

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

AMEENA BROWN and EVAN)
BRAGGS, Individually and as Co-)
Administrators of the Estate of A.B.,)
deceased,)
Plaintiffs,)

v.)

C.A. No. N20C-01-067 PAW

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

Submitted: November 8, 2024

Decided: December 20, 2024

MEMORANDUM OPINION AND ORDER

*Upon Consideration of Defendants' Motion to Exclude the Expert Testimony
regarding Rebreathing to D.R.E. 702;*

DENIED, in part and GRANTED, in part.

Robert Leoni, Esq., of Shelsby & Leoni, PA, *Attorney for Plaintiffs.*

Jennifer C. Wasson, Esq., Carla M. Jones, Esq., and Ryan Kingshill, Esq., of Potter
Anderson & Corroon LLP, *Attorneys for Defendants.*

WINSTON, J.

I. INTRODUCTION¹

Defendants move to exclude the expert testimony of Michael Leshner, a professional engineer who intends to testify about the risk of rebreathing caused by the design of the RnP.² Defendants also move to exclude rebreathing testimony of Plaintiffs' other experts because those experts rely on Leshner's report.³ Only the admissibility of Leshner's testimony, and any additional rebreathing testimony, will be examined below.

II. STANDARD OF REVIEW

Delaware Rule of Evidence ("D.R.E.") 702 governs the admission of expert testimony. Under D.R.E. 702, expert opinion testimony is admissible provided that the witness "is qualified as an expert by knowledge, skill, experience, training, or education" if:

¹ This Memorandum Opinion and Order references the factual and procedural background outlined in the Court's Memorandum Opinion and Order upon Consideration of Defendants' Motion for Summary Judgment, which the Court incorporates by reference. Unless otherwise noted, defined terms are ascribed the same meaning as in the Court's Summary Judgment Memorandum Opinion.

² Defs.' Mot. to Exclude Test. Regarding Rebreathing, D.I. 164.

³ *Id.* Separately, Defendants have moved to exclude the testimony of all of those additional experts, with the exception of Myers, which the Court addresses in its separate Memorandum and Orders. Defs.' Mot. to Exclude Pls.' Expert Darlene Vasbinder-Calhoun, D.O., D.I. 179; Defs.' Mot. to Exclude Pls.' Expert Benjamin Hoffman, M.D., D.I. 168; Defs.' Mot. to Exclude Pls.' Expert Erin Mannen, PH.D., D.I. 184; Defs.' Mot. to Exclude Pls.' Expert Dennis Rosen, M.D., D.I. 177; Defs.' Mot. to Exclude Pls.' Expert Wayne Ross, M.D., D.I. 174.

- (a) the expert’s scientific, technical, or other specialized knowledge will help the trier of the 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 applied the principles and methods to the facts of the case.⁴

The burden falls on the party seeking to admit the expert testimony to show, by a preponderance of the evidence, its admissibility under D.R.E. 702.⁵ “Once expert testimony is challenged, the reviewing court must ensure that the proffered testimony is both relevant and reliable.”⁶ To fulfill this duty, this Court acts as gatekeeper, determining if “the reasoning or methodology underlying the testimony is scientifically valid and ... whether that reasoning or methodology properly can be applied to the facts in issue.”⁷ In making that determination, the Court applies a five-step test that examines whether:

- (1) the witness is qualified as an expert by knowledge, skill, experience, training[,] or education;
- (2) the evidence is relevant [and reliable];
- (3) the expert’s opinion is based upon information reasonably relied upon by experts in the particular field;
- (4) the expert will assist the trier of fact to understand the evidence or to determine a fact in issue; and

⁴ D.R.E. 702.

⁵ *Bowen v. E.I. DuPont de Nemours & Co., Inc.*, 906 A.2d 787, 795 (Del. 2006).

⁶ *Scottoline v. Women First, LLC*, 2023 WL 2325701, at *3 (Del. Super. Mar. 1, 2023) (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 597 (1993)).

⁷ *Gen. Motors Corp. v. Grenier*, 981 A.2d 531, 536 (Del. 2009) (internal quotations omitted) (quoting *Daubert*, 509 U.S. 579, at 592-93).

(5) the expert testimony will not create unfair prejudice or confuse or mislead the jury.⁸

For scientific evidence to be deemed reliable, the testimony must be rooted in science and derived from the scientific method.⁹ Expert testimony is relevant when it assists the trier of fact to understand the evidence or to determine a fact in issue. Thus, the core of a *Daubert* analysis is the “principles and methodology” used in formulating an expert’s testimony, not on the expert’s resultant conclusions.¹⁰ This Court possesses “broad latitude to determine whether any or all of the *Daubert* factors are reasonable measures of reliability in a particular case.”¹¹ “A strong preference exists for admitting evidence that may assist the trier of fact.”¹²

III. ANALYSIS

Defendants do not challenge Leshner’s credentials as an expert, only the methodology he employed, the reliability of his findings, and the relevance of his opinion to the instant case.¹³ As Plaintiffs’ other experts cite to Leshner, indicating

⁸ *Norman v. All About Women, P.A.*, 193 A.3d 726, 729-30 (quoting *Smith v. Grief*, 2015 WL 128004 (Del. Jan. 8, 2015)).

⁹ *Daubert*, 509 U.S. at 590-94.

¹⁰ *Bowen*, 906 A.2d at 794 (citing *Daubert*, 509 U.S. at 595).

¹¹ *Grenier*, 981 A.2d at 536 (internal quotations omitted) (quoting *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999)).

¹² *Norman*, 193 A.3d at 730.

¹³ D.I. 164 at 2.

some level of reliance on his report, the Court first considers the admissibility of Leshner's report.

Leshner formulated his report by conducting a test using a doll placed in several different infant sleep products.¹⁴ Using a model lung placed within the doll, Leshner measured the levels of carbon dioxide over time after placing the doll in various positions within the sleep products.¹⁵ While performing the test using a version of the RnP, Leshner tested three different layers of "soft material."¹⁶ Leshner ran each test three times.¹⁷

Leshner states five conclusions in his report:

(1) An infant sleeping prone on a standard crib mattress and cotton sheet does not experience a hazardous level of carbon dioxide rebreathing; (2) an infant sleeping prone on a soft sleep surface may experience elevated levels of carbon dioxide rebreathing; (3) when sleeping prone on a flat sleep surface, turning the infant's head is an effective countermeasure to rebreathing; (4) when prone or side-facing in the Rock 'n Play, an infant is in a very hazardous position due to the risk of elevated levels of carbon dioxide rebreathing; (5) the design of the Rock n' Play is defective and unreasonably dangerous to infants due to the risk of hazardous carbon dioxide rebreathing.¹⁸

¹⁴ Ex. C to Pls.' Answering Br., D.I. 213, at 5 ("Leshner's Report").

¹⁵ *Id.* at 6.

¹⁶ *Id.* at 12.

¹⁷ *Id.* at 5.

¹⁸ *Id.* at 13-14.

Of his conclusions, the first three provide points of comparison for the final two. Taken together, Leshner posits the RnP’s design is defective because an infant laying side-facing in the RnP faces a heightened risk of “hazardous” levels of carbon dioxide.¹⁹ As his first three opinions serve to contextualize the final two, the Court’s analysis must focus on the admissibility of Leshner’s final two conclusions.

A. LESHNER DID NOT UTILIZE A SUFFICIENTLY RELIABLE METHODOLOGY TO EXAMINE THE SPECIFIC INCREASE IN CARBON DIOXIDE AN INFANT WOULD BE EXPOSED TO IN THE RNP, MAKING HIS TESTIMONY INADMISSIBLE.

“Reliable means testimony must be supported by appropriate validation—i.e., good grounds, based on what is known.”²⁰ Two of the factors *Daubert* instructs this Court to consider are “whether the expert’s theory has or can be tested,” and “the known or potential error rate associated with the theory.”²¹ Defendants devote much of their opening brief to a discussion of *Rovid v. Graco Children’s Products Inc.*,²² a federal case in which the court excluded a similar report prepared by Leshner. The *Rovid* court took issue with Leshner’s failure to perform more than a single test, the lack of statistical rigor applied to his test results, and Leshner’s failure “to explain

¹⁹ *Id.*

²⁰ *Tumlinson v. Advanced Micro Devices, Inc.*, 2013 WL 7084888 at *2 (Del. Super. Oct. 15, 2013), *aff’d*, 81 A.3d 1264 (Del. 2013) (internal quotations omitted) (quoting *Daubert*, 509 U.S. at 597).

²¹ *Id.*

²² 2018 WL 5906075, at *4 (N.D. Cal. Nov. 9, 2018).

or show whether he controlled for the position of the doll on the mattress.”²³ Further, the court found Leshner’s conclusions were unsupported by his data.²⁴ Defendants also point to Leshner’s decision to use slightly different locations in each retest, “a couple inches apart,”²⁵ as a fatal flaw in Leshner’s methodology rendering his results impossible to reproduce because Leshner failed to document the different locations the measurements derived from.²⁶

Unlike *Rovid*, Leshner repeated his testing three times.²⁷ In addition, Leshner documented an approximation of the locations he used when retesting each sleep setting through photographs of each location.²⁸ These photographs provide an opportunity for a subsequent expert to recreate Leshner’s procedure. As a result, Leshner’s theory may be retested and satisfies one factor for reliability under *Daubert*.

However, Leshner is unable to quantify the statistical reliability of his numbers. A review of the data collected by Leshner shows a significant variation in

²³ *Id.*

²⁴ *Id.* at *5.

²⁵ Ex. L to Pls.’ Answering Br., D.I. 213, at 35 (“Leshner’s Deposition”).

²⁶ D.I. 164 at 24.

²⁷ Leshner’s Report at 5; *see also* App. F to Leshner’s Report.

²⁸ Leshner’s Report at 8-11.

the carbon dioxide readings throughout Leshner's retests.²⁹ In his deposition, Leshner explained that he could not quantify what statistical deviation between his measurements would "give him pause."³⁰ Regarding the test of a side-facing doll in an RnP, a test of particular consequence to the instant case given the facts, Leshner opined "[i]t's measuring three different locations, three different configurations. So that spread between 10 and 17 does not give me any pause."³¹ Yet, he does not provide any further explanation as to why that would be true or offer any citation to reaffirm that stance.

Leshner states the variation in the position of the doll when retesting by one or two inches would not affect the reliability of the data.³² However, the fluctuations between the results demonstrate that the one- or two-inch variation in position may have affected the recorded level of carbon dioxide. Leshner provides no other explanation or additional variables, in his report or in his deposition, that would account for this fluctuation in results. Accordingly, the Court cannot have confidence that Leshner's testing utilized a reliable methodology under *Daubert*, and, thus, this Court cannot admit Leshner's expert testimony.

²⁹ App. F to Leshner's Report.

³⁰ Leshner's Deposition at 135-37.

³¹ *Id.*

³² Leshner's Deposition at 121.

B. LESHNER’S CONCLUSIONS ARE NOT ADEQUATELY SUPPORTED BY HIS DATA.

Even if the Court accepted Leshner’s methodology as reliable, his conclusions are not properly grounded in the data he presents. Though the focus under *Daubert* is on principles and methodology and not on conclusions, other factors that might be considered include whether an expert has unjustifiably extrapolated from an accepted premise to an unsupported conclusion.³³ In addition, a court may exclude expert testimony on the ground that an expert’s purported methodology fails to explain his final conclusions.³⁴

Leshner opines that the elevated level of carbon dioxide an infant may be exposed to as a result of the RnP’s design are “very hazardous” and “unreasonably dangerous.”³⁵ This contrasts to the carbon dioxide level found when testing a doll placed on a “standard crib mattress,” which Leshner opines is not hazardous.³⁶

As an initial matter, Plaintiffs conceded that Leshner’s testimony is limited to showing the subject mattress performance in the tests relative to the other mattresses’ performance.³⁷ Leshner expressly limited his task to that purpose: “I tested the CO2

³³ *General Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

³⁴ *Id.*

³⁵ Leshner’s Report at 14.

³⁶ *Id.* at 13.

³⁷ Pls’ Answering Br., D.I. 213, at 10.

rebreathing. I tested it on hard surfaces and on soft surfaces. The softness correlates with the CO₂ rebreathing.”³⁸ Thus, even if Leshner’s testing involved a reliable methodology, his conclusions based upon that testing should be limited to that narrow scope and comparative nature. At best, only Leshner’s first, second, and third conclusions reflect the limited nature of Leshner’s testing.

Further, Leshner’s results do not support his conclusions because his rebreathing results have no objective benchmark or threshold to be compared against. When asked to provide a threshold of what level of carbon dioxide poses a risk, Leshner declined to do so.³⁹ Without providing an objective way to quantify hazardous levels of carbon dioxide, Leshner’s conclusions as to which sleep surfaces are safe, and which are not, appears to reduce to Leshner drawing an arbitrary line.

Leshner’s definition of “hazardous” does not help. Leshner stated at his deposition: “...when you test [a mattress] compared to a bunch of other things, some things are two, three, four, five times higher. The stuff on the low end is the least hazardous... [O]nce you get to three, four times the normal level, certainly that would be hazardous.”⁴⁰ Without supporting evidence or qualifying expertise, Leshner cannot merely assert that any amount of CO₂ rebreathing is hazardous.

³⁸ Leshner’s Deposition at 98.

³⁹ Leshner’s Deposition at 37-40.

⁴⁰ Leshner’s Deposition at 184.

Further, Leshner’s proposed definition renders his “hazard”-related conclusions misleading and meaningless. The Court finds Leshner’s testing and results fail to explain his final conclusions, which provides an independent basis—distinct from the above discussed unreliable methodology—for excluding Leshner’s testimony.

C. THE OTHER EXPERTS MAY NOT RELY UPON LESHNER’S REPORT OR DATA AND MAY ONLY OPINE ON REBREATHING IF INDEPENDENTLY PERMITTED TO DO SO BASED ON THEIR EXPERTISE.

Though the Court will not permit Leshner to testify as an expert witness, the Court must still consider whether Plaintiffs’ other experts may testify regarding rebreathing. Under D.R.E. 703, an expert may base their opinion on inadmissible evidence as long as “experts in the particular field would reasonably rely on those kinds of facts or data in forming an opinion on the subject ...” Leshner’s conclusions, for the reasons stated above, do not meet that requirement, and cannot be relied upon by any of Plaintiffs’ experts.

Given the aforementioned flaws in Leshner’s methodology, the data presented by Leshner may be not utilized by the other experts. More, the other experts’ testimony may not delve into what level of carbon dioxide the infant would be exposed to, or how great a discrepancy in the carbon dioxide levels between the two surfaces would be, if those conclusions are based exclusively on Leshner’s report. However, the other experts may conclude there is a differing exposure to carbon

dioxide levels across different infant sleeping products if such a conclusion is properly supported by their own expertise or other peer-reviewed studies.⁴¹

Mannen's overall conclusions on rebreathing are addressed in the *Daubert* motion surrounding the admissibility of her entire report, but one note bears repeating here. Mannen's opinion on rebreathing relies, in part, on a statistical analysis of Leshner's data.⁴² After that analysis, Mannen opined "that in a side-lying or a 90-degree head turn situation, that an infant would experience *significantly* increased CO₂ inhalation simply due to the design of the product."⁴³ As Mannen's final conclusion regarding the level of CO₂ an infant would experience in the RnP was calculated with the data from Leshner's unreliable methodology, that conclusion must be struck from her testimony.

However, Mannen's testimony regarding rebreathing that does not rely on Leshner's methodology is admissible. Mannen's other conclusions regarding whether an infant would be at risk for rebreathing in the RnP were based on her examination of an RnP, her peer-reviewed research, and her expertise as a biomechanical engineer.⁴⁴ Accordingly, Mannen may still opine: "with this extreme

⁴¹ Leshner's Report at 5-6; *see also* App. C to Leshner's Report.

⁴² Ex. M to Defs.' Mot. to Exclude Test. Regarding Rebreathing, D.I. 164, at 28 ("Dr. Mannen's Report").

⁴³ *Id.* (emphasis added).

⁴⁴ Dr. Mannen's Report at 3-4.

curvature [of the plastic support piece in the RnP], a normal head rotation of 90 degrees will result in contact of the baby's face with the soft plush surface. This constitutes a dangerous rebreathing situation as the infant's face can be directly in contact with plush soft goods, not a mesh material or a surface with free airflow."⁴⁵

Calhoun's opinions regarding rebreathing appear to be reliant on Leshner's report.⁴⁶ She directly cites to Leshner's conclusions regarding hazardous design of the RnP.⁴⁷ She cites to Leshner's Report for the proposition that rebreathing occurs when a side-facing infant comes into contact with the side of the RnP.⁴⁸ Plaintiffs contend Calhoun relies on studies independent of Leshner to support her rebreathing opinions, but the extent of that independent reliance appears to reduce down to Calhoun concluding that rebreathing can occur when an infant's face comes into contact with a soft fabric. Most of Calhoun's discussion of rebreathing refers to either Leshner's report directly, or Mannen's interpretation of that report. Calhoun also does not appear to add any of her own specialized knowledge or training to the discussion of rebreathing. Thus, Calhoun's testimony regarding rebreathing must be excluded.

⁴⁵ Dr. Mannen's Report at 28.

⁴⁶ Ex. E to Defs.' Mot. to Exclude Test. Regarding Rebreathing, D.I. 164, at 17 ("Dr. Calhoun's Report).

⁴⁷ *Id.*

⁴⁸ *Id.*

Hoffman reviewed Leshner's Report⁴⁹ but, as a pediatrician, possesses an independent basis to conclude rebreathing could have contributed to A.B.'s death. To the extent that he seeks to discuss Leshner's Report, that testimony must be excluded. Hoffman's conclusion that "any attempts to breathe would have been hindered by CO2 rebreathing" is admissible to help explain Hoffman's conclusion that A.B. died of suffocation.⁵⁰

Similarly, Rosen references Leshner's Report but, as a pediatric pulmonologist, possesses an independent basis to conclude rebreathing could have played a part in A.B.'s death.⁵¹ Rosen may not refer to Leshner's Report in his testimony. Rosen may opine on the risk of rebreathing generally, and its potential contribution to an infant suffocating.

Ross's rebreathing testimony also does not rely on Leshner's Report.⁵² Ross addresses rebreathing only in the context of determining that "[e]ven if there was not 100% occlusion and A.B. was able to intake some small quantity of air, he would be getting an insufficient amount of oxygen, and he would have been rebreathing

⁴⁹ Ex. P to Defs.' Mot. to Exclude Test. Regarding Rebreathing, D.I. 164, at 13 ("Dr. Hoffman's Report").

⁵⁰ *Id.* at 19.

⁵¹ Ex. Q to Defs.' Mot. to Exclude Test. Regarding Rebreathing, D.I. 164, at 19-20 ("Dr. Rosen's Report").

⁵² Ex. R to Defs.' Mot. to Exclude Test. Regarding Rebreathing, D.I. 164, at 5-6 ("Dr. Ross's Report").

dangerous levels of carbon dioxide.”⁵³ As a forensic pathologist, Ross possess an independent basis to conclude that rebreathing may have factored into A.B.’s death. Ross may not refer to Leshner’s Report in his testimony; however, Ross may opine on the risk of rebreathing generally, and its potential contribution to an infant suffocating.

Lastly, Myers’s report references Leshner’s Report in the context of suggesting that, had Defendants tested the RnP for a risk of rebreathing, their results would have mirrored Leshner’s.⁵⁴ That testimony must be excluded, because it presupposes that Leshner’s conclusions are admissible. Myers may testify why he considers the testing Defendants conducted regarding rebreathing to be insufficient, absent any reference to the results of Leshner’s Report, and he may testify as to how the design facilitates rebreathing by allowing an infant to press his face against the soft fabric.

IV. CONCLUSION

Leshner did not utilize a reliable methodology, and his conclusions are unsupported by his data. Accordingly, his expert report, and any testimony from other experts relying on Leshner’s Report, must be excluded. The other experts may

⁵³ *Id.* at 5.

⁵⁴ Ex. S to Defs.’ Mot. to Exclude Test. Regarding Rebreathing, D.I. 164, at 45 (“Myers’s Report”).

testify regarding rebreathing only to the extent that they rely on other peer-reviewed studies or their own expertise. That testimony may not touch on Leshner's Report or any conclusions reliant on his methodology.

IT IS SO ORDERED.

/s/ Patricia A. Winston
Patricia A. Winston, Judge