

Lucas v Montefiore Med. Ctr.
2018 NY Slip Op 31528(U)
June 14, 2018
Supreme Court, Bronx County
Docket Number: 300657/2010
Judge: Lewis J. Lubell
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SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF BRONX - PART IA-19A

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CARL LUCAS and MICHAEL LIPPMAN, as co-
administrators of the Estate of J.P.,

Plaintiff(s),

- against -

INDEX NO: 300657/2010

MONTEFIORE MEDICAL CENTER, JAMES
GOODRICH, M.D., CHHAVI KATYAL, M.D., and
KIMME CARROLL, R.N.,

DECISION/ORDER

Defendant(s).

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HON. LEWIS J. LUBELL:

Motion by defendants for an order precluding plaintiffs from presenting certain expert testimony at trial as to the issue of causation pursuant to *Frye v United States* (293 F 1013 [DC Cir 1923]) (*Frye*), or, in the alternative, scheduling a *Frye* hearing on the issue of the admissibility of the expert's anticipated testimony on causation, is decided as follows. The issue presented on the present motion is whether plaintiffs have met their burden of proof that their expert's theory that low intracranial pressure causes infarcts in the brain was scientifically accepted and generally accepted in the medical community at the time of the alleged malpractice.

This action seeks damages for allegedly negligent medical care provided to J.P., now deceased, during her admission to Montefiore Medical Center commencing on October 11, 2007. J.P. was admitted to Montefiore Medical Center at the age of fifteen on October 11, 2007, after being diagnosed with a shunt infection at a Rhode Island Hospital and transferred. She was monitored and treated at Montefiore and underwent

a third ventriculostomy and removal and replacement of an externalized ventricular drainage system on October 17, 2007. After surgery she was taken directly to the pediatric ICU where a nurse connected an intracranial pressure monitor to the external ventricular drain. The patient did not emerge from anesthesia although she was stable and breathing on her own. As such, at about 5:30 p.m. a CT of the brain was ordered. The scan showed loss of gray-white differentiation involving the bilateral caudates and cerebellum consistent with acute ischemia. The findings were confirmed on another CT scan, by MRI and by consultation. The patient never regained consciousness and passed away months later.

Plaintiffs' expert is expected to testify in part that defendants departed from good and accepted medical practice in failing to diagnose and treat intracranial hypotension, defined by said expert as negative pressure within the brain, and returning the decedent to the ICU immediately following brain surgery which departure caused permanent brain injury and death.

Movant argues, as set forth in the affirmation of Margaret Parker, M.D., that plaintiffs' expert's theory that the diffused brain infarcts which led to J. P's death were caused by a failure to treat her negative intracranial pressure following the brain surgery was not accepted in the medical community at the time in question (and is not generally accepted in the community today). No such theory has been confirmed in any accepted medical literature. Defendants argue that in view of Dr. Parker's expert opinion that it was not accepted in the medical community in 2007 that negative intracranial pressure could cause diffused ischemic brain infarcts, or any significant brain injury, there is no basis for plaintiffs' expert's proposed testimony that defendant departed from accepted

practice by failing to recognize or treat the episode of negative intracranial pressure following the October 17, 2007 surgery, or that the failure proximately caused her death.

In opposition, plaintiffs argue that the testimony should be admitted and that no *Frye* hearing is necessary. Plaintiffs have provided the court with the affidavit of an expert, Gregory B. Hammer, and with medical articles in support of plaintiff's theory of liability. Plaintiffs agree that Dr. Parker's conclusory affidavit incorrectly states that there is no medical support for a link between hypotension and brain infarcts. Dr. Hammer opined, within a reasonable degree of medical certainty, that there is a direct causal relationship between intracranial hypotension and ischemic infarcts in the brain, and that ICP must be treated to avoid the brain injury that ultimately resulted in J.P.'s death. Contrary to Dr. Parker, this expert describes the theory of the failure to treat negative ICP as constituting a breach of the standard of care as well as a theory that is accepted in the community. Dr. Hammer opines that when J.P. was found to have low intracranial pressure after her operation, the diagnosis of intracranial hypotension was made, which was almost certainly related to over drainage of cerebral spinal fluid during surgery, and that good and accepted practice mandated the immediate increase of the intracranial pressure emergently to prevent ongoing brain compression and compromise that resulted in brain injury.

Plaintiffs have also provided the court with articles that they argue directly contradict Dr. Parker's assertion.

In reply, movants argue that the literature offered by plaintiffs' expert is comprised entirely of case reports and articles which do not refer to intracranial pressure causing cerebral infarcts or significant permanent brain injury, and that these

articles are fundamentally speculative. Defendants argue that a perusal of the articles indicates that they report on anecdotal, individual cases where a relationship between intracranial hypotension and cerebral infarcts is “suggest[ed]”, “thought”, or “hypothesized”. Defendants maintain that this language is not conclusive, and does not demonstrate that plaintiff’s theory was generally accepted in the medical community at that time.

Analysis

New York follows the rule of *Frye* “that expert testimony based on scientific principles or procedures is admissible but only after a principle or procedure has ‘gained general acceptance’ in its specified field” (*People v Wesley*, 83 NY2d 417, 422, 633 NE2d 451, 611 NYS2d 97 [1994], quoting *Frye v United States*, 293 F at 1014). “*Frye* is not concerned with the reliability of a certain expert’s conclusions, but instead with whether the [expert’s] deductions are based on principles that are sufficiently established to have gained general acceptance as reliable.” (*Nonnon v City of New York*, 32 A.D.3d 91,103, 819 N.Y.S.2d 705 [1st Dept. 2006], *affd* 9 N.Y.3d 825, 842 N.Y.S.2d 756, 874 N.E.2d 720 [2007] [internal quotation marks omitted].) “[G]eneral acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion. Rather it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions” (*Zito v Zabarsky*, 28 A.D.3d 42, 44, 812 N.Y.S.2d 535 [2d Dept. 2006] [internal quotation marks omitted].) A *Frye* hearing is not required in a medical malpractice case where novel scientific

issues are not implicated. (See *Johnson v Guthrie Med. Group, P.C.*, 125 A.D.3d 1445, 1447, 3 N.Y.S.3d 828, 831 [4th Dept. 2015] [allowing plaintiff's theory, and holding *Frye* hearing was not required, where plaintiffs' experts laid a foundation for the theory that the child's cognitive deficits were caused by treatment with IFN-a with generally accepted medical principles of the cognitive effects on adults treated with IFN-a, a chemotherapeutic agent, and the cognitive effects of chemotherapy on the developing brain of a child]).

To satisfy *Frye*, a peer-reviewed case study is not invariably required. In *LaRose v Corrao*, 105 A.D.3d 1009, 1010, 963 N.Y.S.2d 712, 714 [2d Dept. 2013]), defendants' expert physician failed to produce a case or study unequivocally establishing that an MRI scan performed within hours of a transforaminal epidural injection would have conclusively revealed any injury caused by that procedure. Nevertheless, he demonstrated that his theory was reasonably permitted by a synthesis of medical literature which established that the expert's theory had an objective basis and was founded upon more than theoretical speculation or a scientific hunch. The absence of textual authority to support the theory pertained to the weight to be given to his testimony, but did not preclude its admissibility.

Nor does *Frye* invariably require that the literature relied on to establish general acceptance must involve circumstances virtually identical to those of the plaintiff. (*Victor Q. v Bronx Lebanon Hosp. Ctr.*, 149 A.D.3d 456, 456, 52 N.Y.S.3d 42, 43 [1st Dept. 2017] [holding that, after *Frye* hearing, articles proffered by plaintiffs were sufficient to establish that it was generally accepted that perinatal hypoxia can be the cause of brain injury, in the absence of evidence of neurological injury in the neonatal

period; that the infants in the articles exhibited manifestations of hypoxia not exhibited by the infant plaintiff was irrelevant].)

In *Ratner v McNeil-PPC, Inc.*, 91 A.D.3d 63, 933 N.Y.S.2d 323 (2d Dept. 2011), as in the present case, plaintiff advanced a novel theory of medical causation. The plaintiff in *Ratner* alleged that the long-term use of acetaminophen caused liver cirrhosis, which was “primarily, if not exclusively, supported by extrapolation from a few observational case studies.” (*Id* at 64.) Plaintiff’s evidence was found to be insufficient to establish a causal link. Significantly, however, the Court opined that:

“Hence, where a plaintiff’s qualified experts offer no novel test or technique, but intend to testify about a novel theory of causation, where such opinion is supported by generally accepted scientific methods, it is proper to proceed directly to the foundational inquiry of admissibility, which is whether the theory is properly founded on generally accepted scientific methods or principles (*see Parker v Mobil Oil Corp.*, 7 NY3d at 447 [explaining that because “(t)here is no particular novel methodology at issue for which the Court needs to determine whether there is general acceptance ... the inquiry here is more akin to whether there is an appropriate foundation for the experts’ opinions”]; *People v Garrow*, 75 AD3d 849, 852, 904 NYS2d 589 [2010] [*Frye* hearing was not required because expert testimony offered by the prosecution did not involve any novel procedures or innovative scientific theory]; *Nonnon v City of New York*, 32 AD3d 91, 819 NYS2d 705 [2006], *affd* 9 NY3d 825, 874 NE2d 720, 842 NYS2d 756 [2007] [in action where plaintiffs alleged that elevated levels of toxic substances at Pelham Bay Landfill caused their injuries, the court held that plaintiff’s experts’ testimony, based upon deductions of epidemiologists and toxicologists, was not novel and therefore admissible without a *Frye* hearing]; *see also Marsh v Smyth*, 12 AD3d at 312-313 [Saxe, J., concurring] [“(u)nlike a newly developed test or process, a (novel) theory about the mechanism of an injury will not prompt the profession generally to weigh in with its own studies or publications on the subject”; thus, “to require proof ... that a propounded theory of causation is accepted by a substantial percentage of the profession, would be to impose a virtually insurmountable hurdle”]).” (*Id* at 73.)

(*See Parker v. Mobil Oil Corp.*, 7 N.Y.3d 434, 447, 857 N.E.2d 1114, 1120, 824 N.Y.S.2d 584, 589 [2006] [inquiry whether plaintiff’s exposure to benzene in gasoline

caused plaintiff to develop acute myelogenous leukemia was “more akin to whether there is an appropriate foundation for the experts’ opinions, rather than whether the opinions are admissible under *Frye*.”])

In *Lugo v. New York City Health & Hosps. Corp.* (89 A.D.3d 42, 929 N.Y.S.2d 264 [2d Dept. 2011]), a medical malpractice action, applying the *Frye* test, the Second Department determined that the opinion testimony of the plaintiffs’ experts that the infant plaintiff’s brain injuries were caused by an episode of severe neonatal hypoglycemia lasting 81 minutes was admissible. The Court reasoned as follows:

“New York courts have also applied the *Frye* test to assess the reliability of an expert’s theory of causation in a particular case. For this category of expert opinion testimony, “it is not necessary ‘that the underlying support for the theory of causation consist of cases or studies considering circumstances exactly parallel to those under consideration in the litigation. It is sufficient if a synthesis of various studies or cases reasonably permits the conclusion reached by the plaintiff’s expert’” (*Zito v Zabarsky*, 28 AD3d at 44, quoting *Marsh v Smyth*, 12 AD3d at 312-313 [Saxe, J., concurring]; see *DieJoia v Gacioch*, 42 AD3d at 979). “The fact that there [is] no textual authority directly on point to support the [expert’s] opinion is relevant only to the weight to be given the testimony, but does not preclude its admissibility” (*Zito v Zabarsky*, 28 AD3d at 46; see *DieJoia v Gacioch*, 42 AD3d at 979).

“Accordingly, this Court has affirmed the preclusion of expert testimony as to causation in circumstances where there was a complete absence of any literature or studies supporting the particular causation theory espoused by the expert. . . .

“Standing in sharp contrast are cases in which the expert’s opinion satisfied the *Frye* test because it was deduced from generally accepted scientific principles and supported by existing data or literature, although the expert could not point to a case or study involving circumstances exactly parallel to those at issue in the litigation to support his or her theory of causation.” (*Lugo v. New York City Health & Hosps. Corp.*, supra, 89 A.D.3d at 57-58.)

In *Heckstall v. Pincus* (19 A.D.3d 203, 797 N.Y.S.2d 445 [1st Dept. 2005]), plaintiff sought to recover damages for wrongful death allegedly resulting from decedent’s consumption of two tablets of Bupropion, prescribed by defendant physician

as a smoking cessation aid. In reversing and dismissing the claims for strict products liability and medical malpractice, the Court found that plaintiff failed to submit scientific evidence sufficient to raise an issue of fact as to whether his theory of causation had gained general acceptance in the scientific community. Plaintiff's evidence consisted of the Canadian Adverse Drug Reaction Letter, reports of the British Regulatory Body MCA and the Center for Drug Evaluation and Research for the improved Bupropion package insert, as well as other studies. This evidence was insufficient because, "Courts have recognized that such observational studies or case reports are not generally accepted in the scientific community on questions of causation." (19 A.D.3d at 205 [citation omitted].) (See also, *Pauling v. Orentreich Med. Group*, 14 A.D.3d 357, 787 N.Y.S.2d 311 [1st Dept. 2005] [at *Frye* hearing, rejecting theory that facial injections of liquid silicone over a long period of time, administered to plaintiff as an acne treatment, could cause a novel disease termed "silicon toxicity," which was largely based on the expert's own observational studies].)

In the present case, the *mechanism* of plaintiff's theory of causation is based on accepted scientific principles culled from various sources (as in *Parker* or *Ratner*), or whether the underlying mechanism of injury is based on novel scientific theories. Moreover, an analysis of the articles presented requires expert elucidation as to whether they are merely anecdotal, or whether the plaintiffs' experts theory is a natural extension of existing knowledge. For example, one article entitled *Intracranial hypotension: clinical presentation, imaging findings, and imaging-guided therapy*, (August 2014) describes spontaneous intracranial hypotension following, *inter alia*, excessive surgical cerebrospinal fluid drainage (as alleged here), and summarizes its

results as, “Clinical presentation as well as diagnostic and therapeutic approaches in intracranial hypotension are very heterogenous.” Another, *Intracranial Hypotension Syndrome: A Comprehensive Review* (February 2004), reports that, “Intracranial hypotension is considered to be a benign condition . . . however, atypical disabling presentations are increasingly recognized including . . . death.”

In this regard, reference must be made to the First Department’s analysis in *Sepulveda v Dayal* (143 A.D.3d 591, 593, 39 N.Y.S.3d 451 [1st Dept. 2016]), in which the infant plaintiff was born with a neuroblastoma tumor, causing spinal cord damage. Physicians did not detect any anomalies during a prenatal ultrasound performed at 30.9 weeks of gestation; the actual images were not preserved. Defendants’ experts opined that a physician could not identify the size of a tumor in utero based upon the size of the tumor at diagnosis, because these tumors grow aggressively and inconsistently, and sometimes even shrink, and thus there was no scientifically accepted standard of “tumor doubling times” in assessing the size and development of a neuroblastoma. On the other hand, plaintiff’s three experts opined that the tumor should have been detected on the sonogram taken at 30.9 weeks. The first stated that because the infant became unable to move her lower extremities soon after her birth, the deterioration must have been “huge” in the infant’s third trimester. A second expert cited articles showing that fetal neuroblastomas have been detected by routine prenatal sonography. The third testified that, based on studies involving mice, and based on the clinical behavior of the infant’s “huge” tumor, the neuroblastoma was more likely than not detectable at the ultrasound performed at 30.9 weeks.

The First Department held that the trial court properly directed that a *Frye*

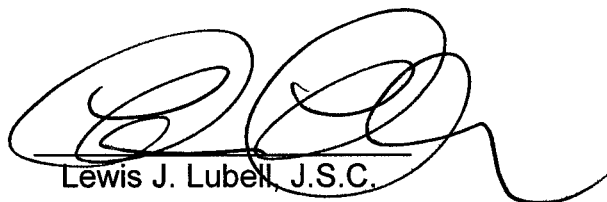
hearing be held, as plaintiffs' experts based their opinions partially on peer-reviewed, published articles stating that routine prenatal sonography had detected fetal neuroblastomas. In so holding, the Court observed the following:

"As noted above, plaintiffs' experts based their opinions partially on peer-reviewed, published articles stating that routine prenatal sonography had detected fetal neuroblastomas. Whether the information conveyed in these articles has gained general acceptance in the medical community, and thus provides support for the opinions of plaintiffs' experts, is precisely the topic of a Frye hearing. To reject the opinions of plaintiffs' experts before holding a Frye hearing would be to make a determination on the soundness of the experts' conclusions—a determination that would be premature without testing the reliability of the scientific evidence that plaintiffs have proffered." (*Sepulveda v Dayal, supra*, 143 A.D.3d at 593.)

This Court accordingly directs a hearing on *Frye* and the related issues raised herein (whether the plaintiff's theory is generally accepted, both generally and at the levels of hypotension at issue in this case; whether there is an appropriate foundation for the expert's opinions; and, whether the opinions represent the standard of care at the time of the alleged medical malpractice).

The parties are directed to confer with each other and communicate acceptable hearing dates to the Part Clerk, who shall then advise the parties of the hearing date(s) approved by the Court.

Dated: JUNE 14, 2018


Lewis J. Lubell, J.S.C.