



**IN THE SUPREME 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,	) ) ) ) ) ) )	No. 48, 2024
Plaintiffs-Below, Appellants,	) )	Court Below: Superior Court of the State of Delaware C.A. No.: N19C-08-135 VLM
v.	) )	
WOMEN FIRST, LLC, and CHRISTIANA CARE HEALTH SYSTEM, INC.	) ) ) )	
Defendants-Below, Appellees.	) )	

**ANSWERING BRIEF OF DEFENDANTS-BELOW, APPELLEES  
CHRISTIANA CARE HEALTH SYSTEM, INC.  
AND WOMEN FIRST, LLC**

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## NATURE OF PROCEEDINGS

This is an appeal of pre-trial evidentiary rulings on the admissibility of expert testimony in a medical negligence case. Defendants moved *in limine* to exclude the opinion of Plaintiffs' sole causation expert, Daniel Adler, M.D., that hypoxic ischemic encephalopathy (HIE) allegedly suffered by the minor plaintiff at birth caused the development of neurobehavioral disabilities diagnosed as autism spectrum disorder (ASD). The Superior Court granted that motion but allowed Plaintiffs an opportunity to disclose a supplemental opinion from the same expert addressing alleged non-autism related injuries. Following Plaintiffs' supplemental disclosure, Defendants moved again *in limine* to preclude the expert's opinion as well as the related opinion of Plaintiffs' life care planner. The Superior Court granted these motions and in doing so also denied Plaintiffs' request for an 11<sup>th</sup> hour *Daubert* hearing and request for relief pursuant to Superior Court Civil Rule 60(b). Defendants then moved for summary judgment. Because the opinions of Plaintiffs' only causation expert had been precluded, the Superior Court granted Defendants' Motion for Summary Judgment. This appeal followed, seeking reversal of the Superior Court's decisions to exclude the opinions of Plaintiffs' causation and life care experts, deny the request for a *Daubert* hearing, and grant relief pursuant to Rule 60(b).

## SUMMARY OF ARGUMENT

1. **Denied.** The trial court correctly exercised its discretionary gatekeeping function in excluding the opinion of Plaintiffs' causation expert that HIE caused the minor plaintiff's ASD because that opinion was not the product of a reliable methodology and was not supported by or grounded in the evidence the expert claimed to rely on. Although the expert invoked "differential diagnosis," he did not rule out other possible causes of ASD or otherwise explain how he arrived at his opinion. The decision was a proper application of D.R.E. 702 and *Daubert*, and consistent with this Court's opinions in *Norman v. All About Women* and *Wong v. Broughton*.

2. **Denied.** The trial court correctly exercised its discretion in denying Plaintiffs' request for a *Daubert* hearing. The trial court had a sufficient evidentiary basis to perform its gatekeeping duties and Plaintiffs failed to articulate any special circumstances warranting a *Daubert* hearing.

3. **Denied.** The trial court correctly excluded the opinions of Plaintiffs' life care damages expert because they were based on an inadmissible causation opinion.

4. **Denied.** The trial court correctly exercised its discretion in denying Plaintiffs' request to reconsider its March 1, 2023, ruling under Del. Super. Ct. Civ. R. 60. The trial court's order was consistent with *Norman* and *Wong*. Dismissal of

Plaintiffs' case for lack of an admissible causation opinion was not an extraordinary circumstance warranting Rule 60 relief.

## COUNTER-STATEMENT OF FACTS

The assessment of J.S.S. immediately following his birth included concern for neonatal encephalopathy of unknown origin.<sup>1</sup> However, within a few days he was “much improved” neurologically.<sup>2</sup> Two weeks later at discharge his treating neurologist found that he had made “an excellent recovery.” An MRI scan of his brain showed no evidence of injury.<sup>3</sup>

Plaintiffs’ initial expert disclosure included only one causation expert, neurologist Daniel Adler, M.D., and attached Dr. Adler’s June 4, 2019, report.<sup>4</sup> In that report Dr. Adler noted the initial assessment after J.S.S.’s birth of encephalopathy and observed that J.S.S. later “evolved a behavioral syndrome characterized in the medical records as within the autism spectrum.”<sup>5</sup> Dr. Adler’s examination confirmed autism, and he opined that “[w]hile the causes of autism are diverse, . . . the cause of [J.S.S.’s] qualitative disturbance of social interaction and play is hypoxic ischemic encephalopathy” suffered at the time of delivery.<sup>6</sup> In the same disclosure, Plaintiffs provided the December 4, 2020 report of life care planner

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<sup>1</sup> A-483-484.

<sup>2</sup> B-001-002.

<sup>3</sup> B-003-004.

<sup>4</sup> A-061-064.

<sup>5</sup> A-061.

<sup>6</sup> A-063.

Jody Masterson, R.N.<sup>7</sup> Nurse Masterson relied on Dr. Adler’s causation opinion in assessing J.S.S.’s future care needs as a result of ASD.<sup>8</sup>

Plaintiffs subsequently produced a July 14, 2021 update from Dr. Adler, in which he reiterated that “[J.S.S.] remains a boy with neurological and neurodevelopmental disabilities and a behavioral syndrome that is within the autistic spectrum[,]” and that it “remain[ed] [his] medical opinion that all of [J.S.S.’s] neurological and neurodevelopmental disabilities are the result of the hypoxic ischemic brain injury that [J.S.S.] suffered during the labor and delivery process.”<sup>9</sup>

When Dr. Adler was deposed, he confirmed that J.S.S. met the diagnostic criteria for ASD,<sup>10</sup> and offered the opinion that HIE was *one of the causes* of ASD.<sup>11</sup> This case was the first time he had ever offered such an opinion.<sup>12</sup>

In deposition, Dr. Adler provided two medical articles, and mentioned two others, to support his opinion that HIE causes autism.<sup>13</sup> None of the articles reports a causal connection between HIE and ASD. One of the articles does not even mention autism.<sup>14</sup> Another mentions autism in one sentence describing another study

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<sup>7</sup> A-074.

<sup>8</sup> A-118, A-122, A-125, A-128, A-135.

<sup>9</sup> A-144-145.

<sup>10</sup> A-168-169 at 84:1-17, 85:6-19.

<sup>11</sup> A-169 at 86:18-21.

<sup>12</sup> A-174-175.

<sup>13</sup> A-149, A-170, A-175-176, B-129-163.

<sup>14</sup> B-129-139.

that reported an elevated rate of ASD in children with moderate and severe neonatal encephalopathy.<sup>15</sup> The third article states only that “[o]ur findings suggest that prematurity, perinatal asphyxia, and low birth weight *may be associated* with ASD[.]”<sup>16</sup> Dr. Adler offered the fourth article, which discusses, *inter alia*, a tentative association between pre-maturity and autism based on limited data.<sup>17</sup> “[only] to support the proposition that behavioral and social interaction problems can occur as a result of brain injury.”<sup>18</sup> Dr. Adler also referenced the CDC's diagnostic criteria for autism spectrum disorder found in the “DSM-5,” but that document nowhere states that HIE is a cause of autism.<sup>19</sup>

When asked for the basis of his opinion that HIE causes autism, Dr. Adler responded:

The papers that I've given you certainly, for example, that children who are pre-term who suffer brain injury can have behaviors that fall within the autistic spectrum and the fact that children who suffer degrees of hypoxia not sufficient to cause severe motor disability can cause behavioral abnormalities and the statement at least in some literature that some children who fulfill the clinical criteria for the behaviors of autism have suffered HIE.

And, number two, the DSM-5 clearly states that autism can be associated with other neurodevelopmental disorders. In my opinion in

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<sup>15</sup> A-176, B-143 (citing Badawi N, Dixon G, Felix JF, *et al.*, Autism following a history of newborn encephalopathy: more than a coincidence? *Dev Med Child Nuerol* 2006; 48:85-9).

<sup>16</sup> B-150.

<sup>17</sup> B-152-163.

<sup>18</sup> A-175-176 at 112:22-113:2.

<sup>19</sup> A-059, A-169.

that case or at least that diagnostic feature is active in this case because HIE is a diagnosis in the medical records and at least in terms of the papers that I gave you, ... talk about behavioral problems in the absence of severe motor disability. And certainly in the article by Dr. de Vries it refers to a specific article that talks about autism *potentially* being the result of HIE.

So I think in this case where there was a moderate encephalopathy... I believe that the perinatal events are the competent producing cause of all of [J.S.S.]'s neurological and neurodevelopmental disabilities, his motor issues, his cognitive impairment, his language issues, and his behavioral problems.<sup>20</sup>

Dr. Adler admitted that the medical literature he relied on suggests only that there *may* be an association between cranial injury or brain damage and autism.<sup>21</sup>

***Indeed, he was aware of no published medical studies or other medical literature stating that HIE causes autism.*** Rather he was simply extrapolating from reports of statistical associations to arrive at a “clinical opinion” as to cause.<sup>22</sup>

My opinion is that brain damage causes a behavioral disorder consistent with autism. That's my opinion.<sup>23</sup>

At the same time, Dr. Adler admitted that a statistical association meant only:

That they're 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.<sup>24</sup>

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<sup>20</sup> A-169-170 at 86:18-89:4 (emphasis added).

<sup>21</sup> A-170-171.

<sup>22</sup> A171-172.

<sup>23</sup> A-172.

<sup>24</sup> A-171.

Dr. Adler identified several factors or conditions that have been associated statistically with autism spectrum disorder, including genetics and certain maternal history.<sup>25</sup> He also acknowledged that according to the CDC, autism spectrum disorder is over four times more common among boys than girls.<sup>26</sup> While Dr. Adler testified at length about J.S.S.’s diagnosis of HIE and his diagnosis of ASD, he did not in any way explain how his opinion that J.S.S.’s HIE at birth caused his ASD was the product of a differential diagnosis.

Defendants next filed a motion *in limine* to exclude Dr. Adler’s causation opinion.<sup>27</sup> Once briefing was completed, oral argument was held.<sup>28</sup> Plaintiffs did not request a *Daubert* hearing to further explore Dr. Adler’s causation opinion in their response to the motion *in limine* or at oral argument.<sup>29</sup> The Superior Court issued its decision granting Defendants’ motion on March 1, 2023, precluding Plaintiffs “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.”<sup>30</sup>

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<sup>25</sup> A-172-173 at 98:13-102:7, A-174 at 106:13-107:10.

<sup>26</sup> A-177 at 117:2-10.

<sup>27</sup> A-210, B-164.

<sup>28</sup> A-250.

<sup>29</sup> A-231, A-250.

<sup>30</sup> Appellants’ Br. Ex. A at 15.



On March 10, 2023, the Superior Court conducted a pretrial conference, at which time Defendants sought a continuance of the trial scheduled to begin on April 3 because the Court’s ruling precluding Dr. Adler’s causation opinion made it unclear exactly what damages, if any, Plaintiffs would be able to pursue at trial.<sup>31</sup> The Court agreed and so postponed the trial, with the expectation that Plaintiffs would provide a new causation opinion from Dr. Adler to address any non-autism related condition he contended the child developed from an anoxic brain injury, as well as a new life care plan to address future care needs for any such non-autism related condition.<sup>32</sup>

On June 8, 2023, Plaintiffs provided yet another report from Dr. Adler.<sup>33</sup> The report gave no indication that Dr. Adler had been made aware that the Court had excluded his opinion that J.S.S.’s ASD was caused by HIE. In fact, the report simply reiterated the *same* opinion the Superior Court had previously found to be inadmissible. Dr. Adler again acknowledged in his “new” report that J.S.S. has “a severe behavioral disorder that has been diagnosed as autism” and “a mixed receptive-expressive language disorder and cognitive communication deficits within the context of autistic spectrum disorder.”<sup>34</sup> He then asserted that “the behaviors

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<sup>31</sup> A-311.

<sup>32</sup> A-356-361, A-371.

<sup>33</sup> A-374.

<sup>34</sup> A-374, A-375.

exhibited by [J.S.S.] fulfil the criteria set in the DSM-5 for autism”; and that “hypoxic-ischemic encephalopathy [HIE] . . . caused the behavioral syndrome seen in [J.S.S.] referred to as autism.”<sup>35</sup>

As he did in his prior reports, Dr. Adler also made vague reference to “motor delay” and “low muscle tone” but he made no effort to quantify these issues or distinguish them—to the extent they exist—from the effects of severe autism.<sup>36</sup>

Dr. Adler’s “new” report included reference to additional medical literature.<sup>37</sup> The three new medical articles cited did not discuss autism.<sup>38</sup> The textbook cited by Dr. Adler included only two general references to ASD, did not mention HIE in connection with ASD, and reported that “[t]he perinatal clinical correlates of ASD . . . in preterm infants are not yet fully delineated.”<sup>39</sup>

Defendants then filed another motion *in limine* to preclude the causation opinion set forth in Dr. Adler’s third report.<sup>40</sup> Plaintiffs produced a “revised” damages report from their life care expert,<sup>41</sup> and so Defendants filed a companion motion to exclude the damages opinions of the life care expert that were based on

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<sup>35</sup> A-377.

<sup>36</sup> A-374-376.

<sup>37</sup> A-377-379, B-201-237.

<sup>38</sup> B-201-237.

<sup>39</sup> B-329.

<sup>40</sup> A-380, B-358.

<sup>41</sup> A-386.

Dr. Adler's causation opinion.<sup>42</sup> Defendants did not seek to re-depose Dr. Adler because his third report restated the same opinion the trial court had already excluded, and so it would have been futile to do so.<sup>43</sup>

In opposing Defendants' second motion *in limine* Plaintiffs did not argue that Dr. Adler had an admissible causation opinion *other than* the one previously excluded by the Court, but rather sought *reconsideration* under Superior Court Rule 60(b) of the Superior Court's March 1, 2023 ruling precluding Dr. Adler's opinion that HIE caused J.S.S.'s ASD.<sup>44</sup> And Plaintiffs for the first time requested a *Daubert* hearing.

The Superior Court issued its opinion on December 15, 2023, granting Defendants' motions, finding that:

[T]he Third Adler Report offers opinions that are not materially different from or better supported than Dr. Adler's previously excluded opinions. They are excluded for the same reasons set out in the Court's [March 1, 2023] Memorandum Opinion. Further, Plaintiffs' efforts to convince the Court to revisit its earlier Memorandum Opinion either are untimely under Rule 59(e) or lacking in extraordinary circumstances under Rule 60. The Court also declines the Plaintiffs' invitation to hold a *Daubert* evidentiary hearing. Dr. Adler has issued three reports, and he has been deposed. The Plaintiffs have had ample opportunity to develop a record that passes *Daubert* muster. Finally,

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<sup>42</sup> A-413.

<sup>43</sup> B-359 at ¶4.

<sup>44</sup> A-417, A-428. Indeed, in their response to the motion, Plaintiffs stated that the exclusion Dr. Adler's opinion "would effectively end Plaintiffs' case." A-426.

because [the life care expert's] testimony and opinions are derivative of Dr. Adler's, they are excluded as well.<sup>45</sup>

Defendants then moved for Summary Judgment, based on what Plaintiffs had already admitted in the motion *in limine* briefing, that once Dr. Adler's causation opinion was precluded, Plaintiffs could not get to a jury on their claim of medical negligence.<sup>46</sup> In response to this motion, Plaintiffs changed course and returned to their previously abandoned argument that Dr. Adler had a causation opinion other than the one that had been previously excluded, *i.e.*, that J.S.S had injuries other than ASD that were caused by HIE.<sup>47</sup> However, as before, Plaintiffs made no attempt to explain the nature and scope of this residual causation opinion.

The Superior Court granted Defendants' motion for summary judgment on January 31, 2024,<sup>48</sup> expressing surprise that Plaintiffs were now contending that fact issues as to causation remained even after the two rulings excluding Dr. Adler's opinion. As the Superior Court put it:

Although the Scottolines state that causation issues of fact remain, they do not identify any other opinion from Dr. Adler, or any other expert, that raises such an issue to be resolved by the fact finder. They insist that the Defendants' claim that Plaintiffs have no expert testimony to establish causation is "entirely erroneous." If they are correct, the motion for summary judgment presents them with the opportunity,

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<sup>45</sup> Appellants' Br. Ex. B at 12. Plaintiffs unsuccessfully sought interlocutory appeal of these rulings. A-453, A-461.

<sup>46</sup> A-472.

<sup>47</sup> A-477.

<sup>48</sup> Appellants' Br. Ex. C.

indeed, the obligation, to identify that testimony for the Court. They identify no such testimony.<sup>49</sup>

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<sup>49</sup> *Id.* at 10.

## ARGUMENT

### **I. THE TRIAL COURT CORRECTLY EXCLUDED THE TESTIMONY OF DR. ADLER BECAUSE HIS CAUSATION OPINIONS LACKED SCIENTIFIC BASIS AND WERE NOT THE PRODUCT OF A RELIABLE METHODOLOGY**

#### **A. Question Presented**

Did the trial court abuse its discretion when it excluded the opinion of Plaintiffs' expert that hypoxic ischemic encephalopathy caused the minor plaintiff's neurobehavioral disabilities diagnosed as Autism Spectrum Disorder?

#### **B. Scope of Review**

The Court reviews evidentiary rulings for abuse of discretion.<sup>50</sup> “To find an abuse of discretion, there must be a showing that the trial court acted in an arbitrary and capricious manner.”<sup>51</sup> “This deferential standard of review is simply a recognition that trial judges perform an important gatekeeping function and, thus, must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable.”<sup>52</sup>

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<sup>50</sup> *Hudson v. State*, 2024 WL 91187, \*5, 9 (Del. Jan. 9, 2024).

<sup>51</sup> *Tumlinson v. Advanced Micro Devices, Inc.*, 81 A.3d 1264, 1268 (Del. 2013) (quoting *Spencer v. Wal-Mart Stores E., LP*, 930 A.2d 881, 887 (Del. 2007)).

<sup>52</sup> *Bowen v. E.I. DuPont de Nemours & Co.*, 906 A.2d 787, 795 (Del. 2006) (internal quotations and citation omitted).

## C. Merits of Argument

### 1. **The Trial Court's Opinion was in Accord with *Daubert* and D.R.E. 702 and was Consistent with *Norman and Wong*.**

Delaware Rule of Evidence 702 governs the admissibility of expert testimony.<sup>53</sup> A qualified expert may give testimony if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (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.<sup>54</sup>

Delaware uses the *Daubert* standard to apply Rule 702.<sup>55</sup> Under *Daubert*, for expert opinion to be admissible: (1) the witness must be qualified by knowledge, skill, experience, training, or education; (2) the testimony must be relevant; (3) the opinion must be based upon information reasonably relied upon by experts in that particular field; (4) the testimony must assist the trier of fact; and (5) not create unfair prejudice, confusion or mislead the jury.<sup>56</sup> Defendants challenged the

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<sup>53</sup> *Id.* at 794.

<sup>54</sup> D.R.E. 702.

<sup>55</sup> *Nelson v. State*, 628 A.2d 69, 74 (Del. 1993).

<sup>56</sup> *Id.*

admissibility of Dr. Adler’s opinions before the Superior Court based on the relevance and reliability prongs of this analysis.<sup>57</sup>

Evidence is relevant if it would assist the fact finder in “understand[ing] the evidence or . . . determin[ing] a fact in issue.”<sup>58</sup> If proffered testimony is not related to the case, then it will not aid in clarifying a contested fact and is, therefore, not relevant.<sup>59</sup> This “helpfulness” or “fit” standard requires that evidence have “a valid scientific connection to the pertinent inquiry as a precondition to admissibility.”<sup>60</sup> 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.”<sup>61</sup>

The party seeking to introduce expert testimony bears the burden of establishing its admissibility.<sup>62</sup> While there is a “strong preference” for admitting expert opinions that “will assist the trier of fact in understanding . . . the evidence,”<sup>63</sup> when the admissibility of expert testimony is challenged, the trial judge, acting as “gatekeeper,” must ensure that the proffered testimony is both relevant and

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<sup>57</sup> A-224-230.

<sup>58</sup> *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702).

<sup>59</sup> *State v. McMullen*, 900 A.2d 103, 113 (Del. Super. 2000).

<sup>60</sup> *Id.* at 113-114; *GMC v. Grenier*, 981 A.2d 524, 529 (Del. 2009).

<sup>61</sup> *Daubert*, 509 U.S. at 590.

<sup>62</sup> *Bowen*, 906 A.2d at 795.

<sup>63</sup> *Norman v. All About Women, P.A.*, 193 A.3d 726, 730 (Del. 2018).



reliable.<sup>64</sup> This inquiry must focus on principles and methodology rather than conclusions, but:

*[C]onclusions and methodology are not entirely distinct from one another. Trained experts commonly extrapolate from existing data. But nothing in either Daubert or the ... [r]ules of [e]vidence requires a . . . court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.*<sup>65</sup>

In *Norman*<sup>66</sup> and *Wong*,<sup>67</sup> this Court addressed the trial court's gatekeeper responsibility and explained that the requirement in Rule 702 that an expert's opinion be based on information reasonably relied on by experts in the field is a guard against the expert's use of inadmissible hearsay, and so does not apply to information—like medical literature—that the expert did *not* review. Thus, an expert's failure to cite medical literature in support of his or her opinion does not, in and of itself, necessarily demonstrate a failure to meet the admissibility requirements of *Daubert* and D.R.E. 702.<sup>68</sup>

Beyond that, the holdings of *Norman* and *Wong* are limited to the facts that were before the Court in those cases. Contrary to Plaintiffs' assertion, these cases

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<sup>64</sup> *Daubert*, 509 U.S. at 597.

<sup>65</sup> *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (citing *Turpin v. Merrell Dow Pharm., Inc.*, 959 F.2d 1349, 1360–61 (6th Cir.1992)) (emphasis added).

<sup>66</sup> *Norman*, 193 A.3d 726.

<sup>67</sup> *Wong v. Broughton*, 204 A.3d 105 (Del. 2018).

<sup>68</sup> *Norman*, 193 A.3d at 731; *Wong*, 204 A.3d at 111.

do not instruct that “so long as [an expert’s] opinion is based on *some information* reasonably relied on by experts, the credibility of his opinion then becomes an issue for a . . . jury to decide.”<sup>69</sup> So, while the holdings in *Norman* and *Wong* clarified one of the factors long applied by Delaware courts to determine the admissibility of scientific and technical expert testimony, they did not, as Plaintiffs argue, disturb the well-established framework of this analysis under DRE 702 and *Daubert*.<sup>70</sup>

Technical and scientific expert opinion comes from many sources and is offered in many contexts. Thus, “courts should apply the factors, as set forth both in *Nelson* and *Daubert*, in a flexible manner that takes into account the particular specialty of the expert under review *and* the particular facts of the underlying case.”<sup>71</sup> Trial courts are typically given “broad latitude” to determine which of these factors (or some other unspecified factors) are “reasonable measures of reliability in a particular case.”<sup>72</sup> Granted, courts must be mindful that clinical medicine (as distinguished from research or laboratory medicine) is an art, and so in that arena some of the *Daubert* factors may not be “an easy fit.”<sup>73</sup> But this caution is not a

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<sup>69</sup> Appellants’ Br. at 20 (emphasis added).

<sup>70</sup> See, e.g., *Minner v. Am. Mortgage & Guar. Co.*, 791 A.2d 826, 842-843 (Del. Super. 2000) (citing *Nelson v. State*, 628 A.2d 69,74 (Del.1993)); *M.G. Bancorporation v. Le Beau*, 737 A.2d 513, 521 (Del. 1999); *Bowen*, 906 A.2d at 795.

<sup>71</sup> *McMullen*, 900 A.2d at 113 (citing *Kumho Tire Co., Ltd v. Carmichael*, 526 U.S. 137, 150 (quoting *Daubert*, 509 U.S. at 593) (emphasis added)).

<sup>72</sup> *Kumho*, 526 U.S. at 153.

<sup>73</sup> *McMullen*, 900 A.2d at 116.

*carte blanche*. Thus, while differential diagnosis “is deemed a reliable method to reach a diagnosis in the medical community, [that] does not necessarily imply that it is admissible under *Daubert*. That is, ‘the mere statement by an expert that he or she applied differential diagnosis . . . does not *ipso facto* make that application scientifically reliable or admissible.’”<sup>74</sup> Put another way, and contrary to Plaintiffs’ contention here, “differential diagnosis” are *not* magic words.

Central to the evaluation of an expert’s claim to rely on a differential diagnosis methodology is the difference between “general” and “specific” causation. “General” causation is established by demonstrating that exposure to a particular injury or substance can cause a particular disease, whereas “specific” causation is established by demonstrating that a given injury or exposure is the cause of a particular person’s disease.<sup>75</sup> Where a “plaintiff is not able to establish general causation, it is unnecessary to consider whether the plaintiff can establish specific causation.”<sup>76</sup> What’s more, it is not usually appropriate to rely on a differential diagnosis to prove *general* causation.<sup>77</sup>

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<sup>74</sup> *Id.* at 116-117 (citing *Soldo v. Sandoz Pharm Corp.*, 244 F. Supp 2d. 434, 551 (W.D. Pa. 2003)).

<sup>75</sup> *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 471 (M.D.N.C. 2006); *Pugh v Cmty. Health Sys., Inc.*, 2023 WL 3361166, at \*7 (E.D. Pa. 2023).

<sup>76</sup> *Doe*, 440 F. Supp. 2d at 471; *Pugh*, 2023 WL 3361166 at \*7.

<sup>77</sup> *Doe*, 440 F. Supp. 2d at 477 (citing *Ruggiero v. Warner–Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005)).

To properly perform a differential diagnosis, an expert must “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” and “then rule out those causes that did not produce the patient's condition by engaging in a process of elimination, eliminating hypotheses on the basis of a continuing examination of the evidence so as to reach a conclusion as to the most likely cause of the findings in that particular case.”<sup>78</sup> “[A] differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion.”<sup>79</sup>

With these precepts in mind, the court must “delve into the particular witness's method of performing a differential diagnosis to determine if his or her ultimate conclusions are reliable.”<sup>80</sup> How far in the court must delve is a matter of discretion and will vary depending on the particular facts of the case.<sup>81</sup> For instance, where the subject matter is firmly rooted in basic clinical medicine, such as in *Norman* (trocar injury in surgery), and where only “specific” causation is at issue as in *Wong* (neck

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<sup>78</sup> *McMullen*, 900 A.2d at 116 n.63 (citing *Creanga v. Jardal*, 185 N.J. 345 (2005) (other internal citations omitted)).

<sup>79</sup> *Doe*, 440 F. Supp. 2d at 471 (quoting *Roche v. Lincoln Property Co.*, 278 F. Supp. 2d 744, 751, (E.D. Va. 2003), *aff'd* 175 Fed. Appx 597,603 (4<sup>th</sup> Cir.2006)).

<sup>80</sup> *McMullen*, 900 A.2d at 117 (citing *Poust v. Huntleigh Healthcare*, 998 F. Supp. 478, 496 (D. N.J. 1998)).

<sup>81</sup> *McMullen*, 900 A.2d at 118 (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 758 (3d Cir. 1994)).

traction during delivery claimed to cause brachial plexus injury), it was enough for the gatekeeper to confirm the expert’s training and clinical experience, together with his knowledge of the operative facts, and confirm that the expert had ruled out other causes.<sup>82</sup>

However, where the expert’s opinion lies in deeper scientific waters, speaks to “general” causation and so is less a function of everyday clinical medicine than research, and where “it is possible that the precepts of science have not caught up with ... the claims of the plaintiff,”<sup>83</sup> much more scrutiny is warranted. So, in cases like *McMullen* (pediatric condition falsification), *Minner* (“sick building” claimed to be the cause of chronic fatigue syndrome and fibromyalgia), and *Scaife*<sup>84</sup> (antipsychotic medication claimed to cause Type II diabetes), the trial court rightly probed and dissected the methodology underlying—and grounds for—the medical opinion. When it was found wanting, the expert opinion was rightly excluded.<sup>85</sup>

The facts in this case are much more akin to *McMullen*, *Minner*, and *Scaife*, than they are to *Norman* and *Wong*. Here, Plaintiffs’ expert, Dr. Adler offered the *a*

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<sup>82</sup> *Norman*, 193 A.3d at 731; *Wong*, 204 A.3d at 111. Further, in *Wong*, general causation—whether lateral traction exerted on a baby’s neck during delivery *can* cause a permanent brachial plexus injury—was not in dispute. Here, the expert’s opinions about general and specific causation are at issue. Appellants’ Br. Ex. A at 12-15.

<sup>83</sup> *Minner*, 791 A.2d at 848.

<sup>84</sup> *Scaife v. Astrazeneca LP*, 2009 WL 1610575 (Del. Super. June 9, 2009).

<sup>85</sup> *McMullen*, 900 A.2d at 120; *Minner*, 791 A.2d at 863; *Scaife*, 2009 WL 1610575 at \*16.

*priori* “general” causation opinion that one complex medical condition, hypoxic ischemic encephalopathy (“HIE”) can cause the development of another complex medical condition, an array of neurologic and neurobehavioral disabilities diagnosed as Autism Spectrum Disorder (“ASD”). Further, Dr. Adler contended specifically that J.S.S.’s ASD was caused by HIE.<sup>86</sup> Once these opinions were challenged, it was well within the trial court’s discretion as gatekeeper to look beyond Dr. Adler’s qualifications as a pediatric neurologist and the Plaintiffs’ conclusory claims that his opinions were supported by good grounds and were arrived at via sound methodology, to determine whether they in fact passed muster under DRE 702 and *Daubert*.

In its careful evaluation of Dr. Adler’s opinions, the Superior Court observed that Dr. Adler acknowledged that ASD is a common diagnosis, is four times more common in boys (J.S.S. is a boy), has no established cause, and that the potential causes are diverse, including unidentified genetic mutations and pre-natal exposure to certain medications.<sup>87</sup> Despite all this, Dr. Adler made no attempt to rule out the

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<sup>86</sup> Defendants did in fact identify expert opinion that disputed the HIE diagnosis, but that dispute is not material to this appeal.

<sup>87</sup> Appellants’ Br. Ex A at 15; *see also Doe*, 440 F. Supp. 2d at 477-478 (“[O]ne conclusion that is generally accepted in the medical community with respect to the causation of autism[] . . . is[] that its cause is genetic, but that the exact genetic sequence of autism is unknown.”) (internal citations omitted).

other known causes or otherwise explain how he reached his causation conclusion.<sup>88</sup> Although differential diagnosis may be used as a scientific methodology, it is unreliable where, as here, there is a plausible alternative cause and the expert offers no explanation for why he has concluded that was not the sole cause.<sup>89</sup> Moreover, as the Superior Court noted, the medical literature that Dr. Adler claimed supported his opinion did no such thing.<sup>90</sup> Indeed, Dr. Adler admitted in deposition that there is no scientific study showing a causal link between HIE and ASD.

At most, the literature *Dr. Adler cited* speculated about a potential association between HIE and ASD. Dr. Adler conceded that statistical association means two conditions are “related to each other but not necessarily linked in terms of cause.”<sup>91</sup> Although an expert may not be required to provide medical literature support for a causation opinion, it was not an abuse of discretion for the Superior Court, in assessing the grounds for Dr. Adler’s opinions, to consider that his opinions were not borne out by the very literature evidence he cited.<sup>92</sup>

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<sup>88</sup> Appellants’ Br. Ex. A at 15. *See also Perry v. Novartis Pharms. Corp.*, 564 F. Supp. 2d 452, 469-70 (E.D. Pa. 2008) (“[O]ur sister courts have excluded experts’ differential diagnoses where they failed to adequately account for the likelihood that the disease was caused by an unknown factor.”) (citing *Doe* and other cases).

<sup>89</sup> *Heller v. Shaw Indus., Inc.*, 167 F.3d 146, 156 (3d Cir. 1999).

<sup>90</sup> Appellants’ Br. Ex. A at 12.

<sup>91</sup> A-171 at 93:7-9.

<sup>92</sup> Appellants’ Br. Ex. A at 12 (studies showing an association between two conditions are not, standing alone, sufficient evidence to support an opinion as to causation. (citing *Wilant v. BNSF Railway Co.*, 2020 WL 2467076 (Del. Super. May

The Superior Court also noted that although Plaintiffs invoked Dr. Adler’s training and experience as a pediatric neurologist as a basis for his opinion, neither Plaintiffs nor Dr. Adler explained how that training and experience was applied to the facts of the case to lead Adler to his causation conclusion.<sup>93</sup> In other words, learned speculation is still speculation. The same “fit” issue exists with Dr. Adler’s review of the medical records and his examinations of J.S.S. While that data admittedly informed his opinion that the child suffered HIE at birth and his agreement with the ASD diagnosis made by the child’s treating providers, nowhere does Dr. Adler explain how this data leads to the conclusion that HIE can *cause* ASD in general, and that it in fact *caused* ASD in this case.

Overall, Plaintiffs and Dr. Adler give only lip service to the idea that his causation opinion is based on *any* methodology, much less a reliable methodology. Perhaps this utter lack of reliable grounds is best demonstrated in Plaintiffs’ Opening Brief where they recite this tautology: “Dr. Adler’s professional opinion, supported by medical literature, establishes a clear association between J.S.S.’ HIE injury and the neurodevelopmental and behavioral challenges necessitating lifelong care.” This is quintessential *ipse dixit*, and the Superior Court was right to preclude it.

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13, 2020) (partially vacated on other grounds, 2020 WL 3887881 (Del. Super. July 9, 2020)).

<sup>93</sup> Appellants’ Br. Ex. A at 13 (citing Fed. R. Evid. 702, Advisory Committee Notes for 2000 Amendments).



## 2. Distorting the Adler Opinion Does Not Make it Admissible

In their zeal to get Dr. Adler’s speculation before a jury, Plaintiffs attempted below—and continue to attempt in this appeal—to twist Dr. Adler’s opinion into one having nothing to do with ASD. So, Plaintiffs argue, Dr. Adler isn’t really offering the opinion that HIE caused ASD, he is offering the opinion that HIE caused neurologic and neurodevelopmental injuries *consistent with*—although somehow distinct from—ASD. From there, Plaintiffs twist the causation question to be whether the child’s disabilities were caused by HIE *or* ASD and assert that the former is Dr. Adler’s opinion.<sup>94</sup> These mental gymnastics simply substitute one false cause logical fallacy (*post hoc ergo hoc*) for another (*cum hoc ergo propter hoc*).

But more importantly, as the Superior Court rightly found, this argument is completely unhinged from Dr. Adler’s actual expressed opinion.<sup>95</sup> It is undisputed that Dr. Adler agrees with the child’s ASD diagnosis, that is, the child’s neurologic and neurodevelopmental disabilities are properly diagnosed as ASD.<sup>96</sup> So, contrary to Plaintiffs’ convoluted assertion, if Dr. Adler is saying those disabilities were caused by HIE, he is saying—without any reliable basis—that HIE caused ASD.<sup>97</sup>

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<sup>94</sup> They also incorrectly assert that the latter is Defendants’ position.

<sup>95</sup> Appellants’ Br. Ex. A at 11-12.

<sup>96</sup> *Id.*; A-169 at 86:18-88:16.

<sup>97</sup> In their Opening Brief, Plaintiffs make even more confusing statements. *See, e.g.*, Appellants’ Br. at 28 (“There is a distinction, however, between the behaviors fulfilling the applicable criteria for the diagnosis of ASD and concluding that the

### 3. Plaintiffs Waived Their Opportunity to offer a Causation Opinion as to Non-ASD related injuries

Although Plaintiffs have admitted more than once in these proceedings that without Dr. Adler’s opinion that HIE caused ASD, they have no case, at other points they implied that Dr. Adler believes that only *some* of J.S.S.’s disabilities properly fall within the diagnosis of ASD while others are unrelated to that diagnosis.<sup>98</sup> So, this variation of the argument goes, even if Dr. Adler is precluded from offering the opinion that HIE caused ASD, and even if Plaintiffs concede that some of the alleged damages in this case are from ASD, Dr. Adler should be able to offer the opinion that the non-ASD related injuries were caused by HIE and, therefore, by Defendants’ medical negligence.

It was this suggestion that kept Plaintiffs’ case alive after the Superior Court’s first opinion precluding Dr. Adler’s testimony. The Court allowed Plaintiffs the opportunity—by way of a new report from Dr. Adler—to demonstrate that they could supply the necessary causation opinion as to any *non-ASD* related injuries.<sup>99</sup>

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ASD is the cause of J.S.S.’ behaviors.”); 21 (“[T]his is not an ‘either-or’ situation where a neurodevelopmental or behavioral disorder must be defined as either HIE or ASD related. Rather the two diagnoses can co-exist.”); 27 (“The collection of symptoms bundled together as autism may also be present due to a separate cause other than what caused the autism.”). If these formulations accurately express Dr. Adler’s opinion, that opinion would only confuse the jury, rather than assist it to *understand* the evidence.

<sup>98</sup> See, e.g., Appellants’ Br. at 18; Appellants’ Br. Ex. C at 10.

<sup>99</sup> A-356-361.

However, what followed—in Dr. Adler’s third report—was a restatement almost verbatim of Dr. Adler’s original opinion, devoid of any attempt to carve out alleged injuries *not* falling under the admitted ASD diagnosis. Was this because Dr. Adler could offer no such opinion? Or was it because Plaintiffs decided that the alleged injuries Dr. Adler *could* somehow parse out in this way were too *de minimis* to proceed to trial on? Regardless, the Superior Court correctly found that the third Adler report did not move the causation needle one iota.<sup>100</sup> And insofar as Plaintiffs continue to raise this alternative theory on appeal it must fail, because they failed below to provide any evidence in the form of expert opinion to support it.

#### **4. The Weight of Authority From Outside Delaware Overwhelmingly Supports the Superior Court’s Decision**

There is also no persuasive support for Plaintiffs’ position in the one autism case from beyond Delaware that they cite, *Ellis v. Fortner*.<sup>101</sup> The Ohio Court of Appeals found in that case only that the trial court did not abuse its discretion, based on the evidence before it, in allowing two experts to offer opinions that a child’s birth injury was the cause of disabilities that had been diagnosed as autism. Moreover, the expert opinion in *Ellis* bears no resemblance to what was before the

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<sup>100</sup> Appellants’ Br. Ex. B at 10; *see, e.g., Pugh v. Cmty. Health Sys., Inc.*, 2023 WL 4408481 at \*14 (E.D. Pa. 2023) (discussing expert’s abstract and peripheral references to developmental abnormalities other than ASD that can occur from HIE being insufficient to establish causation).

<sup>101</sup> *Ellis v. Fortner*, 169 N.E.3d 987 (Ohio Ct. App. 2021).

Superior Court here. For one thing, the experts in *Ellis* relied on MRI evidence of a brain injury and on treating physician opinion linking the MRI evidence to the child's disabilities; whereas here no such evidence exists.<sup>102</sup> Both experts in *Ellis* more or less disputed the child's autism diagnosis. And they based their causation opinions on literature not relied on by Dr. Adler. Indeed, Plaintiffs seem to be clinging to the *Ellis* trial court opinion primarily to improperly bootstrap medical literature into the record not cited by Dr. Adler.

A closer look at the medical literature relied on by the experts in *Ellis* explains why Dr. Adler did not rely on it. The article from *Ellis* included in Plaintiffs' appendix, *Pediatric Traumatic Brain Injury and Autism: Elucidating Shared Mechanisms* includes no discussion whatsoever of HIE, a mechanism wholly distinct from traumatic brain injury.<sup>103</sup> The other two articles cited in the *Ellis* trial court opinion<sup>104</sup> are even less helpful to the proffered expert opinion in that case. *Neurocognitive Outcomes Following Neonatal Encephalopathy* states, "At present

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<sup>102</sup> *Ellis v. Fortner*, C.V.-2016-07-2898 at \*2 (Ohio C.P. 2018) (A-530). In the instant case, there is no dispute that JSS' brain MRI showed no evidence of brain injury. B-001-004.

<sup>103</sup> A-538. The plaintiffs in *Ellis* advanced the theory that the child in that case was injured by **cranial compression** ischemic encephalopathy or CCIE, a mechanism of injury not present in the case at bar. *Ellis*, 169 N.E.3d at 992. It may be that the plaintiffs' experts in that case tried to equate cranial compression at birth with traumatic brain injury, but that is not clear from the record, nor is cranial compression discussed in the article as a type of traumatic brain injury.

<sup>104</sup> A-534-535.

there is no clear association between autism or autistic spectrum disorders and moderate NE [neonatal encephalopathy].”<sup>105</sup> Likewise, *Autism Following a History of Newborn Encephalopathy: More than a Coincidence?*, as the punctuation in the title implies, states that “[o]ur study does not seek to make any conclusion about the aetiology of the ASD’s.”<sup>106</sup>

In light of what the literature cited by the experts actually says, the affirmance in *Ellis*—even on an abuse of discretion standard—is baffling. The case, if anything, supports the Superior Court’s well-reasoned decision to exclude Dr. Adler’s opinions.

Standing in sharp contrast to *Ellis* is *Pugh v. Community Health Systems, Inc.*<sup>107</sup> The plaintiffs in *Pugh* also claimed that the defendants committed medical negligence during the delivery of their son, resulting years later in a diagnosis of ASD. Like Plaintiffs here, the plaintiffs in *Pugh* relied on the opinion of a single neurologist that their son’s autism was caused by HIE at birth.

The defendants in *Pugh* moved to preclude the neurologist’s opinion contending—as Defendants did here—that the opinion did not meet the reliability or relevance requirements of Rule 702 and *Daubert*.

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<sup>105</sup> B-430.

<sup>106</sup> B-438.

<sup>107</sup> *Pugh*, 2023 WL 3361166 (E.D. Pa. May 10, 2023), *reconsideration denied*, 2023 WL 4564783 (E.D. Pa. July 17, 2023).

Like Dr. Adler, the expert in *Pugh* conceded that “[a]utism is a multifactorial complex neurodevelopmental disorder the cause of which can relate to a genetic condition or a multitude of other risk factors.”<sup>108</sup> The expert, nevertheless, based his opinion that HIE was the cause in that child’s ASD based on his physical examination, review of the medical records and a supposed differential diagnosis, as well as a handful of medical articles purporting to find an *association* between HIE and autism.<sup>109</sup> After a thorough analysis of the purported basis for the challenged opinion and relevant case law, the District Court granted the defendants’ motion to exclude the HIE/ASD causation opinion, finding that the expert failed to provide a reliable underlying methodology.<sup>110</sup> The District Court also concluded that the expert had improperly “cherry-picked” the literature for articles providing some support to her opinion without “addressing equivocal or inconsistent findings to her own.”<sup>111</sup> The District Court also found that the expert’s reliance on her experience and diagnosis of S.P. were no substitute for scientific methodology, particularly with regard to “general” causation and so were insufficient under *Daubert*.<sup>112</sup>

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<sup>108</sup> *Pugh*, 2023 WL 3361166 at \*12.

<sup>109</sup> *Id.* at \*4-5.

<sup>110</sup> *Id.* at \*9-13.

<sup>111</sup> *Id.* at \*12. As in the present case, following exclusion of the plaintiffs’ only causation opinion, the District Court granted the defendants’ motion summary judgment. *Pugh v. Cmty. Health Sys., Inc.*, 2023 WL 4408481, at \*1 (E.D. Pa. July 7, 2023).

<sup>112</sup> *Pugh*, 2023 WL 3361166 at \*9-13.

The ruling in *Pugh* and the Superior Court's opinion here are in accord with several courts in other jurisdictions that have excluded autism causation testimony because the proponent offered no scientifically reliable basis for the opinion.<sup>113</sup>

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<sup>113</sup> See, e.g., *Hendrix v. Evenflo Co.*, 609 F.3d 1183, 1998-99 (11th Cir. 2010) (autism allegedly caused by injury from defective child restraint system); *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp. 2d 465, 474-75 (M.D.N.C. 2006) (autism allegedly caused by Rhogam administered during pregnancy); *Melnick v. Consolidated Edison, Inc.*, 959 N.Y.S.2d 609, 619-23 (2013) (autism allegedly caused by premature birth and low birth weight); *Blackwell v. Wyeth*, 971 A.2d 235, (Md. 2009) (autism allegedly caused by vaccines); *Checchio By & Through Checchio v. Frankford Hosp.-Torresdale Div.*, 717 A.2d 1058, 1062 (Pa. Super. 1998) (autism allegedly caused by oxygen deprivation).

## II. THE TRIAL COURT CORRECTLY EXERCISED ITS DISCRETION IN DENYING PLAINTIFFS' REQUEST FOR A *DAUBERT* HEARING.

### A. Question Presented

Did the trial court correctly exercise its discretion in denying Plaintiffs' request for a *Daubert* hearing, made in response to Defendants' second motion in *limine* seeking to preclude the causation opinion in Dr. Adler's third report, which was "practically indistinguishable" from the opinion that the court previously ruled inadmissible?<sup>114</sup>

### B. Scope of Review

The Court applies an abuse of discretion standard in reviewing the trial court's decision to decline a request for a *Daubert* hearing.<sup>115</sup>

### C. Merits of Argument

The trial court has discretionary authority to determine whether to hold a *Daubert* hearing, *i.e.*, an evidentiary hearing to evaluate the soundness of an expert's opinions, prior to trial.<sup>116</sup> Delaware law is clear that such hearings are not mandatory.<sup>117</sup> A *Daubert* hearing is not necessary where the trial court has a sufficient evidentiary basis in the discovery record to perform its gatekeeping

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<sup>114</sup> Appellants' Br. Ex. B at ¶7.

<sup>115</sup> *Hudson*, 2024 WL 91187 at \*5, 9.

<sup>116</sup> *Minner*, 791 A.2d at 844.

<sup>117</sup> *Hudson*, 2024 WL 91187 at \*9; *Minner*, 791 A.2d at 844-45.



duties.<sup>118</sup> Indeed, absent special circumstances, “requests for them should generally be denied.”<sup>119</sup> Here, the Superior Court correctly exercised its discretion in denying Plaintiffs’ request for a *Daubert* hearing.

As an initial matter, it is worth noting the timing of Plaintiffs’ request. Plaintiffs did not request a *Daubert* hearing when they responded to Defendants’ initial challenge to whether Dr. Adler’s opinion in his first and second reports that HIE caused autism was based on sufficient facts or data and whether that opinion was reliable under D.R.E. 702.<sup>120</sup> Plaintiffs only requested a *Daubert* hearing after Defendants filed their second motion *in limine* seeking to preclude the causation opinion in Dr. Adler’s third report.<sup>121</sup> The trial court found the “[t]he causation opinion in the Third Adler Report [to be] practically indistinguishable from the same causation opinion that the [trial court had] ruled inadmissible.”<sup>122</sup> The court further observed that “Plaintiffs implicitly admit as much by their emphasis on *Norman*.”<sup>123</sup>

Citing the three reports issued by Dr. Adler and his deposition testimony, the trial court denied Plaintiffs’ request for a *Daubert* hearing, reasoning that “Plaintiffs have had ample opportunity to develop a record that passes *Daubert* muster.”<sup>124</sup>

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<sup>118</sup> *Minner*, 791 A.2d at 845.

<sup>119</sup> *Id.*

<sup>120</sup> Pls.’ Resp. to Def. CCHS’s First Mot. *in Limine* (Dr. Adler) (A-231).

<sup>121</sup> Pls.’ Resp. to Def. CCHS’s Second Mot. *in Limine* (Dr. Adler) at ¶26 (A-426).

<sup>122</sup> Appellants’ Br. Ex. B at ¶7.

<sup>123</sup> *Id.*

<sup>124</sup> *Id.* at ¶11.

During his deposition, Dr. Adler testified extensively about his supposed methodology and the bases for his opinion that HIE caused autism. Specifically, Dr. Adler testified that he relied on four medical articles as well as the CDC’s diagnostic criteria for ASD (the “DSM-5”) to support his causation opinion.<sup>125</sup> In his third report, Dr. Adler provided additional literature to support his causation opinion.<sup>126</sup> Moreover, the Court heard oral argument on the admissibility of Dr. Adler’s causation opinion at least twice.<sup>127</sup> In short, the trial court correctly reasoned that because Dr. Adler’s third report “offers opinions that are not materially different from or better supported than Dr. Adler’s previously excluded opinions,”<sup>128</sup> the record provided a sufficient evidentiary basis to determine the admissibility of Dr. Adler’s causation opinion.

Appellants’ reliance on *State v. McMullen*<sup>129</sup> is unavailing. *McMullen* involved “Pediatric Condition Falsification,” a relatively new but “generally accepted diagnosis in the pediatric community.”<sup>130</sup> Conversely, in the instant case, Plaintiffs offered no basis in Dr. Adler’s reports or deposition testimony to suggest that even his general causation opinion that HIE causes autism is generally accepted

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<sup>125</sup> A-149 at 7:13-8:18, A-169-177 at 85:16-93:24, 96:18-102:7, 106:13-107:10, 108:2-111:23, 112:22-113:2, 117:2-10.

<sup>126</sup> A-379.

<sup>127</sup> 12/16/22 Hearing Tr. (A-250); 11/20/23 Hearing Tr. (A-428).

<sup>128</sup> Appellants’ Br. Ex. B at ¶11.

<sup>129</sup> *McMullen*, 900 A.2d 103.

<sup>130</sup> *Id.* at 108.

in the medical community. *McMullen* provides no rationale as to why a *Daubert* hearing was warranted in that case, but presumably the trial court had determined that it needed more information to decide whether there was sufficient reliability and relevance as to the *specific* causation opinion of several experts about an issue where general causation was not a concern. Here, Dr. Adler's reports and deposition testimony provided a sufficient evidentiary basis for the trial court to determine lack of reliability and relevance as to general causation. Appellants failed to articulate any special circumstances that warranted a *Daubert* hearing. Nor have they pointed to any additional information that would have been put before the Superior Court in such a hearing, thus leading to the conclusion that a *Daubert* hearing would have been a futile exercise.

Thus, the Court should affirm the Superior Court's ruling.

### **III. THE TRIAL COURT CORRECTLY EXCLUDED THE OPINIONS OF PLAINTIFFS' LIFE CARE PLANNING EXPERT BECAUSE HER OPINIONS ARE BASED ON THE UNRELIABLE CAUSATION OPINION OF DR. ADLER.**

#### **A. Question Presented**

Did the trial court correctly exclude the testimony and opinions of Plaintiffs' life care planning expert, Jody Masterson, RN, where her opinions are based on Dr. Adler's unreliable causation opinion, which was excluded?

#### **B. Scope of Review**

The Court applies an abuse of discretion standard in reviewing the trial court's decision to admit or exclude evidence.<sup>131</sup>

#### **C. Merits of Argument**

Based on Dr. Adler's medical opinions, Plaintiffs sought below to introduce the expert testimony and opinions of Nurse Masterson on the future care needs of J.S.S. In her initial report, Nurse Masterson provided detailed projections of J.S.S.'s future care needs and the cost of that care, to wit "medical care, therapeutic modalities, and equipment and supplies as they relate to his neurological and neurodevelopmental disabilities."<sup>132</sup>

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<sup>131</sup> *Hudson*, 2024 WL 91187 at \*5.

<sup>132</sup> A-075.

Nurse Masterson was deposed on August 3, 2021.<sup>133</sup> During her deposition, Nurse Masterson testified that she spoke with Dr. Adler on November 25, 2020, and discussed “[a]ll of the cost projections and . . . recommendations in the cost projections.”<sup>134</sup> She testified that the cost projections in her report were in “large part” based on her discussions with Dr. Adler.<sup>135</sup> During her deposition, Nurse Masterson also confirmed that J.S.S.’s primary disability is autism spectrum disorder.<sup>136</sup>

On August 8, 2023, following the Court’s first order to exclude Dr. Adler’s unreliable causation opinion, Plaintiffs produced a “revised” life care plan report from Nurse Masterson.<sup>137</sup> Plaintiffs claimed the updated report was different than the original in that it included only future care recommendations unrelated to the child’s autism. However, Nurse Masterson’s “revised report” continued to refer to J.S.S.’s autism diagnosis and focused on services that he receives and will need in the future related to autism. Indeed, Nurse Masterson’s updated report did not address at all how her revised life care plan accounted for the inadmissibility of Dr. Adler’s causation opinion related to autism. Instead, she specifically stated that

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<sup>133</sup> Masterson Dep. Tr. (B-005).

<sup>134</sup> B-040 at 35:2-19.

<sup>135</sup> B-041 at 36:3-8.

<sup>136</sup> B-065 at 60:5-18.

<sup>137</sup> Masterson revised life care plan (A-386).

her revised cost projections were based on Dr. Adler’s 7/14/21 and 6/8/23 reports.<sup>138</sup>

The only reason Nurse Masterson provides for issuing an updated report is to “reflect changes related to [J.S.S.]’s current age of 8 years . . . , life expectancy, review of updated medical records and the re-assessment [she] conducted on 08/03/23....”<sup>139</sup>

The trial court found that Dr. Adler’s third report “offers opinions that are not materially different from or better supported than Dr. Adler’s previously excluded opinions[,]” and granted Defendants’ second motion *in limine* to preclude Dr. Adler’s causation opinion in his third report.<sup>140</sup> Based on that holding, the trial court also precluded Nurse Masterson’s testimony and opinions because they are derivative of Dr. Adler’s.<sup>141</sup> Because the Masterson life care plan is derivative of Dr. Adler’s inadmissible causation opinion, the trial court correctly precluded the opinions stated in Nurse Masterson’s reports for the same reasons it precluded Dr. Adler’s opinions. Accordingly, the Court should affirm the trial court’s ruling.

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<sup>138</sup> A-395, A-399, A-402, A-405.

<sup>139</sup> A-388.

<sup>140</sup> Appellants’ Br. Ex. B. at ¶ 11.

<sup>141</sup> *Id.*

#### **IV. THE TRIAL COURT CORRECTLY EXERCISED ITS DISCRETION IN DENYING PLAINTIFFS' REQUEST FOR RECONSIDERATION UNDER SUPER. CT. CIV. R. 60.**

##### **A. Question Presented**

Did the trial court correctly exercise its discretion in denying Plaintiffs' request to reconsider its March 1, 2023 ruling under Del. Super. Ct. Civ. R. 60 where there is no showing of excusable neglect or extraordinary circumstances?

##### **B. Scope of Review**

The Court reviews a trial court's denial of a motion for relief under Rule 60 for an abuse of discretion.<sup>142</sup> "An abuse of discretion occurs when 'a court has . . . exceeded the bounds of reason in view of the circumstances, [or] . . . so ignored recognized rules of law or practice so as to produce injustice.'"<sup>143</sup>

##### **C. Merits of Argument**

Rule 60(b) provides, in pertinent part, that "[o]n motion and upon such terms as are just, the Court may relieve a party . . . from a final judgment, order, or proceeding for . . . (1) Mistake, inadvertence, surprise, or excusable neglect; . . . or (6) any other reason justifying relief from the operation of the judgment."<sup>144</sup> A Rule

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<sup>142</sup> *Wilson v. Montague*, 2011 WL 1661561 (Del. May 3, 2011).

<sup>143</sup> *Lilly v. State*, 649 A.2d 1055, 1059 (Del. 1994) (quoting *Firestone Tire & Rubber Co. v. Adams*, 541 A.2d 567, 570 (Del. Super. 1988)).

<sup>144</sup> Del. Super. Ct. Civ. R. 60(b). Appellants fail to specify which subsections under Rule 60 entitle them to relief, however, subsections (b)(1) and (6) are arguably relevant.

60(b) motion is a discretionary matter which requires the trial court to weigh the facts and circumstances of the case.<sup>145</sup> For purposes of Rule 60(b), “excusable neglect” is defined as “neglect which might have been the act of a reasonably prudent person under the circumstances.”<sup>146</sup> “A mere showing of negligence or carelessness without a valid reason may be deemed insufficient.”<sup>147</sup> Relief under Rule 60(b)(6) is an extraordinary remedy and requires a showing of “extraordinary circumstances.”<sup>148</sup> Rule 60(b)(6) is “invoked sparingly” because the standard under that section is more exacting than the other sections in Rule 60(b).<sup>149</sup> “Because of the significant interest in preserving the finality of judgments, Rule 60(b) motions are not to be taken lightly or easily granted.”<sup>150</sup>

Here, Plaintiffs twice requested that the trial court reconsider its March 1, 2023 order granting Defendants’ first motion *in limine* to preclude Dr. Adler’s unreliable causation opinion. Plaintiffs made their first request at the November 20, 2023 hearing on Defendants’ second motion *in limine*, nearly nine months after the

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<sup>145</sup> *Cohen v. Brandywine Raceway Ass’n*, 238 A.2d 320, 325 (Del. Super. 1968).

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> *Dixon v. Delaware Olds, Inc.*, 405 A.2d 117, 119 (Del. 1979) (quoting *Jewell v. Division of Social Services*, 401 A.2d 88 (Del. Super. 1979)).

<sup>149</sup> *Wimbledon Fund LP v. SV Special Situations LP*, 2011 WL 378827, at \*6 n.37 (Del. Ch. Feb. 4, 2011) (quoting *CEDE & Co. & Cinerama v. Technicolor, Inc.*, 1994 WL 1753202, at \*1 (Del. Ch. Dec. 6, 1994)).

<sup>150</sup> *MCA, Inc. v. Matsushita Elec. Indus. Co.*, 785 A.2d 625, 635 (Del. 2001).



trial court granted Defendants’ first motion *in limine*.<sup>151</sup> As grounds for Rule 60 relief, Plaintiffs argued that the trial court’s March 1, 2023 order was in violation of *Norman* and *Wong*.<sup>152</sup> After the trial court denied Plaintiffs’ request for Rule 60 relief in its December 15, 2023 order granting Defendants’ second motion *in limine*, Plaintiffs requested reconsideration a second time in their response to Defendants’ motion for summary judgment.<sup>153</sup> The trial court again declined Plaintiffs’ request in its January 31, 2024 order granting Defendants’ motion for summary judgment.<sup>154</sup> In both opinions, the trial court aptly interpreted Plaintiffs’ request to reconsider the March Memorandum Opinion as a Rule 59(e) motion for reargument in disguise because it was “based almost exclusively on the contention that the Court either overlooked or misapprehended controlling legal precedent, *i.e.*, *Norman*.”<sup>155</sup> The trial court held that (1) properly construed as a motion for reargument, Plaintiffs’ motion was untimely, and (2) even if the trial court were to construe Plaintiffs’ request as a Rule 60 motion for reconsideration, Plaintiffs failed to demonstrate extraordinary circumstances warranting reconsideration under Rule 60.<sup>156</sup>

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<sup>151</sup> 11/20/23 Hearing Tr. (A-444–448).

<sup>152</sup> *Id.* Plaintiffs submitted the *Wong* decision in support of their opposition in correspondence to the trial court on November 20, 2023, immediately prior to the hearing on that date. B-426.

<sup>153</sup> Pls.’ Response to Defs.’ Mot. Summ. J. at 5 (A-481).

<sup>154</sup> Appellants’ Br. Ex. C at ¶ 11.

<sup>155</sup> Appellants’ Br. Ex. B at ¶ 11, Ex. C at ¶ 11.

<sup>156</sup> Appellants’ Br. Ex. B at ¶¶ 11-12, Ex. C at ¶ 11.

The trial court correctly declined to reconsider the March 1, 2023 ruling for several reasons. First, and most importantly, for the reasons discussed in the first argument in this brief, *Norman* and *Wong* are not controlling here, and thus, the trial court's order is not in violation of those decisions. Moreover, relief under Rule 60(b) is reserved for cases involving extraordinary circumstances. Plaintiffs cannot meet the high hurdle of Rule 60 relief because dismissal of their case for lack of an admissible causation opinion does not constitute excusable neglect or an extraordinary circumstance.<sup>157</sup> Even assuming, *arguendo*, that Plaintiffs could meet the standard in Rule 60(b)(6), Plaintiffs unreasonably delayed filing their motion.<sup>158</sup> While unreasonable delay is not defined under Rule 60, “Delaware Courts have generally held that a petitioner seeking relief under Rule 60(b) should file a Motion as soon as possible after discovering the need for such a filing.”<sup>159</sup>

Appellants' attempt to distinguish *Wilant*<sup>160</sup> is unavailing. The *Wilant* Court concluded that the expert's causation opinion did not meet the *Daubert* standard for

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<sup>157</sup> *Cohen*, 238 A.2d at 325; *Dixon*, 405 A.2d at 119. *Cf. Mendiola v. State Farm Mut. Auto. Ins. Co.*, 2006 WL 1173898, at \*4 (Del. Super. Apr. 27, 2006) (holding that insurance company's failure to realize that two suits were filed based on the same auto accident was neglect, not extraordinary circumstances).

<sup>158</sup> *Schremp v. Marvel*, 405 A.2d 119, 120 (Del. 1979) (“Plaintiff was[] . . . obliged to act without unreasonable delay (after knowing that his action had been dismissed) in making his [Rule 60] motion.”)

<sup>159</sup> *M.H. v. J.H.*, 2018 WL 7959246, at \*4 (Del. Fam. Nov. 20, 2018) (quoting *E.A.R. v. D.M.R.*, 2018 WL 2714787, at \*2 (Del. Fam. May 22, 2018)).

<sup>160</sup> *Wilant*, 2020 WL 2467076.

admissibility because the evidence cited by the expert identified only a positive association between bladder cancer and the diesel fume exposure at issue in that case.<sup>161</sup> This holding is entirely consistent with cases in other jurisdictions which have excluded expert testimony on the cause of autism on the basis that there is no scientifically reliable basis for that opinion in the medical literature, and thus, the trial court appropriately relied on *Wilant*.

Plaintiffs had ample opportunity, after the trial court granted Defendants' first motion *in limine*, to present a new causation opinion from Dr. Adler to address any non-autism related disabilities that he contends the child developed from an anoxic brain injury. Instead, Dr. Adler's third report merely recycled his previously excluded opinion. For these reasons, the Court should affirm the trial court's ruling.

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<sup>161</sup> *Id.* at \*5.

## CONCLUSION

Plaintiffs mis-read *Norman* and *Wong* as lowering the *Daubert* bar across the board for medical expert testimony. On the contrary, Rule 702 and the *Daubert* criteria are meant to be applied in a flexible manner depending on the opinion being offered. The complex medical opinion offered here warranted a thorough gatekeeper analysis by the Superior Court, pursuant to which the opinion was rightly found wanting in reliability and relevance. When given an opportunity to scale back Dr. Adler's opinion to focus on injuries alleged not to fall within the autism diagnosis, Plaintiffs chose instead to double down on the original—and by then excluded—opinion. Under the circumstances, it should have come as no surprise to Plaintiffs that the result following the production of Dr. Adler's third report was the same, or that their request for another hearing of the same evidence or a complete do over under Rule 60 were denied. For all the foregoing reasons, this Court should affirm the Superior Court's rulings excluding the opinions of Plaintiffs' causation and life care experts, denying the request for a *Daubert* hearing, and denying the request for Rule 60 relief.

**Respectfully submitted,**

**BALAGUER MILEWSKI &  
IMBROGNO**

*/s/ John D. Balaguer*

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