

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

SARAH ANN BERTOLA and)
DALLAS BERTOLA,)
Co-Personal Representatives of the)
Estate of A.M.B., deceased)
and in their own right,)

Plaintiffs,)

v.)

FISHER-PRICE, INC. and)
MATTEL, INC.,)

Defendants.)

C.A. No.: N21C-01-115 FJJ

Submitted: April 16, 2025

Decided: April 21, 2025

OPINION AND ORDER

On the Defendants' Evidentiary Motions

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Jones, J.

INTRODUCTION

Plaintiffs Sarah Ann Bertola and Dallas Bertola (“Plaintiffs”) filed the instant products liability suit against Fisher-Price, Inc. and Mattel, Inc. (“Defendants”) in response to the death of Plaintiffs’ infant child, A.M.B., while sleeping in Fisher-Price’s Rock ‘n Play Sleeper (“RnP”). Plaintiffs allege a defect in the RnP caused positional asphyxiation so that A.M.B. could not breath and eventually passed. Defendants filed a number of *Daubert* Motions. This is the Court’s Order on these Motions.

STANDARD OF REVIEW

Delaware Rule of Evidence 702 governs the admissibility of expert testimony. Delaware has adopted the holdings in *Daubert v. Merrell Dow Pharmaceuticals Inc.*¹ and *Kumho Tire Co., Ltd. v. Carmichael*² to interpret the Delaware Rule.³ In *Daubert* and *Kumho*, the United States Supreme Court interpreted and explained Federal Rule of Evidence 702, which is “substantially similar” to the Delaware Rule.⁴ Delaware Rule 702 states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise, if: (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to

¹ 509 U.S. 579 (1993).

² 526 U.S. 137 (1993).

³ *Bowen v. E.I. DuPont de Nemours & Co., Inc.*, 906 A.2d 787, 794 (Del. 2006) (citing *M.G. Bancorporation, Inc. v. Le Beau*, 737 A.2d 513, 522 (Del. 1999)).

⁴ *Smack-Dixon v. Walmart Inc.*, 2021 WL 3012056 (Del. Super. Ct. Jul. 16, 2021) (citing *Bowen*, 906 A.2d at 794).

determine a fact in issue; (b) the testimony is based upon sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the witness has applied the principles and methods reliably to the facts of the case.⁵

To be admissible, expert testimony must be “relevant and reliable.”⁶ To make this determination, the trial judge engages in a five-step analysis.⁷ This analysis provides that the trial judge finds that:

- (1) the witness is qualified as an expert by knowledge, skill, experience, training, or education;
- (2) the evidence is relevant;
- (3) the expert’s opinion is based on information reasonably relied upon by experts in the particular field;
- (4) the expert testimony will assist the trier of fact to understand the evidence or to determine a fact in issue; and
- (5) the expert testimony will not create unfair prejudice or confuse or mislead the jury.⁸

The burden of establishing that the expert testimony is admissible lies with its proponent by a preponderance of the evidence.⁹ “A strong preference exists” for admitting expert opinions “when they will assist the trier of fact in understanding the relevant facts or the evidence.”¹⁰

⁵ D.R.E. 702; *see also Smack-Dixon*, 2021 WL 3012056 (Del. Super. 2021).

⁶ *Daubert*, 508 U.S. at 597.

⁷ *Smack-Dixon*, 2021 WL 3012056 at *2 (citing *Bowen*, 906 A.2d at 795)).

⁸ *Id.*

⁹ *Id.*

¹⁰ *Smack-Dixon*, 2021 WL 3012056 at *2 (quoting *Delaware ex. Rel. French v. Card Compliant, LLC*, 2018 WL 4151288, *2 (Del. Super. Ct. Aug. 29, 2018) (quoting *Norman v. All About Women, P.A.*, 193 A.2d 726, 730 (Del. 2018))).

Reliable expert testimony is premised on scientific or specialized knowledge which requires the testimony to be grounded in scientific methods and procedures and “supported by appropriate validation – *i.e.*, ‘good grounds,’ based on what is known.”¹¹

Many scientific, technical, or specialized fields are not subject to peer review and publication which is why the test of reliability is “flexible.” A rigid application of the *Daubert* factors to determine testimonial reliability in every field of expertise is not practical.¹² Even with all the advances of medical science, the practice of medicine remains an art, and a diagnosis in the practice of clinical medicine “is not an exact science.”¹³

Again, a gatekeeping judge has “broad latitude” to determine whether an expert’s proffered opinion is based upon the “proper factual foundation and sound methodology.”¹⁴ This “proper factual foundation” language has been distilled from Delaware Rule 702.¹⁵ To meet the criterion for a “proper factual foundation,” an

¹¹ *Daubert*, 509 U.S. at 590.

¹² *Henlopen Hotel v. United Nat’l Ins. Co.*, 2020 WL 233333, at *3 (Del. Super. May 11, 2022).

¹³ *State v. McMullen*, 900 A.2d 105, 114 (Del. Super. Ct. 2006). *See also Moore v. Ashland Chem.*, 126 F.3d 679, 688-690 (5th Cir. 1997), *vacated on reh’g en banc*, 151 F.3d 269 (5th Cir. 1998) (“First, the goals of the disciplines of clinical medicine and hard Newtonian science are different. . . .Second, the subject matter and conditions of study are different. . . .Finally, clinical medicine and hard science have marked different methodologies. . . .In sum, hard Newtonian scientific knowledge. . .is knowledge of a particular and limited kind. . . . Although clinical medicine utilizes parts of some hard sciences, clinical medicine and many of its subsidiary fields are not hard sciences. . . . Consequently, the *Daubert* factors, which are hard scientific methods selected from the body of hard scientific knowledge and methodology generally are not appropriate for use in assessing the relevance and reliability of clinical medical testimony”). The Fifth Circuit’s discussion of the significant differences between disciplines in “hard science” and clinical medicine still holds true even though the decision in that case was ultimately vacated. *Id.*

¹⁴ *Russum v. IPM Dev. P’ship LLC*, 2015 WL 2438599, at *2 (Del. Super. May 21, 2015).

¹⁵ *Id.*

expert’s opinion must be based on “facts” and not “suppositions.”¹⁶ When applied to a medical expert, a causation opinion is admissible when it’s “based on his analysis of the circumstances . . . not mere speculation over the cause.”¹⁷ And a proponent need only show by a preponderance of the evidence that her expert’s opinions are reliable, not that they are correct.¹⁸ So, this Court’s Rule 702 reliability examination must focus on principles and methodology not on the resultant conclusions.¹⁹

Delaware courts generally recognize that challenges to the “factual basis of an expert opinion go to the credibility of the testimony, not the admissibility, and it is for the opposing party to challenge. . . the expert opinion on cross-examination.”²⁰ “The different depth with which [an expert] pursued particular lines of investigation and the different assumptions they made are readily subject to cross-examination and to evaluation by the fact finder for credibility and weight.”²¹ An expert’s testimony will only be excluded in the narrow circumstance where he is shown to have completely neglected the core facts of the case.²² And, under Delaware Rule

¹⁶ *Id.* at 3.

¹⁷ *Norman*, 193 A.2d at 732.

¹⁸ *McMullen*, 900 A.2d at 114 (citing *In Re: Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 744 (3d Cir. 1994)).

¹⁹ *Henlopen Hotel*, 2020 WL 233333, at *2 (“At bottom, the Court’s examination of an expert’s opinion must be solely focused on principles and methodology, not on the conclusions they generate.”) (quoting *Tumlinson v. Advanced Micro Devices*, 81 A.3d 1264, 1269 (Del. 2013)).

²⁰ *Perry v. Berkley*, 996 A.2d 1262, 1271 (Del. 2010). *See also Hodel v. Ikeda*, 2013 WL 226937, at *4 (Del. Super. Ct. Jan. 18, 2013); *Daubert*, 509 U.S. 579, 596 (1993) (“Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.” (internal citations omitted)); *Russum*, 2015 WL 2438599, at *3.

²¹ *Henlopen Hotel*, 2020 WL 233333, at *4; *Perry v. Berkley*, 996 A.2d at 1271 (noting cross-examination rather than exclusion can be the proper method of exploring the bases of an expert’s opinion and the weight to be ascribed thereto).

²² *Russum*, 2015 WL 2438599, at *3.

702, a medical doctor’s opinion “based on his own knowledge” and informed by his review of a patient’s records may certainly be sufficient to clear the *Daubert/Bowen* reliability threshold.²³

EXPERT TESTIMONY REGARDING CONSCIOUS PAIN AND SUFFERING

Defendants seek to exclude the conscious pain and suffering testimony of two of Plaintiffs’ experts, Darlene Vasbinder-Calhoun and Wayne Ross.²⁴ Defendants’ arguments in their Motion were addressed by Judge Winston in *Brown v. Fisher-Price, et. al.*²⁵ This Court defers to and adopts Judge Winston’s ruling in that opinion, and, thereby, **DENIES** Defendants’ Motion to Exclude Expert Testimony on Conscious Pain and Suffering.

TESTIMONY OF DENNIS ROSEN

Defendants seek to exclude Plaintiffs’ pediatric expert, Dr. Dennis Rosen (“Rosen”).²⁶ Rosen is a pediatrician whose expertise is in pediatric pulmonology and sleep medicine.²⁷ Rosen’s general causation opinion is that the RnP “places an infant in an anatomical position that is unsafe for unsupervised sleep and directly contradicts the longstanding recommendations of the American Academy of Pediatrics on safe sleep,” and “positions an infant in a manner which predisposes

²³ See e.g., *Norman*, 193 A.3d at 731-32.

²⁴ Docket Item (“D.I.”) 162

²⁵ See Order Denying the Exclusion of Conscious Pain and Suffering Expert Testimony, N20C-01-067, D.I. 162 (Dec. 20, 2024).

²⁶ D.I. 152.

²⁷ D.I. 190, Exhibit (“Ex.”) A, Rosen’s Expert Report, p.1.

them to neck flexion,” causing positional asphyxiation. Rosen testifies his opinion to the specific cause of A.M.B.’s death is that the infant “slumped forward with her neck in flexion of at least 20 degrees,” which led to “positional obstruction of [her] upper airway passages, was unable to extricate herself from this position, and died as a result of cardiopulmonary arrest.”²⁸

Defendants base their argument on three points: (1) Rosen had “no scientifically reliable basis for any general causation opinion” that the RnP’s incline could cause “supine (face up) infants to die from chin-to-chest positional asphyxiation;” (2) Rosen’s specific causation opinion is based on guesswork and speculation; and (3) Rosen did not, but should have, conducted a differential diagnosis.²⁹

The first two points are identical to Defendants’ arguments concerning exclusion of Rosen in *Brown*, which Judge Winston addressed in an Order.³⁰ Therefore, this Court relies on Judge Winston’s ruling in *Brown* and applies it to this case.

As to Defendants’ third contention, they argue Rosen’s opinion is inadmissible because he did not conduct a differential diagnosis. They further contend Rosen did not consider two prominent alternative causes of death: (1) lack

²⁸ *Id.*, Ex. A. p.18-19.

²⁹ *Id.* p.2-4.

³⁰ See Order Denying Exclusion of the Dennis Rosen’s Testimony, N20C-01-067, D.I. 324 (Dec. 20, 2024).

of restraint use and (2) the presence of a blanket.³¹ Plaintiffs counter that Rosen did consider and rule out other potential causes of death. To support this, Plaintiffs point to sections of Rosen’s report and rebuttal as well as deposition testimony to show Rosen considered and ultimately determined there was no evidence indicating another diagnosis.³² Rosen bases his finding that there was no other cause of death on the fact that A.M.B. was found “in a position which is known to put infants at risk and actual occlusion of their upper airway, and that when that happens, causes death and she died in that position.”³³

Differential diagnosis is a methodological process of exclusion recognized in clinical medicine “involv[ing] the testing of a falsifiable hypothesis . . . through an attempt to rule out alternative causes.”³⁴ It is the Court’s responsibility to determine if an expert uses a reliable differential diagnosis method to come to their conclusion.³⁵ Delaware law grants the courts flexibility in determining the reliability of an expert’s differential diagnosis method.³⁶

Defendants cite to a footnote in *State v. McMullen* which lays out a two-step approach to differential diagnosis taken by the New Jersey Supreme Court.³⁷ Defendants seem to suggest that because Rosen did not take this formal approach to

³¹ D.I. 152 p.22-24.

³² See D.I. 190, Ex. A p.2-4; 17-19; Ex. B. p.2-3; Ex. F 138:10-24, 139:1-16.

³³ *Id.* Ex. F 139:12-16.

³⁴ *State v. McMullen*, 900 A.2d 103, 116 (Del. Super. Ct. 2006)

³⁵ *Id.* at 117.

³⁶ *Id.* at 118.

³⁷ *Id.* 116 n.63 (citing *Creanga v. Jardal*, 886 A.2d 633, 639 (2005)).

his analysis, his opinion is improper. However, case law does not require this approach, and the expert can use whatever reliable methodology to differential diagnostics they see fit. Although Rosen does not conduct an extensive analysis into other potential causes of death, Rosen does address them³⁸ and relies on his methodology and resources used to form his ultimate opinion and conclude that there is no medical cause other than positional asphyxiation that could have led to A.M.B.'s death. In addition, Rosen addressed both the lack of restraint and blanket-use concerns raised by Defendants and, using his experience, training, and reliable resources, ruled out each as a potential cause.³⁹

Based on the above reasons, Defendants' Motion to Exclude the Testimony of Dennis Rosen is **DENIED**.

TESTIMONY OF ERIN MANNEN

Defendants ask the Court to exclude the testimony of Erin Mannen ("Mannen"), Plaintiffs' expert in biomechanical engineering. Mannen's ultimate opinion is that "the defective design of the Fisher Price Rock 'n Play Sleeper results in an unreasonably dangerous biomechanical scenario that negatively influences breathing, increasing the risk for positional asphyxia and/or suffocation, which is what occurred with [A.M.B.]."⁴⁰

³⁸ See D.I. 190, Ex. B p.2-3, Ex. F 138:10-24, 139:1-16.

³⁹ See *Id.* Ex. F 139-42; 143-46.

⁴⁰ D.I. 193 Ex. E, Mannen's Expert Report, p.31.

Defendants base the need for exclusion on two arguments: (1) Mannen cannot testify to medical causation because it is outside her area of expertise, and (2) Mannen's opinions are speculative and lack an evidentiary basis.⁴¹ Under the second basis, Defendants argue Mannen's hypotheses, including (a) the RnP made it easy for an infant to roll into a dangerous "chin-to-chest" or "flexed head/neck" position, (b) the RnP increases an infant's risk for suffocation or positional asphyxiation by placing them in a "flexed trunk" position, and (c) 90-degree head-turn/rebreathing theory, are not supported by evidence or reliable science.⁴² Defendants premise much of their opposition to these hypotheses with the argument that Mannen's studies, her own and others, are unreliable and inapplicable to A.M.B.'s death.

In response to Defendants' arguments against Mannen's 90-degree head-turn/rebreathing theory, Plaintiffs state "there will no medical testimony in the Bertola case opining that rebreathing was a cause of A.M.B.'s death and, consequently, Dr. Mannen will offer no specific causation testimony on this issue."⁴³ In light of Plaintiffs' concession, Defendants' Motion on this point is **GRANTED**.

As to Defendants' other arguments, Judge Winston ruled in *Brown*, that Mannen satisfies the requirements under D.R.E. 702 and *Daubert* to provide causation opinions based on her experience, training, and expertise in biomechanical

⁴¹ See D.I. 168.

⁴² *Id.* p.21-23.

⁴³ D.I. 193 p.39.

engineering.⁴⁴ Judge Winston also addressed the reliability of the studies Mannen uses in her report, including Mannen’s CPSC study as well as the Wang, et. al. study she took part in.⁴⁵ Mannen uses the same resources in her report for *Brown* and *Bertola*.⁴⁶ This Court defers to and adopts Judge Winston’s Order determining the studies and methodology Mannen uses to create her hypotheses and form her final opinions are reliable, applicable to the facts, and admissible.⁴⁷

Based on these reasons, Defendants’ Motion to Exclude the Testimony of Erin Mannen on these two points is **DENIED**.

TESTIMONY OF BENJAMIN HOFFMAN

Defendants seek to exclude the testimony of Plaintiffs’ pediatric expert, Dr. Benjamin Hoffman (“Hoffman”). Hoffman is a pediatrician and an expert in child injury prevention.⁴⁸ Hoffman’s ultimate opinion is the RnP “placed an infant in a position for sleep which was inconsistent with the clear recommendations of the AAP,” and A.M.B “died of positional asphyxiation while in a [RnP] as a result of the inclined position in which it placed her, causing her head to flex downward at the neck, leaving her in a ‘chin to shoulder’ position, obstructing her airway, leading to positional asphyxia.”⁴⁹ In forming this conclusion, Hoffman reviewed A.M.B.’s

⁴⁴ See Order Denying Exclusion of Erin Mannen’s Testimony, N20C-01-067, D.I. 320 (Dec. 20, 2024).

⁴⁵ *Id.* p. 12-20.

⁴⁶ See *Brown*, N20C-01-067, D.I. 211 Ex. G; D.I. 193 Ex. E.

⁴⁷ *Id.*

⁴⁸ D.I. 195 p.1.

⁴⁹ *Id.* Ex. B p.2, 14.

prenatal, delivery, post-partum, and pediatric care medical records, case records pertaining to the incident, and medical studies and literature.⁵⁰

Defendants argue three primary contentions with Hoffman’s testimony: (1) Hoffman is not a biomechanical expert, yet he gives biomechanic opinions; (2) Hoffman’s general causation opinion has no reliable basis in science and his reliance on Mannen’s report deems his opinion inadmissible, and (3) Hoffman’s specific causation theory is inadmissible because it is speculative and does not consider a differential diagnosis analysis.⁵¹

Defendants raised these arguments in *Brown*, and Judge Winston ruled on each of them.⁵² This Court applies and adopts Judge Winton’s rulings in that Order and, thereby, **DENIES** Defendants’ Motion to Exclude Testimony of Benjamin Hoffman.

TESTIMONY OF DARLENE VASBINDER-CALHOUN

Defendants request the Court to exclude the testimony of Plaintiffs’ neonatal expert, Dr. Vasbinder-Calhoun (“Vasbinder-Calhoun”). Vasbinder-Calhoun’s opinion is that the position A.M.B. was found in the morning is “consistent with positional asphyxiation and suffocation due to the incline angle to the RnP,” and that A.M.B. suffered conscious pain and suffering while suffocating in the RnP.⁵³ In

⁵⁰ *Id.* p.2.

⁵¹ *See* D.I. 167.

⁵² *See* Order Denying Exclusion of Benjamin Hoffman’s Testimony , N20C-01-067, D.I. 321 (Dec. 20, 2024).

⁵³ D.I. 189, Ex. A p. 19-20.

forming her opinion, she reviewed A.M.B.’s medical history, prenatal, delivery, and post-birth, the facts of the incident, and medical literature.⁵⁴

Defendants contest Vasbinder-Calhoun’s testimony on three grounds: (1) Vasbinder-Calhoun’s general causation opinion that the RnP’s incline can cause chin-to-chest positional asphyxiation lacks a scientifically reliable basis; (2) her specific causation opinion is speculative, unreliable, and lacks a differential diagnosis analysis; and (3) Vasbinder-Calhoun’s testimony as to A.M.B.’s conscious pain and suffering is not rooted in science and was “invented for purposes of this litigation.”⁵⁵

Judge Winston ruled on the first two arguments against Vasbinder-Calhoun’s testimony in her prior Order for *Brown*.⁵⁶ Because Judge Winston’s Order thoroughly analyzes and rules on the arguments Defendant makes in this Motion, the Court will defer to and adopts Judge Winston’s ruling pertaining to those arguments. The Order did not address Defendants’ third argument in this case; however, as stated above, Judge Winston did permit Vasbinder-Calhoun’s conscious pain and suffering testimony in an Order addressing the expert pain and suffering

⁵⁴ *Id.*, Ex. A, Attachment B – Listing of Documents Review.

⁵⁵ See D.I. 146.

⁵⁶ See Order Denying in Part and Granting in Part Exclusion of Darlene Vasbinder-Calhoun’s Testimony, N20C-01-067, D.I. 323 (Dec. 20, 2024).

testimony.⁵⁷ The Court will defer to and adopt Judge Winston’s rulings in that Order in admitting Vasbinder-Calhoun’s testimony on conscious pain and suffering.

For the above reasons, Defendants’ Motion to Exclude the Testimony of Darlene Vasbinder-Calhoun is **GRANTED** as it pertains to Vasbinder-Calhoun’s general causation opinion that the RnP “can cause death,” and is **DENIED** on all other grounds.

TESTIMONY OF WAYNE ROSS

Defendants ask the Court to exclude the testimony of Plaintiffs’ forensic pathology expert, Wayne Ross (“Ross”). Ross concludes the cause of death was “Complication of Positional Asphyxiation.”⁵⁸ Ross also opines that A.M.B. “suffered conscious pain and suffering for a quantifiable period of time that would have been a minimum of a minute and a maximum of many minutes.”⁵⁹ Ross relied on A.M.B’s and Ms. Bertola’s medical records, autopsy report, and records indicating the facts of the incident in coming to his conclusion.⁶⁰

Defendants argue Ross’s testimony is inadmissible because (1) he lacks a scientific basis for his general causation opinion that the RnP incline can cause chin-to-chest positional asphyxiation; (2) Ross’s specific causation opinion is based on

⁵⁷ See Order Denying Exclusion of Conscious Pain and Suffering Expert Testimony, N20C-01-067, D.I. 322 (Dec. 20, 2024).

⁵⁸ D.I. 191 Ex. C p.4 ¶1.

⁵⁹ *Id.* Ex. C p. 4 ¶4.

⁶⁰ *Id.* Ex. C p.1.

his own speculation and conjecture of the facts; (3) his opinion as to the pathological cause of A.M.B.'s death is only based on his own knowledge and not on other medical literature; and (4) his conscious pain and suffering opinions are "invented for the purposes of this litigation," and not based on a reliable scientific foundation.⁶¹

In a prior order in *Brown*, Judge Winston ruled against the first three arguments Defendants made against Ross's testimony.⁶² The Court relies on and adopts Judge Winston's ruling to the instant Motion. As to Defendants' argument to exclude Ross's conscious pain and suffering testimony, this Court defers to Judge Winston's Order permitting Ross's conscious pain and suffering testimony in the above-mentioned Order addressing the expert pain and suffering testimony.⁶³

For these reasons, the Court **DENIES** Defendants' Motion to Exclude the testimony of Wayne Ross.

IT IS SO ORDERED.

/s/ Francis J. Jones, Jr.

Francis J. Jones, Jr., Judge

cc: *File&ServeXpress*

⁶¹ See D.I. 148.

⁶² See Order Denying Exclusion of Wayne Ross's Testimony pursuant to D.R.E. 702, N20C-01-067, D.I. 325 (Dec. 20, 2024).

⁶³ See Order Denying Exclusion of Conscious Pain and Suffering Expert Testimony, N20C-01-067, D.I. 322 (Dec. 20, 2024).