

SUPERIOR COURT OF THE STATE OF DELAWARE

Scottoline v. Women First, LLC

C.A. No. N19C-08-135 AML (Del. Super. Ct. Mar. 1, 2023) · No. N19C-08-135 AML · Decided March 1, 2023

SUMMARY

The Delaware Superior Court granted Defendants’ motion to exclude the plaintiffs’ expert causation opinion in a medical negligence action. The court held that the expert’s opinion linking hypoxic-ischemic encephalopathy to the child’s autism-spectrum behavioral syndrome lacked a reliable scientific basis and was not the product of a reliable methodology ruling out alternative causes.

CASE DETAILS

COURT	Superior Court of the State of Delaware
WRITING FOR THE COURT	LeGrow, J.
JURISDICTION	Delaware Superior Court
DECIDED	March 1, 2023
DOCKET	N19C-08-135 AML
DISPOSITION	other
PROCEDURAL POSTURE	Defendants moved in limine to exclude plaintiffs’ medical expert’s causation opinion that the child’s hypoxic ischemic encephalopathy caused his autism spectrum disorder or behavioral syndrome within the autism spectrum.
STANDARD OF REVIEW	The court independently assessed the relevance and reliability of the challenged expert testimony under Delaware Rule of Evidence 702 and the Daubert standard; the proponent bears the burden of establishing admissibility by a preponderance of the evidence.
PRECEDENTIAL VALUE	Published memorandum opinion; no separate precedential designation stated in the source.

TOPICS

- expert testimony
- daubert standard
- evidence
- medical malpractice

PRACTICE AREAS

- evidence
- medical malpractice
- health law

QUESTIONS PRESENTED

1. Whether Dr. Adler’s opinion that J.S.S.’s HIE caused his autism spectrum disorder or ASD-related behavioral syndrome had a reliable scientific basis under Delaware Rule of Evidence 702.
2. Whether Dr. Adler employed a reliable methodology to rule in and rule out alternative causes of J.S.S.’s ASD before offering a specific-causation opinion.

HOLDINGS

1. The opinion was inadmissible because it lacked a reliable scientific basis. The cited articles identified, at most, an association between HIE or related perinatal conditions and ASD, and none established that HIE causes ASD.
2. The opinion was inadmissible because Dr. Adler did not use a reliable methodology to distinguish HIE as the cause of J.S.S.’s ASD from other potential causes.

KEY QUOTATIONS

“When a disease or disorder has several possible independent causes, an expert must “employ a definitive scientific process to rule in and rule out” the many potential causes of the disorder before reaching a conclusion.” (at 13)

“That ipse dixit opinion is not based on a reliable methodology and therefore is not admissible under Rule 702.” (at 15)

“For the foregoing reasons, Plaintiffs are precluded from introducing at trial Dr. Adler’s opinion or testimony that Hypoxic Ischemic Encephalopathy caused J.S.S.’s behavioral syndrome that falls within the autism spectrum.” (at 15)

FACTUAL BACKGROUND

J.S.S. was born after an allegedly oxygen-depriving labor and delivery and was diagnosed with hypoxic ischemic encephalopathy, with severe encephalopathy, seizures, and developmental injuries. He later developed developmental delays and behaviors consistent with autism spectrum disorder and was diagnosed with ASD by his school district. Plaintiffs’ pediatric neurologist, Dr. Daniel Adler, opined that the HIE injury caused J.S.S.’s ASD-related behavioral condition. The articles and materials Adler identified showed at most associations between perinatal conditions, HIE, and ASD, and he did not reliably exclude other potential causes, including genetic causes.

PROCEDURAL HISTORY

Plaintiffs filed a medical negligence action in 2019 and amended the complaint in 2021. Defendants moved to exclude Dr. Daniel Adler’s causation opinion under Delaware Rule of Evidence 702. The Superior Court granted the motion and precluded plaintiffs from introducing the challenged opinion or testimony at trial.

DISPOSITION

other

CASES CITED

- Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993)
- M.G. Bancorporation v. Le Beau, 737 A.2d 513, 521 (Del. 1999)
- Bowen v. E.I. DuPont de Nemours & Co., Inc., 906 A.2d 787, 794-95 (Del. 2006)
- Tumlinson v. Advanced Micro Devices, Inc., 81 A.3d 1264, 1269 (Del. 2013)
- Norman v. All About Women, P.A., 193 A.3d 726, 730 (Del. 2018)
- Wilant v. BNSF Railway Co., 2020 WL 2467076, at *4-5 (Del. Super. May 13, 2020)
- Melnick v. Consolidated Edison, Inc., 959 N.Y.S.2d 609, 623 (N.Y. Supreme Feb. 15, 2013)
- Frye v. United States, 293 F. 1013 (D.C. Cir. 1923)
- Minner v. American Mortgage & Guaranty Co., 791 A.2d 826, 854 (Del. Super. 2000)
- Scaife v. AstraZeneca LP, 2009 WL 1610575, at *16 (Del. Super. June 9, 2009)
- Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1319 (9th Cir. 1995)

OPINION

Scottoline v. Women First, LLC

PER CURIAM.

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

LAUREN SCOTTOLINE, individually) and as Parent and Guardian of J.S.S., a) Minor, and
STEVEN SCOTTOLINE,) Parent of J.S.S., a Minor,)

) C.A. No: N19C-08-135 AML

Plaintiffs,)) v.)) WOMEN FIRST, LLC, and)

CHRISTIANA CARE HEALTH)

SYSTEM, INC.)

) Defendants.) Submitted: December 15, 2022 Decided: March 1, 2023

MEMORANDUM OPINION

Upon Defendants' Motion to Exclude Unreliable Causation Opinion of Plaintiffs' Expert: GRANTED. Bruce L. Hudson, Esquire, and Joshua J. Inkell, Esquire of HUDSON & CASTLE LAW, LLC, Wilmington, Delaware, Attorneys for Plaintiffs. Bradley J. Goewert, Esquire, and Thomas J. Marcoz, Jr., Esquire of MARSHALL DENNEHEY WARNER COLEMAN & GOGGIN, Wilmington, Delaware, and David Batten, Esquire of BATTEN LEE, Raleigh, North Carolina, Attorneys for Defendant Women First, LLC. John D. Balaguer, Esquire, and Roopa Sabesan, Esquire, of WHITE AND WILLIAMS LLP, Wilmington, Delaware, Attorneys for Defendant Christiana Care Health System, Inc. LEGROW, J. This is a medical negligence case stemming from the birth of a child. The plaintiffs allege the child was deprived of oxygen during labor and delivery and sustained several injuries as a result of the defendants' negligent medical

care. It is undisputed that the child, now age seven, has an ongoing and permanent behavioral syndrome that falls within the autism spectrum. The plaintiffs' expert opines that the brain injury the minor child sustained during delivery proximately caused the behavioral condition that has been diagnosed as consistent with an autism spectrum disorder. Accordingly, some of the damages the plaintiffs seek are associated with that disorder. The defendants have moved to exclude the expert's opinion that the brain injury caused the minor child's autism spectrum disorder. The defendants argue the expert's opinion is inadmissible under the rules of evidence because it is not supported by appropriate scientific evidence. The defendants also argue the opinion is inadmissible because it is not the product of a reliable methodology that considered and excluded the other, diverse possible causes of an autism spectrum diagnosis. Because the proffered expert's opinion is not borne out by the evidence he cites in support of his causation conclusion, and because he did not use a reliable methodology to rule out the other potential causes for this condition, the expert opinion is not admissible. The defendants' motion therefore is granted. 1

FACTUAL AND PROCEDURAL BACKGROUND

The minor child, J.S.S., was born at Christiana Hospital on July 28, 2015. Four years later, J.S.S.'s parents filed this action against Christiana Care Health Services, Inc. ("CCHS") and Women First, LLC ("Women First" and collectively with CCHS, "Defendants"), the practice that delivered J.S.S. Plaintiffs allege Defendants' negligence caused J.S.S. to be deprived of oxygen during the birth, resulting in tissue and organ damage, including a permanent Hypoxic Ischemic Encephalopathy ("HIE") injury to his brain. The complaint alleges J.S.S. also suffered injuries to other organs, including his kidneys, liver, and muscle systems as a result of oxygen deprivation. J.S.S. was born with "no respiratory effort" and falling blood oxygenation levels. He was intubated within five minutes of his birth and experienced seizures approximately 20 minutes after his birth. The treating neurologist's and neonatologist's records indicate he was "extremely sick" and initial testing was "consistent with severe encephalopathy." J.S.S. was diagnosed with HIE six days after he was born. J.S.S. spoke before his first birthday and walked at approximately 16 months.¹ At 18 months, he stopped speaking. He slowly developed three-word sentences, but 1 Defs.' Mot. to Exclude Causation Opinion of Daniel Adler, M.D., Ex, 1, Report of Daniel Adler, M.D. dated June 4, 2019 (hereinafter, the "First Adler Report") at 2. 2 those sentences rarely were purposeful.² He began reading at age three but has significant attention issues at school.³ J.S.S. receives Special Education services along with occupational and speech therapy.⁴ In 2017 and 2018, J.S.S.'s treating clinicians noted developmental delays and behaviors "consistent with" an Autism Spectrum Disorder ("ASD") diagnosis.⁵ In May 2018, J.S.S. was diagnosed with ASD by his school district.⁶ He was reevaluated in February 2021, and that evaluation confirmed the previous ASD diagnosis. Further testing showed significant developmental delays, including in speech and language, social responsiveness, auditory comprehension, and expressive language.⁷ Plaintiffs filed this action on August 15, 2019 on behalf of J.S.S. and Lauren Scottoline, J.S.S.'s mother. The Amended Complaint, filed March 2, 2021, alleges Defendants provided negligent

medical care while Lauren Scottoline was hospitalized and during her labor and delivery with J.S.S., and Defendants' alleged negligence proximately caused J.S.S.'s injuries, including "physical injuries, emotional pain and suffering past and future, increased risk of harm, loss of chance, 2 Id. at 2. 3 Id. 4 Id. at 1-2. 5 Pls.' Response to Defs.' Mot., Ex. A, at CCHS00480, 483-84, 485-86, 489. 6 Id., Ex. B. 7 Id., Ex. D at 2-3, 10-13, 56, 69. 3 loss of enjoyment of life past and future, extensive medical bills past and future, extensive lifetime care bills, [and] loss of earnings."8 One of Plaintiffs' experts, Dr. Daniel Adler, is a pediatric neurologist whose opinion Plaintiffs offer to prove causation and damages. Dr. Adler examined J.S.S., reviewed his medical history, and issued two reports in this matter: one report dated June 4, 2019 (the "First Adler Report") and the other dated July 14, 2021 (the "Second Adler Report").9 In the First Adler Report, after summarizing J.S.S.'s relevant medical and social history, Dr. Adler opined that "all of J.S.S.'s neurological and neurodevelopmental disabilities are the result of the hypoxic ischemic brain injury [he] suffered during the labor and delivery process." 10 More specifically, Dr. Adler opined that his examination of J.S.S. "confirms that [his] behavior falls within the autism spectrum," and "while the causes of autism are diverse, in this case, the cause of J.S.S.'s qualitative disturbance in social interaction and play is [HIE]."11 Dr. Adler further opined that J.S.S.'s neurological injuries and disabilities are permanent in nature, he will not be able to live independently or be employed in the competitive job market, and he will "continue to require extraordinary medical care."12 The Second Adler Report confirmed that Dr. Adler's 8 Am. Compl. at 8. 9 Defs.' Mot. to Exclude Causation Opinion of Daniel Adler, M.D., Ex, 2, Report of Daniel Adler, M.D. dated July 14, 2021 (hereinafter, the "Second Adler Report"). 10 First Adler Report at 2-3. 11 Id. at 3. 12 Id. at 3. 4 previous findings and opinions remained unchanged after his July 2021 examination of J.S.S.13 CCHS moved to exclude Plaintiffs from introducing at trial evidence that HIE caused J.S.S.'s ASD, including any testimony to that effect by Dr. Adler.14 In support of its motion, CCHS offers two independent bases to exclude Dr. Adler's opinion. First, CCHS argues Dr. Adler's opinion should be excluded under Delaware Rule of Evidence 702 because Dr. Adler has not identified any scientific data or study showing a causal link between HIE and ASD. CCHS contends the articles Dr. Adler cited at most identify an association between ASD and HIE, which is not enough to establish causation. Second, CCHS separately argues Dr. Adler's opinion should be excluded because he has not established specific causation with respect to J.S.S. That is, Dr. Adler acknowledges there are numerous possible causes of ASD, including genetics, but he did not rule out those other causes or utilize a reliable methodology to conclude that J.S.S.'s ASD was caused by HIE. Plaintiffs respond that CCHS mischaracterizes Dr. Adler's opinion as stating that "HIE causes 'Autism'" when his opinion "is that [J.S.S.] suffered an HIE injury at birth which caused physical injuries and also neurological and neurobehavioral symptoms consistent with [ASD]."15 Plaintiffs argue Dr. Adler's opinion, once 13 Second Adler Report at 2. 14 Women First, LLC joined CCHS's motion. See D.I. 163, 169. 15 Pls.' Response to Defs.' Mot. at 4-5. 5 properly characterized, is the product of his training and experience as a pediatric neurologist, and

he relied on four articles that “support his contention that an HIE injury can produce certain behaviors that would fall within the autism spectrum.”¹⁶ Finally, Plaintiffs argue Dr. Adler made a differential diagnosis on the basis of his examination of J.S.S. and review of his medical history.

ANALYSIS

Delaware Rule of Evidence 702 controls the admissibility of expert testimony. Rule 702 allows a qualified expert to testify if (a) the expert’s specialized knowledge will help the trier of fact understand the evidence or determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case. The Delaware rule is substantially similar to Federal Rule of Evidence 702, which the United States Supreme Court construed in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*¹⁷ The Delaware Supreme Court has expressly adopted *Daubert* and its progeny as the correct interpretation of Delaware Rule of Evidence 702.¹⁸ 16 *Id.* at 13. 17 509 U.S. 579 (1993). 18 *M.G. Bancorporation v. Le Beau*, 737 A.2d at 513, 521 (Del. 1999). 6 Consistent with *Daubert*, Delaware courts apply a five-step test to determine the admissibility of scientific or technical expert testimony.¹⁹ That test examines whether: (a) the witness is qualified as an expert by knowledge, skill, experience, training, or education; (b) the evidence is relevant; (c) the expert’s opinion is based upon information reasonably relied upon by experts in the particular field; (d) The expert testimony will assist the trier of fact to understand the evidence or to determine a fact in issue; and (e) the expert testimony will not create unfair prejudice or mislead the jury.²⁰ A trial judge acts as a “gatekeeper” in deciding whether an expert’s opinion has “a reliable basis in the knowledge and experience of the relevant discipline.”²¹ Ultimately, the Court will examine an expert’s opinion based on the expert’s principles and methodology rather than on the conclusions generated.²² The party seeking to introduce expert testimony bears the burden of establishing its 19 *Bowen v. E.I. DuPont de Nemours & Co., Inc.*, 906 A.2d 787, 795 (Del. 2006). 20 *Id.* 21 *Id.* at 794 (quoting *M.G. Bancorporation v. Le Beau*, 737 A.2d at 523). 22 *Tumlinson v. Advanced Micro Devices, Inc.*, 81 A.3d 1264, 1269 (Del. 2013) (quoting *Daubert*, 509 U.S. at 595). 7 admissibility by a preponderance of the evidence.²³ There is a “strong preference” for admitting expert opinions “when they will assist the trier of fact in understanding the relevant facts or the evidence.”²⁴ I. Dr. Adler’s causation opinion as to J.S.S.’s Autism Spectrum Disorder is not admissible because it does not have a reliable scientific basis. Once expert testimony is challenged, the reviewing court must ensure that the proffered testimony is both relevant and reliable.²⁵ Evidence is relevant if it would assist the fact finder in “understand[ing] the evidence or determin[ing] a fact in issue.”²⁶ Expert testimony is reliable if it is premised on technical or specialized knowledge, which requires the testimony to be grounded in reliable methods and procedures and “supported by appropriate validation – i.e., ‘good grounds,’ based on what is known.”²⁷ In his reports, Dr. Adler opines that all J.S.S.’s neurological and neurodevelopmental disabilities are a result of the HIE injury he suffered during labor and delivery.²⁸ Dr. Adler confirmed that J.S.S.’s behavior “falls within the

autism spectrum.”²⁹ While acknowledging that “causes of autism are diverse,” Dr. 23 Bowen, 906 A.2d at 795. ²⁴ Norman v. All About Women, P.A., 193 A.3d 726, 730 (Del. 2018). ²⁵ Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 597 (1993). ²⁶ Id. at 591 (quoting Fed. R. Evid. 702). ²⁷ Id. at 590. ²⁸ First Adler Report at 3; Second Adler Report at 2. ²⁹ First Adler Report at 3; see also Second Adler Report at 2 (“J.S.S. remains a boy with . . . a behavioral syndrome that is within the autism spectrum.”) ⁸ Adler states that “in this case, the cause of J.S.S.[’s] qualitative disturbance of social interaction and play is [HIE].”³⁰ Dr. Adler’s reports do not further explain how he reached this conclusion. Dr. Adler’s reports do not cite any article, study, or other authority in support of his conclusion that HIE can cause ASD. When asked before and during his deposition for the sources he relied on in forming his opinion, Dr. Adler identified four medical articles as well as the diagnostic criteria for ASD listed in the DSM- 5.³¹ None of those sources, however, identify HIE as a cause of autism. The first article, titled “Long-Term Outcome After Neonatal Hypoxic- Ischaemic Encephalopathy,” discusses outcomes for full-term infants with neonatal encephalopathy with hypoxic-ischemic origin, and identifies cognitive and memory difficulties that may continue into childhood even if the infant does not experience motor deficits.³² The authors conclude that “childhood survivors of [neonatal encephalopathy] . . . are at an increased risk of cognitive, behavioral and memory problems.”³³ The article identifies another study that “reported an elevated rate of [ASD] in children with moderate and severe [neonatal encephalopathy],” but the ³⁰ First Adler Report at 3. ³¹ Deposition of Daniel Adler, M.D., Nov. 2, 2021 (hereinafter cited as “Adler Dep.”) at 5-8. ³² Linda S de Vries & Marian J Jongmans, Long-term Outcome after Neonatal Hypoxic-Ischaemic Encephalopathy, ARCHIVES OF DISEASE IN CHILDHOOD -FETAL AND NEONATAL ED., May 5, 2010, at F220, Defs.’ Opening Br. Ex. 4. ³³ Id. at F223. ⁹ article does not conclude that neonatal encephalopathy or HIE causes ASD.³⁴ The second article, a “Point of View” article titled “Neonatal Encephalopathy: An Inadequate Term for Hypoxic-Ischemic Encephalopathy,” addresses the terminology used to describe neonatal encephalopathy presumably caused by HIE and discusses the imaging studies and human and animal studies conducted regarding that disorder.³⁵ The article describes the use and limitations of MRI to diagnose HIE, but does not reference ASD. A third article, “Perinatal Features of Children with Autism Spectrum Disorder,” offers a retrospective review of births of 75 children with ASD.³⁶ The article identifies findings showing “a higher prevalence of prematurity, low birth weight, and perinatal asphyxia among children with ASD,” but notes that the retrospective study design and small sample size were limitations to the study and that “Large prospective studies are needed to clarify the possible association between perinatal complications and ASD.”³⁷ The fourth article, “Long-Term Medical and Social Consequences of Preterm Birth,” discusses various medical and social disabilities associated with preterm birth.³⁸ That article, which was based on ³⁴ Id. ³⁵ Joseph J. Volpe, M.D., Neonatal Encephalopathy: An Inadequate Term for Hypoxic-Ischemic Encephalopathy, ANNALS OF NEUROLOGY, 2012, Defs.’ Opening Br. Ex. 5. ³⁶ Gabriela F. Fezer et al., Perinatal Features of Children with Autism Spectrum Disorder, THE

REVISTA PAULISTA DE PEDIATRIA, (2017), Defs.’ Opening Br. Ex. 6. 37 Id. at 130 (emphasis added). 38 Dag Moster, M.D., Ph.D., et al., Long-Term Medical and Social Consequences of Preterm Birth, THE NEW ENG. J. OF MED. (2008), Defs.’ Opening Br. Ex. 7. 10 a cohort of people born in Norway between 1967 and 1983, states that a recent study “showed an association of preterm birth with features of the autism spectrum,” but cautioned that the findings were based on a very small number of cases in the lowest gestational age groups.³⁹ Finally, the DSM-5 identifies the characteristics of ASD but does not identify HIE as a potential cause for ASD.⁴⁰ Defendants do not contest that Dr. Adler is a well-qualified expert. They instead argue that Dr. Adler’s opinion is not reliable because he has not identified a scientific basis, including the sources discussed above, to support his opinion that HIE causes ASD. Plaintiffs respond that Defendants are mischaracterizing Dr. Adler’s opinion, that his actual opinion is “that the qualitative disturbance of social interaction suffered by J.S.S. is caused by his HIE brain injury,”⁴¹ and that the articles Dr. Adler cites support his contention that “an HIE injury can produce certain behaviors that would fall within the autism spectrum.”⁴² Plaintiffs’ arguments are unconvincing. First, Defendants do not mischaracterize Dr. Adler’s opinion. If anything, it is Plaintiffs who do so. Dr. Adler opined that J.S.S.’s behavior falls within the autism spectrum and that the cause of his disturbances in social interaction and play is HIE.⁴³ In their opposition ³⁹ Id. at 265-66. ⁴⁰ See CTR. FOR DISEASE CONTROL AND PREVENTION, DIAGNOSTIC CRITERIA, AUTISM SPECTRUM DISORDER (ASD) (2019), Defs.’ Opening Br. Ex. 8. ⁴¹ Pls.’ Response to Defs.’ Mot. at 10. ⁴² Id. at 13. ⁴³ First Adler Report at 3. 11 to the motion in limine, Plaintiffs suggest that although J.S.S. was diagnosed with ASD for purposes of receiving educational supports and other therapies, that diagnosis was not appropriate under the DSM-5 because his behavioral disturbances were better explained by a global developmental delay.⁴⁴ But Dr. Adler never offered this opinion in his reports. Rather, during his deposition, Dr. Adler agreed with J.S.S.’s ASD diagnosis and confirmed that it is his opinion that HIE is one of the causes of ASD.⁴⁵ Second, Dr. Adler’s opinion—that HIE is one cause of ASD—lacks a reliable scientific basis. At most, the articles he cited identify an association between HIE and ASD. Dr. Adler could not point to any published medical studies or literature stating that HIE causes ASD.⁴⁶ He acknowledged that a statistical association does not imply causation and explained that a statistical association means two conditions are “related to each other but not necessarily linked in terms of cause. You see them together, but they’re not necessarily causal, meaning you could see hypoxia with autism but hypoxia doesn’t necessarily cause autism.”⁴⁷ Studies showing an association between two conditions are not, standing alone, sufficient evidence to support an opinion as to causation.⁴⁸ For example, a recent decision of this Court ⁴⁴ See Defs.’ Opening Br. at 5-8. ⁴⁵ Adler Dep. at 84, 86-88. ⁴⁶ Id. at 96-97. ⁴⁷ Id. at 93. ⁴⁸ See *Wilant v. BNSF Railway Co.*, 2020 WL 2467076, at *4-5 (Del. Super. May 13, 2020) (partially vacated on other grounds, 2020 WL 3887881 (Del. Super. July 9, 2020)). 12 excluded expert testimony as to causation of the plaintiff’s bladder cancer because the medical evidence cited in support of that opinion identified, at most, a positive association between bladder cancer

and the diesel fume exposure at issue in that case.⁴⁹ The Court concluded the expert's opinions were not borne out by the evidence he cited in support of his opinion.⁵⁰ The same is true here. Plaintiffs also invoke Dr. Adler's training and experience as sufficient support for his opinion.⁵¹ But Plaintiffs cannot cite Dr. Adler's training and experience as a pediatric neurologist without explaining how that experience leads to Dr. Adler's conclusions, why the experience is a sufficient basis to support the conclusion, or how the experience was applied to the facts in this case.⁵² Plaintiffs have not done so in this case, and for all the foregoing reasons Dr. Adler's opinion that J.S.S.'s HIE injury caused his ASD or behaviors diagnosed as ASD is not reliable under Rule 702.

⁴⁹ Id. at 5. ⁵⁰ Id.; See also *Melnick v. Consolidated Edison, Inc.*, 959 N.Y.S.2d 609, 623 (N.Y. Supreme Feb. 15, 2013) (conducting an analysis under *Frye v. U.S.*, 293 F. 1013 (D.C. Cir. 1923) and barring plaintiffs' expert from offering an opinion that the minor child's diagnoses of autism or pervasive developmental disorder were caused by her preterm delivery with a low birth weight because the opinion "was not based on generally accepted science," would be "pure speculation," and required too great an analytical gap between the statistical associations in the expert's cited studies and the actual facts of the case). ⁵¹ Pls.' Response to Defs.' Mot. at 11. ⁵² FED. R. EVID. 702, Advisory Committee Notes for 2000 Amendments ("If the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts. The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'") (citing *Daubert*, 43 F.3d 1311, 1319 (9th Cir. 1995)).

13 II. Dr. Adler's opinion as to J.S.S.'s Autism Spectrum Disorder also is not admissible because it is not the product of a reliable methodology and amounts to little more than the expert's ipse dixit conclusions. Even if the Court concluded that Dr. Adler's opinion as to the causal link between HIE and ASD was reliable as a general matter, the opinion nevertheless fails to satisfy Rule 702's admissibility standard because Dr. Adler did not employ a reliable methodology to conclude that J.S.S.'s ASD was caused by HIE as opposed to another possible cause. When a disease or disorder has several possible independent causes, an expert must "employ a definitive scientific process to rule in and rule out" the many potential causes of the disorder before reaching a conclusion.⁵³ For example, in *Minner v. American Mortgage & Guaranty Co.*, this Court excluded an expert's opinion that the plaintiffs' illnesses were caused by exposure to toxic agents found within the building where the plaintiffs worked because the expert failed to account for and eliminate other possible causes for those syndromes. The Court explained that "[t]he fatal flaw [in the expert's opinion was] that she refused to adequately consider, and eliminate, other possible causes of the Plaintiffs' illnesses through a definitive scientific process."⁵⁴ In *Minner*, there was no known

⁵³ *Scaife v. AstraZeneca LP*, 2009 WL 1610575, at *16 (Del. Super. Jun. 9, 2009) (citing *Minner v. American Mortg. & Guar. Co.*, 791 A.2d 826, 854 (Del. Super. 2000)). ⁵⁴ *Minner*, 791 A.2d at 854.

14 cause of the particular illness at issue, and the expert did not provide a consistent diagnostic or scientific methodology to exclude other possible causes of the illness.⁵⁵ The same is

true of Dr. Adler's opinion. Dr. Adler concedes there is no scientific study showing a causal link between HIE and ASD, and that there are numerous potential causes of ASD, including genetic disorders associated with autism.⁵⁶ Moreover, Dr. Adler testified that ASD is a common diagnosis and is four times more common among boys than it is among girls.⁵⁷ Although the disease is common, has no established cause, and has many potential causes, Dr. Adler's reports do not make any attempt to distinguish J.S.S.'s diagnosis and rule out those other potential causes. Instead, Dr. Adler opines in a conclusory manner that HIE caused J.S.S.'s behavioral conditions that fall within the autism spectrum. That ipse dixit opinion is not based on a reliable methodology and therefore is not admissible under Rule 702.

CONCLUSION

For the foregoing reasons, Plaintiffs are precluded from introducing at trial Dr. Adler's opinion or testimony that Hypoxic Ischemic Encephalopathy caused J.S.S.'s behavioral syndrome that falls within the autism spectrum. IT IS SO ORDERED. 55 Id. at 854. 56 Adler Dep. at 99-100. 57 Id. at 116-17. 15