The study went on to conclude that, “unless a child has predisposing factors such as subdural hygromas, brain atrophy, or collagen-vascular disease, fatal cases of the shaken baby syndrome are not likely to occur

from the shaking that occurs during play, feeding, or in a swing, or **even from the more vigorous shaking given by a caretaker as a means of discipline.**” Duhaime, *supra*.

A second biomechanics study was conducted by Faris A. Bandak in 2004 and reported in 2005 in the professional magazine *Forensic Science International*, Shaken baby syndrome: A biomechanics analysis of injury mechanism. (Defendant's Exhibit #9) The study concluded that, “we have determined that an infant head subjected to the levels of rotational velocity and acceleration called for in the SBS literature, would experience forces on the infant neck far exceeding the limits for structural failure of the cervical spine.” See Bandak, *supra*. In other words, shaking alone would cause broken necks before one would expect to see subdural hematomas and ocular bleeding. The study called for a re-valuation of the current diagnostic criteria for shaken baby syndrome.

Dr. Betty Spivack, M.D., witness for the Commonwealth, testified that physicians will diagnosis SBS when they observe a subdural hematoma bilateral (both sides of the brain) coupled with a retinal hemorrhage observed in both eyes. Thus, the Bandak study was calling for a re-valuation of these criteria for diagnosing SBS. Dr. Uscinski testified that based upon his own experience the subdural hematoma can actually cause the retinal hemorrhaging, and that his opinion is currently finding confirmation based on studies conducted by Japanese researchers who have a great deal of interest in this problem.

In response to the Bandak study, Dr. Susan Margulies and others wrote a published letter to the *Forensic Science International*, criticizing the Bandak study. Dr. Margulies stated, “Based upon his flawed calculations, Bandak erroneously concluded that the neck forces in even the least severe shaking event far exceed the published injury tolerance of the infant neck. However, when accurately calculated, the range of neck forces is considerably lower, and includes values that are far below the threshold for injury. In light of the numerical errors in Bandak's neck force estimations, we question the resolute tenor of Bandak's conclusions that neck injuries would occur in all shaking events. Rather, we propose that a more appropriate conclusion is that the possibility exists for neck injury to occur during a severe shaking event without impact.” *Forensic Science International*, Shaken baby syndrome: A flawed biomechanical analysis, July 20,2005. (Defendant's Exhibit # 12)

Then, Dr. Duhaime and Ph.D. Margulies wrote a response to criticism in a letter to the editor from Drs. Uscinski, Thibault, and Ommaya stating that, “To summarize, new research is needed to determine if injuries can occur in the brain, cervicomedullary junction, or cervical spinal cord as a result of a single or series of head rotations at these low magnitudes, and if these injuries are primary or secondary in nature. Therefore, we cannot yet answer if shaking can cause intracranial injury in infants, and use of terminology that includes this mechanism should be avoided.” See *J. Neurosurg*. Volume 100/March, 2004. (Defendant's Exhibit # 1 4)

After discussing his review of the different reported studies on SBS, Dr. Uscinski testified that considering the latest evidence, we must look at the “unexplained head injury” in a different light. Dr. Uscinski testified that trivial head impact after a fall of as little as 3 feet results in the same impact as hitting a hard surface at 9 miles per hour which is more than twice that

necessary to fracture the skull of an infant. His point was that what seems like trivial head impacts for an infant, like falling off of a bed or out of a chair, may result in a chronic subdural hematoma manifesting itself much later. He pointed out that we should not jump to the conclusion that there has been parental shaking.

Dr. Uscinski testified that when a doctor first sees a child with a chronic subdural hematoma, it might exhibit fresh blood that is interpreted by the doctor of a recent injury. However, Dr. Uscinski stated that fresh blood has been observed in chronic subdural hematomas in adults and does not have to suggest a recent injury at all. In fact Dr. Uscinski stated that most neurosurgeons are aware that fresh bleeding can occur in chronic subdural hematomas along with older bleeding comprising the hematoma. Neurosurgeons are very much aware of this re-bleeding, and have observed it even when they know that there has not been an accompanying second trauma. Dr. Uscinski concluded that, “for an infant presenting with ostensibly unexplained intracranial bleeding with or without external evidence of injury under given circumstances, accidental injury from a seemingly innocuous fall, perhaps even a remote one, or even an occult birth injury, must be considered before assuming intentional injury.” *Neuro Med Chir* (Tokyo) Shaken Baby Syndrome: An Odyssey, (Ronald H. Uscinski) 46,57-61, 2006. (Defendant's Exhibit # 4) He concluded that, “some 32 years of cumulative material yielded inadequate scientific evidence to establish a firm conclusion on most aspects of causation, diagnosis, treatment, or any other matters pertaining to shaken baby syndrome.” Uscinski, supra. He also stated, “it was impossible to determine with scientific rigor what role shaking may have played in abusive head injury in these reported cases. Finally, it was not possible from the case analyses to infer that any particular form of intracranial or intraocular pathology was causally related to shaking, and that most of the pathologies in allegedly shaken babies were due to impact injuries to the head and body.” Uscinski, supra.

The Commonwealth called Dr. Betty S. Spivack, M.D. to the stand to testify. She is a forensic pediatrician with the Office of the Chief Medical Examiner located in Louisville, Kentucky. She graduated from Cornell University with a Bachelor of Arts in 1975 majoring in biology and mathematics. She earned her M.D. degree from S.U.N.Y. at Buffalo School of Medicine in 1979. She completed her residency in pediatrics at Children's Hospital of Buffalo from July 1979 to June 1982. She received a fellowship in pediatric critical care at Children's Hospital of Buffalo from July 1982 to June 1984; and a fellowship in forensic pediatrics from the Child Protection Program, Hasbro Children's Hospital at Brown University in Providence, Rhode Island. She attended an advanced course in child sexual abuse evaluation at Orange, California from June 21 to 25, 2004. Her academic appointments include assistant professor of pediatrics at S.U.N.Y. at Buffalo School of Medicine from July 1984 to April 1989, and at the University of Connecticut from May 1989 to June 1995. She has been an adjunct professor at the University of Hartford; an assistant clinical professor of pediatrics at the University of Wisconsin and the University of Louisville. She has published articles on the subject of SBS including *Pathobiology and Biomechanics of Inflicted Childhood Neuro-*

trauma by Susan S. Margulies, Ph.D., and Betty S. Spivack, M.D. (Commonwealth's Exhibit # 11)

Dr. Spivack testified in the form of a PowerPoint presentation. (Commonwealth's Exhibit #10) She entitled her presentation “The Biomechanics of Abusive Head Trauma” and outlined the history of research in the area of Shaken Baby Syndrome. She then answered additional questions from the Commonwealth and then under cross-examination from the Defense.

Dr. Spivack testified that the injury would tell the story. She stated that the primary brain injury is a direct result of mechanical forces associated with complicating factors. She stated that the Duhaime study had never been duplicated.

She opined that a child with a subdural hematoma and retinal hemorrhages bilateral (in both eyes) and a manifest contusion (bruise that you can see) was sufficient evidence that a doctor would say that a crime had been committed. Presumably, she was talking about that amount of suspicion that would cause a reasonable doctor in Kentucky to believe he/she was legally obligated to report child abuse to the Cabinet for Families and Children. She also testified that a subdural hematoma coupled with bilateral retinal hemorrhages was also evidence of a crime, and would presumably invoke the same responsibility on a doctor to report the incident to the Cabinet.

Dr. Spivack testified that she had co-authored a paper with Dr. Susan S. Margulies, Ph.D. that is titled *Pathobiology and Biomechanics of Inflicted Childhood Neurotrauma*, previous mentioned. In her paper Dr. Spivack pointed out that Ommaya concluded that neck or spinal cord injury would be present in all cases if whiplash only injury caused SDH or other intracranial pathology. “However, previous studies do not consistently support this hypothesis.” See Spivack, supra.

Dr. Spivack also testified that, “Retinal hemorrhages also seem to have a much stronger correlation with abusive head trauma than with unintentional head trauma, even when the unintentional injury is severe.” Spivack, supra.

Dr. Spivack concluded in her paper that, “While the general paradigm of TBI (traumatic brain injury) has a solid research basis, the applicability of this paradigm to the spectrum of injuries seen in victims of abusive head trauma still presents significant gaps and challenges. **Basic biomechanical properties have not been well established for infant skull or brain tissues, nor has the infant neck been well characterized. Early evidence indicates that simple brain mass scaling does not accurately predict threshold for traumatic axonal injury in immature brains. Little or no experimental work has been performed using oscillatory loads, such as shaking, to derive injury threshold in either mature or immature animals.**” See Spivack, supra.

Dr. Spivack posed a number of questions and pointed out that further research will hopefully provide us with the answers. These questions include:

1. What is the deformation tissue tolerance of pediatric brain and cord (for primary injuries, such as contusions, tissue tears, hemorrhages, and axonal transport disruption), and bridging veins?
2. Do repetitive events alter the tissue's thresholds for injury?
3. Is shaking the same thing as whiplash?

4. How does development and myelination affect these thresholds?
5. Do gray and white matter have differing thresholds for injury?

Dr. Spiveck testified that one question lead to another, and that a lot of research was currently ongoing in the area of SBS.

Dr. Spiveck also testified that history plays a significant role in assisting a doctor diagnose child abuse and cited an article that appeared in *Pediatrics* Magazine in 2003 as proof to support her conclusion. Drs. Joeli Hettler, M.D., and Dr. David S. Greenes, M.D. wrote the article that concluded, “We have found that infants who have a head injury and present with no history of trauma are highly likely to be victims of child abuse. Similarly, infants with head injury and persistent neurologic injury and a history of low-impact trauma are highly likely to be victims of abuse. Cases in which the history changes or the injury is blamed on home resuscitative efforts are likely to represent abuse as well. Our data support the use of these historical features as diagnostic criteria for identifying cases of abuse.” *Pediatrics*, Can the Initial History Predict Whether a Child With a Head Injury Has Been Abused? Vol. 111, No. 3, March 2003.

Conclusions of Law and Opinion

The burden of proof is on the party offering the evidence. *Staggs v. Commonwealth*, 877 S.W.2nd 604 (Ky. 1993) Thus, the burden of proof is on the Commonwealth to prove that the offered evidence meets the Daubert test since they are attempting to introduce evidence into the trial of SBS. But, the Defense could not just challenge the SBS expert testimony without producing initial evidence that expert testimony by the Commonwealth’s expert could not be presented to a jury for Daubert reasons. There is a burden shift from the party offering expert testimony to the party opposing the testimony. *Florence, Vs. Commonwealth*, 120 S.W.3d 699, (Ky. 2003) Therefore, the Defense presented their evidence first.

The aspects of the Daubert doctrine are incorporated into KRE 703 that reads:

- (a) The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonable relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.
- (b) If determined to be trustworthy, necessary to illuminate testimony, and unprivileged, facts or data relied upon by an expert pursuant to subdivision (a) may at the discretion of the court be disclosed to the jury even though such facts or data are not admissible in evidence. Upon request the court shall admonish the jury to use such facts or data only for the purpose of evaluating the validity and probative value of the expert’s opinion or inference.

The “preliminary assessment” that a trial judge must make is a “a flexible one” that requires the judge to focus “solely on prin-

ciples and methodology, and not on the conclusions that they generate,” *The Kentucky Evidence Law Handbook* (4th Edition), Lawson, Robert G., (LexisNexis, Matthew Bender, 2003). The assessment the court must make includes, but is not limited to:

- (1) whether the theory or technique in question can be (and has been) tested;
- (2) whether it has been subjected to peer review and publication;
- (3) its known or potential rate of error;
- (4) the existence and maintenance of standards controlling its operation; and
- (5) whether the theory or technique has been generally (or widely) accepted in a relevant scientific community. *Daubert v. Merrel Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-594, 113 S. Ct. 2786, 2796-2797, 125 L. Ed. 2d 469,482-483 (1993).

We, begin our Daubert analysis with whether the theory of SBS can and has been tested. Most of the studies that have been conducted thus far are not conclusive that SBS is caused by shaking the baby.

Dr. Caffey’s study admitted his conclusion that SBS was caused by shaking was, “both direct and circumstantial.” Dr. Caffey suspected that shaking a baby can cause neurological damage and suggested only that a nationwide campaign be initiated. Caffey even stated that his conclusions were, “manifestly incomplete and largely circumstantial.” Caffey, *supra*.

In 1968 Ommaya conducted studies upon rhesus monkeys for the purpose of trying to assess injuries for whiplash for humans in automobile collisions. Ommaya concluded that when the monkey was placed in an acceleration chair that injury to 19 of 50 monkeys sustained head and neck injuries without significant direct head impact. Ommaya, *supra*. Dr. Uscinski pointed out that the key here was no “significant direct head impact.” Later researchers began to realize that the monkeys still possibly sustained impact to their heads as a result of hitting their heads on the back of the chair or on their bodies due to the significant forces involved.

Dr. Uscinski also pointed out that the impact curve created by Ommaya was only a projection of at what threshold the scientists believed humans would sustain injuries. It failed to take into account the different structure of human babies as compared to adult monkeys, and what impact this difference would make.

Dr. Guthkelch conducted a study in 1971 in which he was examining why in some cases the doctors observed SBH’s (subdural hematoma) in babies, some without any other evidence of direct violence. In other words he observed that some babies have no bruises or other evidence of direct violence, yet they still observe subdural hematomas in the baby. Dr. Guthkelch was unable to explain a mechanism for this observation. He concluded his paper by stating that, “Subdural haematoma is one of the commonest features of the battered child syndrome, yet by no means all the patients so affected have external marks of injury on the head. This **suggests** that in some cases repeated acceleration/deceleration rather than direct violence is the cause of the hemorrhage, the infant having been shaken rather than struck by its parent. Such an **hypothesis** might also explain the remarkable frequency of the finding of subdural hemorrhage in

battered children as compared with its incidence in head injuries of other origin, and the fact that it is so often bilateral.” See Guthkeoch, *supra*. Dr. Guthkelch even came out and stated that his idea was only a hypothesis, and that his observations might “suggest” a possible explanation. Dr. Uscinski pointed out that Guthkelch’s work was based on several case studies and not a scientific examination using controlled experiments. Furthermore, Guthkelch leaned heavily on Ommaya’s possibly flawed study.

Next, Dr. Ann-Christine Duhaime, M.D. and Thomas A. Gennarrelli, M.D. conducted a biomechanical study to test the hypothesis that infants were particularly susceptible to injury from shaking due to a relatively large head and weak neck. The research team opined that, “the shaken baby syndrome, at least in its most severe acute form, is not usually caused by shaking alone. Although shaking may, in fact, be a part of the process, it is more likely that such infants suffer blunt impact.” Duhaime, *supra*. The Duhaime study concluded, “Severe head injuries commonly diagnosed as shaking injuries required impact to occur and that shaking alone in an otherwise normal baby is unlikely to cause the shaken baby syndrome.” Duhaime, *supra*. Much of the testing leads one to the conclusion that the baby must experience a blunt head trauma in order to injure the child to the point it has a subdural hematoma and bilateral retinal bleeding. But, blunt head trauma does not always have to leave a mark such as a bruise or other injury. Further research must be conducted in the area of biomechanics of babies.

Faris A. Bandak conducted a second biomechanics study in 2004. This study concluded, “An infant head subject to the levels of rotational velocity and acceleration called for in the SBS literature, would experience forces on the infant neck far exceeding the limits for structural failure of the cervical spine.” See Bandak, *supra*. In other works (*sic*, words), shaking alone would cause broken necks before one would expect to see subdural hematomas and ocular bleeding. Dr. Bandak concluded his paper with a call for a re-valuation of the current diagnostic criteria for shaken baby syndrome.

Dr. Spivack concluded in the paper she co-authored with Dr. Margulies that little or no experimental work had been conducted to determine the thresholds necessary to drive injury in either mature or immature animals such as pigs. Thus, she recommended that research must continue to determine the answer to questions such as whether shaking is the same thing as whip-lash, whether repetitive shaking alter the thresholds for injury, and just how much stresses can a baby brain be exposed to before injuries such as contusions, tissue tears, and hemorrhages begin to occur?

Dr. Spivack testified that, “Retinal hemorrhages also seem to have a much stronger **correlation** with abusive head trauma than with unintentional head trauma, even when the unintentional injury is severe.” See Spivack, *supra*.

A correlation in mathematics does not imply cause and effect. Mathematical correlations are numbers between -1 and +1 that describe when one event occurs, then, another event will follow. A positive correlation means that when one event occurs, one can observe that another event seems to occur as well. A negative correlation means that when one event occurs, then one observes that another event does not occur as often. When an observed set of events is observed, then a correlation of +1

means that the other event always occurs. When an observed set of events are observed, then a correlation of -1 means that the other event never occurs. For example, the amount of beer consumption and teacher salaries have a positive correlation. Does that mean that to raise teacher’s salaries, we must increase beer drinking? Certainly not! Teacher’s salaries and beer consumption are not events that cause each other. Instead, they are events that occur when another factor occurs, as in the example, that the economy is going well and people have money at their disposal. One does not cause the other. When Dr. Spivack observed that there was a stronger correlation between retinal hemorrhages with abusive head trauma than with unintentional head trauma, even when the unintentional injury is severe, this does not mean that every time a doctor observes retinal hemorrhages that abuse has occurred. It may be that the retinal hemorrhage is caused by something else. In fact that is exactly what Dr. Uscinski pointed out. He said that there is increasing evidence from studies currently being conducted in Japan that the retinal hemorrhages are the result of the subdural hematoma blood flowing through paths that were previously unknown.

There can be little doubt that some testing has been accomplished by researchers, however, their conclusions tend to point to shaking alone without impact does not cause the subdural hematoma or retina bleeding. The research is not yet completed and no definitive conclusions have been reached.

The physicians, on the other hand, use a subdural hematoma and bilateral retinal bleeding as criteria for diagnosing abuse in the form of SBS. Dr. Spivack made it clear that physicians currently use this diagnostic criterion. These classical markers of diagnosing an infant brain are certainly in the realm of physician’s duties. However, the diagnosis presupposes the cause. The physician is diagnosing the legal conclusion that someone has battered this child even without manifest signs of bruising, broken bones, or other evidence. The diagnosis is based upon research beginning over 30 years ago that made it into the medical field through research that is ongoing yet not conclusive. In fact the research is beginning to indicate that other causes totally unrelated to child abuse could be responsible for the injuries. The best the Court can conclude is that the theory of SBS is currently being tested, yet the theory has not reached acceptance in the scientific community. The theory of SBS may be accepted in the clinical medical community, but it could be based on flawed studies and concepts that are currently being tested and retested.

The next criterion to be examined by the Court is whether SBS has been subjected to peer review and publication. It certainly has, and the peer review through publication has reached only the conclusion that additional testing must be accomplished before physicians obtain the actual reasons for the observed subdural hematoma and bilateral ocular bleeding absent any manifest injuries such as bruising and broken bones.

There is no known or potential rate of error in the studies that have been completed. Some studies have been conducted in accordance with established scientific protocols rendering their conclusions useful in the area of SBS. However, other studies are merely educated guesses as to the cause of SBS based upon empirical studies, anecdotal cases, and advice to the public based on common sense.

The existence and maintenance of standards controlling the study of SBS certainly exists. However, not all of the studies have observed the scientific method in reaching conclusions. In fact the most damning studies supporting SBS are the ones that failed to follow the scientific method. The more recent studies appear to utilize a more scientific methodology to their research, but their preliminary conclusions appear to support the conclusion that the subdural hematoma and bilateral ocular bleeding are not caused by shaking alone, but require blunt force impact.

Physicians routinely diagnose SBS and that has gained wide or general acceptance in the clinical medical community, if the baby has the two classical medical markers of subdural hematoma and bilateral ocular bleeding without any other manifest injuries. However, this diagnosis is based on inconclusive research conducted in the scientific research community. SBS has gained wide or general acceptance in the clinical community and research community, if the baby has the two classical medical markers of subdural hematoma, bilateral ocular bleeding, and other manifest observable injuries such as broken bones, bruises, etc. To allow a physician to diagnose SBS with only the two classical markers, and no other evidence of manifest injuries, is to allow a physician to diagnose a legal conclusion. If the physician has the two classical markers (subdural hematoma and bilateral ocular bleeding) coupled with other manifest injuries, then the diagnosis arises to more than a legal conclusion—it becomes a medical opinion.

The Court can only conclude that SBS has not gained wide or general acceptance in the scientific community for the purposes of allowing an expert to testify that a baby has been subjected to abuse when the baby exhibits a subdural hematoma, bilateral ocular bleeding with no other manifest injuries such as bruising, broken bones, etc. The Court can further conclude that based on the medical signs and symptoms, the clinical medical and scientific research communities are in disagreement as to whether it is possible to determine if a given head injury is due to an accident or abuse. Therefore, the Court finds that because the Daubert test has not been met, neither party can call a witness to give an expert opinion as to whether a child's head injury is due to a shaken baby syndrome when only the child exhibits a subdural hematoma and bilateral ocular bleeding. Either

party can call a witness to give an expert opinion as to the cause of the injury being due to shaken baby syndrome, if and only, the child exhibits a subdural hematoma and bilateral ocular bleeding, and any other indicia of abuse present such as long-bone injuries, a fractured skull, bruising, or other indications that abuse has occurred.

Order & Holding

Therefore, the Court orders and holds that neither party may call a witness to offer an expert opinion that a baby has received injuries as a result of being shaken, unless there exists clinical evidence of at least (sic, least) one subdural hematoma, bilateral ocular bleeding, and any other indicia of abuse present such as long-bone injuries, a fractured skull, bruising, or other indications that abuse has actually occurred.

Entered this 17th day of April, 2006.

LEWIS D. NICHOLLS
CIRCUIT JUDGE

I, Allan Reed, hereby certify that a true and correct copy of this document has been sent by U. S. Mail, postage repaid, to the following:

Hon. Clifford Duvall
Commonwealth Attorney
20 I Harrison Street
Greenup, Kentucky 41144

Hon. Samuel Weaver
Department of Public Advocacy
Courthouse 3d Floor
Catlettsburg, Ky. 41120
(606)-739-4 161
Fax (606)-739-8388